TOPIC: THE WORLD TRADE ORGANISATION (WTO)–TRADE RELATED ASPECT OF INTELLECTUAL PROPERTY RIGHT AGREEMENT (TRIPS) AND THE REGULATION OF COUNTERFEIT PHARMACEUTICAL PRODUCT IN NIGERIA.

By

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ABSTRACT

In recent years, there has been a massive surge in the scale of Counterfeit Pharmaceuticals in Nigeria. It violates the Intellectual Property Rights (IPR) standard adopted by the World Trade Organisation-Trade Related aspect of the Intellectual Property Right (WTO-TRIP) Agreement. The effect of the WTO-TRIPS strict protection of Intellectual Property Rights creates problems for developing countries. It has provoked counterfeit pharmaceutical activities worldwide, and which is prevalent in Nigeria.

This thesis is an in-depth study of the concept and state of 'counterfeit pharmaceuticals' and its application within the WTO-TRIPS framework as transposed in Nigeria. The aim is to ascertain, by way of the theoretical and qualitative methodology, the viability of the WTO-TRIPS agreement for addressing the scourge of counterfeit pharmaceuticals in Nigeria. The concept of counterfeit drugs will be explored, and its parameters defined as a premise for challenging the viability of the WTO-TRIPS and the Nigerian Counterfeit regulatory framework. The justification for this research is because the issue of counterfeit is topical and important for developing countries especially in light of the legal, social, development and health implications of counterfeit. Using Nigeria as a case study will set a standard for other developing and LDC's.

In fulfilling this study's objective, the thesis notes that Nigeria is a member of the World Trade Organisation and its predecessor, the General Agreement on Trade and Tariff, since its independence in 1960. Nigeria is bound by all WTO trade policies, including the standards mandated by the WTO-TRIPS agreement. The historical analysis of the WTO is relevant to set a standard for testing how viable its rules and policies are in

tackling counterfeit. Nigerian history will be discussed, particularly regarding its legal policies on Intellectual Property to assess if the wholesome adoption of WTO-TRIPS rules can curb the surge in counterfeit pharmaceuticals. In that section, the laws of the foremost Nigerian organization for the regulation and control of drugs will be analysed to provide a contextual background to the problem of counterfeit. It will determine if its approach to confronting the counterfeit crisis is adequate and within the stated requirement of WTO-TRIPS.

Finally, a comparative analysis of the WTO-TRIPS and the Nigerian legal policies on IP will be tested to determine the shortcomings and possible reforms to its policy. This study will shed more light on the theoretical perspective of the suitability of the legal regime of the WTO-TRIPS to the regulation of counterfeit drug surge. Lastly, the thesis will make recommendations on reducing the prevalence of counterfeit drugs without relying on the WTO-TRIPS safeguards.

DECLARATION

Under the Regulations for Higher Degrees and Research, I hereby declare that the whole thesis now submitted for the candidature of Doctor of Philosophy is a result of my research and independent work except where reference is made to published literature. I also hereby certify that the work embodied in this thesis has not already been submitted in any substance for any degree and is not being concurrently submitted in candidature for any degree from any other institute of higher learning. I am responsible for any errors and omissions present in the thesis.

Contents

To My Son and Husband Nathaniel and Richard Nweke

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List of Abbreviations

ACTA Anti-Counterfeiting Trade Agreement (ACTA

AIDS Acquired Immunodeficiency Syndrome

ART Anti-Retroviral Therapy

ARV Anti-Retroviral

AU African Union

BIRPI Bureaux for the Protection of Intellectual Property

CA Court of Appeals

CDC Centre for Disease Control and Prevention

CPs Contracting parties

CPs Contracting Parties

DCS Developing Countries

DG Director-General

DMFT Differential and More Favourable Treatments

DSB Dispute Settlement Body

DSM Dispute Settlement Mechanism

DSU Dispute Settlement Understanding

ECJ European Court of Justice

ECOWAS Economic Community of West African States

EDL Essential Drug List

EFCC Economic and Financial Crimes Commission

EPO European Patent Office

EU European Union

FCT Federal Capital Territory

FDI Foreign Direct Investment

FHC Federal High Court

FTA Free Trade Agreement

GATT General Agreement on Tariff and Trade

GDP Gross Domestic Product

HIV Human Immuno-deficiency Virus

ICJ International Court of Justice

IMPACT International Medical Products Anti-Counterfeiting Taskforce

INTERPOL International Criminal Police Organisation

IPC Intellectual Property Committee

IPMG International Pharmaceutical Manufacturers Group

IPF International Pharmaceutical Federation

IP Intellectual property

IPRs Intellectual Property Rights

ISO International Standard Organisation

LDC Least Developed Countries

MDGs Millennium Development Goals

MFN Most-Favoured Nation Principle

MNCs Multinational Corporations

MPCs Multinational Pharmaceutical Corporations

MTNs Multilateral Trade Negotiations

NAFTA North America Free Trade Agreement

NT National Treatment Principle

NTBs Non-Tariff Barriers

MOH Ministry of Health

NAFDAC National Agency for Food and Drug Administration and Control

NGO Non -Governmental Organisation

OECD Organization for Economic Cooperation and Development

OTC Over the Counter

PCT Patent Co-operation Treaty

PMA Pharmaceutical Manufacturers' Association

PhRMA Pharmaceutical Research and Manufacturers of America

R&D Research & Development

STIs Sexually Transmitted Infections

SC Supreme Court

TRIPS Trade-Related Aspects of Intellectual Property Rights

NOTAP National Office for Technology Acquisition and Promotion

UDHR Universal Declaration of Human Rights

UK United Kingdom

UN United Nations

USA United States of America

WHO World Health Organization

WIPO World Intellectual Property Organisation

List of Diagrams

List of Cases

Adenuga V. Ilesanmi press and sons Ltd (1986)1 FHCLR 308

Arewa Textile Industries. V.Finetex Limited (2003) 7 Nigerian Weekly Law Report.

Barewa Pharmaceutical Limited. v. The Federal Republic of Nigeria, (2019) LPELR-47385 (SC)

Dyketrade Ltd. v. Omina (Nig.) Ltd 43 NIPJD (SC 2000) 57/1995.

Ferodo Ltd v. Ibeto Ind. Ltd (2004) LCN/3262(SC)

Gucci America Inc V. Frontline Processing Corp 08 Civ.5065 (2008)

Honda Place Limited V. Globe Motors (2005)14 NWLR

Inwood Labs Inc. V. Ives Labs Inc 456 U.S. 844 (1982)

Johnson L V, (1778) Vol.1 'PC 53(Reproduced in Hayward's case, 196-201)

Madukolu v. Nkemdilim (1962) 2 NWLR.

Pfizer Specialties Limited V. Chyzob Pharmacy Limited (LER [2006] CA/L/282/2001)

Pinner v Everett (1969) 64 Cr App R 160

Sandford case (1584) Cory's Entries BL MS Hargrave 123

Tiffany Inc V. eBay Inc 600 F.3d 93 (2d Cir. 2010)

1.1 Statement of the problem in the Nigerian Drug System

Nigeria is a member of the World Trade Organisation (WTO) since its inception in 1995. It has been a Member of the General Agreement on Trade and Tariff (GATT) since its independence in 1960. Although the WTO Agreements adopts a single-undertaking system, where membership in one agreement means membership in all WTO Multilateral agreements, Nigeria gained membership status in the WTO agreement by signing on to the Marrakesh Agreement[1]. Under the WTO trade liberalisation policy, Nigeria had significantly opened its market compared to other developing countries and implement the WTO Agreement[2], including the Trade-related aspect of intellectual property rights (TRIPS).

Although the Trade-Related aspect of Intellectual Property Right agreement (TRIPS) had as part of its policy the intent to inhibit the problem of counterfeit, while still protecting IP in the international trade system, reports have shown that counterfeit drugs exist regardless of measures put in place by both state and international authorities. To gauge the perversity of counterfeit, data from the Pharmaceutical Society Institute indicates that the incidents of counterfeit have increased by 102% from 2016 to 2018[3]. Also, the PSI counterfeit seizure reports that over 844 counterfeit

[1]The WTO Marrakesh Agreement 1994, Available www.wto.org/English/res_booksp-_e/agrmntseries1_wto-agree-e.htm Accessed (December 14, 2015)
[2] World Trade Organisation Summary Sheet on Nigeria Available https://www.wto.org/english/tratop_e/tpr_e/s247_sum_e.pdf Accessed (03 May 2021)
[3] OECD -Trade in counterfeit Medicine Available https://www.oecd-ilibrary.org/sites/fe58fe07-en/index.html?itemId=/content/component/fe58fe07-en Accessed (03 May 2021)

incidents[4] despite consolidated efforts from various international organisations. As the name implies, counterfeit Pharmaceutical is 'a drug which is deliberately and fraudulently mislabelled regarding identity and source '[5]resulting in high morbidity, mortality, and damage to public health structure[6]. Also, a 'counterfeit drug' can be regarded as 'any drug or medical product, which is not what it purports to be, coloured, coated, or polished. The damage it creates is far greater than the therapeutic value' it purports to resolve[7]. It can increase the progression of diseases and compromise the health and safety of patients and eventually death. The perversity of counterfeit has destabilized the slated intention of the Nigerian constitution, which is to guarantee the right to health for all its citizens. Therefore, it can be said to undermine Nigerians' right to quality medicine needed for the treatment of diseases[8].

The problem of counterfeit drugs is equally severe in other parts of Africa, following a recent study organized by the World Health Organisation (WHO). Sample data collated from state governments and police seizures of counterfeit drugs in Africa provided evidence, and it estimates that 42% of all counterfeit medicines reported from 2013 and 2017 originated in Africa[9]. Whereas the PWC believes the proportion of counterfeit pharmaceuticals in some African countries could be as high as 70%, this supports the claim of counterfeit perversity in Africa[10]. The problem of counterfeit is multidimensional and requires a strong legal solution to reduce its prevalence given

[4] PSI Incident Trend Available https://www.psi-inc.org/incident-trends Accessed (03 May 2021)
[5] WHO Guidelines for the development of measures to combat counterfeit drugs
[6] Robert Cockburn and others' The Global Threat of Counterfeit Drugs: and Why Government Must Communicate the Dangers, (2005) Vol. 2 (4) PLoS Medicine e100
[7] Section 12 of the Nigerian counterfeit and fake Drugs (Miscellaneous provision) Act, Cap C34, Laws of the federal republic of Nigeria (LFN)2004
[8] The Constitution of Nigeria 1999, CAP 23 LFN
[9] BBC NEWS, Counterfeit Drugs May Kill You or cause Superbugs' September 2013 Available http://www.bbc.co.uk/news/health-24270737Accessed (May 16, 2016)
[10]BBC NEWS, Fake Drugs: How Bad is Africa's Counterfeit Medicine problem? Available http://www.bbc.com/news/world-africa-51122898 Accessed (October 05,2020)

the above-mentioned issues. Resolving counterfeit is a pertinent issue especially in Nigeria and other developing and LDC'S.

Consumption of Counterfeit drugs has resulted in over 700,000 deaths in Africa annually, with most of the drugs originating from China, India, Mexico, and Brazil[11]. An example is discovering a lethal amount of melanin in a baby formula with little or no active ingredient[12]. The Nigerian Government is inundated with providing essential medicine and proper health facilities for its citizens regardless of counterfeit medicine prevalence. Counterfeit drugs and other public health issues significantly affect people's health in Nigeria. Although Nigeria has made a tremendous effort to reduce the scale and impact of counterfeit drugs, it remains largely unresolved[13].

The economic implication of counterfeit is multifaceted: counterfeit stifles economic growth of countries; It can reduce financial incentives; technological know-how and can decrease product value in Pharmaceuticals[14]. Consequently, the economic effect of counterfeit pharmaceuticals can lead to a massive loss in legitimate drugs sale. As Peter Bloch, Ronald Bush, and Leland Campbell point out, a high percentage of legitimate goods producers face damages to brand reputation due to counterfeit[15]. Hence, in a bid to save the brand name, producers fail to inform consumers of the potential existence and consequence of counterfeit pharmaceuticals, which has further increased counterfeit growth.

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[11] Jeremy M. Wilson and Roy Fenoff, 'The Health and Economic Effect of Counterfeit Pharmaceuticals in Africa(2011) A-CAPPP Backgrounder, Available http://a-capp.msu.edu/sites/default/files/files/africabackgroundfinal.pdfAccessed (April 25, 2016)

[12] Elizabeth Gasiorowski Denis' Crackdown on Counterfeiting' International Standard Organisation (Jan 2014), Available http://www.iso.org/iso/news.htm?refid=ref1809 Accessed (March 30, 2016)

[13] M Ohuabunwa, 'Health care Delivery in Nigeria, Past Present and the Future' (2002) Vol.31 Nigerian Journal of Pharmacy pp15,

[14] IBID Ohuabunwa

[15] Bloch, Peter H., Ronald F. Bush, and Leland Campbell, (1993) "Consumer 'Accomplices' in Product Counterfeiting: A Demand-Side Investigation," *Journal of Consumer Marketing*,10:4, 27-36

The plague of counterfeit pharmaceuticals, especially in Nigeria, is now regarded as a global phenomenon with far-reaching consequences. For example, counterfeit consumption led to the death of 2,500 children in the Niger Republic from vaccines donated by the Nigerian Government[16]. Besides, the death of 109 children was reported in southern Nigeria, following counterfeit paracetamol consumption. The drug was found to contain toxic ethylene glycol solvent instead of propylene glycol[17]. Factors attributed to counterfeit Pharmaceutical prevalence include inadequate drug supply, high rate of infectious diseases such as malaria, HIV, Tuberculosis, and tropical diseases. Other factors include the irrational use of drugs, low database, and ineffective alliance between government agencies and other professional bodies responsible for controlling pharmaceuticals. It is imperative to examine Nigeria's drug situation, starting from the pharmaceutical market[18].

The Nigerian pharmaceutical market is estimated to be worth more than US$ 600 million as of 2009, and it is expected to grow significantly at around 12 % yearly to reach US$ 717 million by 2019[19]. Despite the Nigerian Government's best efforts to promote pharmaceuticals' domestic production, Nigeria remains mostly dependent on imported pharmaceutical products. According to Okoli, out of the 130 existing Pharmaceutical companies in Nigeria, only 60 is in active manufacturing. Even though the installed capacity is estimated to produce 50% to 70% of the total drug needed in

[16] New York Times -Fighting Fake Drugs Available https://www.nytimes.com/2006/12/12/opinion/12tue4.html Access (03 May 2021)
[17] Dora Akunyili, 'Fake and Counterfeit Drugs in the Health Sector: The Role of Medical Doctors,' (2004) Vol.2 No.2 Annals of Ibadan Postgraduate Medicine PP 19

[18] Harvey E Bale' Consumption and Trade in off –Patented Medicine, Commission on Macroeconomics and Health', Available www.icrier.org/pdf/bale65.pdf Accessed (April 25 2016), see also Roger Bate, Making a Kill: The Deadly Implication of the Counterfeit Drug Trade (Washington Dc, AEI Press, 2008)

[19] Pharmaceutical sector profile: Nigeria, Global UNIDO Project, Available www.unido.org Accessed September 13, 2020)

Nigeria, pharmaceutical companies' capacity utilization is below 30%[20] this means much-needed drugs will not be unavailable. It will enable counterfeit drug suppliers to take advantage of this loophole to supply drugs in high demand such as drugs for blood pressure, antimalarials, HIV Aids medication and, antibiotics knowing the need is high.

The delivery of drugs in Nigeria is nearly chaotic; drugs are sold everywhere at a fraction of its actual price[21]: from sale in open markets, kiosks, patent medicine stores, unregistered wholesalers, which is distributed by illegal pharmaceutical manufacturers. There is no proper mechanism to regulate the inflow of drugs in the health sector in Nigeria. It is common to see a public display of medicines in the market and motor parks without proper consideration of the weather condition that enables the breakdown of the drug's active ingredient [22]. From the facts stated above, it is evident that Nigeria's pharmaceutical distribution system is poorly organized and mismanaged. The situation is so dire that counterfeiters are so skilled in making counterfeit medicine look authentic[23].

The seriousness and impact of the problem are reflected in a 2018 Lancet study, which ranked Nigeria health care quality 142nd out of 195 countries[24], which is extremely

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[20] S Okoli, 'Pharma Industry in Distress,' (2000) Vol22 Pharma news Issue 3 pp 1

[21] The Berkeley MDP- How to Combat Counterfeit Drugs in Nigeria, Available https://mdp.berkeley.edu/how-to-combat-counterfeit-drugs-in-nigeria/ Accessed(October 05, 2020)

[22] Adelusi Adeluyi, 'Drug Distribution: Challenges and Effects on the Nigerian society', Keynote speaker at the Annual National Conference of the Pharmaceutical Society of Nigeria, November 2000

[23] BBC News, 'Solving the Problem of Fake Drugs in Nigeria
Available' https://www.bbc.co.uk/news/av/business-47640706/solving-the-problem-of-fake-drugs-in-nigeria Accessed (June 18, 2020)

[24] Fullman N and others (2018). 'Measuring performance on the Healthcare Access and Quality Index for 195 countries and territories and selected subnational locations: a systematic analysis from the Global Burden of Disease Study 2016*391*(10136) The Lancet, 2236
GBD 2016 Healthcare Access and Quality Collaborators. Measuring performance on the Healthcare Access and Quality Index for 195 countries and territories and selected subnational locations: a systematic analysis from the Global Burden of Disease Study 2016. *Lancet*. 2018;391(10136):2236-2271. DOI:10.1016/S0140-6736(18)30994-2

low compared to other countries, underpins the enormity of the problem. The mortality rate at birth for an average Nigerian is estimated at 46 years for males, 47 years for females, compared to Ghana and South Africa, whose life expectancy is estimated to be about 55 and 50 years[25]. It is a frequent occurrence from a country where infectious diseases, malaria, diarrhoea, river blindness, tuberculosis, and ultimately HIV, are part of its citizens' everyday lives. Unfortunately, counterfeit drugs and a lack of essential medicine such as Antimalarial and HIV drugs have exacerbated the prevalence of counterfeit. A recent review of the chemical components of some Antimalarial drugs confirms that over 36% of the medicines tested failed the chemical analysis[26].

Another problem attributed to the growth of counterfeit Pharmaceuticals is the existence of weak intellectual property laws in Nigeria. Intellectual Property protects the right of manufacturers by providing absolute protection for knowledge and creation. It gives a manufacturer monopoly right over an invention to the exclusion of all others. A manufacturer relies on this right to protect marketable intellectual inventions, given the high research and development (R&D). In this light, IP is a justification for the economic exploitation of Pharmaceutical products. However, this absolute right gives rise to counterfeiting, which is an infringement of IP. Thus, counterfeiting amounts to theft, for it misleads the consumers and can damage manufacturers' goodwill.

The WTO–TRIPS framework created a more robust patent protection regime by restricting statutory monopoly to an inventor to enjoy the right to its invention solely. This protection regarding pharmaceuticals implies that it enabled pharmaceutical

[25]WHO Mortality Fact Sheet 2006
[26] WHO, 'Malaria rapid Diagnostic test performance
Available', http://whq.who.int/publication/2010/9789241599467_eng.pdf Accessed (May 23, 2016)

companies to manipulate the price and supply of medicines, inadvertently making them inaccessible and extremely expensive to the public, especially in developing countries. The limitation is the protection between IPR and the quest to have access to medicine, over and above the safety of IPR, introduced the element of counterfeit pharmaceuticals into Nigeria. It has become a topical issue as much as access to medicine issues. In response to the problems raised about counterfeiting, the proposed chapters aim to evaluate the definition, implication, and counterfeit evidence by considering the established framework's contextual scope for regulating counterfeit. It will provide an opportunity to clarify the link between IP and counterfeit concerning Pharmaceutical. The outcome of this study will highlight the current state of counterfeit pharmaceuticals in Nigeria. Analysis from this research will inform policymakers if the WTO-TRIPS framework can effectively mitigate the scourge of counterfeit Pharmaceuticals.

THE STRUCTURE OF THE THESIS

The thesis is divided into six main chapters. Chapter one will present an overview of the General Agreement on Trade and Tariff/World Trade Organisation (GATT/WTO) Intellectual Property (IP) framework and counterfeit issues in the Nigerian drug system. The Origin of IP concerns in the early GATT system and its transition through the WTO framework under the TRIPS agreement is discussed. The chapter illustrates in detail the many problems of counterfeit medicines in Africa generally and specifically in Nigeria. It also highlighted other international bodies with responsibility in the IP area and how the development question is associated with drug access and IP protection. The purpose is to create a premise invariably for questioning the viability of the WTO/TRIPS framework for counterfeit regulation. Chapter two explores the

concept and state of counterfeit pharmaceuticals in international trade to derive a workable interpretation that forms a framework for analysing the WTO/TRIPS and Nigeria drug regulatory systems. It will also provide a legal analysis of the debate concerning counterfeit, fake, and substandard medicine whilst still discussing the substantive nature of counterfeit.

Chapter three analyses the WTO/ TRIPS agreement and brings out its objects and core principles and the aspects of TRIPS provision about counterfeit pharmaceuticals. It also presents other international cooperative regimes for access to medicines such as the WHO, WIPO, and their role concerning TRIPS implementation and counterfeit drugs. Chapter four will expound on Nigeria's IP legal and institutional framework for implementing WTO/TRIPS and counterfeit regulation. It sets a precedent to analyse counterfeit and the implication of the TRIPS agreement transposed in Nigeria's legal system and the relative effect of the wholesome transfer of laws into the Nigerian legal system.

Chapter five pulls the research together in critical evaluation of the TRIPS standards and Nigerian counterfeit regulation to ascertain the TRIPS' effectiveness concerning counterfeit drugs' conceptual and theoretical framework parameters. It will identify synergies and discrepancies and propose legal and policy reforms on both the Nigerian domestic regime and WTO global system to ensure effective redress to the problem of counterfeit pharmaceuticals. Lastly, Chapter 6 will consolidate all the findings of the chapters and discuss the implication of the WTO-TRIPS in regulating counterfeit.

Chapter 1- GATT/WTO

Intellectual Property Framework, Nigerian Economy, and Counterfeit Drugs: An Overview

'The evil of fake drugs is worse than the combined scourge of malaria, HIV/Aids, armed robbery, and illicit drugs' (Dora Akunyili (2002)

1.1 Introduction

This chapter presents an overview of the General Agreement on Trade and Tariff/World Trade Organisation (GATT/WTO) IP framework and counterfeit issues in Nigeria. The Origin of IP concerns in the early GATT system and its transition through the WTO framework under the TRIPS agreement is mapped out. The chapter illustrates in detail the many problems of counterfeit medicines in Africa generally and specifically in Nigeria. It also highlights other international bodies with responsibility in the IP area and how the development question is associated with drug and IP protection. The purpose is to create a premise invariably for questioning the viability of the WTO-TRIPS framework for counterfeit regulation.

1.2 THE STRUCTURE OF THE GATT/WTO, IP, AND THE ISSUE OF COUNTERFEIT'

The GATT agreement is the source of the WTO framework. The GATT Agreement entered into force in 1948, signed by 23 nations in Geneva on October 30, 1947. The formation of GATT [27] is motivated by two significant events. The first was the great depression that shook the global economy after the 1st World War and the embrace of protectionism by developed countries, which failed to reciprocate trade concession, especially with developing countries. The second event was the economic pressure from the United States (US) after the 2nd World War. It necessitated creating a unified multilateral organization (GATT) to protect the trade interest of member countries. Although the GATT did not address intellectual property in its formative years, the US still linked this to its trade activities by imposing sanctions against states with weak intellectual property laws[28]. It has necessitated creating a unified multilateral organization to defend member countries trade interests, thus forming an international organization to regulate free trade. The rationale behind this is to understand the theoretical underpinning for the inclusion of IP in international trade. The GATT provides trade in goods between nations,[29] to ensure openness, fairness, and non-discrimination. To achieve these objectives, the GATT's drafters acknowledged that a total reduction of tariffs is impossible. Thus, the agreement endorsed much greater transparency on tariffs as a form of protection against trade barriers. The GATT's

[27] The GATT Years/ From Havana to Marrakesh, Available https://www.wto.org/English/thewto_e/whatis_e/tif_e/fact4_e.htmAccessed (January 6, 2016) From 1948 GATT agreement provided the rules for the regulation of international trade. Its original goal was to establish a third institution to regulate the international economic corporation's trade aspect, joining the World Bank and International Monetary fund. GATT recorded the highest growth rate in international trade, and it aimed to correct the legacy of protectionist measures, which was a norm from the early 1930s

[28] Bagwell, K., & Staiger, R. W. (1999). An economic theory of GATT. Vol. 89, No 1 *American Economic Review*, pp.215-248.

[29] Ralph Ossa, 'New Trade" Theory of GATT/WTO Negotiations,' (2011) Vol. 119, No. 1 Journal of Political Economy, pp.122-152.

primary focus is liberalizing trade by controlling the government's actions to create a competitive market economy.

Over time, new issues arose within GATT, which GATT failed to respond to, thus undermining its credibility and effectiveness. The issue includes trade-in service, intellectual property, and dispute settlement[30], which by the early 1980s, became relevant to world trade realities. Global trade had expanded far beyond GATT's scope: for example, it now recognises the importance of Intellectual Property in cross-border technology transfer, research and development, especially pharmaceutical products.[31] This emerging trend on the role of intellectual property (and other regulatory gaps) convinced GATT members of the need to re-design the multilateral trading system. Thus, when the Uruguay Round of Trade Talks was launched in 1986, intellectual property was a significant addition to the negotiating agenda culminating in the adoption of the TRIPS Agreement. How did the GATT members manage to extend its horizons to include what was seemingly a non-trade matter? How did an issue area under the control of the World Intellectual Property Organisation (WIPO) end up on the Uruguay round of trade talks?

The text of the GATT provided for the regulation of IPR within its framework. The first provision is found in *Article XII (3)(C), which states that states should* not apply restrictions that will prevent the importation of commercial samples or prevent compliance with patent, trademark, copyright, or similar procedures for it is possible to adopt measures which will expand trade rather than restrict international trade[32]. Also, Article XI (6) *permits contracting parties to cooperate, prevent the use of trade*

[30] John. H. Jackson, 'GATT and the Future of International Trade Institutions, (1992) Vol.18 Issue 1 Brooklyn Journal of International law', 11-30, GATT is regarded as the most binding agreement relating to trade, yet GATT cannot be recognized as a treaty.

[31] Maria Nelson, Michelle Vizurraga, and David Chang, 'Counterfeit Pharmaceuticals: A worldwide Problem,' (2006) Vol. 96 Trademark Representative, 1068 -1100.

[32] Article XII (3)(C)

names in such a manner that is inconsistent with its identity, and be detrimental to such geographical indication in the contracting party[33]. The second provision on Intellectual Property Rights is provided for in Article XX (d). This article allows *for the use of necessary measures to secure compliance with rules and laws that are not contradictory to GATT agreement provisions.* This includes those relating to the protection of patent, trademark, and copyright[34]. Equally, Article XVIII (10) of GATT further states that restrictions cannot be applied to prevent commercial samples importation or prevent compliance with patent, trademark, copyright, or similar procedures[35].

By interpreting the IPR provision of GATT, it is evident that the GATT framework regarded IPR as a condition to accessing free trade. The reality is that GATT cannot be said to be protecting 'the right' to intellectual property. Instead, it is protecting the right to trade. Moreover, if GATT intended to make IPR an international trade standard, it would have made annexes provisions instead of inserting scant indications of Intellectual Property protection within its framework. The motive for the inclusion of IPR within later GATT trade talks stemmed from intense lobbying by the United States, the EU, and Japan. The aim here was to provide more robust protection of intellectual property by linking it to global trade policy. The protection of IPR was first raised in 1978 during the Tokyo Round of trade talks sub-group 'Customs Matter'. The US appealed for the support of other developed countries to negotiate international rules to prevent commercial counterfeit. It is aimed at finding solutions by creating rules and procedures for the prevention of counterfeit in international trade. The contracting parties discussed matters informally until it was raised formally in the preliminary

[33] Article XI (6) GATT
[34] Article XX (D) GATT
[35] Article XVIII (10) GATT

negotiation of GATT ministerial meetings. Some of the contracting parties challenged the WIPO's competence in regulating the affairs of IP, given its shortcoming in handling the breach of IP, which resulted in the introduction of counterfeit goods into the world trading system. WIPO's apparent failure instigated the need to have a Universal organisation within the GATT framework instead of having two different organisations for the same purpose.

Further actions within GATT was reached in 1983, after due consideration from the Director-General of WIPO. After findings on *specific provisions* relating to the organisation's experience with the implementation of counterfeit measures in the WIPO framework, to serve as a guide for the contracting parties of GATT. The contracting parties agreed that an expert group would be opened to all contracting parties who had the right to intellectual property. To clarify the legal and institutional aspect of IP in the multilateral trade negotiation of GATT.[36]

Another reason for the inclusion of IP within GATT is the effect of counterfeiting on IP. Counterfeit goods are fake items, usually of lower quality and standard as opposed to the original item. It is generally sold at a lower price to attract buyers. However, the commercial implication of counterfeit's can be exemplified as the practice of affixing false trademark on products and passing it off as the original. The implication of consuming counterfeit products can lead to death or outright dissatisfaction[37]. Moreover, the firm whose goods or drugs are counterfeited will lose revenue, and the

[36]Multilateral Trade Negotiation, the Uruguay Round –Work Undertaken in GATT Concerning Trade – Related Aspect of Intellectual property Rights, including Trade in Counterfeit Goods MTN.GNG/NG11/W/4 6 May 1987
Available http://www.wto.org/gatt_docs/english/sulpdf/92020093.pdfAccessed(20 January 2016)

[37] Gary Bamossy and Debra L. Scammon, 'Product Counterfeiting: Consumers and Manufacturers Beware in NA- Advances in consumer Research Vol.12 (ED) Elizabeth C. Hirchman and Morris B. Holbrook, Provo, UT: Association for consumer Research 1985, p.334.

goodwill of the company may be adversely affected. Hence this necessitated the need for the protection of IP as counterfeiting became a vital issue in the 1970s and 1980s[38].

Developed countries canvassed for the adoption of the IP principle under the Uruguay Round to protect the creativity of multilateral companies in the course of international trade. However, developing countries opposed the notion of transferring IP to the GATT framework, claiming that IP falls under the scope of intangible goods, within WIPO's jurisdiction, and GATT ought to recognise WIPO status as a multilateral organisation capable of protecting IP.

Nevertheless, the subject of IP is included in the WTO's multilateral trading system, as part of the conditions for succeeding GATT[39]. It is formed to promote international economic growth by establishing legally binding rules to govern trade amongst states. Thus, efforts are made through a series of multilateral negotiations known as trade rounds', to establish a new multilateral agreement that incorporates trade and IP in one forum. After a series of negotiating difficulties, the Uruguay Round was concluded in 1994 in Marrakesh, Morocco. This Uruguay Round further liberalised trade and established a permanent structure to manage international trade procedures. It is regarded as the most extensive of all rounds of trade talks resulting in the creation of the WTO.[40]

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[38]Wertheimer, Albert I. "The irony of drug product selection." *American journal of public health* Vol 70 Issue 5 (1980), pp.473-473.

[39] The issues include the divide in textiles and clothing, and some of the newer issues debated in the WTO, for example the developing countries have organized themselves into alliances such as the African Group and the Least-Developed Countries Group. In many others, the developing countries do not share common interests and may find themselves on opposite sides of a negotiation. A number of different coalitions among different groups of developing countries have emerged for this reason. The differences can be found in subjects of immense importance to developing countries, such as agriculture.

[40] The Tokyo Round during the seventies was the first major attempt to tackle trade barriers that do not take the form of tariffs, and to improve the system. The eighth, the Uruguay Round of 1986-94, was the last and most extensive of all.

The WTO is an international organisation formed to promote and regulate global trade in goods, trade in services, intellectual property, and it has a viable dispute settlement mechanism[41]. It provides a framework used by states to implement trade regulations. Part of the WTO's function includes administering and implementing multilateral and plurilateral trade agreements under its umbrella[42]. It provides a forum to monitor member country trade policy and cooperate with other international organizations involved in global trade and economic policymaking. The WTO is seen to be an extension of GATT even though its scope is broader.[43]

Ministerial representatives from different member states regulate the activities of the WTO. It holds a ministerial conference every two years where trade matters are discussed, and decisions are reached. It has an organizational structure which, at the top, is the Ministerial Conference and followed in authority by the General Council. The General Council comprises representatives of member states whose primary duty is to ensure the WTO's day-to-day running. The General Council directs the Dispute Settlement Body (DSB), which oversees trade disputes among states. For instance, the WTO uses trade measures to enforce compliance from its members in developing and developed, through the DSB which is regarded as a 'forum of last resort'[15]. It is principally unique for it adds security and predictability to the World trading system by preventing member states from taking unilateral actions against each other outside the WTO framework.

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[41]Agreement Establishing the WTO-Wold Trade Organisation (January 1 1995), www.wto.org/english/res_e/booksp_e/agrmntseries1_wto_agree_e.htm, (December 14, 2015).
[42] Richard Blackhurst, 'The WTO and Global Economy' (1997) Vol.20 World Economy pp.527-544.
[43] Note that the WTO is a permanent organisation whereas the application of GATT agreement is just on a provisional basis. Frederick M. Abbott, 'Distributed Governance at the WTO-WIPO: An Evolving Model for Open-Architecture Integrated Governance', (2000) Vol 3 issue 1, Journal of International Economic Law, pp.63-81.

The WTO introduced a robust standard for the protection and enforcement of IP by creating the WTO-TRIPS agreement. The TRIPS agreement protects member states IP rights and issues penalties for failure to adhere to WTO IP Law[44]. It utilizes different enforcement procedures. Such as civil, administrative, provisional and border measures to protect IP[45]. TRIPS IP framework includes protection for copyright in respect of the right of performance, producer of phonograms, sound recording and broadcasting organizations[46]. Protection of trademarks, geographical indications, service marks[47], industrial designs[48], patents, designs and integrated circuits[49]. Also, within the TRIPS agreement spectrum is the provision for a minimum standard to measure IP. It proffered meanings to IP rights, the scope of IP, exception, and obligation in the context of the Paris Convention, Berne Convention, and the Rome Treaty[50]. Given the stated fact that one of the directives of TRIPS Agreement is to enhance freedom of IP cue from WTO goal of 'freedom of trade' to strengthen economic growth[51]. The TRIPS agreement works concurrently with the WTO objective; thus, it can be said to create a balanced system for trade and IP regulation. However, trade and IP cannot exist simultaneously with counterfeit. Counterfeit stifles economic growth and development, to the point that it diminishes ideas, inventive

[44]Frederick M. Abbott, 'Distributed Governance at the WTO-WIPO', supra pg 66.
[45]' World Trade Organisation, overview' : TRIPS Agreement (1 January 1995) at www.wto.org/english/traptop_e/trips_e/intel2_e.htm,(December 19 2013).
[46] 'Agreement on Trade-Related Aspect of Intellectual Property Right' (January 1 1995), supra article 9-14 .
[47] TRIPS Agreement, Supra, Article 15-24.
[48] TRIPS Agreement supra Article 25.
[49] TRIPS Agreement supra article 27 and 35.
[50] TRIPS Agreement supra article 1(3).
[51] Ruth L. Okediji 'WIPO-WTO Relations and the future of global IP norms ', supra 14.

steps, reduces the transfer of technology[52] between developed and developing countries. The term counterfeit within the framework of the TRIPS agreement is defined as 'the use of a trademark or mark like trademark without the permission of the rights holder' [53]. Scholars believe that the provisions of this definition risk prioritizing IP over other salient issues, including public health, even though protecting IP is essential in fostering innovation and generating breakthrough solutions, especially in the pharmaceutical sector.

Pharmaceutical research and development depend on firm patent protection, not just for the product, but for the process for which a pharmaceuticals product is manufactured. The International Federation on Pharmaceutical Manufacturer Associations (IFPMA) argued that "patents have nothing to do with counterfeiting and counterfeiting has nothing to do with patents"[54]. This statement is absurd and contradictory because patent rights in pharmaceuticals create a strong incentive to develop medicines. However, the prohibitive cost of patented medicine is a driver for counterfeit. Cost is a key driver of IP and IP restricts access to much-needed medicine. Thus a correlation can be made between cost, IP and Counterfeit. The subject of pharmaceutical patent protection within the WTO-TRIPS is very contentious for both scholars and international organisations, especially in response to the WTO-TRIPS Agreement's viability in addressing the scourge of counterfeit pharmaceuticals within its framework of binding principles.

[52] Peter K Yu,' Toward a Nonzero-Sum Approach to Resolving Global Intellectual Property Disputes: What We Can Learn from Mediators, Business Strategies, And International Relations Theorist,' (2002) Vol 70 University Of Cincinnati Law Review pp.569-650.

[53] WTO-TRIPS (1994)Availablehttps://www.wto.org/english/docs_e/legal_e/27-trips_05_e.htm

[54] International Federation of Pharmaceutical Manufacturers Association – IFPMA '10 principles of Counterfeit Medicine' (May 2010) Available at www.ifpma.org>content>news>ifp

1.3. INTERNATIONAL ORGANISATIONS AND DRUG ACCESS ISSUES

WIPO plays an essential role in developing IP and the connection between trade and IP. The first stage relates to the Paris Convention for the Protection of Industrial Property in 1883, and the Berne Convention for the Protection of Literary and Artistic Work (1886).[55] These agreements have been revised several times to fit new circumstances like technological development and the public's growing health care demands. The first phase of WIPO's growth is its creation in 1967. This organisation had the sole responsibility for the administration and control of matters relating to IP internationally.[56] WIPO limits the powers of other United Nations agencies such as the United Nations Development Programme (UNDP), United Nations Industrial Development Organisation (UNIDO), and the United Nations Conference on Trade and Development (UNCTAD), thus harnessing its authority in IP[57]. WIPO administers 23 treaties that deal with the procedural standards of different types of IP[58]. IP rights protected under WIPO consist of trademarks and copyright. It covers artistic works, photographs, architectural design, music, distinctive signs, industrial designs, trade secrets and new plant varieties.

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[55] Supra Ray August,' International Business Law text case ,Ch. 9B.
[56]World Intellectual Property Organisation WIPO (1967) Available http://www.wipo.int/portal/en/index.htmlAccessed (8 January 2016).

[57] Ruth L. Okediji ,'WIPO-WTO Relations and the Future of Global IP Norms', Netherlands Yearbook of International Law 2009, pp.69-125.

[58] 'WIPO-Administered Treaties' ,at www.wipo.int/treaties/en/(10 December 2015).

WIPO's function can be summarised to encompass the promotion of IP development internationally and the harmonization of national legislation in different countries to facilitate the transfer and growth of technology. It also offers legal assistance to developing states in IP; it shares information regarding the protection of IP and provides education on IP rules and procedures.[59] One view suggests that member states to WIPO never accepted the jurisdiction provided by the treaty.[60] Similarly, changes in International law due to technological advancement made the traditional rulemaking system of WIPO inadequate as a multilateral treaty.[61] Furthermore, it is said to lack both the capability to provide for the growing trend of intellectual property protection and the strict consensus present within the WTO-TRIPS framework.[62] Therefore, due to the incessant demands made by the developed countries during the Uruguay round, primarily as a result of the apparent incapability of WIPO as a regulating body in the area of intellectual property protection, resulted[63] in the inclusion of TRIPS as an annexe agreement during the creation of the WTO.

[59] Convention establishing the world intellectual property organization (signed at Stockholm on July,

[60] Yoshifumi Fukunaga,' Enforcing TRIPS: Challenges of Adjudicating Minimum Standard Agreements' (2008) Vol 23 Berkeley Technology Law Journal 867

[61] Edward Kwakwa, 'Some Comments On Rulemaking At The World Intellectual Property Organisation', (2002), Vol 12 Issue 1Duke Journal Of Comparative And International Law 179
Abbott Frederick M, 'Future of the Multilateral Trading System in the Context of TRIPS', The Article, Hastings
(1997) Vol.20, Issue 3 International and Comparative Law Review, PP 661

[63]Frederick M. Abbott, 'Distributed Governance at the WTO-WIPO,' 2000, vol. 3, Issue 1Journal of International Economic Law, 63

1.4 WTO-TRIPS PROTECTION, DRUGS ACCESS AND THE DEVELOPMENT QUESTION

The WTO-TRIPS Agreement is based on the mandate of developing a legal framework to effectively regulate the protection of IPRs on a global level through balancing the views of two opposing groups. The developed countries (i.e. the IPR advocates and protectionism promoters), and the developing countries (i.e. the IPR antagonist and free trade promoters)[64] One of the primary requisites of the WTO-TRIPs is to avoid unilateral retaliation in trade, consequently, prompting the need for a world body that would foster global protection of IPR and technological enhancement in developing countries[65]. The merit of the TRIPS agreement is it allows for more robust patent protection, which confers limited statutory monopoly to an inventor to enjoy the right to its invention solely. This protection of pharmaceuticals enables an investor to control a patented pharmaceutical product's price and supply. In so doing, making them inaccessible and extremely expensive to treat diseases, especially in developing countries like Nigeria.

On the other hand, TRIPS opponents argue that restrictive patents will unduly increase the cost of pharmaceuticals in developing countries[66]. These countries have expressed their dissatisfaction with the TRIPS agreement in how it has been

[64]Xavier Seuba, 'Free Trade of Pharmaceutical Products: The Limits of Intellectual Property Enforcement at the Border' (2010) ICTSD Programme on IPRs and Sustainable Development, Issue Paper No. 27, 9 www.ictsd.org/download/2011/.../free-trade-of-phamaceutical-products.p. Accessed (4 April 2015).

[65]Carlos M. Correa Intellectual property rights, the WTO and developing countries, the TRIPS policy Option 2000 (Zed books: London).

[66]The World Bank-' Developing Available' http://data.worldbank.org/about/country-and-lending-groups Accessed (19 January 2016).

implemented and interpreted[67] as it increases protection more than what was negotiated during the trade rounds. In reiterating the importance of IP, Secretary-General Kofi Annan stated that 'Intellectual property protection is the key to bringing forward new medicines, vaccines and diagnostics urgently needed for the health of the world's poorest people'[68]. A significant number of developed and developing countries have improved their protection level for intellectual property rights in the past two decades, and industry encourages this positive trend for innovation and patient access to new medicines. However, the application of IP to developing countries has some limitations as highlighted with empirical evidence when UNCTAD noted 'that some elements such as patent regime will adversely affect the pursuit of sustainable development strategies by raising the prices of essential drugs to levels that are too high for the poor to afford'[69]. One of the Sustainable development goals for developing countries is to support research and the development of universal access to affordable medicine. Maybe the term affordable is unclear, affordability with patent is unaffordable in Developing Countries. In clear terms, patent protection does not advance the developmental strategy of developing countries neither does it reduce the incident or scale of counterfeit rather the scale of counterfeit is on the rise.

Counterfeit pharmaceuticals' growth is attributed to the high cost of medicine (IPR), poverty, easy supply chain, free trade, advanced technology, and ineffective legislative mechanism. However, the resultant effect from the use of counterfeit pharmaceuticals motivates this study. Counterfeit leads to an untimely death, therapeutic failure or

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[67] Peter K. Yu, 'The Objective and Principles of the TRIPS Agreement', (2009) Vol. 46 Houston Law Review, pp.980-1046.

[68] United Nations United Nation Secretary general to lead fight against HIV/AIDS (2001), Available https://www.un.org/press/en/2001/sg2070.doc.htm Accessed (01 June 2021)

[69] UNCTAD, 'Intellectual property right: implications for development', Policy discussion paper - UNCTAD- ICTSD Project on IPRS and sustainable development (August 2003) http://.www.iprsonline.org/unctadictsd/policy%20discussion%20paper/pp_introduction.pdf>

adverse severe effect or reactions. Counterfeit pharmaceuticals' threat is increasing as the World Health Organisation (WHO) estimated that fake pharmaceutical sales would reach $75 billion globally by 2016[70].

So far, the research has presented an overview of the GATT/WTO IP framework. It has examined the issues and adverse effects of counterfeit in the Nigerian drug economy. It has also introduced IP concerns in the early GATT system and its transition through the WTO and the TRIPS agreement. The chapter illustrated in detail the many problems of counterfeit medicines in Africa, and specifically in Nigeria. It also highlighted other international bodies with responsibility in the IP area and how the development question is associated with drug access and IP protection. The chapter has established the premise for questioning the viability of the WTO-TRIPS framework for counterfeit regulation and will, in chapter two, seek to develop the analytical framework from the concept of counterfeit pharmaceuticals through which to test the WTO-TRIPS and consequently, the implementation of TRIPS in Nigeria. IPR seems a plaudible justification for the increase in counterfeit drugs because price is a key stimulant for counterfeiting, and price increase in pharmaceuticals stems from IPR. IPR is a product of the WTO/TRIPS agreement to regulate creative knowledge. Although Unique, the after effect is counterfeit especially in an unregulated economy like Nigeria.

1.5 AIMS, RESEARCH QUESTIONS AND OBJECTIVES

[70] World Health Organisation –'World Malaria Day , The Growing Threat from Counterfeit Medicines'(2016)
Available http://www.who.int/bulletin/volumes/88/4/10-20410/en Accessed (25 April 2016).

The thesis aims to address the viability of the WTO-TRIPs agreement to address the scourge of counterfeit pharmaceuticals in Nigeria. It is premised on the investigation of the following research questions:

I. Is the WTO-TRIPS agreement an adequate framework for addressing counterfeit drugs in Nigeria?
II. What type of legal rights and procedural laws are adopted by the WTO-TRIPS Agreement that can be relied on for the regulation of counterfeiting in Nigeria?
III. What is the role of other international organisations in counterfeit drug regulation?
IV. What are the IPR deficiencies in the Nigerian standards and regulatory system for IPR that account for the issue of counterfeit?
V. Is the 'counterfeit' pharmaceuticals issue in Nigeria a legal problem demanding legal solution through the WTO-TRIPS or a conceptual and definitional problem?

1.5.1 Research Objectives

1) To provide a contextual background to the problem of counterfeit Pharmaceuticals in poor African states, especially in Nigeria.
2) To establish the theoretical, normative, and legal meaning and scope of application of the concept of 'counterfeit' pharmaceuticals.
3) To analyse the WTO-TRIPS agreement concerning the theoretical, normative, and legal parameters of counterfeit pharmaceuticals.
4) To examine the legal and regulatory framework of the Nigerian drugs system connected with the implementation of the WTO-TRIPS standards

5) To reveal the role of international standards bodies that facilitate access to medicines in developing countries in counterfeit pharmaceuticals
6) To discuss the relationship between the Nigerian-TRIPS drug control system and the international medicine access systems for regulating counterfeit.

1.6 METHODOLOGY

In determining the appropriate methodology for this thesis, research was conducted on different methodologies concerning the topic and its legal research focus. Any researcher must determine the social order's perception under investigation to enable them to identify the appropriate paradigm to guide the research.[71] The method utilised by a researcher in discovering knowledge is what is technically referred to as methodology.[72] It includes the techniques for collecting data utilised for the research and an explanation of how the data is used to address the objectives of the study.

Max Weber once wrote that a '*professional methodologist employs a complex and highly specialized battery of technical, logical concepts'.*[73] While not purporting to be 'a professional methodologist', this researcher considers the use of the concept of 'counterfeits pharmaceuticals'. It has a technical connotation because of its association in the medical and legal fields, it has a logical appreciation.

[71] Mark Saunders, Peter Lewis and Adrian Thornhill, *Research Methods for Business Students*, (New Jersey, Prentice Hall, 2007, p. 102).
[72] Ibid.
[73] Max Weber, supra p.1803.

The thesis adopts the qualitative methodology involving a case study to achieve the research objectives. Qualitative research is the application of qualitative techniques within a qualitative paradigm, which is different from a quantitative paradigm. A paradigm is a belief that guides the way we do things or a pattern or research system.[74] Legal research is different from pure sciences and social sciences, which raises the concern over whether the paradigm concept is necessary for studying a legal inquiry. Hergret stated that there is no scientific description of the law[75], but a legal paradigm is essential to categorize identifiable legal concepts needed in theory building.[76]

Qualitative research involves using words in describing the findings of the investigation. It is characterized by the researcher being closely involved with the context under study.[77] Qualitative research is about meanings: it is critical and exploratory. It uses multiple sources of data, and it does not provide a single answer to questions. This methodology focuses on small-scale studies that allow for a detailed and in-depth description of the issue under investigation. Such studies usually adopt a holistic approach to provide a complete picture of the problem being investigated rather than just focusing on studying isolated sets of variables.[78] It is opposed to quantitative research that involves numbers, identification of variables, and it requires theory-testing and deduction and values objectivity. In other words, quantitative analysis emphasizes the use of numbers in describing the findings of the research.[79][80]

[74] Juergen Habermas *Knowledge and Human Interest*, (London: Heinemann Publishing 1970).
[75] James E Hergret 'The Scientific Study of Law: A Critique,' (1984) Vol. 24, No. 2 Jurimetrics, pp.99-126.
[76] Peter Ziegler 'A Paradigm of Legal Research,' (1988) 51Modern Law Review 569-592.
[77] Ibid.
[78] Ibid.
[79] Ibid.
[80] Ibid.

Since the study investigates the viability of the WTO-TRIPS agreement to address the problem of counterfeit drugs via the qualitative methodology because the qualitative research process is characterised by its flexibility, adaptability, and openness to accommodate new variables that are likely to unfold during the research process. The research questions and objectives aim to unravel the meaning of 'counterfeit pharmaceuticals and construct a theoretical, analytical framework to study the WTO-TRIPS regime and implementation in Nigeria to address counterfeit drugs to be conducted within such a flexible framework. Such an approach is akin to 'exploratory' research that is identified by Fisher. It advocates for enough flexibility to accommodate potential change during an investigation, mainly if the new data emerging necessitates change.[81]

McConville and Chui perceive legal research methodology as systematic and complex.[82] It can be internally focused, that is, a perception of law as a self-contained entity or through the insight of another discipline to investigate a legal problem.[83]. On this note, it is feasible for the thesis investigation on counterfeit drugs to broaden its perception to WTO-TRIPS law.

This is done by adapting insight into 'counterfeit pharmaceutical' concept as applied in other disciplines to bring out its meaning to investigate the legal problem of counterfeit medicines under the global regulatory framework of the WTO-TRIPS law. There are different legal methodology categories that one should examine to ascertain the most appropriate to attain the research objectives. The types of legal methodology include

[81] Exploratory research studies aim of investigating what is taking place, seeking novel insights, asking questions, and assessing the issue under investigation using a new perspective; see C. Fisher, *Researching and Writing a Dissertation*, Edinburgh, Pearson Education, 2007, p. 100.
[82] Mike McConville & Wing Hong Chui, W.H. (Ed) *Research Methods for Law,* (Edinburgh University Press 2007).
[83] Ibid.

black letter methodology, doctrinal analysis, jurisprudential perspective, legal realism, critical legal studies, and postmodernist theories of law, queer theory, empirical research methodology, socio-legal research and Feminist legal theory.[84] The doctrinal analysis is termed the purest form of legal methodology because it concerns itself with policy analysis, while the black letter methodology focuses on the language of the law as interpreted from statutes and case law.

However, neither of these methods can adequately relate to policy documents like Critical Legal Studies (CLS), Socio-Legal research and Empirical research methods. The CLS is a technique of legal analysis that exposes the hidden political nature of law. It throws light on the interpretation of a legal language, especially in the context of rights. CLS believes that placing one's trust in the legal system is misplaced and may be subject to manipulation.[85] However, critics of CLS believe that it is trivial for it attempts to prove the law is a matter of social policy and that legal rules must be identified by choosing between principles and procedures. Another similar opinion on critical legal studies is that it is radical. It assumes law to be politics between two competing interests with moral views that cannot be reconciled objectively.[86]

Socio-legal research is interdisciplinary, emerging, and it is theoretical and methodologically a diverse sphere of socio science. Previous knowledge of socio science is not a requirement for a socio-legal researcher, it is an interface between Law and socio science. A shortcoming of socio-legal research is it is so modern it lacks a broad technique of investigation, unlike other methodology which is based on established traditions of research. Counterfeit pharmaceuticals and intellectual

[84]Caroline Morris & Clan C Murphy. *Getting a PhD in Law*, (Oxford and Portland: Hart Publishing 2011).
[85] Ibid.
[86] Donald Brosnan, *Serious but Not Critical,* 60 Southern California Law Review 259, 396 (1986); John Stick, *Can Nihilism Be Pragmatic, 100* Harvard Law Review. 332-401 (1986).

property is intertwined in this research, both are opposing theories. However, by using socio-legal research it can inform the study of law and society[87]. Counterfeit is a social condition that needs legal clarity to change the situation using continuous re-examination and re-evaluation of concepts that existing methodologies cannot solve[88].

Empirical research is grounded in observation, experience, and investigation of the socio-legal approach to law. Empiricists want to know the impact of the law, how it works, how the actors in a legal system behave and the overall effect on people in the real world, otherwise called the *rule of inference.*[89] To Epstein and King, every law or policy violates one or more rules of interference for it affects public policy; such rules become valueless because it contains many unfounded claims.[90]

Another crucial legal methodology is legal realism; a legal realist assumes law is about the experience, not strict adherence to the courts' normative standard, statute and treatise. Kalman describes legal realism as a legal reasoning method and education, involving a form of functionalism or instrumentalism. The original realists sought to understand legal rules regarding their social consequences to understand better how law functions in reality.[91] Law is what a court will do or say within the limit set by statute, and public opinion as such legal realism saves us from the consequences of legal order and social control. It is the practical applicability of the law to real-life situations by seeking a realistic attitude when interpreting the court's opinions or treatises.

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[87] Banakar, Reza, and Max Travers, eds. *Theory and method in socio-legal research*. Bloomsbury Publishing, 2005.
[88] Schiff, David N. "Socio-legal theory: social structure and law." *The Modern Law Review* 39.3 (1976): 287-310.
[89] Lee Epstein and Gary King, 'The Rules of Inference*,'* (2002) Vol *69,* Issue 1, University of Chicago Law Review, pp.1-133.
[90] Jack Goldsmith and Adrian Vermeule, 'Empirical Methodology and Legal Scholarship', (2002) Vol.69 The University of Chicago Law review, pp.153-156.
[91] Hans Meyerhoff, 'From Socrates to Plato, in The Critical Spirit Essays in Honour of Herbert Marcuse 187, 200 (K. Wolf & B. Moore eds. 1967).

According to Roscoe Pound, legal realism challenges the dominance of authority of the historical analytic schools established in the 19th century. In his view, legal realism sterns for reality on the basis that all legal movement within the last two hundred years grows from it, and as such legal realism existed, but only recently with a new name. Therefore, conceptualising legal realism, it is evident that the experience from reality is as important as a legal rule, doctrine, statute and concept.[92] A legal realist believes that legal rules are often vague and ambiguous as they contain abstract concepts such as reasonableness, title and duress, which are subject to broad interpretation by a reasonable person. Secondly, realists argue that due to the lack of indeterminacy of abstract concepts and judicial precedents' manipulation, it is impossible to contradict rules. Legal realism hopes to discover the truth embedded in social practices to balance the interest between parties. Contrasting legal realism with CLS, realism engages in normative legal arguments without formalisation by focusing more on the relationship between the state, society law and the individual.

This study will adopt a mixture of critical legal analysis, legal realism, socio-legal research and empirical research to test the international and domestic regulatory instruments that affect counterfeit drug production under the WTO-TRIPS. Empirical study and CLS is essential in this research because it will present a forum to understand the complexities within the WTO regime clearly. This approach will create a normative dimension in structuring what we look for, i.e., the definition and meaning of 'counterfeit pharmaceuticals' and what we see in international economic law,[93] and its viability of the WTO-TRIPS agreement to address counterfeit drugs. Whereas

[92] Max Radin, 'Legal Realism' (1931), Vol.31, Issue 5 Columbia Law Review, pp.824-828.
[93] Gregory Shaffer, Power, *Governance, and the WTO: A Comparative Institutional Approach*, M. Barnett & R. Duvall (Ed) In Power in Global Governance, (Cambridge: Cambridge University Press 2005), pp.130-160.

Socio-legal research is significant in this paper because it connects law to society by examining how the law is reflected or perceived against socio issues.

Dunoff & Trachtman rightly affirm the advantage of empirical research, in providing a critical theory of law and economies,[94] a benefit which our analytical, conceptual framework on 'counterfeit pharmaceutical should entail. Similarly, Goodman and Jinks also note that empirical research illustrates the law's conceptual analysis through the social influence mechanism.[95] The exposition of the concept of counterfeit pharmaceuticals in a variety of frameworks including economic, human rights/social and political aspects will help us to analyse the Nigerian-TRIPS legal and regulatory system to ascertain the viability of the Global IPR regime under WTO-TRIPS. However, legal realism is vital to this research for the policy is based on intuitive judgements of rights and wrong, fairness, and unfairness.

The thesis employs a case-study approach. The case study approach is used for evaluation, through which a researcher develops an in-depth analysis of a case or subject. [96] It describes a comprehensive examination of a single entity that uses various evidence sources, facilitating a holistic understanding of a particular topic.[97] The explored case can cover an organisation, a group of people, a community, a process, event or issue. It is perceived that data obtained from single case studies are often detailed and rich, although it is equally cautioned of the danger that findings in a case study research cannot always be generalised.

[94]Jeffrey L Dunoff & Joel P Trachtman, 'The Law and Economics of Humanitarian Law Violation in International Conflict' (1996) 93 American Journal of International Law pp.394-409.
[95] Ryan Goodman & Derek Jinks, 'International Law and State Socialization: Conceptual, Empirical and Normative Challenges' (2005) 54 Duke Law Journal pp.983-998.
[96] Creswell, John W *Research Design*, (London: Sage 2014).
[97] Saunders, Lewis and Thornhill, p.102.

The thesis is organised under an inductive research approach that is characterised by an understanding of the meanings that people associated with events, intimate knowledge of the context of a study, collecting qualitative data, and using a flexible structure that allows changes, as the study progresses, can effectively resolve theoretical questions.[98] So that in adopting the qualitative method to investigate 'counterfeit' pharmaceuticals in varying permutations can test the effectiveness of the WTO-TRIPS and the Nigeria-TRIPS regulatory systems, the thesis places emphasis on having an in-depth and rich account of the counterfeit phenomena and its legal application as opposed to an attempt to emphasize generalizing the findings. Therefore, a case study approach will be a useful tool in providing the flexibility to question the counterfeit medicines conceptual framework within WTO-TRIPS and to determine the technical and legal realities associated with counterfeit pharmaceutical regulation in Nigeria given the TRIPS complexities.

1.6.1 Data Collection

Data for the research will be collected from primary and secondary sources. Evidence will be collected from various documentary sources (images and words), which, according to Fisher, must have been recorded devoid of the researcher's intervention.[99] Documents that will be used to shed light on the case study will be obtained from various sources, including digital, visual, sound, and printed forms over which they had no intervention. Primary documentation will mainly comprise legal and policy instruments from the WTO, Nigerian law and other legal instruments of international organisations. Secondary documents will be derived from books,

[98] Saunders, Lewis and Thornhill, p.98.
[99] Fisher, p. 102.

journals, reports, policy studies, legal encyclopaedias, periodicals, and technical data on drug distribution, working papers, conference proceedings, newspapers and electronic sources. These sources of documents will inform the chapters of the thesis.

1.6.2 Ethical Considerations

The research will be guided by professionalism and respect for ethical considerations, completing the UEL Graduate school research ethics training. This research will not involve the participation of human subjects; therefore, ethical approval will not be required

1.7 RESEARCH SIGNIFICANCE AND CONTRIBUTION TO KNOWLEDGE

From a conceptual point of view, this research will illuminate our understanding of the theory of counterfeit drugs by applying the theoretical perspectives of the pharmaceutical industry to study the suitability of the legal regime of WTO-TRIPS regulation of drugs IPR to address the problem of counterfeit medicines and consequently its impact on human health. As discussed above, scholars have focused more on providing drugs and protecting business rights and access to medicines. Several research and policy studies have been conducted on the WTO-TRIPS from

the perspective of human rights, poverty, access to medicine, public health, HIV Aids, and so on, mainly in relation to developing countries.[100]

Counterfeit drugs have primarily been looked at outside legal literature, especially in technical and policy studies on medical and pharmaceutical or public health. It appears that the concept and issue of counterfeit medicines as a specific focus of study has not been pursued by way of legal research. The result of this non-legal outlook to counterfeit drugs negates a thorough appreciation of the depth and scope of dimensions of the problem and impact of counterfeit drugs and consequently, the legal, policy, regulatory, administrative, and judicial responses that may address it. This research will achieve a structured appreciation of the concept of counterfeit pharmaceuticals and the frame within which to explore the viability of current legal instruments and institutions on drug control deriving from the multilateral trade framework.

The findings from this thesis will shed light on how developing countries can effectively eradicate counterfeit drugs without sole reliance on the WTO-TRIPS provision. It will equally contribute to the existing legal rules for regulating international trade, especially trade in counterfeit pharmaceuticals. The problem of counterfeit drugs is prevalent in developing countries in Africa, including Nigeria. By undertaking a case study on Nigeria, the largest economy in Africa with approximately 200 million people, the study will provide an important reference point for policy and legal development on

[100] Steve Charnovitz, 'Triangulating the World Trade Organisation', (2002) 96 American Journal of International Law, pp.28-55; Baskaran Balasingham 'Trade in Pharmaceuticals under the TRIPS Agreement' (2011) 11 University College Dublin Law Review, pp.1-24; Michael Blakeney 'Intellectual property and Economic Development' (1998) 14 International Trade Law and Economic Development pp.238-264; Carolyn Deere Birkbeck, *The Implementation Game, The TRIPS Agreement And The Global Politics Of Intellectual Property Reforms In Developing Countries*. (Oxford: Oxford University Press (2009); Susan K Sell, 'TRIPS and Access to Medicine Campaign,' (2002) 20(3) Wisconsin International Law Journal) pp.481-522.

addressing counterfeit drugs, but also other aspects of regulation, which the investigation will reveal.

1.8 RESEARCH LIMITATION

Given the pervasiveness of counterfeit drugs, which is further compounded by the problem of access to medicines in developing countries, there is a temptation to perceive the study as sociological research. Based on the impact of this phenomenon on poverty and invariable the more critical questions on development, public policy on health like the millennium development goals and domestic public health. While the thesis considers these topical issues, it does not purport in-depth studies of these, nor does it purport to proffer solutions.

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1.9 LITERATURE REVIEW

The TRIPs agreement is known as the most comprehensive international legal instrument for regulating IPR; its framework provided patent protection for copyright, patent, plant breeders, geographical indications, trademark, industrial designs, and trade secrets. The agreement stipulated minimum standards and enforcement for these rights. This means that member countries cannot confer a lower level of protection than provided under TRIPs. All WTO-TRIPs members are therefore obligated to protect IPR in all fields of technology, including the patent for the pharmaceutical product (product and process).

The WTO-TRIPS agreement did not give a clear definition of intellectual property rights. Still, generally, it can be defined as those rights imposed by a state upon individuals for a prescribed term, to prevent unauthorized exploitation as a benefit from

the creation of the human intellect[101]. The rationale for justifying IPR as a legal right is mostly for economic reasons. As Dutfield and Suthersanen rightly stated, IPR is an institutional means for firms to be rewarded or an incentive for research and development. [102]. Firms depend on rewards as a form of return for inventive steps, and it is essential for growth. The TRIPS agreement guarantees protection of IPR within the WTO multilateral framework of 'one size fits all system'. Scholars like Dutfield, posit that the one -size -fits all approach of the WTO-TRIPS agreement is strengthened by the extension, of the scope of patentable subject matter to crucial areas such as pharmaceutical, life form, genetics and plant varieties. The ruling regarding patentable subject matters includes anything under the sun made by man.[103] This meant that TRIPs created stringent conditions, especially for developing countries, which lacked IPR to medicine nor hold productive capacity.

Empowered by TRIPs, pharmaceutical companies set high prices for patented products. This high price is one of the critical factors restricting access to medicine in developing countries. According to Drahos & Braithwaite, the goal of having a global IPR paradigm is not to create a market economy for the developed countries but a needy population[104] . However, Oguamanam did not support this point; he posits that the adverse health needs of developing countries, especially in Africa, show the negative impact of strict pharmaceutical IPR protection by multinational corporations

[101] Michael Blakeney, M *Trade Related Aspect of Intellectual Property Rights: A Concise Guide to the TRIPs Agreement*, (London: Sweet & Maxwell (1996),

[102] Gregory Dutfield & Uma Suthersanen, *Global Intellectual Property Law* Cheltenham: (Edward Elgar Publishing 2008).

[92] Carlos M Correa, *Intellectual Property Rights, the WTO and Developing Countries, the TRIPS Policy Option* (Zed books: London (2000).

[103] See the landmark case of *Diamond V. Chakrabarty*, where the Supreme Court held that patentable subject matters include anything under the sun made by man; see G Dutfield. 'Does the One Size Fit All?' (2006), 26 Harvard International Law Review, pp.50-54.

[104] Peter Drahos & John Braithwaite, *Information Feudalism: Who Owns the Knowledge Economy*, (New York: The New Press 2002).

without concern for the human rights implications[105]. The issue of human rights under the TRIPs agreement relates to access to essential medicine. The debate revolves around how to balance the inflated price of drugs and people's health needs.

On this issue, Cynthia Ho argues that pharmaceutical companies' human rights implications concerning patenting needs should be considered because access to medicine affects all citizens of the world[106]. Therefore, knowledge about how drugs are protected should not be limited to a few people. Similarly, Sell examined the access to medicine debate from a political standpoint. Sell argued that the overall cost of TRIPs is steeper than dollars, but will be paid with human lives, especially in the face of the HIV/AIDS epidemic[107]. Adding to the access to medicine debate, Attaran researched by collecting data from 65 low-income countries and comparing it with the WHO list of essential medicine. His study proved that patent may not be a direct cause of essential medicine unavailability in developing countries. However, he suggests that poverty poses a far greater limit to access to medicines than patents[108].

Ho posits that an analysis of different patent perspectives should advance a better understanding of how to balance patent rights and access to medicine. According to Ho, this patent perspective will have a significant impact on how the law is perceived and how laws are interpreted[109]. So, access to medicine can be deemed a privilege to patent owners to promote innovation. On the other hand, Lazzarini introduced a

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[105] Chidi Oguamanam, *Intellectual Property in Global Governance, A Development Question* (Routledge 2012).

[106] Cynthia Ho, *Access to Medicine in the Global Economy*, (Oxford University: Press New York 2011),

[107] SK Sell, 'TRIPS and Access to Medicine Campaign', (2002), 20 Wisconsin International Law Journal, pp.481-522.

[108] Attaran, A.' How do Patent and Economic Politics Affect Access to Essential Medicine in Developing Countries,' (2004), 23(4) Health Affairs, pp.155-166.

[109] Cynthia Ho, 'Global Access to Medicine: The Influence of Competitive Patent Perspective, (2011) Vol 35, Issue 1 Fordham International Law Journal 1-97, Zita Lazzarini.' Making Access to Pharmaceuticals a Reality: Legal Options under TRIPS and The Case Study of Brazil' , (2003), 6 Yale Human Rights and Development Journal, pp.103-138

different approach by stating that the conflict between IP and human rights could be resolved if the trade exceptions under TRIPs are fully utilized. This exception includes an exception from patentability, parallel imports and compulsory licensing; it is a powerful tool for countries with serious public health needs, especially developing countries. Ruth Gana argues that the real challenge facing developing countries is a developmental issue and not the defects of an international proprietary system such as access to medicine under TRIPs[110]. Thus, she asserts that developing countries need to embark on comprehensive developmental strategies in education, marketing, economic policy, foreign investments and technological issues instead of blaming TRIPs.

The focus of developing countries' health advocates had been getting affordable drugs into their supply systems. This introduced the element of counterfeit pharmaceuticals into the system because the need for access to medicine became more important than the protection of IP rights under TRIPs. Counterfeit is a global problem. Even if its scope is still unknown, the WTO estimates that over half of the drugs in developing countries are counterfeit. Some of the arguments on counterfeit drugs are that counterfeit is primarily an issue of intellectual property. IP not only increased the price of innovative medicines but also aggravated counterfeit drugs[111]. Counterfeit pharmaceuticals become an even greater problem for firms given the huge margins between the market price of drugs, R & D costs and issues of patent infringement, and how less costly counterfeits erode firms' profit margins.

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[110] Ruth L Gana, 'Creativity Died in the Third World, Some Implications of the Internationalisation of Intellectual Property' (1995-1996) 24 Denver. Journal of International Law & Policy, pp.109-144.

[111] Charles Clift 'Combating Counterfeit, Falsified and Standard Medicines: Defining the way forward?' Chatham House Briefing papers (2010).

Another major attribute to counterfeit highlighted by Bird is the inadequate laws, weak enforcement mechanisms and the absence of criminal penalties for counterfeiters[112]. Attaran, Bates and Rogers argue that counterfeit remains legal in international law, mostly due to the problems of the definitional scope of counterfeit. The term counterfeit has different meanings attributed to it by different countries, as up until now, no uniform definition has been proposed globally. To them, criminalizing counterfeit medicine on an international scale will offer significant results over the states' approach. They assert that the *actus rea* and *mea rea* of counterfeit medicine should be considered, which means offenders can be quickly punished[113].

The extent of counterfeit drugs is mostly unknown, but it keeps increasing daily. The WHO 2010 estimated that the counterfeit drug market could reach $ 75 billion as of 2010, and 25% of counterfeit drugs are consumed in developing countries. WHO presents results from a survey conducted on 20 countries from 1999-2000? The result indicated that 60% of drug counterfeits occurred in developing countries[114]. Some of the consequences of the consumption of counterfeit medicines include death, as seen in some developing countries. One example is the Republic of Niger in 1995, where 2500 children died from fake meningitis vaccinations, 89 deaths in Haiti in 1995 from the consumption of counterfeit paracetamol syrup, and 30 deaths in Cambodia after taking fake anti-malaria drugs[115]. Another consequence of counterfeit stated by Nelson, Chang & Vizurraga is that it stifles economic investment and impedes the

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[112] Robert C Bird, 'Counterfeit Drugs a Global Consumer Perspective' (2008) Vol 8 Issue 3 Wake Forest Intellectual Property Law Journal, p.387.

[113] Amir Attaran, Roger Bate, Megan Kendal, 'Why and How to make an International Crime of Medicine Counterfeiting', (2011) 9 Journal of International Criminal Justice, pp.325-354.

[114] World Health Organisation (2010) 'Substandard and Counterfeit Drug Medicines, Available http://www.who.int/mediacenter/factsheets/2003/fs275/en/

[115] World Health Organisation (WHO) General Information on Counterfeit Medicine 2007, Available http://www.who.int/medicine/srvices/counterfeit/overview/en/

economic growth of states.[116]. Counterfeiters have a total disregard for health and safety measures; neither are they concerned with product quality, nor do they pay import or export taxes.

Research by Cockburn and others suggests that companies and governments are reluctant to publish the extent of counterfeit not harm sales of the brand–names product. They surveyed to check the presence of a reliable database on counterfeit drugs, and the findings showed that the WHO has received only 48 reports from 1999-2002. This estimate is less compared to the death rate, so this report proved the point of non-disclosure[117]. Similarly, Newton and White conducted a survey in Cambodia, 138 drugs were tested, and the result showed that 38% of the 138 were counterfeit drugs.

A common theme from this literature discussed above is the anomaly around the TRIPs agreement, access to medicine, counterfeit drugs, IP regulation and disclosure. The primary intention of TRIPs is to create a legal and uniform patent administration system for members of the WTO. However, instead, it shifted its focus from IP protection to medicine without delimiting its focus. Scholars on TRIPS focused on the human rights, developmental and economic aspects of TRIPs, without considering the side effects of unregulated drugs, which are counterfeit pharmaceuticals. TRIPs set a viable administrative system and gave patent rights but failed to regulate the technical aspect of drugs production. Most research on counterfeit tends to test its consequence, extent and effect but fails to look at the legal aspects of counterfeit.

[116] Maria Nelson, Michelle Vizurraga and David Chang 'Counterfeit Pharmaceutical a Worldwide Problem,' (2006) 96 Trademark Review, pp.1068-1100.

[117] Robert Cockburn and others 'The Global Threat of Counterfeit Drugs: and Why Government Must Communicate the Dangers,' (2005), Vol. 2 (4) PLos Medicine e100

In conclusion, it can be suggested that there existed an anomaly or dichotomy of concepts, especially in respect of Pharmaceuticals, thus creating a regulatory paradox under the WTO. Hence from a legal viewpoint, some questions need clarifications such as what type of right is protected by TRIPS? Can procedural laws be relied on for the regulation of counterfeit? Is patent protection the problem, or is the problem in the developing world and Nigeria, particularly one of access to medicine? The International Federation on Pharmaceutical Manufacturer Associations (IFPMA) support this position in a statement that "patents have nothing to do with counterfeiting and counterfeiting has nothing to do with patents''[118] . Therefore, what type of medicines amounts to counterfeit, could it be substandard drugs, imitation, or fake drugs? All these issues would be discussed in this research.

Chapter 2 - The Concept and State of Counterfeit Pharmaceutical in International Trade

2.1 Introduction

The preceding chapter discussed the rationale for the inclusion of IP within the WTO-TRIPS multilateral trade system. It presented an overview of the GATT/WTO

[118] International Federation of Pharmaceutical Manufacturers Association – IFPMA '10 principles of Counterfeit Medicine (May 2010) Available at www.ifpma.org>content>news>ifp.

framework and counterfeit in the Nigerian drug economy. It examined the origin of IP and its transition under the TRIPS agreement. The chapter also analysed the many problems of counterfeit and the International Organisation with the responsibility of tackling IP-related matters. To question the viability of the WTO TRIPS framework to regulate counterfeit pharmaceuticals. This chapter aims to unravel the distinctive nature of counterfeit in response to the theoretical issues raised about counterfeit, by evaluating the definition, implication and evidence of counterfeit, while considering the contextual scope of counterfeit products. It will provide an opportunity to clarify the link between IP and counterfeit pharmaceutical products. It will show that despite the definitional question, counterfeit has a direct significance to the current state of pharmaceutical regulation globally with reference to Nigeria.

Counterfeit is regarded as a global catastrophe with perverse consequences. For example, counterfeit is said to be the major cause of unnecessary morbidity, mortality, and loss of public confidence in medicines and health facilities[119]. It also leads to an untimely death, therapeutic failure or adverse severe effect or reactions. The threat of counterfeit pharmaceuticals is on the increase as it was estimated by the World Health Organisation (WHO) that counterfeit pharmaceutical sales would reach $75 billion globally by 2016[120]. Although there is no reliable estimate on the actual value of counterfeit pharmaceutical market size, getting a reliable figure is a challenge. Still, the best guess estimate is that it is over $4.35 Billion with lifestyle drugs, pain killers, and antibiotics leading the trend[121].

[119] Robert Cockburn and 'The Global Threat of Counterfeit Drugs: Why Industry and Governments Must Communicate the Dangers.' (2005) PLoS Med 2(4): e100. doi: 10.1371/journal.pmed.0020100

[120] World Health Organisation –World Malaria Day , 'The Growing Threat from Counterfeit Medicines '(2016) Available http://www.who.int/bulletin/volumes/88/4/10-020410/en/ Accessed (25 April 2016)

[121] Securing Industry 2020, Study estimates world trade in fake medicines is worth €4bn Available https://www.securingindustry.com/pharmaceuticals/study-estimates-world-trade-in-fake-medicines-is-worth-4bn/s40/a11550/#.X2Dz_3lKjIU Accessed (15 September 2020)

What then is 'counterfeit'? It is a relative term, which is subject to different interpretations like a correlation of terms. The colloquial meaning of counterfeit differs from different countries or firms. Typically, there seems to be a connection between the legal impact of counterfeit in international trade and the economic, social, developmental, and humanitarian aspects of counterfeit. Indeed, to establish this connection, it is essential to understand the objective, scope, nature, and counterfeit scale. The World Customs Organization considers counterfeit as a crime of the 21 century and a risk to every nation[122]. It is so dangerous that it can reduce a country's economic output and industrial competitiveness[123].

The problem of counterfeit is believed to be more rampant in developing countries as against developed countries. The WHO estimates that about 30% of the medicines consumed in Africa is counterfeited and over 70% of the medicine sold in Nigeria is either counterfeit drugs or substandard. This results in over 700,000 deaths from counterfeit consumption annually in Africa, with most of the medicines originating from China, India, Mexico and Brazil[124]. Another aspect recognized for the growth of counterfeit Pharmaceuticals is the existence of weak intellectual property laws in

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[122] World custom organisation WCO (2004) The First Review on Customs and Counterfeit Available http://www.wcoomd.org/en/media/newsroom/2006/august/the-first-review-customs-and-counterfeiting-2004.aspx (Accessed 22 April 2016) this review provides an overview of the alarming growth of the trade in counterfeit by the world custom organisation. By indicating possible measures to curb this menace within the organisation's disposal, the Secretary General of WCO, Michel Danet, affirms that Counterfeiting and piracy have reached an intolerable proportion. It is a threat to public health and safety. Custom officials reported in 2004 a total of 4,000 cases on counterfeit and seized more than 166 million worth of counterfeit goods.

[123] Peter H. Bloch, Ronald F. Bush and Leland Campbell, "Consumer Accomplices in Product Counterfeiting: A Demand Side Investigation', (1993) Vol. 10 Issue 4 Journal of Consumer Marketing, PP 27. Countries like Kenya lost a substantial amount of coffee crop due to counterfeit fertilizer, also in the USA Job losses as a result of counterfeit is estimated to 210, 000 jobs. The supply and demand aspect of counterfeit is analysed, the author points out that research is mainly conduced on the supply aspect of counterfeit, which in this article is not the case, major emphases is placed on the demand aspect of counterfeit.

[124] Jeremy M. Wilson, Roy Fenoff, 'The Health and Economic Effect of Counterfeit Pharmaceuticals in Africa' A-CAPPP Backgrounder, (2011) Available http://acapp.msu.edu/sites/default/files/files/africabackgroundfinal.pdf Accessed (25 April 2016)

developing countries. Intellectual Property protects the right of manufacturers by providing absolute protection for ideas and creativity. It gives a manufacturer monopoly right over inventions to the exclusion of all others. A manufacturer relies on this right to protect marketable intellectual inventions given the high cost of research and development (R&D). In this light, IPR is a justification for the economic exploits of Pharmaceutical products. But this absolute right gives rise to counterfeit drugs which is an infringement to IP.

Another key issue discussed within this chapter is the historical development of counterfeit, particularly how it is perceived, justified, and adapted to fit the circumstance or position the term finds itself. For without experience, future dynamics is incomprehensible in terms of law and legal history. The study of counterfeit needs to connect, alter, and advance the understanding of modern-day law and help identify relevant principles and practices concerning Counterfeit[125]. The definitional problem analysis is expected to add to the existing definitions on the subject by adopting a workable interpretation of counterfeit from current definitions and terminologies. It will contrast and compare the concept of counterfeit with similar ideas like Knockoff, imitation, fake and substandard pharmaceuticals. It will identify the effect of globalisation, free trade, legal enforcement mechanisms on counterfeit distribution. The theoretical, legal and policy aspects of counterfeit medicines will be emphasized in constructing the framework for analysing the legal character of counterfeit in international trade. The chapter will also explore the economic, technical, and institutional aspects of counterfeit Pharmaceuticals to establish a conceptual and

[125]Markus Dirk Dubber, 'Historical Analysis of Law,' (Spring, 1998) Vol. 16 No. 1, Law and History Review, pp. 159

theoretical framework for testing the viability of the WTO/TRIPS systems in the regulation of counterfeit.

2.2 Evolution and Definition of counterfeit

Understanding the evolution of a concept is instrumental in developing a theoretical meaning. In this scenario, the concept of counterfeit is a critical unresolved issue in international trade law[126]. To resolve this contextual issue, examining the history of counterfeit will provide a framework to decide its scope and its relation to modern-day international trade and health issues. Counterfeit first arose as a concept from the early 27BC after the discovery of counterfeit wine in Rome[127]. Similarly, coin counterfeiting gained prominence around the sixteenth and seventeenth centuries in France. The act of counterfeiting coins involves the smuggling, production, and use of forged coins usually carried out by goldsmiths, trade merchants, soldiers, and even priests. A typical example of counterfeit occurred in France where replicas of the official coinage of the protestant king were made by parallel minting by the supporters of the pope to undermine the reign of the king[128].

Similarly, historical evidence suggests that in Spain, criminals forged letters of credit used in monetary transactions to evade the law. For instance, at that time, financial institutions made an adverse decision not to disclose the extent of this crime to the

[126]Davison Mark. *Pharmaceutical anti-counterfeiting: combating the real danger from fake drugs*. John Wiley & Sons, 2011, see also Agbaraji, Emmanuel C., Deborah O. Ochulor, and Gloria N. Ezeh. "Food and drug counterfeiting in the developing nations; the implications and way-out" *Academic Research International* 3.2 (2012): 24

[127] Tim Philips, Knockoff: *The deadly Trade in Counterfeit Goods: The True Story of the World's Fastest Growing Crime Wave*(United States of America : Thomson Shore Ltd, 2005), see also Jason Rutter and Jo Bryce The consumption of counterfeit goods : Here be pirates , Sage publications, Vol. 42(6): (2008) 1146–1164

[128] Peggy Chaudhry, and Alan Zimmerman, *protecting your Intellectual Property Right: Understanding the Role of Management, Government, consumers and Pirates* (New York: Springer, 2013)

public does not undermine its authority or increase the scale of Counterfeit[129]. Another important reason attributed to the growth of counterfeit is the recognition of trademarks or similar marks. This proprietary mark of proof and quality is noted to have been in existence in China around 5000 years ago[130]. The introduction of trademarks or similar marks in trade made a significant impact on the course of trade and the perception of counterfeit. It created an opportunity for merchants to mark products uniquely in a bid to circumvent counterfeiters. These marks appeared in various products from pottery, brick and tiles, oil lamps, and paintings to textiles. However, enforcement of this mark was mostly unknown at that time, but it appears that punishment was meted out to offenders by Roman commercial institutions[131].

These marks extended to the middle age, with building merchants attaching symbols to distinguish their product from low-quality knockoffs. By the 13th century in England, the law became compulsory to have marks inscribed on products, and infringement on this mark amounted to prosecution such as imprisonment and capital punishment of perpetrators[132]. The first registration of trademark in England dates back to 1875[133]. However, the first known case in England for the prosecution of infringement of a mark is the Sandford case of 1584[134].

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[129] Mark Galeotti, *Part of Wickedness and crime: The under World of the Renaissance Italian City*, (Gonafalon Press: Italy, 2012) The growth of crime, counterfeit, murder and the harsh punishment melted out to offenders in renaissance Italy is evaluated. The area of counterfeit is traced from coinage to forged credit notes by educated Italians in a bid to elude the authorities and it was regarded as a norm.

[130] Shoen Ono, *Overview of Japanese Trademark Law*, (Yuhikaku: Japan, 1999) pp1-39 Trademark plays a vital role in the choices of consumers. Consumer rely on trademark to make product choices, it is unique in trade for without trademark goods cannot be identified. Without Trademarks manufacturers cannot profit from extensive corporate effort in research and development. Trademarks protect goods from counterfeit and knockoff or imitation. The main function of a trademark is for identification and it can be used in different capacity like a name, title, country, all signs, symbols, business mark, service mark etc

[131] Ibid Dr Shoen Ono, Overview of Japanese Trademark Law

[132] Abbott, G. W, Sporn, LS, *Trademark counterfeiting* (New York: Aspen Publishers 2011)

[133] Jeffery Belson, Certification *marks, A special report* (London: Sweet and Maxwell 2002)

[134] Sandforth case (1584) Cory's Entries BL MS Hargrave 123

In addition to the limitation on trademark, the Venetian law of 1474 introduced protection for an invention in the form of patent by granting exclusive rights for inventive steps.[135] Over the next 2000 years, the single act of copying resulted in the growth of counterfeit and in the words of Dr Fredrick Mostert 'every product known to mankind can be entirely copied[136]'. This shows the extent to which products can be counterfeited. Products subject to counterfeit include luxury goods, consumer products, cars, bags, pharmaceuticals, computers, electronic products, etc. The list is endless; as technology increases, so do counterfeit goods also increase.

Counterfeit products are sold through various channels from high street shops, black markets to online market platforms. However, trade-in counterfeit has uniquely adapted to changing trade policies to circumvent legal and regulatory impediments to its distribution. The intention behind counterfeit is 'deceit', meaning to portray what is not as what it ought to be to unsuspecting buyers or consumers. As seen in the words of Higgins that counterfeit in legal parlance is like passing off goods of low quality as the original aimed at deceiving the unsuspecting buyer and defeating the traditional purpose of the product[137].

[135]Kamill Idris, 'Intellectual Property a Power Tool for Economic Growth' (WIPO: Issue 888 of WIPO Publication, 2003)

[136] Fredrick W. Mostert, Martin B Schwimmer, 'Notice and Takedown for Trademarks' (2011), Vol.101, No.1 The Law Journal of International Trademark Association, 249- 281

[137] Richard Higgins, 'Counterfeit Goods', (1986) Vol. 29 Journal of Law and Economics, 211 This paper indicated the importance of trademark by stating that branded goods is purchased by a particular class of consumers to demonstrate the preference for that goods. Thus, counterfeiting of that product trademark affects the overall need of the makers of the product resulting in the change of motive of consumption with the growth of counterfeit. By examining the market factor behind counterfeit product purchase amongst Americans, the research showed that consumers are indifferent about the manufacturers of goods but about the quality and price.

2.2Liberalisation, Internet trade and Counterfeit

A restrictive trade regime is practically impossible in this era of globalisation. This is mainly due to the liberalization of trade. Liberalization is regarded as the most important macroeconomic tool for developing and developed countries economies for higher economic growth[138]. It is the remover of restriction, the openness of trade, relaxation of laws and privatization. Essentially, liberalization promotes competition by stressing the significance of the flow of technology, knowledge and information across borders[139]. It encourages the growth of the private sector, facilitates FDI and the simplification of regulations. Nevertheless, it is essential to note that liberalisation of trade and counterfeit are two different issues, yet they are interconnected. Thus, it is pertinent to give a conceptual clarification to the theory of liberalization to identify the level at which its provision is consequential to the expansion of counterfeit in international trade, particularly pharmaceuticals.

To provide context to the theory of liberalization, previous studies have expanded the different impacts of liberalization, starting from its complex quality, for example, it leads to the creation of trade agreements[140], development of supranational organisations such as the WTO[141] It allows for the movement of people and services, reduction in prices or price variation and it broadens the choice of quality goods and services

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[138]Iskra Stanceva-Gigov 'The Benefits of Trade Liberalization and Its Contribution to Economic Growth Economic Development' No. 3/ 2016 PP 166-178, 168

[139]Ibid

[140] European commission on trade Available http://ec.europa.eu/trade/policy/countries-and-regions/agreements/index_en.htm Accessed (09 August 2017) Trade agreement is created to strength the economy of states and to create jobs , it equally enables business to compete more at a global forum without fear of marginalisation thus giving consumers wider choices of product and services at a lower cost.

[141] Eric. W. Bond, 'Adjustment Costs and the Sequencing of Trade Liberalisation', (2008) Vol 31, Issue 1pp The World Economy 1467-19

available. Indigenous and non-indigenous companies also benefit from trade liberalization by channelling resources to where returns are highest, thereby increasing productivity[142].

Although to a large extent, liberalization of trade changed the perception of trade in all facets, it is not without its shortcoming, as highlighted by Goldberg and Nina Pavcnik According to them, trade liberalization can lead to increased migration, poverty, inequality, cultural globalization, and removal of border control[143]. Gerard Capri and Patrick Honohan observed that liberalization could influence the reduction of state control on the financial sector, which is deemed a stimulant to the increasing economic crisis. Notably, this shortfall can reduce the interest rate of states. For example, in Mexico, after the debt crisis, the interest rates were reduced to activate the growth of domestic resources[144]. LA Winters and McCulloch maintain that there is a direct link between poverty and liberalization of trade. Recent evidence proves that although free trade and openness can sustain the growth of an economy, there is no tangible proof to show that liberalisation eliminates poverty. For instance, sustainable growth of an economy depends mostly on increased productivity[145] , but if productivity increases more than output, this could affect change. In the words of Kaplinsky, liberalization leads to instability[146]. The relative outcome of instability can cause diversion of output,

[142] OECD Trade Liberalization Available http://www.oecd.org/tad/tradeliberalisation.htm Accessed (09 August 2017)
[143]Goldberg, Pinelopi K., and Nina Pavcnik, *Trade, Inequality, and Poverty: What do we Know? Evidence from recent trade liberalization episodes in developing countries* No. w10593 National Bureau of Economic Research, 2004
[144] Gerard Caprio, Patrick Honohan and Joseph E. Stieglitz, (ed) *Financial Liberalization, How far, How fast* (Cambridge, 2006) pp10-11)
[145] Alan L. Winter, Neil McCullochi, Andrew McKay, 'Trade Liberalisation and Poverty: The Evidence So Far, Journal of Economics Literature Vol XL.II (2004) PP72- 115, 74
[146] Raphael Kaplinsky, 'Globalisation and Economic Security,' issue 6 (200) Vol 49, 1IDS Bulletin PP13-24

for which the consequence can cause the overflow of counterfeit goods as in the case of Nigeria.

Besides this point, liberalization of trade increased the import and export of counterfeit goods such as pharmaceutical products, given the lax border control of states. WTO-driven trade liberalization policies have accelerated this development.[147] The WTO applies a systematic approach towards evaluating the impact of its trade policy on the running of the multilateral trade system. The WTO Trade Policy Review Mechanism (TPRM) is part of the WTO's overall surveillance machinery, and in its scope, it covers matters relating to IP. It is regarded as an integral organ of the WTO system, with the sole purpose of

‘*’contributing to improved adherence by all members to the rules, discipline and commitment made under the multilateral trade system...for smoother functioning and greater transparency in and understanding of trade policies and practice of members*.’’[148]

The idea that TPRM serves to monitor WTO member states application of its policies; for instance, free trade seems unrealistic, for there is no evidence to support the unique applicability of TPRM in the liberalization of trade.

Nevertheless, the WTO is credited for the expansion of free trade through its liberalization policies which also include the principle of non-discrimination, most favourable nation policy, parallel importation and fair-trade policies. It allowed the

[147]Robert L. Morris , ‘Trade Union and Globalisation : A Caribbean's workers Education Guide’(Port of Spain: International Labour Organisation 2002) Available http://www.ilo.org/wcmsp5/groups/public/---Americas/---or-lima/---sro-port_of_spain/documents/publication/wcms_224178.pdf (Accessed 29 August 2016) The WTO policies include the principle of Non-discrimination, most favourable nation policy, parallel importation across all market, rule to promote fair trade and free competition, technical assistance to developing countries.

[148] World Trade Organisation (WTO) ‘Trade Policy Review Mechanism’ (TPRM),Availablehttps://www.wto.org/english/docs_e/legal_e/29-tprm_e.htm Accessed (22 March 2020)

reduction in tariff and non-tariff barriers, ensuring the integration of global trade[149] and individualism. However, given the WTO policies on trade liberalization, it can be said to create a dilemma by allowing member states 'trade' without setting standards for the product and processes across different borders. Neither do member countries adhere to WTO policies; and even if they adhere, its approach can be restrictive in certain trade forums (developing/LDC). Therefore, it begs the question in this instance whether WTO trade liberalization policies conflict with the overall objective of the WTO. If this is the case, it could be asserted that the WTO is a liberalization mechanism responsible for reducing borders controls, which may have led to the growth of counterfeit.

Trade Liberalization Versus Globalisation

Another important aspect of trade liberalisation is the impact of globalisation on counterfeit. These paradigms are interconnected; they both stress the value of removing barriers to trade and privatization of public-owned firms, thus enhancing economic growth and creating one global marketplace. However, this study is not concerned with the entire concept of globalisation, but it specifically examines its complex influence on public health, particularly pharmaceuticals. Cornia argued that globalisation could lead to important health expansion if properly managed by generating high health returns[150] and advanced domestic growth. On the contrary, this

[149] Gao Shangquan, 'Economic globalisation: Trend, risk and Risk prevention' Available http://www.un.org/en/development/desa/policy/cdp/cdp_background_papers/bp2000_1.pdf Accessed (30 August 2016) examined the impact of economic globalisation it reflect the continuing expansion and integration of world economies, an irreversible market trend. Two reasons are attributed for this growth, is science and technology and cross border division of labour. The advancement of technology reduced the cost of transportation and communication amongst nations. For example, ocean shipping cost half of the normal amount in the 1930's even production and manufacturing of cars is not limited to just Germany, Britain and America but now produced in other countries.

[150] Giovanni Andrea Cornia, 'Globalisation and Health: Results and Options,' (2001) Vol.79 No. 9 Bull World Health Organisation.

seems implausible because the suppression of borders has allowed trade in counterfeit to flourish. It can, therefore, be claimed that globalisation can exacerbate counterfeit.

Having established this conflict, what then is globalisation, and what is the link between globalisation and counterfeit, particularly counterfeit pharmaceuticals? Does globalisation influence the way we perceive counterfeit, or is it possible that it may have made the problem of counterfeit bigger or worse? The meaning of globalisation is not fixed or definite[151], as scholars like Ronald Robertson strenuously argued that the concept of globalization is essentially the compression of the world and global interdependence amongst states leading to the integration of culture, religion, economy and technology[152]. One consequence of globalisation[153] is that it can reduce the number of regulatory obstacles to the movement of goods and services amongst states because it excludes the principle of territoriality. However, the benefit of globalisation is remarkable in every aspect, but the adverse consequence of globalisation is multifaceted. It is linked to terrorism[154], migration, poverty, death, reduction in trade barriers[155] and an increase in counterfeit drugs.

[151] John Goldring,' Globalisation and Consumer Protection Laws,' (2008) Vol. 8 8 Macquarie Law, Journal. pp 79-101.
[152] Ronald Robertson., *Globalisation: Social Theory and Global Culture* (Sage Publishing: London, 1992).
[153] Globalisation replaced the concepts of internationalization and trans nationalisation, it is used to describe the global interaction of people, culture, trade, politics, technology, human right, migration etc.
[154]Counterfeit Pharmaceutical a serious threat to patent safety Available http://www.pfizer.com/files/products/CounterfeitBrochure.pdf Accessed (29 August 2016) Counterfeit has become a lucrative business for criminals around the world. It is not subject to border restrictions and profit from counterfeit is more than profit made from the sale of heroin and cocaine. Equally the penalty for trafficking counterfeit drugs is less than the penalties for hard drugs.
[155] Matthias Yao., 'Trade Unions and Globalisation', available at <http//www.apro.techno.net.au/docs/apr922.doc Accessed (29 August ,2016).

The globalisation of counterfeit pharmaceuticals utilizes a complex production, distribution, and sale mechanism. It is an economic trend that is heightened by advanced technology and a restructured global economic system[156]. The globalisation of technology improves the reproduction and production of counterfeit pharmaceuticals, making them virtually identical to the original medicine. As the flow of technology between states is increasing, so are counterfeit pharmaceuticals. The technological equipment for counterfeiting is readily available at a reasonable price, making it possible for reverse engineering in the production of drugs. Counterfeiting is neither subject to any border restriction nor legal impediment, and therefore it can be produced in any country. Recent research compiled by Pfizer indicated that counterfeit Pfizer drugs had been found in 75 countries around the world[157]. The most famous case is the production and sale of counterfeit Pfizer Viagra Lipitor, Centrum Vitamins and Chapstick[158].

To compound further, the issue of counterfeit pharmaceuticals is the role of Multinational Corporations (MNC) as a result of the globalised economy. Pharmaceutical firms outsource the production and packaging of drugs to different countries in a bid to reduce production costs through cheap labour, more access to raw materials and thus more significant levels of profit. For example, API finished dosage manufacturing is shifting to developing countries, and Pill-fillers come from one country and coating from another source[159]. Pharmaceutical companies have

[156] Hsiao-Hung Chang, 'Fake Logos, Fake Theory, Fake Globalization,' (2004) 5: 2Inter-Asia Cultural Studies, 222.
[157] Counterfeit Pharmaceutical a serious threat to patent safety Available http://www.pfizer.com/files/products/CounterfeitBrochure.pdf Accessed (29 August 2016)
[158] Barbara Morgan 'Crack down on counterfeit Pharmaceuticals,' Available http://www.pbs.org/wgbh/nova/next/body/uncovering-counterfeit-medicines/ Accessed (29 August 2016).
[159] The Economist , 'Bad Medicine', Available http://www.economist.com/node/21564546 Accessed (29 August 2016).

moved production sites to low-income countries like China and Indonesia. Firms ought to adopt a multi-faceted anti-counterfeit strategy for the protection of pharmaceuticals in these low-income countries[160] . These strategies ought to be backed by sanctions to regulate production and distribution, but this is not the case. To Hopkins, Kontnik and Turnage, another reason for the growth of counterfeit pharmaceuticals includes low trade barriers, consumer complicity, expansion of markets, and the growth of brands[161]. The globalisation of the pharmaceutical industry affects intellectual property rights; for example, it affects patent, generic and biotech drugs. It also leads to a decline in the number of innovative drugs produced for the treatment of diseases.

Common to the various analysis of globalisation, it is perceived to be unpredictable and complex or possibly optimistic (easy flow of trade, growth in world economy and technology advancement) or pessimistic. In the context of counterfeit drugs, globalisation demands that policymakers hold manufacturers of these products accountable for product quality per international standards and therefore adopt measures for a robust legal framework to regulate counterfeit drugs.

Internet trade and counterfeit

Counterfeit seems to thrive more because of the globalisation of trade from free trade zones to the growth of the internet. The sudden increase of the internet has heightened the counterfeit predicament by creating an enabling environment in cyberspace for counterfeit sellers and consumers to buy and sell counterfeit products. It creates a

[160] Kelvin Lewis, 'The Fake and The Fatal: The consequences of Counterfeit', Available https://www.iwu.edu/economics/PPE17/lewis.pdf Accessed (30 August 2016).
[161] Kenaway Molouk Kenaway, 'The Economic Impact of Counterfeit Goods in Egypt', (2013), Vol. 3, Issue 3 International Journal of Business and Management Research, p.111.

platform for anonymity, thus hiding the identity of counterfeiters, as counterfeiters do not need to bypass any border restriction or abide by any trade regulation. The issue of the safety of drugs purchased over the internet is a genuine concern for consumers and policymakers. A pharmaceutical purchase over the internet most often consists of the sale of outdated drugs, expired drugs or sale of medicines that contain no ingredient or a reduced amount of active ingredient and therefore provides no protection against diseases[162]

The key factor attributed to the growth of counterfeit products online is the ease of website creation and removal. The implication of this is that counterfeit product sellers can reach consumers globally, and it is not limited to corporations anymore. In the same way, consumers are exposed to the internet and have the freedom to purchase goods from any online seller without proper verification if the product is genuine or fake. The impact of online counterfeit trade on consumers is grave because consumers' health and safety are at risk from the consumption of substandard and toxic goods.

The solution to reducing online sales is complex and often problematic[163], specifically the question of responsibility and legal measures to curb counterfeit product sales needs to be resolved. On this point, Gelin and Elings believe that instead of prosecuting counterfeiters, the service providers should be held accountable in

[162] John A. Vernon, Stephan Goupil and Joseph H. Golec, 'The Internet and Pharmaceutical Importation: Economic Realities and other Related Issues,' (2006)16 Alb. L.J. Sci. & Tech. 545 the focus of this research is on the safety of imported pharmaceuticals in the USA. This issue is broad, and complex been that there is no proper estimate of the inflow of drugs or the quality considered before sale over the internet.

[163]International Trademark Association INTA- 'Addressing the Sale of Counterfeit over the Internet' Available http://www.inta.org/advocacy/document/inta%20best%20practices% Accessed (12 April 2016)

law.[164]Under the principle of contributory liability for IP infringement relying on the case of *Inwood Labs Inc .v. Ives Labs Inc.*[165]Here, the Supreme Court held the generic drug manufacturer could be held liable under contributory liability if they intentionally supplied goods knowing it was under a trademark, and this equally applies to third party supplies of patented goods such as internet service providers.

However, the court took a different turn in the case of *Tiffany Inc V. eBay Inc*[166] by rejecting the argument of contributory liability. The court relied on the principle laid out in *Inwood supra*, that liability cannot be imposed on the defendant for failure to anticipate the possible sale of counterfeit products on its website. However, if the defendants failed to act upon information of possible counterfeit products, they were not held liable for damages. Relying on the contributory liability is a limited approach, for it does not extend to the international regulation of counterfeit; it is just within a jurisdiction.

2.2.1 Free Economic Zone

A free economic zone (FTZ), sometimes called free trade zone (FTZ) is defined by the International Trademark Association to be an area within the jurisdiction of a state where custom control is absent or reduced. Another definition by Grubel states that an FTZ is a geographically defined area where different economic activities take place without government taxation and regulation[167]. It is not subject to any international and

[164]Scott Gelin, G Roxanne Elings 'Contributory Liability for Trademark Counterfeiting in an Ecommerce world, NYU (2010) Vol.1, No 2 Journal of Intellectual Property and Entertainment Page 44. This paper provided tips for service providers for contributory liability. That a service provide should ensure that the immediate knowledge of any form of counterfeiting on its site should be reported accordingly and removed or else faced prosecution in law as seen in the case of Gucci America Inc V. Frontline Processing Corp 08 Civ.5065 (2008).
[165]Inwood Labs Inc.V. Ives Labs Inc 456 U.S.844(1982)
[166] Tiffany Inc.V. eBay Inc No 08-3947-cv2010 U.S App
[167]Herbert G. Grubel, 'Towards a Theory of Free Economic Zones,' Weltwirtschaftliches Archive Bd.118, H.1 (1982) PP39

local trade, banking, and tax laws. FTZ is characterized by warehouses, factories, industries, and wharves[168]. FTZ is particularly significant to trade for it creates a platform for legitimate businesses to play a vital role in international trade and development. It is estimated that there are over 3000 FTZ spanning across 116 countries with the fundamental objective to enhance foreign exchange and develop export-oriented industries[169].

The benefit of FTZ is tremendous; FTZ creates a shift from import -substitution to export-led trade policies; it can reduce foreign exchange overheads; attracts foreign investment, and increase foreign earnings through exports. FTZ generates inter-firm communication and a new form of division of labour amongst industries. It involves a shift of labour-intensive industries from developed to developing countries, and thus, it creates employment opportunities for locals of the developing countries and increased output[170]. However, the rise of the FTZ leads to negative externalities, which according to the OECD in 2010 include money laundering, racketeering, fraud, smuggling and sale of counterfeit goods.[171]

Counterfeiters use the FTZ to repackage, manufacture and re-label finished counterfeit drugs without fear of prosecution. It undermines the purpose for the creation of the free trade zone, which is trade liberalisation. To Liang, the FTZ provides

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[168] International Trademark Association ,' Role of Free Trade Zones and Free Port in the Transhipment and Transit of Counterfeit Goods', (Nov 2006) Available http://www.inta.org/advocacy/pages/roleoffreetradezonesandfreeportsinthetransshipmentandtransitofcounterfitgoods.aspx Accessed (14 April 2016)

[169] Angela Shah, 'Free Trade Zones Attracts Criminals,' *New York Time* Available http://www.nytimes.com/2010/11/11/world/middleast/11iht-m11mtrade.html?_r=0 Accessed (9 September 2016)

[170] David Wall, 'China's Economic Reform and Opening-Up Process: The Role of the Special Economic Zones,' (1993) 11 Development Policy Review PP 243

[171] OECD-FATF, Money Laundering Vulnerabilities of Free Trade Zones ,2010 Available http://www.fatf-gafi.org/media/fatf/document/reports/ml%20vulnerabilities%20free%20trade%20zones.pdf Accessed (14 April 2016)

an “opportunity for unscrupulous individuals to whitewash counterfeit drugs in a bid to avoid regulatory oversight by states”[172]. Also, a report by the New York Times indicates a link between the FTZ and the supply of counterfeit pharmaceuticals following the seizure of many counterfeit drugs in a Euro Gulf warehouse within the FTZ. This incident revealed how the FTZ is used to supply counterfeit from China to Hong Kong, to Britain and ultimately leading to the internet[173]. Over the internet, the medicine will be sold as the original product regardless of its consequence. As more countries create more free trade zone, so does the scale of counterfeit increase. A particularly recent example is the seizure of counterfeit drugs from Heathrow Airport in London, where customs officers intercepted counterfeit products from renowned companies such as Pfizer, Novartis, Procter and Gamble. Following a proper investigation, the counterfeit drugs were eventually traced to an FTZ in Dubai[174].

2.2.3 ACCULTURATION

The objective of this section is to raise questions on the forces that can influence the escalation of counterfeit pharmaceuticals aside from the economic, legal and technical aspects. One of such concepts is the concept of acculturation. This section will assess the relationship between acculturation and counterfeit by suggesting that acculturation could be another reason for the growth of counterfeit. Acculturation is a rapidly changing field of study; it is a multidimensional concept[175] on human diversity to

[172] Free trade zones and counterfeit drugs:’ An Interview with PSMs Bryan Liang and Netherland Antilles Chief of Staff of the Inspectorate of Public Health,’ (12 July 2010) , Available http://www.safemedicines.org/2010/07/free-trade-zones-and-counterfeit-drugs-an-interview-with-psms-bryan-liang-and-netherlands-antilles-c.html Accessed (09 September 2016)

[173]Walt Bogdanich, ‘Counterfeit Drugs path Eased by Free Trade Zones,’ *The New York Times* (2007)https://www.nytimes.com/2007/12/17/world/middleeast/17freezone.html

[174]Walt Bogdanich, ‘Counterfeit Drugs path Eased by Free Trade Zones,’ *The New York Times* (2007)https://www.nytimes.com/2007/12/17/world/middleeast/17freezone.html

[175] Berry J.*W Acculturative as varieties of adaptation, in Acculturation: Theory, Models and Some New Finding* (Boulder: West view, 1980) pp 9

change from one cultural context to another context. It is also the union of different cultures, values and beliefs resulting in changes to the way of life, religion, custom, culture and health[176].

Acculturation as a concept can be traced to the 1880s, and it is believed to have originated from Europe, during the colonial era resulting in the movement of people, culture, religion, and art over a long time[177] . Acculturation can be defined as ‘’a phenomenal, which results when groups of individuals having different cultures[178] come into continuous first-hand contact, which subsequently changes the original cultural pattern of both groups’’[179]. This definition identifies the existence of two different cultures coming into play or interacting, which in turn may influence the actions of an individual. The action may be a positive influence or negative influence, some of which can remarkably alter the balance of society.

Although it the most widely used definition of acculturation, ironically, this definition is somewhat perceived to be ambiguous or vague, for it only emphasizes the individuals, not on the actions of the acculturating individuals. For example, the interaction of different cultures, beliefs, lifestyles and values of individuals may result in the original culture being lost in transmission, thus leaving the individual to assimilate the new way of life resulting in individualism. The scary part of this, is the possibility of the influence

[176] Seth J. Schwartz and others, ‘Rethinking the Concept of Acculturation, Implication for Theory and Research,’ 2010 ,65(4) The American Psychologist 237

[177] Linda M. Hunt, Suzanne Schneider and Brendon Comer, ‘Should ‘acculturation’ be a variable in Health Research A Critical Review of Research on Hispanics,’ (2004) Vol 59, Social Science and Medicine 973 it’s becoming necessary in the United State to determine the culture of citizens in relation to their health sectors. Acculturation explains the root or behavioural pattern of individuals and corporation. People choose a pattern based on their cultural believes and ideas and it can influence their overall wellbeing.

[178] Culture means the way people feel, act and think in relation to their religion, region, nation, occupation, gender, ethnicity etc.

[179] David L. Sam and John W. Berry, ‘Acculturation: When individuals and Groups of Different Cultural Background Meet’(2010) Volume 5, Perspectives on Psychological Science Vol 472

of harmful vices on acculturating individuals in their modern society, for example, the increase in criminal activities, terrorism, human trafficking and counterfeiting. One suggested reason for this negative influence is the stress and conflict involved in the acculturation process within the individual as the individual acquires new cultural values which may influence the individual behaviour. Also, Ferrell and Gresham recognise the significance of the unique cultural difference in the decision-making process of the acculturating individual[180]. In this context, acculturation could be a stimulant to the rise in counterfeit pharmaceuticals as it influences the choice people make with regards to products. Instead of using available products with therapeutic effects, cultural shifts influence the decision-making ability of choice, which inadvertently leads to the purchase of counterfeit drugs. Also, by the process of acculturation, there is a shift from the use of Traditional African Medicine (TAM), for more sophisticated medicine. TAM is a cultural heritage particular to Africans; it is a skill passed on from the ancestors for the treatment of diseases [181]; therefore, integrating TAM have been hindered due to acculturation.

2.3 COUNTERFEIT PHARMACEUTICAL: MEANING AND DEFINITIONAL QUESTION (WHAT IT MEANS, HOW IT IS PERCEIVED AND APPLIED)

A definition is the statement of the meaning of a concept; it ought to be clear and uncontroversial. If a definition is controversial, questioning established procedures and rules[182] is necessary to determine how best to proffer a coherent meaning to the term.

[180] O.C Ferrell & Larry G Gresham, 'A Contingency Framework for Understanding Ethical Decision Making in Marketing,' (1985) Vol. 49, Issue 3 *The Journal of Marketing*), 87

[181]Elujoba, Anthony A., O. M. Odeleye, and C. M. Ogunyemi. 'Traditional Medicine Development for Medical and Dental Primary Health Care Delivery System in Africa.' (2005) Vol 2 issue 1 *African Journal of Traditional, Complementary and Alternative Medicine pp* 46.

[182] Jerome E. Bickenbach, Jacqueline M. Davies, '*Good Reasons for Better Arguments'* (Peterborough: Broadview Press, 1997)

This is precisely the position of counterfeit pharmaceuticals, which is an unresolved issue in international trade law. Conflict exists between the implicit and explicit interpretation of the definitions of counterfeit medicine. As Jackson rightly opined that '*'the lack of a clear widely accepted definition of counterfeit pharmaceuticals might be an obstacle to adopting an effective measure to tackle the issue"*[183]. Even the WHO rightly observes that '' *the definition of counterfeit used in different countries differs enough to create problems in the implementation of necessary measures to combat it"*[184].

The word 'counterfeit' is subject to multiple interpretations, and thus, arguably, there is no exact definition to the term counterfeit. Etymologically the word counterfeit comes from the Latin word '*contra facere'* which means '*to imitat*e'[185]. From a legal stance, the word counterfeit means to imitate, without authority to deceive or defraud by passing the forged item as the original[186]. Different organisations, agencies, Governments and Non-governmental organisations (NGOs)[187] defined the word counterfeit to meet specific objectives or standards. Over time the definition of counterfeit has evolved to encompass different terms in place of counterfeit. These

[183]Amir Attaran, Roger Bate, Megan Kendail, 'Why and How to Make an International Crime of Medicine Counterfeiting', (2011) Vol.4, No.4 Journal of International Criminal Justice,) pp947-9

[184] WHO – 'Combating Counterfeit Drugs: A Concept Paper For Effective Collaboration,' Available http://www.who.int/medicines/services/counterfeit/combatingcounterfeitdrugs_conceptpapers.pdf Accessed(d 21 May 2016)

[185] Eric Przyswa, 'Counterfeit Medicine and Criminal Organisations, International Institute of Research against Counterfeit Medicine' (IRACM) 2013, Available www.iracm.com Accessed (16 May 2016)

[186] Black's Law dictionary ,' Definition of Counterfeit' Available http://thelawdictionary.org/counterfeit/ Accessed (16 May 2016)

[187] World Trade Organization WTO (1994), 'Agreement on Trade Related Aspects of Intellectual Property Rights, Including Trade in Counterfeit Goods' Available http://www.wto.org/english/docs_e/legal_e/27-trips_05_e.htm (Accessed 22 April 2016), OECD , The Economic Impact of Counterfeit , (2007) Available https://www.oecd.org/sti/38707619.pdf Accessed (22 April 2016),The International Organisation for standards (ISO),Crack Down on Counterfeit (2014) http://www.iso.org/iso/news.htm?refid=Ref1809 John Pink and others. 'Defining the Types of Counterfeiters, Counterfeiting, and Offender Organizations' *Crime Sci* **2,** 8 (2013). https://doi.org/10.1186/2193-7680-2-8

terms include substandard drugs, fraudulent goods, piracy and imitation. This discrepancy made the task of defining counterfeit more complex.

The need to have a universally acceptable definition of counterfeit is almost next to impossible since states have legislation on counterfeit that is unique to their environment and circumstances. For example, in Nigeria counterfeit drugs is defined by Section 12 of the Nigerian counterfeit and fake Drugs (Miscellaneous provision) Act, which states *inter alia* 'that *counterfeit drug is any medicine or pharmaceutical product, which is not what it purports to be, coloured, coated or polished which damage is far greater than the therapeutic value than it is*[188]. Similarly, Section 96 of the Indian drug and cosmetic act 1940 define a counterfeit drug as *(a) A drug imported under a name belonging to another drug (b) imitation, substitute or resembles another drug (c) if the label bears the name of an individual company purporting to be the manufacturer (d) if it been substituted, wholly partly by another drug and substance*[189]*.* These definitions of counterfeit are similar and convincing, but it begs the question of counterfeit drugs regulation such as the inability of states to agree on a uniform definition of counterfeit. For instance, if the definition of counterfeit in India and Nigeria is similar, it will ease adjudication. This can create a consistent system where penalties are universal in all jurisdictions, thus reducing technicalities. Secondly, the definitions tend to stress the importance of counterfeit finished products as against the process or substance used in the creation of a counterfeit drug. This means that there is no explicit support for creativity or IP, which inadvertently creates a gap between what the law provides and what it ought to protect. It is equally logical that both laws should give legal recognition to counterfeit, but no distinction is made to address the

[188] Cap 34 LFN Nigeria
[189] Indian Parliamentary Standing Committee on Health and Family Welfare-Fifty-9 report on the function of the central drug standard control organisation (New Delhi, 2012)

difference between counterfeit drugs and other similar concepts like substandard drugs.

Similarly, Counterfeit is defined by the WTO-TRIPS Agreement to include the use of a trademark or similar mark which is identical to a registered trademark without due authorization of the right owner of the mark[190]. This definition of counterfeit sets recognisable objectives and standards. It is unique for it recognised IPR, but in the aspect of Public health, it is vague, as it undermines the public health aspect of IP. It prioritises the enforcement of the right holder's right over health. Equally, this definition fails to consider the extensive research and development undertaken by inventors in the context of Pharmaceuticals.

This creates confusion and can prevent access to much-needed medicines. Staake and Thiesse point out that the definition of counterfeit by TRIPS may be technically correct even though it fails to specifically clarify to what extent counterfeit will be a problem to access to medicine. It can be suggested that the definition of counterfeit permitted by the WTO can be reframed or redefined as the ''trade and imitation of pharmaceutical without the authorization of the right owner, which goes against the set standard and quality requirement permitted by Law''[191]. This definition highlights

[190] World Trade Organization WTO -TRIPS 1994, Article 41 'Enforcement of Intellectual Property Rights 'Available http://www.wto.org/english/docs_e/legal_e/27-trips_05_e.htm (Accessed 28 March 2016) For the purpose of the TRIPS agreement the right holder is a person who is legally entitled to assert a right over IP. Thus, the agreement defined counterfeit to include counterfeit trademark or any packaging bearing without due authorization a trademark which belongs to a right holder and this will infringe on the right of the holder.

[191] Thorsten Staake, Frederic Thiesse and Elgar Fleisch, 'The Emergence of Counterfeit Trade: A Literature Review' , (2009) Vol.43, Issue 3 European Journal of Marketing , pp320 This article discussed the issue of counterfeit and illicit supply chain from different management related aspect. It highlights the implication of counterfeit on international trade stating that counterfeit has developed into a severe threat to companies and consumers. Some of the implication faced by companies includes loss of revenue owing to substitution effect of fake goods and loss of brand name for fear of counterfeit. The authors traced the growth of counterfeit from early publication and research to differentiate the public perception of counterfeit

some fundamental principle which the TRIPS agreement omitted such as *'standards'* and *'quality*. Another acceptable definition of counterfeit is the definition proposed by WIPO. It defined counterfeit as the imitation of product that gives the impression of being the original product made by the genuine manufacturer[192]. Equally, the U.S. International Trade Commission defined counterfeit as "the unlawful use of a registered trademark on a product that is identical or like the product for which the trademark is registered and used''. The connotation in these definitions are similar but lacks uniform meaning which is misleading and can undermine possible solutions to counterfeit drugs.

Similarly, the World Health Organisation (WHO) defined counterfeit medicine as ''one which is deliberately and fraudulently mislabelled concerning identity and source. It applies to both branded and generic medicine and may include a product with the correct ingredient or wrong ingredient''. However, following the persistent demand by member states to the WHO for harmonisation, the old definition was amended to reflect other forms of counterfeit. Giving that the WHO is a standard-setting organisation it rightly amended the old definition to include ''sub-standards, spurious, falsely labelled, falsified, counterfeit, medical product (SSFFC)[193]''.To Attaran and others, the new classification by the WHO may be misleading given the peculiar

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[192] World Intellectual Property Organisation – WIPO Intellectual Property Handbook (2008) Available http://www.wipo.int/edocs/pubdocs/en/intproperty/489/wipo_pub_489.pdf Accessed (22 April 2016) Counterfeit product belongs to the category of luxury goods with well-known trademark such as Gucci, Rolex and Cartier. This view on counterfeit fails to include other goods not sold under trademark but protected by other forms of intellectual property such as patent, copyright and design. The danger of counterfeit cannot be quantified but recent report from a farm in Africa estimates that counterfeit pesticide destroyed a year worth of crops on a farm, imagine the effect on humans. To make counterfeit actionable the law refers to such infringement as trademark infringement in some jurisdiction whereas in other jurisdiction counterfeiting is prevented by court infringement and fines but no solid punishment for offenders have been provided.

[193]WHO. Report of the working group of member State on Substandard/Spurious/Falsely-labelled/falsified/counterfeit medical product (2011), available http://apps.who.int/gb/ssffc/pdf_files/a_ssffc_wg2_3.en.pdf Accessed (19 September,2016)

attribute of each term to pharmaceuticals[194]. As each term reflects a peculiar characteristic of fake medicines, merging all in one body removes the individuality of each term. For example, a substandard drug is different from a falsely labelled drug in all forms. In addition, this new classification circumvents the importance of intellectual property in the control of counterfeit pharmaceuticals. This definition broadens the scope of counterfeit, resulting in more definitional questioning.

The GATT anti-counterfeiting code described counterfeit as ‘’the wrongful benefit through deceit with the intent to deceive consumers of a branded product ‘. In support of this definition, the United Nation Office on Drugs defines product counterfeit as a form of consumer fraud, where a product is sold, purporting to be something that it is not, which it is different from the crime of copyright[195]. It is evident that the definitions of counterfeit are all interrelated and for obvious reasons: there seem to be peculiar similarities between these definitions even to the extent of having the same phrase, hence the complexity reflected in the various meanings of counterfeit as highlighted above.

One reason attributed to the inconsistencies amongst the definition of counterfeit is the ‘technical terminology’ in the definitions. There seems to be an over-arching need to balance infringement of intellectual property within the scope of counterfeit, which invariably will undermine the specific requirement of the different forms of IP. Also, the definitions failed to reflect the relationship between the cause and effect of counterfeit.

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[194] Amir Attaran and others, ‘How to achieve International Action on Falsified and Substandard Pharmaceuticals,’ BMJ 2012

[195]United Nation Office on Drug and Crime, Counterfeit Product Available https://www.unodc.org/documents/data-and-analysis/tocta (Accessed 29 March 2016)

It only addressed the registered authority of intellectual property rights holders, not the problems of counterfeit.

The definitions of counterfeit failed to specify the difference between pharmaceuticals and other consumer products; it classified all the definitions as one. The health implications, for example, the degree of harm, due to the consumption of counterfeit pharmaceuticals, supersedes the responsibility for the protection of IPRs. Medicines ought to be compound administered to restore a medical diagnosis in humans, which is subject to strict protection[196]. Instead, the economic aspect of counterfeit is applauded more than health repercussions. It would be more apt to treat both issues together by having a uniform definition that encompasses both health and economics. Equally, the definitions fail to state the theoretical approach to counterfeit drugs. For example, the fundamentals and weaknesses of each definition are not considered. Given this, it is necessary to examine the other relative terms used in place of counterfeit if it will reflect or undermine the definition of counterfeit pharmaceutical.

2.3.1 TECHNICAL ASPECTS: KNOCKOFF, IMITATION, FAKE AND SUBSTANDARD PHARMACEUTICALS

Different terms have been used in place of counterfeit, thus creating confusion on the actual word to use when discussing counterfeit pharmaceuticals. These terms include substandard, knock-off goods, falsification, and imitation, all of which fall within the component needed for the violation of IP rights. It is, therefore, essential to examine these terms in lieu of counterfeit pharmaceuticals in a bid to determine if the right words can effectively tackle the public health issue of unsafe medicines. If proper

[196]WHO- Essential Medicine and Health Product, Available http://www.who.int/medicines/services/essmedicines_def/en/ Accessed (16 May 2016)

technical terminology can be established, it will improve how institutions or organisations such as the WTO can set standards for the regulation of counterfeit.

The first technical terminology is ***Knock off goods***, these are products which to some extent are like the original product, but it is not sold as the actual product[197] , for example, passing Gucci watches as Guuci, Seiko as Aseikon. Knockoff mainly affects the trade name as opposed to counterfeit this involves the full product. A knockoff is also regarded as another form of copying the tangible property right of a product; it restricts innovation and loss of monopoly by the creator. It is evident from this definition of Knockoff that it cannot be equated with counterfeit pharmaceuticals but mainly associated with luxury goods such as phones, cars, bags, clothes which exhibit a particular brand associated with prestige apart from its practical utility[198]. The sale of knock off goods is run by a huge criminal empire, and its size can be equated with the size of Wal-Mart, mostly products from china[199].

It is vital to differentiate between knockoff goods and ***mislabelled goods***. Firstly, knockoff goods do not include pharmaceuticals, whereas mislabelled goods mainly affect the pharmaceutical product. It involves the sale of medicine in a different package other than the original package with the sole intention of deceiving an unsuspecting buyer. The package is altered to fit the peculiar features of the original medicine such as manufacturing number, batch number and any other unique attribute in the original drug. In a bid to bypass border control, health regulators and law

[197] Gary Bamossy, Debra L. Scammon, 'Product Counterfeiting: Consumer and Manufacturers Beware' in NA- Advances in consumer research vol. 12, Eds Elizabeth C. Hirschman and Morris B. Holbrook, Provo UT: Association for consumer research, pg. 34

[198]Arghavan Nia and Judith Lynne Zaichkowsky, 'Do Counterfeit Devalue the Ownership of Luxury Brands?' (2000) Vol.9, No7 Journal of Product and Brand Management, pp 485-497

[199] Tim Philips Knockoff: *The Deadly Trade in Counterfeit Goods: The True Story of the World Fastest Growing Crime (*Kogan Page: London, 2005)

enforcement agencies, a famous example is the purported sale of a weight loss medicine Xenical- or Listat in the USA. The packaging appeared to be so authentic that it was difficult to differentiate the mislabelled medicine from the original[200].

Whereas, substandard pharmaceuticals are drugs that do not meet the required standard whether it is health and safety standards and the medicine contains little or no active ingredient needed to make up a drug compound, or it fails to meet other required standards necessary to qualify the medicine as safe for treatment. Such medicine may or may not be legitimately produced to meet the specific standard required by law[201]. Sometimes, substandard medicine may contain the same active ingredient found in the original medicine, but it is of low quality which invariably means the drug will be inactive or useless[202]. Also, substandard medicine is usually produced by authorized manufacturers, but it fails to meet the quality standard prearranged for it. This means the medicine is defective for failing to meet the specification set out for it by the authorising body or country. However, differences exist between substandard pharmaceuticals and fake pharmaceuticals.

A fake pharmaceutical is a medicine that claims to be what it is not, and it is solely intended to mislead the consumer. According to Medicine Sans Frontiers, a fake medicine is deliberately and fraudulently mislabelled to give false information on the medicine, in a bid to mislead the public as to its source and content. It creates a serious threat to the general public, for it contains no active ingredient[203]. In the broader

[200] Ten M.Ham , 'Health Risks of Counterfeit Pharmaceuticals, Drug Safety' Vol.26 (2003), R.Jotcham, 991-997Understanding and Evaluating Security Technologies for Pharmaceuticals, in Combating pharmaceutical fraud and counterfeiting, SMI conference Documentation, London, SMI Publishing, 2003.
[201] Medicine Sans Frontiers (MSF), 'Substandard and Counterfeit Medicines,' Available http://www.msfaccess.org/spotlight-on/substandard-counterfeit-medicines Accessed (16 May 2016)
[202]Ajoy Bera and Ashish Mukherjee, 'Counterfeit and Spurious Drugs: Big Challenge to the Health Care System' Worldwide,' (2013) vol.4 issue 3 International Journal of Pharmaceutical Sciences PP48
[203] MSF IBID 17

context of counterfeit pharmaceuticals, the definitions provided for fake, substandard and knock-off, if synchronized, could fit the particular purpose and framework of counterfeit drugs. Subsequently, the definition which reflects all these features in one body is seen in the definition by the WHO on counterfeit pharmaceutical stating that ''counterfeit medicine is deliberately and fraudulently mislabelled concerning identity and 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 (inadequate quantities of ingredient(s) or with fake packaging[204]'' This definition tries to reflect key element found in the definition of substandard, fake and counterfeit pharmaceuticals. As such, instead of dwelling on the definitional issues, strategies should be adopted to address the problem of counterfeit.

It is important to note that the definition by the World Health Organisation (WHO) introduced a new element to the concept of counterfeit pharmaceutical, which is a generic medicine. This has been a subject of several arguments amongst scholars on the place of generic medicine within the framework of counterfeit pharmaceuticals. It is thus important to know the meaning of generic medicine. According to the, WHO *generic medicine is generally manufactured without a license from the inventor, and it is sold after the expiration of patent rights*[205]. Also, the European Union Medicine Agency defines *generic medicine as a medicine that is developed to be the same as*

[204] World Health Organisation WHO, ' Essential Medicine and Health Product,' Available http://www.who.int/medicines/regulation/ssffc/definitions/en/ Accessed (18 May 2016) Substandard medicine called OOS product is said to be genuine medicine produced by manufacturers authorised by the NMRA. As such giving a universally agreed definition will be essential for clarity but it cannot alter the position of member state legislation, with stated rules in place for regulating counterfeit.

[205]WHO–'Generic Drug, 'Availablehttp://www.who.int/trade/glossary/story034/en/index.html. Accessed (18 May 206)

a medicine that has already been authorized, and it contains the same active substances as found in the initial dose[206].

It is different from counterfeit medicine based on the following reasons. Firstly, from a physiological perspective, generic medicine is similar to the original for its bioavailability is the same as the molar dose, and it has the same effect, efficacy and safety as the original medicine[207]. Secondly, generic medicine is cheaper than the actual medicine because generic manufacturers do not conduct preclinical trials and clinical studies given that these trials and studies have already been carried out by the IPR holder or manufacturer and the necessary cost borne accordingly[208] . Thirdly, the economic benefit of generic medicine cannot be ignored; most countries use generic medicine to control healthcare costs. Hence generic medicine is identical to the original medicine for it contains the same composition of the active ingredient. However, generic medicine can be counterfeited because it makes essential medicine less expensive and accessible to the poor in developing countries. In conclusion, generic medicine is not the same as counterfeit medicine; nonetheless, generic medicine can be counterfeited owing to the failure to adhere to regulatory obligations.

2.3.2 ECONOMIC DEVELOPMENT ASPECT OF COUNTERFEIT –DRUGS

Imagination is more important than knowledge Albert Einstein

[206] European Medicine Union, 'Question and Answer Available' http://ec.europa.eu/health/auhorisation-procedures_en.htm Accessed (20 May 2016) Generic medicine marketing approval in the EU can be authorised in three ways, firstly the approval of the centralised procedure, followed by the decentralised procedure and the national procedure.

[207] Suzanne Dunne and others, 'A Review of the Differences and Similarities between Generic Drugs and their Originator Counterparts, including Economic Benefits Associated with Usage of Generic Medicines, Using Ireland as a Case Study,' BMC Pharmacology and Toxicology Vol.14, No.1, pp2-19

[208] Generic Drugs: Overview of ANDA review process, Available http://www.fda.gov/downloads/drugs/newsevnts/ucm167310.pdf Accessed (20 May 2016)

The purpose of this section is to provide an overview of the economic implication of counterfeit, whilst still reiterating the possibility of regulating counterfeit within the WTO-TRIPs framework. This part will examine the acuity of protecting investor's rights, the cost of producing and the affordability of drugs, but first, the impact of counterfeit will be discussed briefly. It is difficult but not impossible to quantify the economic impact of counterfeit pharmaceuticals, nevertheless no matter the value implicated in counterfeiting; this practice results in the loss of legitimate goods and goodwill of pharmaceutical companies. To Peter Bloch, Ronald Bush and Leland Campbell a high percentage of producers of legitimate goods incur damage to brand reputation as a result of counterfeit. Thus, producers in a bid to save brand name fail to inform consumers of the potential existence of counterfeit pharmaceuticals.

The economic impact of counterfeit is multifaceted; it causes financial mayhem to business. Secondly, it is a continuum of problems ranging from loss of technical know-how, loss of IP right, low productivity, loss of income and brand name. Accordingly, to the International Chamber of Commerce (ICC), counterfeiting will cost businesses between US$500 million to US$700 million annually. Also, the Organisation for Economic Cooperation and Development (OECD) estimates that over 5% of global trade involves trade in counterfeit goods amounting to the tune of US$176 billion as of 2007[209]. Along this line, Price Water House Cooper (PWC) estimates the global impact of counterfeit on trade and investment to reach US$650bn per annum, with product

[209] OECD, 'The Economic Impact of Counterfeit' (1998) Available http://www.oecd.org>sti>ind Accessed (27 March 2016) This report states the impact of counterfeit trade that anything can be counterfeited ranging from clothes , watches, food, electronics, airplanes, electronics, pharmaceuticals etc. Counterfeit goods are mainly produced in China, India, Philippine, turkey, USA and in Africa. The overall effect according to this report is total lack of product safety but the sole goal of making profit has made counterfeiting a global phenomenon .Equally part of the reasons attributed for counterfeit includes lack of proper information as to the scale of counterfeit by states, corporations in a bid to protecting brand names or identity. Also, countries with weak IP regulations mostly in developing economies allows counterfeit to thrive.

seizures in Europe estimated to the tune of almost €1bn[210]. A recent report by the ICC projected the global economic and social impact of counterfeit would reach $1.77 trillion by 2015. It is equally estimated that domestic production and consumption will reach $370 billion to 570 billion globally[211]. These figures result in the increase of low-quality products at excessive prices to unsuspecting consumers regardless of the dangers from its application.

Counterfeit goods can be purchased all over the globe, as the world customs organisation opined in 2008 when counterfeit goods destined to 140 unsuspecting nations was discovered by the organisation.[212] This goes to show the extent to which counterfeit products can be found in almost every country. It is mainly smuggled to avoid paying import tax and border inspection. A recent data collated by the World Customs Organisation shows that 65% of counterfeit shipment comes from China, making it two-third of global trade. This problem is not limited to Asia alone: counterfeit is produced in South America, Europe and Africa. In 2008 over 200 million counterfeit products were discovered in the European borders, and this number has increased in the last ten years. This goes to show that the network for trading in counterfeit is the largest multibillion-dollar underground investment, with a sophisticated supply chain amongst states. Counterfeit results in the loss of investments in both developing and

[210]Price Waterhouse Coopers, 'Counterfeit Goods in the UK, Who is buying what and why?' (October 2013) Availablehttps://www.pwc.co.uk/.../anti-**counterfeiting**-consumer-survey-October *(Feb*

[211]Global impact study International Chamber of Commerce , 'The Impact of Counterfeiting and Piracy; to reach US$1.7 Trillion by 2015 (Feb 2011) Available http://www.iccwbo.org/news/articles/2011/impact-of-counterfeiting-and-piracy Accessed (29 March 2016) This report is an update from the old OECD report on counterfeit that states the estimate of counterfeit as of 2008 is us$250 billion. But this study shows a up to date estimates and additional impact of counterfeit not specifically treated by the OECD. This report posits that counterfeit exist outside the framework of the law which makes the estimate challenging to identify.

[212] World custom organisation detection of counterfeit product destined to 140 nations

developed economies; it provides cheap alternatives for ignorant and helpless consumers with little or no knowledge of the quality of the counterfeit product.

Grossman and Shapiro have examined the economic effect of counterfeit by using a two-country model (Deceptive Counterfeit). The model suggests that it is not unusual for multinational firms, to produce low-quality generic products as well as imitate brand name domestic products. This, in turn, affects a consumer's ability to differentiate from the original product[213]. The fundamental inference drawn from this model is that the outcome of counterfeit creates the problem of imperfect information and imperfect intellectual property right. This model equally highlights some rational economic expectations of counterfeiting, such as it creates an additional avenue for import, and raises the price of generic products. Counterfeiting also harms consumers of brand name products, and it can alter the cost and quality of goods.

On a similar note, the OECD adopted a two-phased model to determine the economic impact of counterfeit. By differentiating the demand and supply aspect of counterfeit, the OECD posits that the demand aspect of counterfeit is driven by three key factors namely, product quality and price, quality of consumer and institutional environment of the said product. Whereas the supply aspect is driven by the market forces available at a time, distribution network and the risk factor in perpetuating the criminal act of counterfeit[214]. Based on what has been said, both models itemized the economic

[213]Gene .M .Grossman, Carl Shapiro,' Counterfeit Product Trade', NBER Working Paper No. 1876 (Also Reprint No. r1086)Issued in March 1986, (1988) Vol 78, No 1 American economic review, pp 59, The authors used a two-country model approach to determine trade in both legitimate and counterfeit Products .By stating that Domestic firms trademarks on products is infringed by the effect of counterfeit, with the use of foreign suppliers to deliver low quality products to legitimate market. The effect of this on unsuspecting countries with no technological know how to deal with this issue, however the authors describe the normative effect of counterfeit to consumers and Finally, provided a welfare analysis of border inspection policies on counterfeit.

[214] 0ECD/ EUIPO, 'Trade in Counterfeit and Pirated Goods, Mapping the Economic Impact' *(*OECD Publishing, Paris 2016*)* This report highlights the difference between primary and secondary market, stating that primary market are markets where are deceived to believe that they are purchasing legitimate goods whereas secondary market is a market where consumers willingly purchase

problems of counterfeit; they rightly point out the importance of protecting IPR of companies, to achieve this, the legal requirement must be clearly defined. To effectively discuss this point, the thesis will examine the company, price, individuals, and government perspective on counterfeit. The rationale here is to demonstrate how counterfeit undermines the growth of IP in society.

(I)*Pharmaceutical Companies perspective on counterfeit*- The overall economic impact of counterfeit on pharmaceutical companies cannot be overemphasized. This is primarily due to the lack of quantitative data used to verify the scale of damage by counterfeit on the economy. Companies operating illegally usually do[215] not disclose their activities or earnings to relevant government agencies for fear of prosecution. On the other hand, legitimate firms, especially pharmaceutical companies, obviously suffer a loss of revenues from royalties, sales and profit, and they also incur the unnecessary cost of fighting counterfeiters. This cost undermines future investment in research and development (R&D), thereby decreasing innovation. Manufacturers of pharmaceuticals invest billions of dollars in R&D, for it is the life wire of any pharmaceutical company, and if properly harnessed, it will be beneficial to the world, irrespective of class. R&D involves innovative steps such as clinical trials, regulatory approval, drug manufacturing, marketing, branding, which are all capital intensive and time-consuming (between 10- 15 years).

The long-time frame for the development of pharmaceutical R&D can be attributed to the persistent discovery of new diseases that afflict the human body without end due

counterfeit products having been influenced by the demand and supply aspect of trade. Counterfeit drives major economies of states due to the conditions as globalisation, e-commerce, post crisis revival of trade etc.

[215] The Global Growth of Counterfeit Trade, Available file:///C:/Users/ifueko/Downloads/9781461455677-c1%20(1).pdf Accessed (10 October 2016)

to changing life patterns, demographics, globalisation, technological advancement and environmental dynamics thus necessitating increasing inquiry into the development of new drugs[216]. Equally, pharmaceutical research deals with experimental or theoretical work undertaken primarily to acquire new knowledge of the underlying foundations about observable facts, without any application or use in view of properties and structures will be evaluated to test hypotheses, theories and law. Pharmaceutical researchers focus on broad fields of general interest, with an explicit intention to discover a broad range of future applications[217]. The pharmaceutical industry contends that the regime of patent is not adequate to guarantee the risk factor involved in Pharmaceutical R&D. It compels researchers to advocate for longer terms of patent to have leverage over market competition and to hinder the sale of counterfeit drugs in the market[218].

It is essential to point out also that R&D in the pharmaceutical field encourages the growth of foreign direct investment (FDI). For example, in Brazil, the introduction of the Brazilian intellectual property law in 1996 increased the percentage of FDI from $4.4 billion in 1995 to $32.8 billion in 2000. IP is regarded as a ''hidden treasure'' and a significant contributor to the growth of any company. For example, following the discovery of the antibiotic azithromycin by Pliva in 1980 and licensed to Pfizer, Pliva recorded a growth rate of over $1.5 billion by 2001[219]. This shows the extent IP can enhance the earning power of a company; its value cannot be quantified.

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[216] Chidi Oguamanam, 'Patent and Pharmaceutical R&D: Consolidating Private –Public Partnership Approach to Global Public Health Crisis,' (2010) Vol. 13, No4 The Journal Of World Intellectual Property, Pp556-557

[217] Frascati Manual 'Proposed Standard Practice For Survey'- OECD(2002): At Www.Oecd.Org/.../Frascatimanualproposed...Accessed (11 August. 2014) This Manual Contains Definitions of Basic Concepts, Data Collection Guidelines and Classification for Compiling Statistics

[218] Ibid

[219] John Reed , 'Drug Maker Pliva Launches' Wall Street Journal, GDR to Raises $270 Million, Available http://www.wsj.com/articles/sb893710917765008500 Accessed (16 October 2016)

The relevance of IP to the pharmaceutical industry cannot be over-emphasized; it protects the pharmaceutical investor's right. But can the protection of investor's right guarantee safer lifesaving drugs? It seems rather unlikely in this present circumstance where free trade subsists purely for financial motivation rather than global health needs[220]. In the words of Sachs, ''Global market force inevitably skews the direction of research and development towards diseases that assure the highest financial gains''[221].

(II)Price motive

Generally, counterfeit goods and pharmaceuticals are produced in countries with lax IP laws and weak labour standards. Weak laws allow manufacturers to trim down the actual price of production to make excessive profit from the sale of counterfeit goods. As the United Nations office on drugs and crime points out, large numbers of counterfeit seizures originate from China and India[222]. Despite laws prohibiting the production and sale of counterfeit pharmaceuticals, it has become a norm in recent times, mainly due to the price of drugs.

The comparative prices of drugs vary from state to state, and the demand and supply of drugs fluctuate because of price. It is a significant public health concern that the primary focus of most pharmaceutical companies is profit-making not on the efficacy of drugs. This notion of profit is further emphasised with the sale of life-saving

[220]Patrice Trouiller and others, 'Drugs for Neglected Diseases: A Failure of the Market and a Public Health Failure,' (2001) Vol 6, issue 11Tropical Medicine and International Health, PP 945
[221]Jeffrey Sachs, 'Helping the World's Poorest', (1999) Vol 14 Economist PP 17
[222]United Nation Office on Drug and Crime, Counterfeit Product Available https://www.unodc.org/documents/data-and-analysis/tocta (Accessed 29 March 2016) Counterfeit product is different from product counterfeit. Product counterfeit is a form of consumer fraud perpetuated by organised group activity. Usually most countries treat counterfeiting offence as a serious offence, which is why counterfeit is carried out in countries with lax IP laws. This research identifies the supply and production sites of counterfeit, indicating countries like china and India. With the annual market value of 2 billion per year and an annual monetary value of US$.2 billion. The growth of counterfeit in these countries is attributed to high productivity and low cost of production.

medicines for an exorbitant price for the benefit of investors. For instance, during the HIV/Aids[223] Epidemic, the price of antiretroviral drugs varied between developed and developed countries. The South African HIV crisis is a perfect example of exorbitant drug pricing. The percentage of people living with HIV in South Africa was estimated to be 12.2% of the total population which amounts to 6.4 million people living with the virus. The new infection rate was estimated to be 500,000 in 2004, 430, 000 in 2009 and 330, 000 by 2014[224]. Likewise, the United Nations Program on HIV/AIDS (UNIAID) estimated that by 2015 the number of people living with HIV in South Africa would be approximately between 6,700 000 - 7 400 000 million people[225]. Given this large number of people, obtaining medical care and Antiretroviral Drugs (ARV) (a drug that helps to reduce the reproduction of HIV).

This anomaly is owing to the ridiculous price of ARV: most ARV drugs are novel and protected by patent, thus making them expensive and relatively of low quantity giving the number of people in need of it. A study by the Centre for International Health and Development Boston University reviewed the cost of acquiring ARV in South Africa is estimated at over $ 1,700 per patient in a year showing both higher input price and complete cost estimates[226]. Compare this figure to 15 years earlier when the ARV cost

[223] Acquired immunodeficiency syndrome (AIDS) is caused by a virus that carries RNA instead of the DNA, resulting in the destruction of the human immune system by the Human Immunodeficiency virus. The HIV virus invades the body using reverse transcriptase enzyme. HIV virus was first discovered by the National Institute of Health, the Harvard University and the Pasteur Institute in France.

[224] HIV Statistics South Africa – Prevalence, province, antiretroviral treatment (ART https://www.tbfacts.org/hiv-statistics-south-africa/ Accessed (25 August 2017)

[225]UNIAIDHIV/AIDSestimate2015, South Africa, Available http://www.unaids.org/en/regionscountries/countries/southafrica Assessed (25 August 2017)

[226]Sydney Rosen and Lawrence Long, How Much Does It Cost to Provide Antiretroviral Therapy for HIV/AIDS in Africa? Health and Development Discussion Paper No. 9 October 2006 Centre for International Health and Development,

more than $10,000 per person a year, but gradually this price reduced to $350 then to $150 per year following the introduction of generic medicine[227] .

Generic medicine has made it possible to treat HIV at a relatively low cost for developing countries. It is essential to understand the impact of a generic drug on the general development of counterfeit. A generic medicine is seen as a reliable substitute to patented highly-priced drugs. A BBC report suggests that a generic drug can cost between 30% and 80% less than the original drug, and the generic drug market globally is estimated to be worth more than $225 billion. This figure might increase to $358 Billion if more patented drugs expire[228], and this is a significant concern for investors. However, the issue of generic medicine will not be discussed in detail. Nevertheless, it is worth reiterating that the price of a drug is linked to the business commitment of investors, which is profit, and this can create an enabling environment for the growth of counterfeit drugs.

III. *State/ individual economic perspective*- From the discussions above, it can be inferred that the most important economic task of pharmaceuticals companies is profit maximization, given this goal, is there a social responsibility on states to deliver innovative drugs to its ailing population? According to Milton Friedman, the primary role of a state is the provision of defence, protection of citizen's rights and the establishment of a viable economy by enforcing contracts and free trade[229]. Based on

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[227] United Nation Development Programme UNDP, World AIDS Day: record drop in cost of HIV treatment. Nov 30, 2015, Available http://www.undp.org/content/undp/en/home/presscenter/articles/2015/11/30/world-aids-day-record-drop-in-cost-of-hiv-treatment.html Accessed (25 August 2017)

[228] James Brumley, 'What's the Real Impact of Generic Drugs? Expiring patents hurt market share for big Pharma Names,' Investors Place Feature Writer June 28, 2012, Available http://investorplace.com/2012/06/whats-the-real-impact-of-generic-drugs/#.WaFj77pFzIUAccessed (26 July 2017)

[229] Milton Friedman The Role of Government in Education (1955)

this last function, a State' government plays a crucial role in the sale and distribution of drugs.

In pursuit of this goal of a viable economy, a state can intervene in different instances. For example, a state can set standards, policies, goals for the regulation of pharmaceuticals within its territory. However, the high fixed cost of pharmaceuticals may undermine potential government control, but it cannot obstruct a states directive on drugs. This cost needs to be balanced against the societal needs for new drugs; this can only be achieved by state involvement in the pricing and rationing of drugs[230]. Given the complex market structure of pharmaceuticals, state or government involvement is essential for the pharmaceutical market to function effectively.

The responsibilities of states provided by the WTO include the following:

- The provision of licensing, examination of premises, registration of drugs, control of marketing and independent drug information.
- Policies on professional licensing standards for pharmacists, doctors and other health professionals and the establishment of codes of conduct
- Ensure access to pharmaceuticals by subsidizing essential drugs for the poor through public health service
- Rationalizing the use of the drug for the public[231]

Given the above responsibilities, it seems that the primary function of a national government is to ensure access to health care, including essential drugs. Government is to ensure the eradication of counterfeit pharmaceuticals from the entire population.

[230] Richard G. Frank, 'Government Commitment and Regulation of Prescription Drugs, Health Affairs' Vol.22 No. 3, (2003) PP 46

[231] Sara Bennett, Jonathan D. Quick and German Velasquez, 'Public –Private Roles in the Pharmaceutical Sector: Implications for Equitable Access and Rational Drug Use,' World Health Organisation WHO/DAP/1997.12

It is rather disturbing to imagine a state without formal government policies on drugs. Such a situation will stimulate the growth of counterfeit drugs. In conclusion, this section examined the economic instances for the sudden increase of counterfeit drugs from a hike in price, to the need to make a profit and preserve research and development by pharmaceutical firms.

2.3.3 Human right and social aspects of counterfeit Pharmaceutical

''The evil of fake drugs is worse than the combined scourge of malaria, HIV/Aids, armed robbery and illicit drugs'' Dora Akunyili (2002)

Ever since the inception of the pharmaceutical industry, it has been known for integrity and good organization, but more recently, it has been plagued by different institutional and non-institutional dynamics such as the patentability of drugs, TRIPS flexibilities, accessibility and counterfeit pharmaceuticals. The problem of counterfeit pharmaceuticals knows no border, and it involves people from different continents, particularly the developing and least developed countries. The key objective of this section is to create a benchmark on the human and social aspects of counterfeit drugs on people, which is the access to medicine issue. The next section will discuss briefly the impact of counterfeit medicines in Nigeria to develop a framework for solving the problem. Before considering the different arguments on drugs, it is important to examine the history of pharmaceuticals in a bid to discover their fundamental nature and correlation to man.

Medicine is regarded as a substance that has a physiological effect when ingested or otherwise introduced into the body. However, it is worth knowing that there is a clear delimitation between medicine and pharmaceuticals, as the latter relates to the

manufacture and sale of medicines[232]whilst relying on IP rights and market agreement. The system created by the pharmaceutical industry spurred innovation and productivity for investors, but it relied mainly on cost control measures for survival. In the words of Cockburn, ''*Drug development in today's new institutional arrangements could turn out to be faster and better, but not cheaper''* [233] which inadvertently restricts accessibility to life-saving drugs for the treatment of infectious diseases such as HIV, Tuberculosis, malaria and Ebola[234] with patients in developing countries who cannot afford to pay for the needed drug. For example, during the Ebola epidemic in Liberia, Guinea, Sierra Leone and Nigeria[235] thousands of lives were lost to the virus, the question was not about patent, IP protection or brand name but the availability of drugs. The method of getting drugs does not matter to a sick person in a developing country, but the availability of anything that can bring aid.

The focus of developing countries like Nigeria is getting affordable drugs into its supply chain. This can introduce the element of counterfeit pharmaceuticals into the system because access to medicine is more important than the protection of IP rights. Counterfeit is a global problem; while there might be uncertainty about its true scope. WTO estimates that over half of the drugs in developing countries are counterfeit. Some scholars argue that counterfeit is primarily an auxiliary from intellectual property.

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[232]Pharmaceutical." *Merriam-Webster.com*. Merriam-Webster, n.d. Web 19 June 2017.A pharmaceutical can be in different form, can be a drug, ointment, prescription drug, tonic, tablet, portion, palliative and syringe etc.

[233] Iain M. Cockburn, 'The Changing Structure of the Pharmaceutical Industry,' (2004) Vol. 23 No 1, Health Affairs PP 10

[234] Lawrence O Gostin, Daniel Lucey and Alexander Phelan, 'The Ebola Epidemic: A Global Health Emergency'. (2014) Vol.*312*(11), *Jama*, pp.1095.The Ebola virus is carried by Fruit bats likely to infect the human body by close contact with the body fluid such as bush meat, pigs, and other animals. Symptoms are similar to the symptoms of malaria and typhoid fever—as well as endemic haemorrhagic fevers such as Lassa—rendering symptomatic differential diagnosis difficult.

[235] Lawrence O. Gostin, Eric A. Friedman, 'Ebola a Crisis in Global Health Leadership,' (2014) Vol. 384, The Lancet PP 1323

IP not only increased the price of an innovative drug but also aggravated the problems of counterfeit drugs. Accessibility is a pervasive problem given the considerable margins between the market price of drugs, R&D cost and issues of patent infringement. All these facilitate the growth of counterfeit pharmaceuticals.

Underlying motivations

The problem of counterfeit pharmaceuticals remains a significant challenge for states, particularly in Africa. Inadequate medicines and other public health issues affect people's health in developing countries. There is hardly any comprehensive data to quantify the scale of counterfeit. The reporting system in most countries is weak, with no freedom of the press in most jurisdictions. Even when there is freedom of the press, gaps exist in the decimation of information between the developed and developing countries. Equally, on the reach of counterfeit pharmaceuticals, Hyeonho points out that the health risk of counterfeit pharmaceuticals is numerous. For example, the discovery of a lethal amount of melanin in baby formula and the sale of pharmaceuticals with little or no active ingredients[236].

The danger of counterfeit Pharmaceuticals is particularly severe in Africa, although it is difficult to estimate the extent of counterfeit due to the non-availability of reliable data from states. However, data from national governments in Africa, police seizures and sample data collected from the international organisation will be used to develop the body of evidence on counterfeit drugs in Africa. The WHO estimates that 10 percent of drugs sold globally are counterfeit[237] and out of this 10%, 30% is drugs sold

[236] Elizabeth G.Denis 'Crackdown on Counterfeiting' International Standard Organisation (Jan 2014), Available http://www.iso.org/iso/news.htm?refid=ref1809 Accessed (30 March 2016)
[237] BBC NEWS, 'Counterfeit Drugs 'May Kill You or cause Superbugs ' September 2013 Available http://www.bbc.co.uk/news/health-24270737 Accessed (16 May 2016)

in Africa, from this estimate shows that 50 % of the total drugs produced globally is sold and consumed in Africa.

The Nigerian Government, on the other hand, is confronted with the major task of providing essential medicine and proper health facilities for its citizens despite the prevalence of counterfeit medicine. Counterfeit remains a great issue to the Nigerian government, and it may appear most pharmaceuticals in Nigeria is fake, substandard or counterfeit[238]. The menace of counterfeit pharmaceuticals in Nigeria can be traced from 1985 to 2000, and the situation has not changed to date[239]. It is imperative to examine the drug situation in Nigeria, starting from the pharmaceutical market.

The Nigerian pharmaceutical market is estimated to be worth more than US$600 million as of 2009. It is expected to grow significantly at around 12 per cent yearly to reach US$ 717 million in 2011, but recent figures indicate that the Nigerian pharma market can rise as much as 9% a year over the next ten years reaching $3.6 billion by 2026 making it, one of the largest pharmaceutical markets in Africa[240]. However, most of these pharmaceutical products are imported, despite the Nigerian Government best efforts to promote domestic production of pharmaceuticals. According to Okoli out of the 130 existing Pharmaceutical companies in Nigeria, only 60 are inactive manufacturing despite the installed capacity estimated to produce 50% to 70% of the total drug needed in Nigeria. This means that the capacity utilization of pharmaceutical companies is below 30%[241].

[238]Ohuabunwa, M,' Health Care Delivery in Nigeria, Past Present and the Future, (2002) Vol.31' Nigerian Journal of Pharmacy pp15-17

[239]W.O. Erhun, O. O. Babalola, M.O. Erhun, Drug regulation and control in Nigeria: The Challenge of Counterfeit drugs, (2001) Vol.4, Issue 2. Journal of Health and Population in Developing Countries pp 23

[240] McKinsey and Company, Tainai Holt, Laura Millroy, Matthews Mmopi, Wining in Nigeria; Pharma's next frontier

[241] S Okoli, 'Pharma Industry in Distress' (2000) Vol22 Issue 3 Pharma News pp 1

Equally, the delivery of an essential drug in Nigeria is chaotic; drugs are sold everywhere from sale in the open market, sales in patent medicine stores, wholesalers and pharmaceutical manufacturers. There is no proper mechanism in place to make checks and balances of the inflow of drugs in the health sector in Nigeria. It is a common occurrence to see a public display of drugs in the market and motor parks, without proper consideration of the weather condition that enables the breakdown of the active ingredient in the drug.[242] From the above facts, it is evident that the Nigerian public health care system is poorly organised and mismanaged. It is so disheartening that the WHO in the year 2000, ranked the Nigerian health care system as 187 out of 191, which is extremely low compared to other countries. At the same time, the mortality rate at birth for an average Nigerian is estimated at 46 years for males and 47 years for females, compared to Ghana and South Africa whose life expectance is estimated to be about 55 and 50 years[243]. However, it is worth reiterating that access to the right medicine will address public health issues in Nigeria significantly.

2.3.4 Legal Aspect to counterfeit Pharmaceutical

Counterfeit pharmaceuticals lead to therapeutic failure and ultimately, death. It demoralizes public trust in the health care system of a state. To guarantee public health, states penalise acts that are deemed illegal to the proper distribution of pharmaceuticals. The legal aspect of counterfeit pharmaceuticals will be the requirement mandated by law for the production, protection, distribution and sale of pharmaceutical products. The black's law dictionary defined a counterfeit drug 'as a drug made by a person other than the genuine manufacturer, by copying or imitating

[242]Adelusi Adeluyi, 'Drug Distribution: Challenges and Effects on the Nigerian Society,' Keynote speaker at the 73rd Annual National Conference of the Pharmaceutical Society of Nigeria, November 2000

[243] WHO Mortality Fact Sheet 2006

an original product without authority or right with a view to deceiving or defrauding and marketing the forged drug as the original'. This definition highlights specific legal flaws, for example, intention to deceive (Fraud), the act of copying (imitation), without authority (intellectual property right). Existing laws of states can penalise these acts locally and internationally.

The law will only penalise an offender if a breach has occurred, and it can be established within the law as a breach. Counterfeit pharmaceutical is the breach of IP rights, rights which accrue to the owner of the creation of the mind. This right ensures that the right holder is empowered to deal with it to the exemption of all others after it has been recognised as a right by the state. Countries set out rules and procedures for regulating infringement of IP right[244] by both civil and criminal proceedings. The penalties for counterfeit vary from country to country. Generally, brand owners can sue counterfeiters in a civil court for damages and injunctions, and the government can sue counterfeiters in a criminal court. The penalties include fines and imprisonment. For example, in Nigeria protection of IP right is found within the patent and design Act of 1970[245] and Nigeria is also a signatory to other international conventions that advocate for IP, such as WIPO, and Paris Convention etc. Once the right has been granted, nobody can deal with it or use it for any commercial purpose. In case of infringement, *section 25* of the Patents and Designs Act 197 provides for remedies of damages, account and injunction with Federal High Court retains exclusive jurisdiction to entertain such matters.

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[244] Margot E. Kaminski, 'An Overview and the Evolution of the Anti-Counterfeiting Trade Agreement.' PIJIP Research Paper no. 17, (2011) American University Washington College of Law, Washington, DC

[245]Patents and Designs Act of 1970. Cap 344 of Laws of the Federation of Nigeria 1990

One of the international agreements Nigeria ratified is the WTO- TRIPS agreement whose framework advocates for free trade. It creates safeguards for the affordability and availability of pharmaceuticals[246], which include parallel imports and compulsory licence. Given this safeguard, does IP right include the removal of protection with the prevalence of counterfeit? One dispute is the interpretation of legal provisions within the WTO-TRIPS. To ensure clarity on this subject, Lyons argues that law as it is or as it ought to be are two different concepts. A legal provision is typically ambiguous or inconsistent; problems will arise if a complex term such as the definition of counterfeit pharmaceutical interferes with the specific mandate of TRIPs law[247]. TRIPs set out standards, guidelines for regulating pharmaceuticals, and there is an assumption that states ratify these standards for the regulation of counterfeit drugs. However, if TRIPS law is too old to define what counterfeit is or how to prosecute or curtail it, it means the problem of counterfeit has grown more than the WTO and law. So how is the law applied in this instance, if the WTO has no adequate legal machinery to protect IP rights and pharmaceuticals?

For clarity, this thesis will briefly assess some sections (*Article 41 & 61)* of the WTO-TRIPS Agreement to highlight certain ambiguities in the law. *Article 41(1)- ''States Members shall ensure that enforcement procedures as specified in this Part are available under their law to permit effective action against any act of infringement of intellectual property rights covered by this Agreement, including expeditious remedies to prevent infringements and remedies which constitute a deterrent to further*

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[246] Umar Abubakar Dubagari 'An Appraisal of Nigeria's Membership and Participation in the World Trade Organisation (WTO), (2016} Volume 21, Issue 7,) IOSR Journal Of Humanities And Social Science (IOSR-JHSS) PP 56-65

[247] David Lyons, Moral Aspect of Legal Theory; Essay on law, Justice and Political Responsibility (Cambridge University Press, 1993)

infringements. These procedures shall be applied in such a manner as to avoid the creation of barriers to legitimate trade and to provide for safeguards against their abuse".

Comment- Article 41 deals with all the provisions of Part III and as such affects *Article 41- Article 61*. This clause provides that the procedures shall be applied to avoid ". Creation *of barriers to legitimate trade and to provide for safeguards against their abuse,*" which is very ambiguous especially in the context of Articles *41-61.*

There are some flaws in these articles: what constitutes legitimate trade is not defined and is therefore left to individual members own local laws as set out in paragraph 5 below. This leads to a lack of uniformity in which what is legitimate trade in one member country may be deemed illegitimate in another. To circumvent the provisions, a member must make laws to fit the activities that are unfavourable into the unlawful classification. Although there is a provision to safeguard against the abuse of such provisions, it is hard to determine what an abuse of the process would be. Suppose a party lays claims to violation of the requirements, in that case, it will be difficult to determine or justify why that party is entitled to the same right legally in a member state, and it is illegal in another.

2- ‘*'Procedures concerning the enforcement of intellectual property rights shall be fair and equitable. They shall not be unnecessarily complicated or costly, or entail unreasonable time-limits or unwarranted delays."*

Comments-

a) The provisions requiring fairness and equity in enforcement comes with an imperative tone, with the word "Shall," presumably it is obligatory. This is a perfect clause, but:

i. It only guarantees protection as much as the jurisdiction or member within which a dispute arises. Building on the points in paragraph 1 above and bearing in mind the effects of paragraph 5 below, the complexity and cost aspects would be invariably different between members.

ii. The complexity issues mentioned would be made more pronounced given the conduct is illegal in one member state or at least carries a severe penalty like a hefty fine or imprisonment or light penalty, however in other states this illegal activity may be acceptable.

iii. Since in paragraph 5 below it is made explicitly clear that there is no obligation to adopt or provide a different legal regime for Intellectual Property to that of local laws, the speed of the enforcement process will differ significantly.

Section 3 ‘’*Decisions on the merits of a case shall preferably be in writing and reasoned. They shall be made available at least to the parties to the proceeding without undue delay. Decisions on the merits of a case shall be based only on evidence in respect of which parties were offered the opportunity to be heard’’.*

Comment-

b) The provision that decisions on the merits of a case should "preferably" be in writing with reasons is a very wide loophole for members to pick the preferable option which might not necessarily be just. This means decisions on the eligibility of a person to bring a claim can be made orally and the claim dismissed for lack of merit if the panel members prefer to take such a stand. This automatically shuts the doors for a just system as it is open to abuse and defeats the stated aims in paragraph 1 above of preventing abuse of the enforcement process.

4. *''Parties to a proceeding shall have an opportunity for review by a judicial authority of final administrative decisions and, subject to jurisdictional provisions in a Member's law concerning the importance of a case, of at least the legal aspects of initial judicial decisions on the merits of a case. However, there shall be no obligation to provide an opportunity for review of acquittals in criminal cases''.*

Comment-

c) The provision of a right to review by a judicial authority is not an explicit right to appeal. Furthermore, such a review becomes more complicated if the decision not to pursue a case or that a claim is without merit was made orally and no reasons or next to none is given. There is also no obligation to restore a claim even if the review makes a finding that there was a case to answer, in essence, it would be more like a post-mortem as opposed to part of the process of enforcement, depending on what the member concerned determines.

5. *''It is understood that this Part does not create any obligation to put in place a judicial system for the enforcement of intellectual property rights distinct from that for the enforcement of the law in general, nor does it affect the capacity of Members to enforce their law in general. Nothing in this Part creates any obligation concerning the distribution of resources as between enforcement of intellectual property rights and the enforcement of the law in general.''*

d) This is the most important damaging clause to focus on when assessing *Article 41.* As mentioned in all the paragraphs above, it is not a binding process and is subject to manipulation by individual members. It is also subject to the strength and weaknesses of member judicial systems.

Article 61- ''Members shall provide for criminal procedures and penalties to be applied at least in cases of wilful trademark counterfeiting or copyright piracy on a commercial scale. Remedies available shall include imprisonment and monetary fines enough to provide a deterrent, consistently with the level of penalties applied for crimes of a corresponding gravity. In some cases, remedies available shall also include the seizure, forfeiture and destruction of the infringing goods and of any materials and implements the predominant use of which has been in the commission of the offence. Members may provide for criminal procedures and penalties to be applied in other cases of infringement of intellectual property rights, where they are committed wilfully and on a commercial scale.''

Comments: -There is a provision therefor criminal sanctions, including imprisonment and or fines. Such remedies could be given *"...in cases of wilful trademark counterfeiting* ***or*** *copyright piracy on a commercial scale."* However, given the loopholes in Article 41 that allows members to adopt different standards of justice suitable to their respective jurisdictions then it risks individuals being imprisoned for conduct within one jurisdiction in which they would otherwise be fined for in another.

The definitions of (1) Wilful trademark counterfeiting and (2) Copyright piracy on a commercial scale will both have to be looked at within individual jurisdictions. Also, it is worth noting that the remedies "*shall*" be provided for, which is an obligatory term. But the provision (as worded) is made as an alternative provision of (1) ***or*** (2) above which means a member can choose to make such remedies available for one and not the other. So, after scaling the hurdles of definition, then a party seeking remedy must contend with which provision is provided for in a jurisdiction whether (1) or (2). There will inevitably be severe inconsistencies across jurisdictions regarding definitions and

provisions for remedies between members, and as such, there is a lack of uniformity in the process. Justice must be uniform; otherwise, it will be deemed unequal.

Section B

2.4 Dealing with the definitional question of counterfeit Pharmaceutical

Attaining a workable interpretation of counterfeit pharmaceutical, consist of any law, treaty and policy which must essentially work towards the goal of a regulating standard within the economic, social, legal and technical framework not just about law or business, but all aspects are unified in one all-encompassing definition. From what has been gathered previously, to attain a viable definition of counterfeit, the concepts must necessarily cohabit towards achieving a specific goal: various institutions can work to accomplish a common goal, which is a clear definition of counterfeit pharmaceutical instead of using the wrong alternative or connotation. Counterfeit is not a standard that should be met, but what is perceived as wrong within the various institutions. Therefore, it is the responsibility of the state to protect the owners of the property right through legal means. A state should protect, promote and implement all human rights.

2.4‘Counterfeit pharmaceuticals'- A Legal framework for trade Regulation.'

This section reviews the legal framework for regulating counterfeit pharmaceuticals, which will be able to provide for access to medicine, investors rights whilst advocating for a practical and effecting law, enactment, and decree to control counterfeit. This framework is needed to establish a persuasive national regulatory authority to ensure the production, use and access to pharmaceuticals is effective and uniform nationally.

In this context, emphasises will be placed on the Nigerian legal system for guidance on its substantive and the procedural rule of law on pharmaceuticals.

Nationally, various laws and policies exist in Nigeria for the regulation and control of drugs[248], each of which plays a specific function depending on the legal responsibility of each institution. The Law on drugs must be unambiguous and comprehensive, clearly stating the manufacturer, drugs, invention, process, product, consumers, and rights. For example, who is the manufacturer and is his licence to manufacture valid within a particular jurisdiction, as well as what right accrues to the IP right holder.

The role of law is to establish national drug policies, regulatory bodies, courts, and enforcement mechanisms to continually enforce the law. Some of the pharmaceuticals policies and laws in Nigeria include:

- *Drugs and related products Decree 19 (1993)*
- *Poisons and Pharmacy Act Cap 535 LFN 1990*
- *Food and Drug Act Cap 10 LFN 1990*
- *National Drug Law Enforcement Agency Cap 253 LFN 190*
- *Patent and Proprietary Medicine Vendor License*
- *Consumer Protection Council Decree No. 66 of 1992*
- *Trade Malpractices (Miscellaneous Offenses Decree No. 67 of 1992)*
- *Counterfeit and Fake Drugs Miscellaneous Provisions Act (Cap 73, Law of the Federation, 1990)*
- *Counterfeit and Fake Drugs and Unwholesome Processed Foods (Miscellaneous Decree 25 of 1999) 6Essential Drug list*
- *Drug Revolving Fund*

[248] Olusegun Akinyandenu, 'Counterfeit Drugs in Nigeria: A Threat to Public Health,' (2013) Vol.7 Issue 36 African Journal of Pharmacy and Pharmacology, PP 2571

- *National Health Insurance Scheme*
- *National Primary Health Care*
- *HIV/AIDS Emergency Action Plan- 2001*
- *National Antiretroviral Programme -2001*[249]
- *National Agency For food and Drug Administration and Control (NAFDAC)*

These policies are an enactment of government legislation on drugs to promote access to a safe, effective and affordable non-counterfeit drug[250]. To enhance uniformity, a new framework should be developed by parties involved in the sale and manufacturer of pharmaceuticals, such as industry, lawyers, scientists, pharmacists, medical practitioners, government agencies and economists [251]. It is crucial not to interpret legal provisions narrowly, so doing will undermine compliance to legal rules, hence creating a viable environment for counterfeit drugs to thrive.

2.5.1 Intellectual Property Rights

IP rights are also necessary within the legal framework of trade in counterfeit, both at the national and international level. At the international level, rules for the protection of IP can be found in the Berne Convention for the protection of literary and artistic work, the Paris Convention for the protection of industrial property, the WIPO Patent Law Treaty, WIPO Corporation Treaty and the WTO-TRIPS Agreement. This research core emphasis will be the WTO-TRIPS, this agreement provides for the administrative,

[249] Kristin Peterson and Olatubosun Obileye, 'Access to Drugs For HIV/AIDS and Related Opportunistic Infections in Nigeria,' A status report on the socio-political , economic and policy climate on drug availability for people living in with HIV/AIDS and recommendation for future access, Policy Project Nigeria Available http://pdf.usaids.gov/pdf_docs/pnacr139.pdf Access (30 August 2017)
[250] National Drug Policy, Federal Ministry of Health in Collaboration with the WHO 2005 Available http://pdf.usaid.gov/pdf_docs/pnacr139.pdf Accessed (30 August 2017)
[251] Ransome O. Kuti, 'National Drug Policy in Nigeria,' (1992) Vol.13, No 3 Journal of Public Health policy PP 367

criminal and civil enforcement measures of IP rights whilst preventing trade in counterfeit.

One of the rights protected by TRIPS is the prevention of use by a third party without the consent of the right holder. If infringed, the right holder can obtain an injunction to restrict usage, and damages in the form of compensation can be awarded. Also, there will be payment of pre-established damage by the infringer and the destruction of infringing goods. A Member state is duty-bound to implement procedures and penalties in the case of wilful counterfeiting, which must include penalties such as imprisonment and fines[252].

As a signatory to the TRIPS Agreement, Nigeria is duty-bound to comply with all the provisions of the agreement, including standards on IPR by being a member of the WTO. Given the fact that Nigeria is a developing country, the TRIP agreement stipulates that, by 2000, Nigeria ought to bring its National IP laws in line with TRIPS standards. Such standard includes changing its existing IP (patent) rules to fit the TRIPS requirement. A typical example of this is the extension of Patent life span to 20 years for new pharmaceutical products and processes. The inclusion of patent protection within the WTO rules monopolised drugs, and it escalated the issue of access to drugs and introduced counterfeit Pharmaceuticals[253].

The standards of TRIPs on pharmaceuticals include the availability of protection for products and processes for new innovative drugs, security and availability of the patented drug at a national level. To mitigate any negative impact of patent protection, TRIPS made provisions for public health safeguards, in the Doha Declaration

[252]Peggy E. Chaudhry and Michael G. Walsh, 'An Assessment of the Impact of Counterfeiting in International Markets: A Piracy Paradox Persists,' (1996) , Vol 31(3) Columbia Journal of World Business PP 34

[253] P. Boulet and others 'Pharmaceuticals and the WTO Agreement, Question and Answer' , March 2000, Available http://apps.who.int/medicinedocs/pdf/whozip18e/whozip18e.pdf Access (31 August 2017)

permitting members to take measures to protect public health. The measures include compulsory licence, parallel importation and extension of the Transition period for Least –Developed Countries (LDC). On the other hand, the pharmaceutical industry argues against TRIP safeguards, especially against Compulsory licence, saying it will have a devastating consequence on patent and may reduce the incentive on future R& D[254] and lead to a cultural change[255] if the standard of TRIPS is adopted entirely. However, the question remains how does counterfeit not become counterfeit, having established these laws and policies? In the face of this question, if counterfeit pharmaceutical is to be used, it should correlate with stated purpose within a Legal framework because the law is known to manage relationships whilst still maintain social order. In conclusion, counterfeit is a significant issue, which needs particular attention both at a national and state level. Although TRIPS has created standards, it is evident that the agreement places more value on public safety and access than on IPR as seen in the Doha declaration.

2.5.2 Economic Rights

The previous sections examined the protection of investor rights; the cost of production, price and the overall economic implication of counterfeit. This part is going to test the relationship between the legal institution of trade and economic rights to pharmaceuticals. It has been established that the pharmaceutical industry thrives on the right to patent, which is a legal right for protection against counterfeit. Therefore,

[254]WHO- Essential Medicine and Health Product, 'The Doha Declaration on the TRIPS Agreement and Public Health' Available http://www.who.int/medicine/areas/policy/doha_declaration/en/ Access (31 August 2017)
[255] Ellen 'T Hoen ,'TRIPS , Pharmaceutical Patent and Access to Essential Medicine Settle, Doha and Beyond,' Available http://apps.who.int/medicinedocs/pdf/whozip18e/whozip18e.pdf Access (31 August 2017)

the rights of a pharmaceutical investor will be discussed to determine if, the right is excessive or disproportionate. The right of an investor according to the OECD can be protected by a stable legal and regulatory framework domestically or internationally, which must be adequate, transparent and predictable to withstand changing conditions of trade, for example, counterfeit pharmaceuticals.

Pharmaceutical Investors can recoup the cost of production by IPR protection; it is a valuable component for any investor; it is the keystone of the pharmaceutical industry. IP can be used to protect new inventive steps, R&D, promotion etc. which is all capital intensive and cumbersome. Scholars such as Lincoln posit that 'the patent system fuels the interest to the fire of genius[256], it ensures strong market position, exclusivity, licencing and positive image. Therefore, obtaining IPR is a strategic necessity for firms. For this work, emphasis will be placed on the WTO Law. The first issue to be tested with the WTO standard is the price of pharmaceuticals. The cost of pharmaceuticals determines the development, market value and availability of drugs. Price control is purely within the prerogative of drug companies, even though this right is authorized by the rule of government and international law. From previous definitions of IP, states have the prerogative to grant the right to IP and regulate how this right will be exercised. It may seem that there is a disparity in who is controlling what especially with regards to pricing. This issue transcends the contingent quality of pharmaceutical products.

The second issue to be tested is the responsibility of states to ensure the right to safe drugs at a national level with its policies, institutions and rules. It is the primary responsibility of a state to provide access to safe medicine within its jurisdiction by

[256] Gerald J. Mossinghoff and Thomas Bombelles, 'Intellectual Property Protection and the Pharmaceutical Industry' (1996) Vol. 31, Issue 1 Columbia Journal of World Business PP 33

passing TRIPS flexibilities into legislation. States can equally amend measures on import duties on drugs, ensure equal opportunity of drug distribution in a bid to attaining the highest standard of health.

2.5.3 Technological Right

The legal framework of trade includes laws, code, policies, legislation which provide standards for the protection of property right. To ensure security, the WTO made provision in Article 7 for the enforcement of IP rights, such right ‘’*shall contribute to the promotion of technological innovation, dissemination of technology, to the advantage of the producer which is beneficial to social and economic needs and the stability of right and obligation*‘’[257]. The need to balance rights and infringement of IP within the all-encompassing scope of the WTO invariably undermines the regulation of counterfeit pharmaceuticals within WTO-TRIPS law. The TRIPS rule on technology ought to address health policy, product safety, access and the quality of drugs safety standards. If a drug does not meet the quality standard proposed by the WTO-TRIPS law, does it mean it is counterfeit? A useful measure on drugs should give a specific meaning first, instead of the different connotations proffered this includes fake, substandard, imitation, and counterfeit drug.

Conclusion

The purpose of this chapter is to unravel the unique form of counterfeit, by identifying the different phases and implications of counterfeit, more so the complex contribution

[257] WTO TRIPS-Issue on Technology Transfer, Available http://www.wto.org/english/tratop_e/trips_e/techtransfer_e.htm Accessed (2 September 2017)

of liberalisation and globalisation to the growth of counterfeit pharmaceuticals seems to influence the perception of counterfeit globally. For example, it introduced the concept of free trade to reduce border control which increased the movement of goods and services across nations, including counterfeit pharmaceuticals.

Also, this section emphasized, the impact of globalisation on the surge of counterfeiting. It introduced the element of technology, which improved the production and distribution of counterfeit, thus making the original product similar to reverse engineering. Visibly, the negative side of globalisation usually out weights the positive effect. However, with the same technology, counterfeits can be detected using holograms, and the use of forensic technology will make it difficult for counterfeit drugs to enter the market.

Another important issue discussed above is the definitional question; there is no definite meaning to it? Different institutions, states, scholars have given diverse meanings to counterfeit to fit their various organisational needs. For instance, the economist perceives counterfeit as product imitation, passing off, deceptive, whereas a legal expert believes counterfeit as a crime of defrauding, altering, falsification which is punishable within the law. In comparison, the human rights aspect perceives counterfeit from the public health purview, given access to medicine problems in developing countries. The confusion from these terms indicates that the problem cannot be solved if there is no harmonization amongst all stakeholders. Counterfeit results in loss of investments in both developing and developed economies; it provides a cheap alternative for ignorant and helpless consumers with little or no knowledge of the quality of the counterfeit product.

Chapter 3 The WTO-TRIPS Agreement and Regulation of Counterfeit Pharmaceuticals

Section A

3.1 The TRIPS Agreement

The fundamental principle of the TRIPS agreement's will be discussed starting with the linkage between the General Agreement on Trade and Tariff/World Trade Organization (GATT/WTO). Without these two interrelated trade instruments, there will be no TRIPS agreement. The WTO came into existence on 1 January 1995. Part of the deal negotiated by the contracting parties to GATT.124 countries signed this multilateral agreement to supersede the GATT that came into existence in 1948. The WTO agreement is essentially the constitution for world trade. In principle, it is an embodiment of rules, procedures, laws for regulating international and national trade amongst ratifying states [258]and *considered the new GATT*[259].

The WTO agreement is formed from the principles pre-negotiated at the General Agreement on Tariff and Trade (GATT)[260]. It is designed to boost international trade by eliminating unnecessary quotas, tariffs, and states' subsidies. The WTO is a typical example of a free trade agreement (FTA); FTAs significantly impact the liberalization

[258] Member states to the WTO are now 164. The countries include Afghanistan, Albania, Armenia, the united kingdom, the united states of America, France, Germany, Belgium, Poland, India, Brazil, Demark, South Africa, Mali, Togo, Nigeria, Algeria, Italy, Netherlands, Australia, Holland, Finland, Fiji, Guyana, Gambia, Gabon, China, Jamaica, Japan, Jordan, Liberia, Luxembourg, Latvia, Malta, Morocco, Mongolia, Mexico, Norway, Namibia, Oman, Pakistan, Panama, Peru, Philippines, Quarter, Rwanda, Russia, Romania, Sierra Leone, Slovenia, Sri Lanka, Sweden Etc.

[259] Adrian Otten' The TRIPS negotiations: An overview' Page 55 in 'The Making of the TRIPS Agreement Personal insights from the Uruguay Round negotiations' Edited by Jayashree Watal and Antony Taubman
Available https://www.wto.org/english/res_e/booksp_e/trips_agree_e/chapter_3_e.pdf Accessed (19 November 2018)

[260] 23-member countries signed GATT. It's an offshoot from the International Trade Agreement. It came into force on 30 June 1948, with the sole aim of tariff reduction

of trade[261]. The effect of this reduction increased world economic growth, making GATT/WTO one of the most successful international organizations[262].

The creation of a robust WTO was not surprising. Despite the hopes of the GATT of the immediate post War era, and notwithstanding the various rounds of trade talks conducted under its umbrella and authority, the GATT failed to effectively check the rise and abuse of a myriad of Non-Tariff Measures (NTM) that had come to replace tariff barriers. The new trade barriers were primarily regulations, such as dumping orders and subsidies that distorted international trade. These practices were particularly problematic for developing country members of the GATT. Moreover, the GATT did not have a robust enforcement mechanism. Neither did GATT members predict the changing nature of the global economy and changing comparative advantage. Therefore, the GATT did not cover trade in services and intellectual property's impact on international trade. Subramanian and Wei contend that GATT promotes unevenly reciprocal liberalization of business by allowing developed countries to have leverage over developing countries, by exempting the former from trade obligations[263], thereby encouraging protectionism.

It was these gaps in the trading system that necessitated the negotiation and creation of the WTO- a global trade organization. The WTO Agreement is more in tune with the currents of globalization, the demand for open markets via heightened trade

[261] Omiunu, Ohiocheoya, Ohio. "Is there any Coherence on the Role of Sub-National Actors in the Evolving Mechanisms for International Trade Interactions? A Comparative Analysis of Belgium and Canada." (2016)
[262] Judith L Goldstein, Douglas Rivers, and Michael Tommz, 'Institutions in International Relations: Understanding the Effect of GATT on World Trade,' (2007) 61(1),) International Organization pp.37
[263] Arvind Subramanian & Shang-Jin Wei 'The WTO Promotes Trade, Strongly But Unevenly,' 2007 vol. 72, issue 1 Journal of International Economics Page 151

liberalization, and an organization that responded to shifts in the global economy, new comparative advantage in the emerging field of trade in services strides in intellectual property. Therefore, the WTO agreement emerged as a complex legal text covering a wide range of rules, procedures, and fundamental principles of trade in a multilateral system. Some of these guiding principles include non-discrimination, reciprocity, transparency, and special and differential treatment. The WTO is classified as a negotiating forum, liberalization forum, legalization forum, and dispute settlement forum. Therefore, as a prelude to my thesis's core, the WTO rules on intellectual property, emergence, and the principle will be discussed below.

3.1.1 WTO as a Product of Negotiation

As noted earlier, the WTO agreement is a product of negotiation within the GATT Agreement. Approximately seven rounds created a unique all-encompassing multilateral agreement. The main content of the WTO agreement comes from the Uruguay negotiation from1986-1994. Still, the other rounds include tariffs reduction, the Kennedy round (anti-dumping), and the Tokyo round, which is equally significant. These negotiations helped liberalize trade, reduce protectionism, non-tariff barriers, protect least developed countries, and now liberalize trade-in service and protect Intellectual Property.

Table 1. GATT and WTO Negotiating Rounds of Multilateral Trade GATT trade rounds

Year	Place/name	Subjects covered	Countries
1947	Geneva	Tariffs	23
1949	Annecy	Tariffs	13
1951	Torquay	Tariffs	38

1956	Geneva	Tariffs	26
1960-1961	Geneva Dillon Round	Tariffs	26
1964-1967	Geneva Kennedy Round	Tariffs and anti-dumping measures	62
1973-1979	Geneva Tokyo Round	Tariffs, non-tariff measures "framework." agreements	102
1986-1994	Geneva Uruguay Round	Tariffs, non-tariff measures, rules, services, intellectual property, dispute settlement, textiles, agriculture, creation of WTO, etc.	123

[264]

The Geneva talks of 1947 are the first round of negotiations within the GATT framework. It is a significant determinant of the successes of GATT in the reduction of trade barriers globally. Before this reduction, protectionism was the norm, given the fact that states had stiff tariff measures, tight import quotas, and state control of the foreign exchange. Thus, protectionism in high tariffs and import quotas stifled the growth and expansion of global trade[265]. Twenty-three states met to negotiate tariff reduction; Bown and Irwin estimate the average tariff in 1947 to be around 40% with GATT reducing tariff to an average of 22% for industrialized states over the years, which had a minimal impact on trade, especially for non-GATT members. It is

[264]Source - The GATT years: from Havana to Marrakesh https://www.wto.org/english/thewto_e/whatis_e/tif_e/fact4_e.htm?sid=qSjyTN

[265] The GATT years: from Havana to Marrakesh, Available https://www.wto.org/english/thewto_e/whatis_e/tif_e/fact4_e.htm#rounds Accessed (November 01, 2018)

important to note that figure might not be accurate owing to the lack of credible official data on the average tariff quotas of states[266]. To further reduce trade tariffs, from 1949-1964, four trade rounds, namely Annecy, Torquay, Geneva, and Geneva Dillon Rounds, were concluded by state members in GATT.

The general justification for the progressive revision of GATT rules has always been to avoid making them obsolete. Thus, the members have consistently identified key areas that needed to be strengthened to prepare GATT for new ventures or circumstances. Such recent events include the involvement of developing and L.D.C. in rules-making and I.P. The dramatic expansion of GATT began with the Tokyo round of trade talks. Whether this round was successful or not is subject to debate, it demonstrated GATT's ability to go beyond traditional measures in a bid to protect trade.

The GATT needed to expand its scope and deepen its rules with the expansion of developing country membership and the increasing power of the European Union (now bargaining as a single entity). Therefore, the Tokyo round of 1973-1979 is needed. This round lasted for five years, with very tough issues put forward for dialogue such as international trade rules on dumping, and the anti-dumping codes of governments, eliminating the delay of import licenses, government procurement, restructuring the current trading system to facilitate granting trade preferences to developing countries, rules on resolving disputes, etc.[267] The Tokyo round created a framework for

[266] Chad P Bown and Douglas A. Irwin, 'The GATTs Starting Point, Tariff Levels' Circa 1947, World Bank Development and Research Group and International Integration Team April 2016, policy research working Papers 7649

[267] GATT Doc. MTN/26fRev 2 (April 11, 1979) reported that delegations representing twenty-two nations had drawn up "comprehensive records" of their reciprocal tariff commitments and that these delegations had undertaken to conclude their tariff negotiations by June 30. These twenty-two countries were Australia, Austria, Bulgaria, Canada, Czechoslovakia, the E.E.C. Nine, Finland, Hungary, Japan, New Zealand, Norway, Sweden, Switzerland, and the United States

improving international trade, with particular importance to differential, special, and favourable treatment to developing countries in feasible aspects of a universally accepted trade mechanism[268]. It revised the anti-dumping rules to include the length of the investigation, set price for export/import, the imposition of anti-dumping duties, and the type of injury. It also introduced six codes of non-tariff measure binding on ratifying members. Despite this round's significant success, it was not detailed enough to accommodate new market opportunities based on the liberalization of trade in service, trade-in I.P., etc. The apparent failure of intellectual property, the early initiatives, did suggest the possibility of a trade institution expanding its reach to encompass issues tangentially related to trade in goods. Thus, the Tokyo round laid the groundwork for the GATT as a body to regulate counterfeiting.

The world trade is altered by the Uruguay Round when the international economy struggled due to recession and uncertainty. It led to the creation of the W.T.O., an organization with a distinctive trade structure not found in other agreements such as the dispute settlement system for the resolution of trade disputes amongst member states[269]. Secondly, the agreement made provision for the development of new trade areas, thereby expanding the GATT agreement's scope to include trade-in service and intellectual property. Thirdly, the number of participating members of the developing and L.D.C. continued to increase, giving these members an increasingly influential voice in decision making. By this means, it restored confidence in the multilateral trading system of the GATT agreement.

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[268] Thomas R Graham, "Reforming the international trading system: the Tokyo Round trade negotiations in the final stage" (1979) Vol 12 Issue 1 Cornell International Law Journal, pp.1-42.

[269] Winham R Gibert (ed), *An Interpretative History of the Uruguay Negotiations, in The World Trade Organisation: Legal, Economic and Political Analysis* (Patrick F.J Macrory, Arthur E. Appleton, Michael G. Plummer ed, Springer: New York, 2005)

3.1.2 Trade Forum

Trade is the act of buying and selling goods and services, whereas a forum is the exchange of ideas or views on trade. Therefore, the WTO is a trade forum based on the following reasons. The WTO is a multilateral agreement that provides a framework for trade in goods and services and intellectual property. It is a comprehensive legal text covering agriculture, telecommunication, textile, clothing, banking, food regulation, pharmaceuticals, industrial standards, and intellectual property for its member country[270]. The WTO covers most aspects of trade with the sole purpose of ensuring a free, fair, and foreseeable trade environment for the benefit of all members[271].

The current Director-General of the WTO, Roberto Azevêdo, has painted a picture that affirms the WTO's impact as a trade creating and trade facilitating international organization. In the World trade statistical review, he notes that the WTO maintains and enhances economic development and the reduction of poverty. The estimates currently available are on the back of the WTO World merchandise export have increased by 32% since 2006 to 64%, reaching $16 trillion in 2016. The bulk of this growth has been in the manufacturing and agricultural sectors of the World Economic, which increased from 37% to 67%[272].

The WTO also adopted the Trade Facilitation Agreement (TFA) to boost trade by restructuring export and import, custom measures and speeding up the flow of goods and services across member state borders. It is anticipated that the TFA could

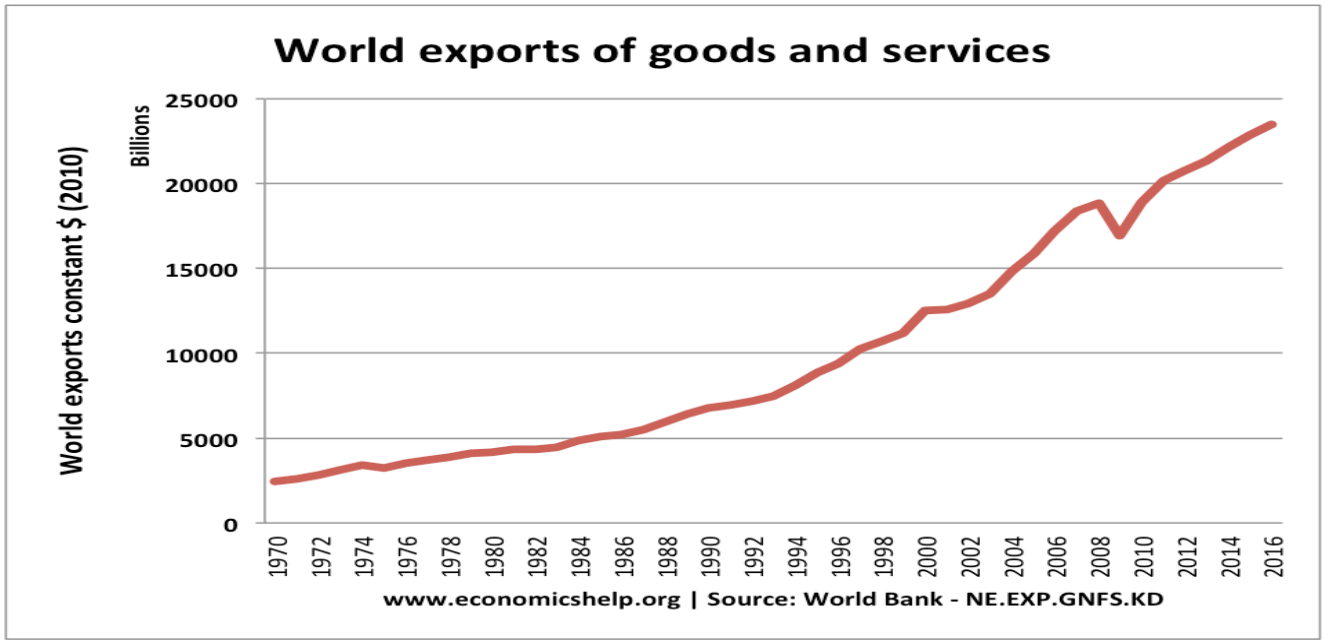
[270] WTO- Principles of a trading system
Available,https://www.wto.org/english/thewto_e/whatis_e/tif_e/fact2_e.htm Accessed (24 October 2018)
[271] Rose, Andrew K. 'Do we really know that the WTO increases trade' (200) *Review* 94.1 4): *American Economic* 98-114.
[272] World Trade Statistical Review 2017,
Available https://www.wto.org/english/res_e/statis_e/wts2017_e/wts2017_e.pdf Accessed (29 October 2018)

increase overall trade by 2.7% while at the same time reducing the financial cost associated with trade by 14.3%, thus boosting business by $1 trillion a year. This agreement ensures special and differential treatment for developing and Least Developing Countries (LDC). Such treatment includes early warning mechanisms, expert groups, shifts between categories, and grace periods to improve the global flow of goods. For example, in Nigeria, the TFA helped the Nigerian customs service modernize its information system to a single platform to lodge standardized documents at a single entry point for all exports and imports in the country[273].

The GATT/WTO also acts as a trade catalyst for productivity and growth by granting member states some economic benefits. For example, the WTO imposes less stringent conditions on trade by promoting free trade, unlike what is obtained when protectionism, non-tariff barriers, industrial policies, and subsidies designed to encourage industrial development lead to economic stagnation. Advocates for free trade argue that eliminating trade barriers will increase economic growth, decrease preferential policies, abolish tariffs, and reduce government interference in trade. However, it is worth mentioning that it did, to a certain extent, looking at the growth of export and import rate from 1970 to 2016.

Table 2. World export of goods and services

[273] It allows the Nigerian custom to operate in a line of international best practices, with a short waiting period to clear goods using a single system, and it maximizes revenue through a speedy clearance process



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This data put together by the World Bank indicates a steady growth of world export, mostly because of free trading rules proffered by the WTO directed at the rapid industrialization of member states, particularly the developing and least developed countries. Although this data shows growth, one would wonder at what expense this growth is achieved. Economic scholars like Chang speculate that free trade generates a perverse outcome that induces the demand for dependency, such as the evolution of poor working conditions, slavery, outsourcing of jobs, working below the minimum wage, and economic and environmental[275] damage. In his view," *free trade hurts the developing countries, as it imposes on them neo-liberal macroeconomic policies that hamper their ability to invest in its economies and create jobs"* [276]. Therefore, the drive

[274]World Bank national accounts data, and OECD National Accounts data files Available https://data.worldbank.org/indicator/NE.TRD.GNFS.ZS Accessed (26 October 2018)

[275] Werner, Antweiler, Brian R. Copeland, and M. Scott Taylor "Is Free Trade Good for the Environment? (2001) Vol 91, issue 4, American Economic Review 877. This paper analyses the effect of openness of the market to the increase of pollution in the Environment using a theoretical model on the impact on pollution by grouping it into scale, composition and then examine this theory using data on sulphur dioxide concentrations from the Global Environment Monitoring Project.

[276] Ha-Joon Chang, *Bad Samaritans: The Myth of Free Trade and the Secret History of Capitalism*. (Bloomsbury Publishing USA, 2010)

towards free trade as spearheaded by the WTO has its advantages, but a more critical standpoint exposes its flaws: the developing countries have not developed. Instead, they are duty-bound by WTO trade policies, rules, and regulations. Developing countries are compelled to encounter developed countries in an arena that does not accommodate their interests and aspirations.[277]

Another benefit of the WTO is that it operates a transparent trade policy for member states government using notifications to inform other member states and the WTO of new systems, laws, and measures[278]. This policy's primary rationale is to regularly monitor trade practices to increase transparency and understanding between states. It will also periodically assess the effect of multilateral trade policies on the world trading system, and as a result, improve the quality of intergovernmental debate. This practice steers the unification of trade policies and considers the economic and developmental policies of states (Developing/LDC), but this notification is not without scrutiny in terms of the amount of time it takes to review state policies.

3.1.3 Forum of International Rules

Pacta sunt servanda is a fundamental principle of international law that stresses that states comply with international obligations, and this tenet applies to WTO law. It is an

[277] Frank Garcia, (2007) "Is Free Trade "Free"? Is It Even "Trade"? Oppression and Consent in Hemispheric Trade Agreements," Seattle Journal for Social Justice: Vol. 5: Issue. 2, pp.505-532.
[278] Understanding of the WTO: The Agreement, trade policy Reviews: Ensuring Transparency Available http://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm11_e.htm Accessed (25 October 2018)

essential legal principle that states are bound to comply with treaty obligations for ratifying to it[279]; Breach of a state's international obligation opens it up to sanctions permitted by law. More precisely, this rule has its foundation from the *rule of law* propounded by *Grotius* in his words, "*rules transcend national borders, and they are significant to international law*." Law will only be obeyed if it is certain that the world will be chaotic without laws. On this note, the WTO is formed as a legal entity made up of rules, rights can sue, be sued, and obligations, which is binding on member states for the regulation of international trade. To determine the status of the WTO, Article VIII provides that as follows:

1. The WTO shall have a legal personality and shall be accorded by each of its Members such legal capacity as necessary for the exercise of its functions.

2. The WTO shall be accorded by each of its Members such privileges and immunities as are essential for the exercise of its functions.

3. The officials of the WTO and the representatives of the Members shall similarly be accorded by each of its Members such privileges and immunities as are necessary for the independent exercise of their functions in connection with the WTO.

4. The privileges and immunities to be accorded by a Member to the WTO, its officials, and the representatives of its Members shall be similar to the rights and immunities stipulated in the Convention on the Privileges and Immunities of the Specialized Agencies, approved by the General Assembly of the United Nations on 21 November 1947[280]*.*

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[279] Tarcisio Gazzini, 'The Legal Nature of WTO Obligations and the Consequences of their Violation, European 2006 Volume 17, Issue 4, Journal of International Law, Pages 723, https://doi.org/10.1093/ejil/chl024

[280] WTO Analytical Index WTO Agreement – Article VIII (Practice) Available https://www.wto.org/english/res_e/publications_e/ai17_e/wto_agree_art8_oth.pdfAccessed (21 October 2018) see alsohttps://treaties.un.org/pages/viewdetails.aspx?src=ind&mtdsg_no=iii-2&chapter=3&lang=en

This means WTO has its own legal identity in international trade, for it is the first agreement with a viable framework on trade. The WTO differs from its predecessor, the GATT, for it recognized and gave legal status to states by regarding them as *member states* instead of *contracting parties*. It provided member states protection against unfair trade practices and the ability to carry out trade without interference. To solidify its status as a truly international organization, the WTO member, therefore, constitutes it as a body of legal order to govern its member states' activities. The WTO is an integrated and distinctive legal order that governs the actions of member states.

Forum for the Settlement of dispute

The WTO has a significant organ for resolving trade disputes and maintains the 'rule of law' amongst state members to the WTO. This vital forum is what distinguishes the WTO from its predecessor, the GATT agreement. Although the GATT agreement had a provision for Dispute Settlement Understanding (DSU), whose rules provided for consultation instead of adjudication, and this provision is found in Article XXII and XXIII of GATT 1947, which states inter alia

''Each contracting party shall accord sympathetic consideration to, and shall afford adequate opportunity for consultation regarding, such representations as may be made by another contracting party concerning any matter affecting the operation of this Agreement and reach a satisfactory solution''[281].

This provision mandated member states to make the consultation a means of resolving disputes, and Article XXIII on *nullification and impairment* required contracting parties to investigate and make an appropriate ruling if there is no agreeable adjustment.

[281] *Article XXII Consultation, Available https://www.wto.org/english/res_e/publications_e/ai17_e/gatt1994_art23_gatt47.pdf Accessed (16 October 2018)*

Alternatively, in severe circumstances, parties can act, retaliate or suspend the application, make concessions if applicable, and parties have the right to withdraw from agreements pending due notice. This provision underlined some institutional shortcomings of the GATT agreement. For instance, Amin emphasizes that the GATT DSU is generally weak as it had no deadlines for the institution of claims, nor does it have a viable process to institute claims[282], and the most worrisome is the lack of a binding legal ruling, interpretative issues, and ambiguity [283]making way for a more legal and proficient DSU within the WTO.

The newly reformed DSU under the WTO is unique, for it is an embodiment of binding rules and regulations for the settlement of a dispute. It is structured in an orderly manner to reduce trade conflict amongst member states. Additionally, the DSU under the WTO handles difficult and more technical issues. Moreover, the structural defects such as delays and the right to block the adoption of panel reports have firmed up the WTO DSU in comparison to its GATT predecessor[284]. Under the WTO, the adjudication system is thought to be the most useful [285]for it *preserves right over might*.[286] Statically, the prominence of the DSU is remarkable, for it is used frequently by a member state for the settlement of a dispute. For instance, the number of consultation requests by member states increased from 1995 to 2016, with over 350

[282] Amir Alavi, 'African Countries and the WTO Dispute Settlement Mechanism' 2007 Vol 25(1) Development Policy Review, PP 25-42
[283] John H. Jackson, 'The World Trading System,' (1990) Volume 14, Issue 1 Fordham International Law Journal
[284] Evaluation of the WTO Dispute Settlement System: Result to date available https://www.wto.org/english/tratop_e/dispu_e/disp_settlement_cbt_e/c12s2p1_e.htm Acces sed (18 October 2018).
[285] R E Hudec, *The Adequacy of WTO Dispute Settlement Remedies: A Developing Country Perspective" in Development, Trade, and the WTO: (*Hoekman, B., Mattoo, A., English, Ped (2002).
[286] Julio Lacarte-Muró and Petina Gappah, 'Developing Countries and the WTO Legal and Dispute Settlement System: A View from the Bench.' (2000) Vol 3 issue 3 Journal of International Economic Law, pp.395-401.

dispute settlement decisions and over 573 [287]consultation requests[288]. This trend has continued upwards and is thus a big leap from what is previously obtained in the GATT Agreement.

The newly restructured DSU is recognised; it is deemed to be less political and more legally oriented. Developing countries quickly utilized it by initiating more disputes to protect their market rights. However, observers of the WTO have pointed out various shortcomings of the DSU to include the fact that it is technical and complex for developing countries' development. Busch and Reinhardt approached this issue by suggesting that the number of concessions developing countries retain within the WTO could affect getting a favourable trade policy[289] without fear of trade retaliation. The DSU is problematic in developing countries lacking the appropriate legal capacity during proceedings, unlike their developed counterparts. This gap remains unresolved, given the vast inequality existing between the former and the latter.

Busch and Reinhardt also posit that the gap between developing and developing countries created a breach in the legal capability to bring an action before the Dispute Settlement system[290], for example, the cost factor. To prepare, file proceedings, an experienced workforce such as staff, diplomats, economic experts, and an outstanding legal team needs to be assembled to have a viable case, but it is an unlikely situation for Developing and LDC who lack this resource. These problems subsist until now,

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[287] Arie Reich, The effectiveness of the WTO dispute settlement system:A statistical analysis. Transnational Commercial and consumer Law, (Springer:Singapore, 2018)

[288] Evaluation of the WTO Dispute Settlement System: Result to date available Statistics: the first eight years of experience, https://www.wto.org/english/tratop_e/dispu_e/disp_settlement_cbt_e/c12s2p1_e.htmAccessed (18 October 2018).

[289] Marc L. Busch & Eric Reinhardt 'Developing Countries and General Agreement on Tariffs and trade/world Trade Organization Dispute Settlement.' (2003) Vol 37 issue (4): Journal of World Trade PP 719

[290] March L Busch and Eric Reinhardt, 'Developing Countries and GATT/WTO Dispute Settlement '(2003a) Vol 37 issue (4) Journal of World Trade PP 719

even after various calls for a systematic re-evaluation [291]of member states' legal capacity. This is because proceedings are lengthy and complicated, comprising new and old legal obligations uprooted from the GATT, trade rounds, and previous decisions that are binding on all members as a single integrated undertaking.

In conclusion, the shift from being an international trade entity under GATT to a renowned legal regime, backed by a viable dispute settlement mechanism, not only increased participation but made trade easier for fear of prosecution. Its legality is unique, but where do developing countries with limited legal resources fit into this system.

3.1.4 Innovation and TRIPs Agreement

This section discusses the reasons for protecting intellectual property and why a specialized agreement WTO /TRIPS is created within the WTO to deal with issues relating to IPR. The factors that influence the creation of IPR, such as product, competition, market availability, research, and development, are examined. The role of IPR within different industries, particularly the pharmaceutical industry, and the legal characteristics for the protection of IPR, will be analysed to determine if IP ensures legitimate protection for creativity or just a mere economic tool proliferated by multinational corporations. The previous chapter discussed the historical development of IPR, but this section will start by describing the meaning of innovation and creativity that apportion strict ownership to a potential invention.

[291] Marc L. Busch, Eric Reinhardt, and Gregory Shaffer, 'Does Legal Capacity Matter? Explaining Patterns of Protectionism in the Shadow of WTO Litigation' (2008)
Available https://pdfs.semanticscholar.org/318b/da42b9b060372795c8b9428511296bda704c.pdf
Accessed (23 October 2018)

All innovation starts from a concept, enabling new ideas such as improvement of quality or quantity. It can also be a technological or scientific process to such an extent that a right accrues from it. IP preserves the proprietor's right of inventors by turning it into income, and it gives complete control to sales, marketing, and packaging. IP confers dignity and authority to an inventive step. However, Merge is sceptical about this all-encompassing right, as it may restrict free and open access to viable knowledge. Therefore, he advocates establishing boundaries or legal constraints to manage IP within a specific perimeter[292].

IP confers a right on creators, thus making it a right to IP. Such right comprises patents, copyright, trademark, trade secret, and industrial design. This protection's moral justification encourages innovation and prevents third parties from exploiting the benefit accrued from it[293]. This right is not automatic: WIPO states that an invention must meet several criteria for it to be eligible for protection. For example, patent, which is a core IP issue, requires that for a subject matter to be patentable, it must be new or novel, must be industrially applicable, must show sufficient inventive step towards its creation, and must meet the required standards laid down by statute[294].

Fundamentally, novelty can be determined by examination, and it must be undisputed. Also, the requirement for an inventive step refers to the question *as to whether the invention "would have been obvious to a person having ordinary skill in the art*" [295]. It

[292] Robert Merges, *Justifying Intellectual Property*, (Harvard University Press: London,2011) This author discusses the issues relating to IP by emphasizing the importance of IP to producers, but is a skeptic on the freedom of access to knowledge but argues that IP should be based on some ethical foundation, firstly he traced the IP through the philosophy of Kant, Hegel, Locke, and issues of distributive justice and concluded that IP rights are indispensable right of a functioning society.

[293] European Patent Office, About Patent, Available www.epo.org/patent/grant-procedure/about-patent.html Accessed (09 November 2018)

[294] World Intellectual Property Organisation (WIPO), WIPO Intellectual Property Handbook: 'Policy, Law and Use' Available www.wipo.int/export/sites/www/about-ip/en/iprm/pdf/ch2.pdf Accessed (09 November 2018)

[295] IBID WIPO

is a difficult test to prove, but it can be determined by a thorough examination to warrant protection. However, certain subject matters are excluded from being patentable to preserve morality, or it is deemed unsuitable for the protection of public health, animal or plant life, the environment, and micro-organism. The next unpatentable subject matter includes diagnostic, therapeutic, and surgical treatment of humans and animals. The production of plants and animals using non-biological and microbiological processes[296] .

Undoubtedly, IP plays a vital role in the growth of the world economy, as knowledge obtained from technology increases revenue for firms and government; it allows competition between industries based on superior quality and price[297], which is different from what is previously obtained, before the advent of technology. Competition yields more innovative products and drives prices, both of which benefit the consumer as hitherto expensive goods are now within reach. Also, goods can perform the task more efficiently. In the words of Cottier, "*the absence of sufficient protection for IP creates an unfair competitive trade environment, especially for industries operating in a foreign environment"* [298]. IPR is a powerful tool for growth in invention, investment, innovation, and employment and needs to be protected. This is essential because it creates jobs, enables competition as well as protects consumers and investors. IP is relevant in all sectors of the economy, such as agriculture, education, medicine, entertainment, pharmaceutical, and culture. The list is endless.

[296] Article 27 (2) WTO-TRIPS agreement, an example of a biological process not patentable, is conventional animal breeding, such as tissue culture, gene creation from plants, and unethical scientific processes.

[297] Bart Verspagen,' Intellectual Property Right in World Economy,' Paper for the WIPO Arab Regional Symposium on the Economic Importance of Intellectual Property Rights, Muscat, Sultanate of Oman, February 22-24, 1999 Available http://meritbbs.unimaas.nl/verspagen.html Accessed (09 November 2018)

[298] Thomas Cottier, 'The Prospects for Intellectual Property in GATT,' (1991) Vol 28 Common Market Law Review, pp385

Critics of IP oppose this submission, bearing on the fact that the impact of IP depends on states' developmental advantage. The higher the level of development, the more robust IP would be to its growth. For example, developed countries recorded an increase in growth via IP protection, unlike their developing and LDC counterparts, where providing more robust IP protection would cripple its local industries[299] and " *may cause wasteful duplication of investment in R&D"* [300]. Also, in support of this point, stricter IP will give a sole monopoly to Multinational industries with the right technological capacities to the detriment of developing countries and LDCs. It is one of the arguments upheld by countries like India, South Africa, Brazil.

To Keith Makus, IP is a vital asset with economic value and recognized ownership right backed by law to control the idea[301] solely. Some known benefits to the IP creator include access to novel markets, income generation[302], and dynamic competition. Besides, it leads to the advancement of technological knowledge and permissible right of distribution and protection. As noted, the need to have more excellent protection of IP became necessary since it enhances innovation. After examining 100 firms in the USA, scholars like Mansfield suggest that if not for IP protection, inventions would not be achieved because imitation is common practice, particularly in the pharmaceutical industry[303].

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[299] Elhanan Helpman, 'Innovation, Imitation, and Intellectual Property Rights' (1993) Vol.61 No 6, Econometrica, pp. 1247 Argues that the North invents new technology and the South imitates them. Stating that the protection of IPR hurts developing/LDC resulting in imitation in order to meet up with the status of goods even if such imitation might be unbeneficial to its economy

[300] Maskus, Keith Eugene, *Intellectual Property Rights in the Global Economy* (Peterson Institute, 2000)

[301] IBID

[302] Saha, Chandra Nath & Sanjib Bhattacharya' Intellectual property rights: An overview and implications in the pharmaceutical industry' (2011) Vol. 2 issues, 2): Journal of Advanced Pharmaceutical Technology & Research 88

[303] Edwin Mansfield, 'Patent and Innovation: An Empirical Study' (1986) Vol 32 issue 2 Management Science PP 173

IPR can be credited for the surge in the global pharmaceutical industry, predominantly in the area of medical research. It costs around $750 million and between 12-15years of clinical trials to develop, market, and sell a single drug. Strong protection will enable firms to recoup research and development costs and make good returns on investment. Thus, obtaining a legal document to protect the general public's invention is wise, with a minimum term of 20 years from the date of application. This requirement applies in both Developing and LDCs for product and process. Although, before the advent of the WTO-TRIPS Agreement, states only provided patent protection for a process (method, technology, or chemical composition or steps), not the product (the finished drug) for fear of imitation through the process of reverse engineering. The protection of the process enabled manufacturers to produce a generic version of the original, giving the transitional period provided by the WTO-TRIPS[304]. However, once the patent right expires, companies are free to create generic versions of the actual product without investing in R&D; this medium increased the manufacturing of generic drugs globally, accounting for over $5billion in drug sales annually[305].

The need to safeguard valuable economic growth necessitated policymakers to negotiate and institutionalize laws and policies to regulate changing circumstances of trade to conform to modern realities and harmonize the rules of IP. The establishment of a rule-based system in the WTO-TRIPS Agreement sets a minimum standard for the regulation of IPR, and it gives IP legal status. TRIPS standard defined the subject matter; it protected and allowed permissible exceptions. It set a minimum duration for protection for member states of the TRIPS agreement by the substantive obligation

[304] WTO -Essential medicine and Health Product, Available http://www.who.int/medicines/areas/policy/wto_trips/en/ Accessed (13 November 2019)
[305]Lara J. Glasgow, 'Stretching the Limits of Intellectual Property Rights: Has the Pharmaceutical Industry Gone too far?' (2001) Vol 41 Number 2 The Journal of Law and Technology, PP 227

provided in the Paris Convention, for the protection of industrial property (Paris convention), the Berne Convention for the protection of literary and artistic work(Berne Convention)[306], the World Intellectual Property Organisation (WIPO)[307].

In order words, the TRIPs agreement is known as the Berne and Paris-plus agreement[308]. Amongst these stated agreements, TRIPs is considered the most successful for it combined provisions from Berne, WIPO, and Paris Agreement and added a new mechanism for the regulation of IP, such as the dispute settlement mechanism, parallel imports, national treatment, Doha declaration, and other necessary TRIP flexibilities. With this new mandate, the WTO/TRIPS agreement enjoyed widespread acceptance and domestic compliance from states. Therefore, to fully understand the purpose of the TRIPs agreement, it is pertinent to examine the objective of creating the TRIPs Agreement that allowed TRIPs to enjoy widespread ratification and domestic compliance by member states.

3.1.5 Post TRIPs Era

Negotiation on Trade-related aspects of intellectual property was initiated in the Punta Del Este Declaration of 1986, which resulted in the legal framework of a multilateral agreement within the WTO known as the TRIPs agreement. The name *Trade-related aspect* of IPR suggests to policymakers and negotiators that a link truly exists between

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[306]Berne Convention for the Protection of Literary and Artistic Works, Availablehttp://www.wipo.int/treaties/en/ip/berne/ Access (15 November 2018) ,The Berne Convention, adopted in 1886, ensures the protection of the right and work of authors such as poets, painters, musicians, and authors etc. By providing minimum protection to regulate, control, who use of the creation

[307] Convention Establishing the World Intellectual Property Organisation (WIPO) Available http://www.wipo.int/treaties/en/convention/ Accessed (15 November 2018)

[308] The provision relating to the Paris Convention and to the Berne Convention is found in Articles 2.1 and 9.1 of the TRIPS Agreement, the Agreement adds additional obligations on pre-existing issues previous conventions were inefficient or silent on.

Trade and IP. Practically, global industries recognized that intellectual property protection stems from innovation, creation, and invention and guarantees continual competitiveness in world trade. However, before the implementation of the TRIPs agreement, various arguments, both positive and negative, arose amongst negotiating member states, such as GATT's vague IP provision, the political ideology of states members, the involvement of non-state actors, the original mandate of the negotiations, trade-off and linkage with other essential areas of negotiations, needs of developing state members and finally the legal status of previous IP organization (WIPO).

I. *Vague IP provision in GATT agreement:* The GATT agreement provided a multilateral framework for trade in goods. It is regarded as all-encompassing and unique, for it allowed several modifications to its framework to fit new trade regimes for 47 years. The GATT agreement modified several critical aspects in its provisions, such as providing trade and development, national treatment, most favourable nation's policy. However, the provision on IP the GATT was deemed vague and needed amendment in the Uruguay round of negotiations. The discrepancy stemmed from earlier international agreements before GATT. For example, the patent provision in the Paris Convention granted a short length of time for patent protection, although it ought to be longer to ensure that right holders benefit from creation. Most of these conventions failed to provide minimum protection for IPR; neither did they stop counterfeit or piracy. However, the GATT agreement recognized the critical link between trade and IP by incorporating some IP provisions. For example, Article III.4 of GATT provides that:

''IV. The products of the territory of any member state imported into the territory of any other contracting party shall be accorded treatment which is not less favourable than that accorded to like products of national origin in respect of all laws, regulations and requirements affecting their internal sale, offering for sale, purchase, transportation, distribution or use.''[309]

Also, in Article *XX: (d): GATT General Exceptions to secure compliance with laws or regulations which are not inconsistent with the provisions of this Agreement, relating to patent protection, trademarks, copyright and the prevention of deceptive practices[310].*

GATT 1947 provided the basic rules of the trading system, but it lacked standards[311]. What is the point of having an IP rule that undermines what it aims to protect? Besides, the IP rule did not enforce the obligation on members for breach of its rules. In the GATT agreement, the enforcement mechanism allows parties to seek remedies in domestic courts, unlike what is obtained in the TRIPS Agreement[312]. The inadequacy of a viable enforcement and dispute settlement mechanism within GATT made GATT an inadequate IP forum

II. *On the issues of non-state actors*, the private sector consisting of industries, firms, and banks[313] canvassed for IP protection on the negotiating agenda given the potential value of IP.In the operation of global trade, especially the

[309] THE GENERAL AGREEMENT ON TARIFFS AND TRADE ("GATT 1947") Available http://www.worldtradelaw.net/uragreements/gatt.pdf.download Accessed (22 November 2018)
[310] Ibid
[311] Huala Adolf, 'Trade-Related Aspect of Intellectual Property Rights and Developing Countries, The developing (2001) Vol 39 Economies pp49
[312] Emery Simon, 'GATT and NAFTA Provisions on Intellectual Property,' (1993) Vol 4 Number 1 Fordham Intellectual Property Media and Entertainment Journal
[313] Companies like Mayer, Pfizer, Brown & Platt, IBM, Washington, General Electric, DuPont, FMC Corporation, Hewlett-Packard, Johnson & Johnson, Merck, Monsanto, Rockwell International, and Warner Communications.

United States private sector, which campaigned for a more robust IP regime different from what is obtained in the GATT agreement, in a bid to get maximum profit from IP related goods. The Uruguay round created an avenue for greater protection by increasing negotiation. It develops a comprehensive agreement to address inadequate IP regime that upholds the growth of imitation, counterfeit, and piracy, constituting severe loss to domestic and local IP based industries. Given the resources used for research and the development of new ideas, getting a financial reward for R&D will stimulate the expansion and growth of new technologies. As counterfeit increases, it becomes more problematic to regain economic returns on innovative products, which will deter innovation. However, a contrary view of the innovation theories is, that IP rights may be used for profit to control the entire market rather than the protection of innovation.

III. During the negotiation in the Uruguay round, developing / LDC opposed having a more robust IP regime. It would deter the growth of local industries, and it would merge corporate ownership of ideas, increasing the technological gap between the north and south[314]. A more robust IP will discourage the prospect of future development on these stated grounds developing, and LDCs refused to negotiate. Nevertheless, the proposed agreement did not permit member states to choose; it is one complete agreement. Developed /LDC realized it would be impossible to negotiate the draft agreement without losing out on the TRIPS agreement's potential benefit. Such benefit includes increased access to the agricultural and textile market, having a reputable dispute settlement

[314] Carolyn Deere, *The Implementation Game, The TRIPS Agreement and the Global Politics of Intellectual Property Reform in Developing Countries* (Oxford University Press, England,2009)

mechanism. At the time of negotiation, developing countries exported mostly textiles and agricultural products; it is unlikely that IP would benefit their economy. Nevertheless, IP advocates, particularly the developed states, argue that adequate protection will stimulate local and international industries[315]. The developed countries demand excess protection far beyond what TRIPs initially offered, which ignores the unique economic, medical, and developmental needs of Developing/LDC. This made developing states vulnerable to the new IP standards and had to amend, update, interpret existing rules, guidelines, and laws on IP. The administration and enforcement mechanism needed re-organization to reflect the TRIP's standard despite the social and financial challenges in these countries.

3.1.6 The Basic Principles of TRIPS Agreement

The GATT and GATS agreements introduced the principles conveyed into the TRIPS agreement; this basic principle is found in article 1 of the GATT agreement provides for trading principles states ought to adhere to, such as the most favoured nation treatment, reciprocity, transparency, tariff binding and reduction[316]. Aiming to promote growth, facilitate trade, employment, and development amongst state members to the agreement. Each principle will be examined briefly, starting from the **National Treatment** policy found in *Article 3(1) (2)* of the Preamble of the WTO-TRIPs

[315] Carol J. Bilzi, Towards an Intellectual Property Agreement In the GATT: View from the Private Sector, GA., (1989) Vol 19, Issue 2 Journal of International & Comparative Law pp 343
[316] WTO- Part 1 General Provision and Basic Provisions
Available https://www.wto.org/english/docs_e/legal_e/27-trips_03_e.htm Accessed (28 November 2018)
WTO- Part 1 General Provision and Basic Provisions
Available https://www.wto.org/english/docs_e/legal_e/27-trips_03_e.htm Accessed (28 November 2018)

agreement. It provides *inter alia* that Member *shall* accord to the nationals of other Member states, treatment no less favourable than what it accords its nation on the subject of IP, by the provisions and exception found in the Paris Convention, Berne Convention, and the Rome Convention or the Treaty on Intellectual Property in Respect of Integrated Circuits.

Members *may* benefit from the stated exceptions allowed within the judicial and administrative procedures, including the description of a place of service within the jurisdiction of a member state to ensure compliance to the provision of the agreement in order not to constitute a restriction to trade[317]. The language of this provision is straight forward although the use of the words '*shall'* connote a future intention or action. In contrast, the word '*may'* connote the existence of an obligation on member states to adhere to this provision. Still, the strength of this obligation cannot be determined if the provision made use of *'must'* it would suggest absolute commitment for member states and would have reduced the power in the exceptions to this rule.

The next provision is the **most favoured nation treatment** found in Article 4, which sums up as any privilege, favour, immunity on IP granted to members of a nation must be accorded immediately without conditions or prejudice to nationals of other Member's states. By the international agreement for the protection of IP in existence before the establishment of TRIPs, neither should it constitute arbitrary or unjustifiable discrimination against nationals of other states Member of TRIPs. One reason for inserting this provision in the TRIPs Agreement is to prevent discriminatory trade practices such as offering a better IP deal to nationals of one state and not according to similar reciprocal treatment to other state members, thereby undermining the

[317]J.H Reichmann, 'Universal Minimum Standards of Intellectual Property Protection Under the TRIPs Component of the WTO Agreement' (1995) Vol.29 No 2 International Lawyer pp 345

international IP system. But this provision is limited in scope for it only regulates some form of IP, for example, patent, copyright, trademark, industrial design, geographical indication, Trade secret, and integrated circuit design whilst omitting other key neighbouring rights protected by the Rome Convention and the international convention for the protection of performance[318].

The basic principle of the TRIPs agreement is not all-encompassing, theoretically strict adherence to this principle is narrow, for practical usage is not guaranteed amongst member states in securing a predictable trading environment. Equally, the framework of the WTO –TRIPS allow for basic exceptions and restrictions, which connotes different interpretations to fit a circumstance, for example, developing countries applied quantitative restrictions on imports in the agricultural and industrial sector, which is allowed as part of exception of the agreement. Part of the exceptions and restriction is the Most Favourable Nation (MFN) found in article XXIV, based on Regional Agreement, tariffs and trade barriers can be reduced, as such Regional Preferential arrangement is deemed an exception to the MFN rule. For example, in Africa, there are other regional agreements such as the Economic Community of West African States (ECOWAS), the South African Development Community (SADC)[319], All of which pose a threat to the enactment of the MFN policy by member states to the WTO-TRIPS. The African RECS perceived that the MFN policy will restrict Foreign

[318] J.H Reichmann, 'Universal Minimum Standards of Intellectual Property Protection Under the TRIPs Component of the WTO Agreement' (1995) Vol.29 No 2 International Lawyer pp 345

[319] WTO- Regional trade agreements and preferential trade arrangement, Availablehttps://www.wto.org/english/tratop_e/region_e/rta_pta_e.htm Accessed (28 November 2018) A Regional trade agreement is defined as reciprocal trade agreements between two or more partners. It includes free trade agreements and customs unions. In contrast, the Preferential trade arrangements (PTAs) in the WTO are unilateral trade preferences. It includes the Generalized System of Preferences schemes under which developed countries grant preferential tariffs to imports from developing countries, as well as other non-reciprocal preferential schemes granted a waiver by the General Council.

Trade especially limiting the bargaining power of developing countries and would prefer preferential tariff treatment (duty-free entry) which can increase production and economic well-being of the continent. The TRIPS Agreement has an additional objective, which is, intellectual property protection should contribute to technical innovation and the transfer of technology. In such a way that both producers and users will benefit from it, at the same time enhance economic and social welfare.

3.2 Core Objective of the TRIPS Agreement

Explicitly, the objective is in the preamble of the TRIPs Agreement, in contrast, the general Principle of the TRIPs agreement is in Articles 7 and 8 of the Agreement. It is a bold declaration of purpose for the protection of IPR. To fully understand the TRIPS agreement, it is important to conceptualize the TRIPs framework to determine what it aims to protect from the beginning to use it to cross-examine the role of TRIPS in the regulation of Counterfeit pharmaceuticals.

The objective of TRIPS in Article 7 includes, among other things;

"*The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations."*

To interpret the text's language, Article 26 of the Vienna Convention on the law of treaties states that *every treaty in force is binding upon the parties to it and must be*

performed by them in good, and in the same faith[320]. This means that the makers of the TRIPS agreement's objective intend for it to be binding unconditionally on member states [to the Agreement] even if this provision is overlooked, it is an integral part of the TRIPs agreement. The statutory interpretation provides that a statute's words should be read in context in a *clear and ordinary form*[321]. In other words, this provision's scope creates rights and obligations on member states for the protection of IP to the benefit of producers and users of creative knowledge.

Article 7 created a unique legal framework for the international IP regulation that promotes economic development for member states to the WTO. It laid IP standards to foster technological innovation, transfer, and dissemination of technology amongst member states to benefit both producers and consumers of technology within the confines of a rule-based IP system. However, suppose the focus of this objective is only on technology. In that case, other non-technological aspects of IP will suffer inadvertently, limiting the focus of article 7 on the technology-specific goal. However, from another perspective, the objectives in Article 7 can provide valuable guidance in implementing the TRIPS Agreement, following the IP obligations canvassed for by developed countries during the negotiation to promote technology transfer, cooperation, and legal assistance in developing and LDC[322]. The justification of IP held by developed states portrayed a monopolistic intent for the benefit of technology producers at the expense of developing user count.

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[320] Vienna convention on the law of treaties
Available http://legal.un.org/ilc/texts/instruments/english/conventions/1_1_1969.pdf Accessed (22 November 2018) treaty" means an international agreement concluded between States in written form and governed by international law, whether embodied in a single instrument or in two or more related instruments and whatever its particular designation

[321] **Lord Reid** said in **Pinner v Everett (1969**), "*In determining the meaning of a word or phrase provided in a statute, the question to ask is what is the natural and ordinary meaning of that word or phrase in its context in the statute."*

[322] Peter K, Yu. 'The Objectives and Principles of the TRIPS Agreement.' (2009) Vol 46 Houston Law Review. PP 979

Article *8 provides for the Principles of TRIPs that,*

1. Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.

2. Appropriate measures, if consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices that unreasonably restrain trade or adversely affect the international transfer of technology.

The TRIPS agreement's minimum standard of protection is regarded as one of the most exceptional protection standards for intellectual property. The IP standard defined the right to be protected, the subject matter of protection, the rights to be conferred and permissible exceptions to those rights, and the minimum protection[323]. To determine the objective of article 8, Correa utilized the *consistency test,* which posits that member states are restricted from upholding their public interest in IPR legislation. However, it must be" *consistent with the provisions of this Agreement.'* Analytically, it gives member states conditions for IPR protection within the Agreement. Any deviation from the stipulated condition would amount to a breach of the WTO law, thus leaving room for alternative IP solutions in states' national laws [324].

[323] Overview the TRIPS Agreement,
Available https://www.wto.org/english/tratop_e/trips_e/intel2_e.htm Accessed (11 October 2017)

[324] Carlos M. Correa, *Intellectual Property Rights, the WTO, and Developing Countries, the TRIPS Agreement and Policy Options* (Zed Books: London,2002)

Section B

3.3. International Cooperation on Pharmaceuticals and Counterfeit

Member states legally endorse the minimum standard specified by the WTO-TRIPS agreement. However, the issue of medicine counterfeit seems to undermine the TRIPS standard's applicability, resulting in member states seeking alternative measures to stop counterfeit medicine's manufacture and distribution. The problem of Counterfeit medicine is multidimensional, from its devastating health repercussion to the challenge of differentiating counterfeit medicine from authentic medicine. Above all, it is a public health risk. Therefore, international cooperation is needed to stop counterfeiters' activities by making them less lucrative, backed by enforceable sanctions.

Trade-in counterfeit medicine is mostly made popular by the massive demand for inexpensive patented medicine, particularly in developing countries and LDCs, price is a driver for the growth of counterfeit drugs. A gap is created when the price of medicine varies in different jurisdictions because of PI. The outcome is the introduction of counterfeit in the supply chain. Equally, the right owner may have lost the IP right to sue for infringement or detect low quality or counterfeit products for PI erodes the legal right to IP. Counterfeiters have taken advantage of the weak enforcement mechanism to infiltrate the drug market in countries. Without proper enforcement, counterfeit pharmaceuticals will continue to grow because of global demand to the detriment of public health. It is vital to rekindle international cooperation, amongst

states to reduce exploitation and monopolization [325], especially given counterfeit drugs' perversity on international trade.

Based on the stated supposition, international cooperation, if harnessed, can effectively foster a means to end counterfeit incidence. If only law enforcement organizations work together, sharing information on anti-counterfeit strategies, uniform accessible data service, staff training, develop policies and implement stringent legal remedies to tackle counterfeit activities. By having a unified organization consisting of pharmaceutical companies, distributors, customs officials, government agencies, government leaders, investigators, traders, and enforcement agencies. With the sole aim of setting up anti-counterfeit measures that include devices, methods, techniques[326], and business practices to protect and distribute pharmaceuticals. International cooperation is essential as a preventive measure against the activities of counterfeiters and to protect IP. It can strengthen IP enforcement and protect the health and safety of consumers. Some notable organizations created from the international cooperative purpose of combating counterfeit will be discussed below to determine if anti-counterfeit strategies can thwart counterfeiters' activities beyond government, regional, and international law.

3.3.1 Anti-Counterfeit Trade Agreement: Innovative policies on counterfeit Pharmaceuticals

[325] Robert W Sussman, Paul A. Garber, and Jim M. Cheverud. "Importance of Cooperation and Affiliation in the Evolution of Primate Sociality." 2005 128.1: 8 American Journal of Physical Anthropology PP 4.

[326] Dipika Bansal and others, 'Anti-counterfeit Technologies: a Pharmaceutical Industry Perspective. (2013) Volume 81 Issue 1 Scientia Pharmaceutical,

This section will examine innovative policies that will combat counterfeit pharmaceuticals. The strengths and weaknesses of this policy will be reviewed to determine its capacity as a viable framework to curtail counterfeit. Anti-Counterfeit Trade Agreement (ACTA) is a plurilateral agreement that consolidates all previous IP protection agreements to form one body of rules to improve IP enforcement. It is a standard-setting agreement negotiated for three years by the United States, Japan, the European Union, Switzerland, and other emerging economies with the sole goal of ensuring international corporation, enforcement practices, and the creation of a viable legal framework for the enforcement of IPR against counterfeit trade activity militating against the development of IP. It covers all the categories of IP subject matter from sections 1-7 of part II of the TRIPs agreement. Fundamentally, this agreement does not create new IP rights but creates an enabling standard against infringement of existing IP rights. The whole process leading to ACTA formation has been contentious as it has neither transparency nor accountability[327]. It is perceived as a threat because it contends with subsisting IP agreements such as WTO-TRIPs, and it restricts access to essential medicine and the overall development of IP.

Counterfeit is the primary reason for IP infringement; it is so big that it is larger than the economies of over 150 nations. The International Chamber of commerce (ICC) postulates that counterfeit and piracy infringe on IP, reaching an estimated value of $917 billion as of 2015, with the cost of piracy to music and the movie industry amounting to $213 billion[328]. The International Chamber of Commerce-Counterfeiting and Piracy (BASCAP) predicts that, in the future. The scale of counterfeit in the

[327] Peter K, Yu. 'Six Secret s (and now open) fears of ACTA' Vol 64 (2011): *SMUL Review* 975. During the negotiation of the ACTA, it was highly secretive with its draft provision rarely published to include comments/observations from IP scholars, the World Intellectual Property Organization (WIPO), and the World Trade Organization (WTO).

[328] International Chamber of Commerce ICC, 5 Ways Counterfeiting Hurts Society, and what can we do about it. published 2017, Available http://iccwbo.org accessed (5 December 2018)

economy will range between $524-959 billion by 2022[329]. The risk posed by counterfeit products cannot be quantified. It goes from mild to life-threatening conditions, and even death from the use of counterfeit products [330]. It undermines creativity and inventive steps, with counterfeiting so prevalent, especially in developing and LDC.

To this end, ACTA is formed as an enforcement mechanism against counterfeit. The first part will briefly discuss the negotiating history of ACTA, giving reasons to undermine the multilateral trading system of existing IP forums. The second part analyses the innovative policies set up for counterfeit regulation and the critical treaty obligation members adhere to sustain the requirement of this agreement. Equally, the implication of ACTA rules on IP Trade-in countries like Nigeria, especially in the pharmaceutical sector, will be examined. Finally, it will conclude by stating the importance of ACTA to IP rights holders and its usefulness as an effective agreement to tackle unconventional IP practices.

The effectiveness of trade to the economy of states cannot be simplified; it is the backbone of any nation, particularly in developed countries like the USA, Japan, and the European Union. The protection of creative knowledge is essential for these countries' economic growth, but this cannot be achieved without IP. IP is utilized in virtually all sectors of the economy from quality products (trademarks- used to distinguish products), technological and pharmaceutical industry (Patent-protects unauthorized usage of an inventive step), and the entertainment industry (copyright protects creative works). To this end, protection is essential in the face of large-scale imitation, piracy, and counterfeit activity that affect the economy, resulting in global

[329] ICC- The economic impact of counterfeiting and piracy – report prepared for BASCAP and INTA Available https://iccwbo.org/publication/economic-impacts-counterfeiting-piracy-report-prepared-bascap-inta/ Accessed (5 December 2018)

[330] OECD named Products counterfeited includes clothing, literary and artistic work. Automotive, chemicals, electronics, electrical component, pharmaceuticals, tobacco, household goods, toys, furniture certificates, etc

trade issues. Counterfeit has devastating economic, human, and social costs, with its unlimited growth likely to cause more damage in future[331]. Counterfeit product is perpetually increasing and can be purchased from the internet, high street, and local markets, with products ranging from food, drinks, toys, clothes, technology, and pharmaceutical. This leads to loss of technical know-how, tax/ revenue, employment, and eventually death. The impact of each harmful effect stated above will be discussed briefly, starting from the impact on employment.

Counterfeit can be credited to have led to the loss of 2.6 million jobs globally due to black market sales [332]. In the EU alone, IP industries provide approximately 26% of employment, and OECD estimates that counterfeit results in the loss of around 800,000 jobs and 14.3 billion in tax revenue[333]. The effect on employment is examined from two perspectives. Firstly, counterfeit creates shifts of rights from lawful IP manufacturers to unlawful infringing parties. Counterfeiters depend on the young to manufacture goods with perverse working conditions. Secondly, it damages the growth of legitimate companies' reputation and R&D built over the years resulting in loss of profit and sales[334]. Due to the perverse nature of counterfeit trade, counterfeiters avoid prosecution, neither do they obey quality standards nor regulatory authority like legitimate firms. Given the business's potential loss, the government equally loses much-needed revenue from sale diversions such as corporation tax, sales tax, and income tax of up to $89 billion per year. These funds should be used to

[331] Adrian Furnham, 'The Effect of Life Values and Materialism on Buying Counterfeit Product,' 2007 Vol 36 Journal of Socio-Economics, pp 677 counterfeit is not a materialism product, but lack of value for branded product citing up bring and family values as a precondition for the surge of counterfeit.
[332] Arlee Sowder, 'The Harmful Effect of Counterfeit Goods,' (2013) Athens State University https://www.athens.edu/journal/spring-2013/asowder-couterfeit/
[333] European Economic and Social Committee, fake products cost 800,000 jobs annually available https://www.eesc.europa.eu/en/news-media/news/fake-products-cost-8000000-jobs-annually accessed (December 4, 2018)
[334] International AntiCounterfeiting Coalition IACC, what is counterfeiting, available https://www.iacc.org Accessed (December 5, 2018)

run other areas like building roads, hospitals, R & D, and creating employment opportunities.

Counterfeit poses a deadly health risk, especially pharmaceuticals. Consumption of an unregulated pharmaceutical product poses a health risk and even death. It can undermine the reputation of legitimate manufacturers of medicine and lead to loss of credibility and loss of expenditure used for R&D. Counterfeit pharmaceuticals could contain inactive or no active ingredient or unapproved drugs. A recent study by the WHO estimates that one in 10 medicines in developing countries and LDCs is counterfeit. An example is a drug for malaria, which accounts for 65% of counterfeit medicine and possibly responsible for the deaths of thousands of children from diseases such as malaria and pneumonia, and HIV every year[335]. Equally, the surge of counterfeit in developing countries continues daily. For example, cancer patients in America took Avastin, a cancer antibody treatment, only to discover[336] it contained no active ingredient, thus jeopardizing consumers' health. The unending phenomenon compels strict actions by the government, businesses, and consumers to set up a viable organization to tackle the magnitude of counterfeit trade and equally harmonize the regulatory framework of trade in IP.

The economy of the EU and other developed countries relies on IP protection against the act of counterfeit. Without durable protection, creativity will come to a halt, forming a joint coalition of like-minded states to stop patent infringement, copyright, trademark industrial design, geographical indication, and other necessary IP rights.

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[335] The Guardian10% of drugs in developing countries are fake, says WHO **Available,** https://www.theguardian.com/global-development/2017/nov/28/10-of-drugs-in-poor-countries-are-fake-says-who
Accessed (December 5, 2018)

[336] Sean Riley, Keeping it Real – 'The Fight against Fake Drugs' The Association for Packaging and Processing Technologies, May 19, 2017, Availablehttps://www.pharmamanufacturing.com/articles/2017/keeping-it-real-the-fight-against-fake-drugs/Accessed (December 5, 2018)

Counterfeiters abuse the IPR in great measure that it dwindles the economy of dependant states. It does not only affect the economy, but it creates severe social problems, as indicated above. All these factors resulted in the negotiation of ACTA to tackle counterfeiters.

The ACTA factsheet laid down the goal of the Agreement is to provide a robust international framework that improves existing enforcement laws on intellectual property rights (IPR) at both international and domestic levels backed up by sanctions in criminal and civil proceedings[337] in a bid to sustain global economic growth. The preamble of the Agreement indicates that the agreement advocates for the enforcement of IP rights due to counterfeit goods' proliferation. With the desire to deter (financial, human, environmental, economic) risks posed by counterfeiters' criminal act to legitimate trade. ACTA is keen on ensuring a balance in states' legal systems within the scope of the Agreement not to create a conflict of interest while still respecting and recognizing the WTO-TRIPS Agreement's provisions as a guide it complements the TRIPs agreement[338].

The nature and scope of ACTA obligations are provided in article 2 inter alia that "*Each Party shall give effect to the provisions of this Agreement…Can implement in its law more extensive enforcement of intellectual property rights than is required by this Agreement*. This means that members can pick and choose an appropriate forum in the judicial, administrative, or legal enforcement authorities to implement ACTA

[337] Fact Sheet, The Anti-Counterfeiting Trade Agreement (ACTA) Updated November 2008, Available http://trade.ec.europa.eu/doclib/docs/2008/october/tradoc_140836.11.08.pdf Accessed (December 6, 2018)ACTA tackles large scale, criminal activities and it is not about limiting civil liberties or harassing unwilling consumers

[338] **Final Text of ACTA Agreement (May 2011),** Final released the text of the Anti-Counterfeiting Trade Agreement (ACTA) Available, https://www.eff.org/document/final-text-acta-agreement-may-2011, Accessed (December 6, 2018)The Agreement is not a barrier to trade, it intends to create supportive measures to enforce IPR infringement including digital, copyright infringement in a bid to allow right holders benefit from their creativity

provisions within its legal system with the sole responsibility to initiate individual proceedings against the counterfeiter. If the word of ACTA is transcribed, it is worth noting that it gives prominence to the provisions of TRIPs, especially articles 7&8, i.e., The objective of TRIPs shall be read in such a way that the main point of the Agreement remains unchanged. For example, ACTA defines a counterfeit trademark as an infringement of goods, packaging without the authorization of a right-holder under the law of the country of the trademark owner supported by a requirement, which stipulates that the words of this Agreement should be interpreted in a like manner as words found in WTO-TRIPS. Therefore, there may not be a distinction between the rights protected by both agreements. What is the essence of ACTA, if TRIPs is protecting IPR? To discuss this, proponents of ACTA claim that ACTA's goal is not to alter the domestic laws of states, but rather to ensure countries with strong IP standards develop unified IP rules to tackle the surge of IP.

Another criticism of this Agreement is the issue of transparency during its negotiations. During the negotiations of ACTA, the procedure showed the Agreement is done mostly in secrecy outside the forum of all Intellectual Property standard-setting organizations, neither were IP stakeholders and civil society included in the negotiating process[339]. The issues raised by this group include (I) the undemocratic nature of ACTA, (ii) global domination of trade by developed countries, (iii) the invasion of privacy to restrict civil liberties, and (iv) will make the developing countries lower. Another worrisome issue is the notion that ACTA might compel internet providers to disclose users' information, which contravenes the fundamental human right to private

[339]The negotiating process took four years, largely done in secrecy, with the outcome intended to affect millions of people economically, financially, and medically. One worrisome issue of compelling internet providers to disclose user's information which contravenes the basic human right to private life guaranteed by the Magna carter

life guaranteed by Article 8 of the fundamental human rights Act [340]. The ambiguous nature of ACTA leads to confusion for its stated aim to combat commercial counterfeit. Instead, it appears to extend willful infringement for financial gain, which is prejudicial to IP rights owners' interests. For example, it obstructs the privacy of ordinary citizens as well as the right of digital content providers[341]

Nevertheless, the analysis of documents used during the negotiating round of ACTA indicates that member states exchanged and shared information amongst its minister's present in the rounds. However, this document was not accessible to public members until June 2008 during the stakeholders meeting in Brussels, where issues and concerns raised by concerned groups were discussed and explained in detail. ACTA secrecy claim hinges on two points, firstly, if ACTA can be regarded as a trade agreement as it is not unusual to have secrecy during trade negotiation. Nonetheless, ACTA may not represent an actual trade agreement as it fails to promote free trade, but further inhibits trade, neither does its preamble portray it as a trade agreement. It only mentions international trade a few times without a clear indication to facilitate trade. Secondly, ACTA does not intend to change the domestic laws of member states, but it aims to advance a more robust international IP enforcement system already existing in these countries' domestic systems, so disclosure might not be unnecessary if the domestic laws will not be affected by the rules of ACTA[342].

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[340]Equality and Human Right Commission, Article 8 Right to private Life, Available https://www.equalityhumanrights.com/en/human-rights-act/article-8-respect-your-private-and-family-life Accessed(December 12, 2018) Article 8 protects your right to respect for your private life, your family life, your home and your correspondence (letters, telephone calls and emails, Also the Human Rights contains all the basic rights and freedoms to which all human beings are entitled to such as the right to life, liberty, right to civil and political rights, freedom of thought and speech and expression, the right to equality before the law, social, cultural and economic rights, the right to food, the right to work, and the right to education, etc.

[341] Charles R McManis, 'The Proposed Anti-Counterfeiting Trade Agreement (ACTA): Two Tales of a Treaty." Vol.46 (2009): Houston. Law *Review PP* 1235

[342] Kimberlee Weatherall, Politics, Compromise, Text and the Failures of the Anti-Counterfeiting Trade Agreement,' 2018), Vol.33 Sydney Law Review, PP 229

ACTA may be a typical case of forum shifting initiatives concluded by industrialized countries to protect private IP rights owners. It advocates for a stronger IP regime beyond the WTO-TRIPs Agreement, which will not contravene the provisions of TRIPs. Then again, ACTA goes beyond TRIPs in placing enforcement procedures on both export and import, thus infringing on the provision of TRIPs. Equally, the current ACTA agreement allows for the inclusion of intermediaries and third parties. It also goes beyond TRIPS by making damages within its text sufficient to compensate for any injury suffered from breach of counterfeit or imitation. For *instance" Article 9 (damages) provides in the enforcement of intellectual property rights, its judicial authorities have the authority to order the infringer who, knowingly or with reasonable grounds to know, engaged in an infringing activity to pay the right holder damages adequate to compensate for the injury the right holder has suffered as a result of the infringement'* [343]. This value is not specific; it may include future loss or the market value of the goods. It is also notable that ACTA provides for the criminal procedure in Article 23 for wilful trademark counterfeiting or copyright and the related right to piracy on a commercial scale. This statement is quite ambiguous. Firstly, there is no measure to determine what amounts to a commercial scale; neither is the term *related right* said to include patent rights. In a bid to go over and above the WTO-TRIPS, the drafters of this Agreement made contradictions in the text of the Agreement, as seen above.

[343] Anti-Counterfeiting Trade Agreement December 3, 2010, Article 9 Damages, Available https://trade.ec.europa.eu/doclib/docs/2010/december/tradoc_147079.pdf Accessed (December 13, 2018)it states inter alia that Each Party to the Agreement shall provide, in civil judicial proceedings concerning the enforcement of IPR, its judicial authorities have the authority to order the infringer who, knowingly or with reasonable grounds to know, engaged in an infringing activity to pay the right holder damages. Adequate to compensate for the injury, the right holder has suffered as a result of the infringement.
In determining the number of damages for infringement of intellectual property rights, a Party's judicial authorities shall have the authority to consider, among other things, any legitimate measure of value the right holder submits, which may include lost profits, the value of the infringed goods or services measured by the market price, or the suggested retail price

In this conclusion, the interest in developing countries is not considered by the negotiators of ACTA. Some developing countries registered their discontentment on ACTA; for example, Brazil criticized ACTA for propositioning a single remedy against counterfeit and piracy. Others believe that ACTA did not follow the TRIP standard or safeguard, for it provided only one remedy against counterfeiting and piracy: repression. For example, the Agreement failed to address the practice of seizing genuine generic medicine in transit through the EU port en route to South America and Africa, which was detained for breaching patent, for failing on its strict patent laws even if not protected in the country of destination[344]. ACTA restricts access to essential medicine as seen from the detention of funded medicine Aurobindo destined for Nigeria for the treatment of HIV/AIDS, claiming it is a counterfeit drug without substantial evidence to support this claim, as unknown to them that the medicine did not contain counterfeit neither did it infringe on any IP right[345]. ACTA does not harmonize the laws or standards of trade to allow access to pharmaceuticals for developing and LDCs like Nigeria, with no technological output or creative capacity for drug production, but who rely on counterfeited/generic drugs for its health care needs. From the analysis, ACTA enforcement procedure measures in Article 12 mandates the judicial authority to exercise jurisdiction to prevent IP infringement of goods from entering the channel of commerce, and the parties can request for *an injunction against a broad class of actors, including third parties, and mandate interception of goods in transit by customs officials applying the IP law of the transit* country".

[344]Henning Grosse Ruse-Khan, 'A Trade Agreement Creating Barriers to International Trade: ACTA Border Measures and Goods in Transit.' (2010): Vol 26 American University International Law Review, 645. An example is that the Netherlands' custom authorities detained a large stock of generic medicine destined for Africa, some of it is destroyed, and others were released after a considerable time lapse.

[345] See UNITAID Statement on Dutch Confiscation of Medicines Shipment, UNITAID, Available HTTP://www.unitaid.eu/en/resources/news/156-united-statement-on dutch-confiscation-of-medicines-shipment.html

Although this section excludes pharmaceutical patents, this exclusion is not guaranteed. It can be used to block the passage of generic drugs, for example. The German customs seized the shipment of Amoxicillin, which was held for four weeks for similarity to another drug produced by Glaxo Smith Klein (Amoxil). This and other similar incidents show the negative effect of ACTA on health care[346].

The negotiation of ACTA prompted various debates due to non-disclosure of provisions and other similar issues in the Agreement's text. While to the industrialized countries, ACTA is a unique platform for aggregating all the IP rights into a strong dynamic framework for the benefit of IP right providers, to the developing/LDC countries or non-party members of ACTA, some of its provisions go beyond TRIPS, especially the border measures, which restricts the distribution of much-needed medicine. ACTA is not an agreement for all; it is only for the selected few who favour profit over life, unlike its counterpart, the TRIPS agreement, which is open to all member states globally. It would not be astonishing that ACTA intends to replace the existing IP mechanism in the long run by consolidating/merging its framework within a single regime backed by sanctions imposed by the developed countries only.

3.3.2. Principles and element of International Medical Product Anti Counterfeit Taskforce –IMPACT

The growing trend towards protecting IP has been welcomed by developed and developing countries, given counterfeit perversity. Although the anti-counterfeit trade

[346] Andrew Rens, 'Collateral Damage: The Impact of ACTA and the Enforcement Agenda on the world's Poorest People." (2010) Vol.26 American University International law Review: 783.Brook K Baker,' ACTA-risks of third-party Enforcement for access to medicines' (2010) Vol. 26 American University International Law Review 579

agreement tried to enforce stiff penalties on defaulters of IP, developing countries perceived that this protection was mostly inadequate. It may be safe to suggest that this organization, even if it is themed "*globally unique*," is ineffective in reducing the scourge of counterfeit. Nonetheless, another organization created to regulate the scourge of counterfeit goods was inaugurated by the World Health Assembly (WHA) Resolution 41.16. This resolution permits the WHO to start programs for the prevention of import, export, and smuggling of counterfeited or substandard pharmaceuticals. One such initiative led to the establishment of the International Medical Products Anti-Counterfeiting Taskforce (IMPACT) in 2006. This was the first of its kind, which was solely dedicated to pharmaceuticals and medico-surgical materials[347].

The goal of IMPACT is to restrict the production, selling, marketing, and distribution of counterfeit pharmaceuticals. With the support of governmental and non-governmental anti-counterfeit agencies, drug regulatory authorities, manufacturers of patented medicines, and all IP related organizations [348]by adopting a transparent approach to combat counterfeit through any means possible with state of the art infrastructures, legislations, rules, procedures of enforcement and effective communications on counterfeit.

This research will not seek to state IMPACT's history; it will focus on what it aims to achieve. It will seek to examine why, after 12 years of IMPACT's establishment, counterfeit pharmaceuticals are still on the increase. Therefore, questioning is crucial. The first part will discuss the definitional question of counterfeit, for, without a clear

[347]Albert I. Wertheimer and Perry G. Wang, Counterfeit *Medicine, Policy, Economies, and Countermeasures* (ILM Publications, St Albans, 2012)

[348] IMPACT representatives include the following, Interpol,), World Customs Organization for Economic Cooperation and Development (OECD, World Bank, World Intellectual Property Organization, World Trade Organization, International Federation of Pharmaceutical Manufacturers' Associations, Council of Europe International Generic Pharmaceuticals Alliance, ASEAN Secretariat, European Commission, International Pharmaceutical Federation, International Council of Nurses, World Medical Association, and Pharmaciens sans Frontière

delimitation, enforcement is not possible. This is because, until now, there seems not to be a specific law to cover infringement of medicine without settling for the all-encompassing generic definitions of counterfeit medicine. Even if the WHO attempted to define counterfeit medicine, is it sufficient if measured against the proportion. Lastly, the research will evaluate IMPACT's effect on the distribution and flow of medicines to developing countries.

IMPACT has many objectives: creating a necessary mechanism to secure political commitment supported by a secure legal framework backed by sanctions. This collaboration facilitates progress in the following areas: securing political will and commitment, adequate legal framework, and implementation. Others include curtailing the surge of counterfeit medicine based on laid down rules and procedures of enforcement, defining roles, ensuring the availability of funds, useful administrative tools to create awareness of the severity of the counterfeit medicine on public health[349].

Whereas the definitional question of counterfeit arises all the time, to establish the definition, it is vital to explain medicine's meaning. Medicine is any substance used to treat illness or restoring or modifying a physiological function in human beings. In contrast, essential medicines satisfy the urgent health care needs of the public[350]. Therefore, *medicine is an essential substance used for the treatment of diseases in*

[349] International Monitoring pact on Anti-counterfeit Taskforce –IMPACT, Available http://apps.who.int/medicinedocs/documents/s20967en/s20967en.pdf Accessed (20 December 2018) IMPACT Participants are encouraged to conduct activities which are consistent with the objectives mentioned above under their responsibility and according to their respective policies and principles. Fund-raising efforts of IMPACT Participants for their activities will be subject to their respective policies and principles

[350] World Health Organisation Essential Medicine and Health Product Available https://www.who.int/medicines/services/essmedicines_def/en/ Accessed (18 December 2018) Essential medicines satisfy the priority health care needs of the population. The medicine that makes this list is selected due to health care needs and its relative relevance to the society and safety to ensure there is a standard or functioning health system, particularly in developing and LDC.

human beings. Medicine is an invention from human intellectual knowledge inevitably protected by law for either process or product from unauthorized usage. Counterfeit amounts to unauthorized use, which the World Health Organisation defines as follows:

WHO definition of counterfeit medicine	IMPACT definition of counterfeit medicine
'' is one which is deliberately and fraudulently mislabelled concerning its identity or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct or wrong ingredients, without active ingredients, with insufficient active ingredients or with fake packaging."	*'' describes a medical product with a false representation of its identity or its source. This applies to the product, its container or other packaging or labelling information. Counterfeiting can apply to both branded and generic products. "Counterfeits may include products with correct ingredients/components or with wrong ingredients/components, without active ingredients, with incorrect amounts of active ingredients or with fake packaging."*[351]

First, the WHO is a standard-setting organization, and this definition seems to be concerned about intellectual property protection rather than public health safety. Although it complements TRIPS' definition of counterfeit, Clift opines that the WHO should be more concerned about the quality, safety, and efficacy of pharmaceutical products[352] rather than IP. However, after various deliberations, the WHO working group concluded that the definition of counterfeit medicine above would not sufficiently

[351] International Monitoring pact on Anti counterfeit Taskforce –IMPACT, Availablehttp://apps.who.int/medicinedocs/documents/s20967en/s20967en.pdfAccessed (20 December 2018)

[352] Charles Clift,' Combating Counterfeit, Falsified and Substandard Medicines: Defining the Way Forward?'
Centre on Global Health Security | November 2010,
Available https://www.chathamhouse.org/sites/default/files/public/Research/Global%20Health/1110bp_counterfeit.pf Accessed(20 December 2017)

explain its intent and purpose. It is in contrast with public health. As such, a new definition (*substandard/spurious/falsely labelled/falsified/counterfeit (SSFFC)* medical products)[353], with each specific term dealing with a cause instead of a complete legal text that bears no apparent meaning. The SSFFC arrangement is precise, for it divides the terminologies relating to counterfeit medicine and IP by removing terms like" *one which is deliberately and fraudulently mislabelled concerning its identity and source,"* which is an IP term, as such, alienating it in the new SSFFC text.

There appears to be a gap in this definition. Firstly, what does it aim to protect? Besides, can it be refined to ensure state agencies and regulatory bodies work together to achieve a common goal of safeguarding pharmaceuticals through the legislative provision of states and the stakeholders in the manufacturing, export, and import of pharmaceutical products? In the same vein, the Pharmaceutical Security Institute (PSI) supports this position by recognizing the definition proffered by regulatory bodies globally. However, since there is no concise official definition of counterfeit pharmaceuticals in most countries, how will counterfeit be resolved?

To PSI, "*Counterfeit medicines are products deliberately and fraudulently produced and/or mislabelled concerning identity and source to make it appear to be a genuine product and applies to both branded and generic products"* [354]. Looking at this definition, it tends to partly originate from the definition proffered by the WHO, as clearly the wording of both organizations are similar. It may be possible that similarity connotes harmony as to purpose, not as to the problem's scope. Whereas the definition of counterfeit proffered by IMPACT complements the WHOs definition, for

[353] Substandard, spurious, falsely labelled, falsified and counterfeit medical products, Frequently Asked Questions, April 2014
Available https://www.who.int/medicines/services/counterfeit/faqs/SSFFC_FAQ_print.pdf Accessed (18 December 2018)
[354] Pharmaceutical Security Institute Available http://www.psi-inc.org/counterfeitsituation.cfm Accessed (17 December 2018)

example, the text "*applies to the product, its container or other packaging or labelling information,"* which suggests the protection of trademark instead of public health. Undoubtedly, IMPACT is a tool of the WHO; it is not a legal entity; neither can it take any actions without the authorization of state members, agencies, organizations, or institutions. Its powers are, therefore, limited.

One of the critical areas within the mandate of IMPACT is regulatory implementation to help the national authorities implement measures to control the export, import, and distribution of medicine to developing countries/LDC. It is done by maintaining an effective communication strategy, coordinating health authorities, customs, police force, manufacturers, distributors, and health professionals of state members of suspected counterfeit products [355]. Nevertheless, lately, IMPACT's functions have been criticized for restricting access to essential medicine, and it advocates for a TRIP-plus standard. The consequence of this move is detrimental to public health,[356] given the first fact that IMPACT ought to regulate the scourge of counterfeit. However, it tends to restrict access to generic medicine, which is disastrous for developing and LDC. In summary, the need to regulate counterfeit supersedes public health concerns. However, IMPACT and ACTA's aim explicitly contravenes what TRIPS aims to achieve, especially with developing countries and LDCs, even though it has efficient regulatory policies on counterfeit drugs, its enforcement framework is beyond TRIPs.

[355] IMPACT- Counterfeit Drugs Kills, May 2008
Available https://www.gphf.org/images/downloads/library/whoimpact2008_counterfeit_drugs_kill.pdf
Accessed (20 December 2018)
[356] Paul N Newton and others' The Primacy of Public Health Considerations in Defining Poor Quality Medicines' (2011) 8, no. 12 PLoS Medicine e1001139.

Chapter 4 the Nigeria IP Framework and Counterfeit Regulation

4.1 Introduction

This chapter examines the conditions that make counterfeit thrive in Nigeria irrespective of the national and international IP policies in place to regulate counterfeit pharmaceuticals. Part one of this research looks at Nigeria's geographical scope in chronological order from economic, social, and public health perspectives. Part two demonstrates through a historical purview how Nigeria's legal system evolved from colonialism to an enforceable legal institution based on the rule of law. Part three will analyse the intellectual property framework applicable in Nigeria before going into the core of the research, which is introducing the intellectual property framework in Nigeria. These include customary laws, rules, laws decree, edits concerning the rules set by TRIP. The issue is why counterfeit pharmaceutical is still on the increase despite TRIP rule and Nigeria domestic rules. The inquiry concludes with suggestions on how to make the Nigerian laws and WTO IPR work effectively together.

Counterfeit pharmaceuticals, as the name connotes, is a replica of the original medicine devoid of any active ingredients used to treat diseases. Counterfeit medicine does not meet any regulatory standards, and it poses serious health problems, even

death[357]. It, therefore, begs the question of why counterfeit drug is is so prevalent in Nigeria.

In straightforward terms, counterfeit drug is persistent for the following reasons: (I) Price –In a country with a poverty headcount ratio of less than $1.90 a day and over 53% of the population[358] are living in abject poverty, counterfeit drugs are seen, as a cheaper alternative to brand-name drugs. In Nigeria, medicine is not state-funded like most developed countries: individuals must provide for their own health care needs. It is incredibly difficult to afford essential medicines due to the 20 years patent restriction placed on drugs. Pharmaceutical companies have the sole right to profit from the product of their research and development but not to the public's detriment. There should be symmetry between the needs of pharmaceutical companies and public health care for both parties' mutual benefit.

On the price issue, big Pharma argues that the least amount spent on research and development is around 2.558 billion dollars. In other words, the amount of money spent on raw materials, manufacturing, clinical trials, failure until the drug is approved is enormous [359]. More recently, the Tufts centre for the study of drug development pegs the cost of developing a new drug from invention to market approval to be around $2.6 billion. This report originates from information supplied by ten pharmaceutical companies from 106 randomly selected drugs within a specific time, with over half of these monies spent on post-approval development studies, such as the safety and

[357] Erwin A Blackstone, Joseph P Fuhr, and Steve Pociask' The Health and Economic Effects of Counterfeit Drugs.' 2014; Vol 7 issue (4): Am Health Drug Benefits pp216.
[358] The world Bank Poverty and equality data country indicator Nigeria, Available http://povertydata.worldbank.org/poverty/country/NGAAccessed (February 9, 2019) in the words of Paul Orhii, of Nigeria's drug agency, part of the problem Nigeria faces is due to the presence of a shambolic system and porous borders".
[359] The Guardian Why do new medicine cost so much and what can we do, available https://www.theguardian.com/news/2018/apr/09/why-do-new-medicines-cost-so-much-and-what-can-we-do-about-it Accessed (February 11, 2018)

efficiency of a drug. If successful, the next set of funds will be on marketing and the possibility of the new drug failing [360]. For example, Biomarin and Genzyme's recent review estimates R & D's cost for medicines for the treatment of rare diseases, to be on an average between $195 million to $963 million[361]. Looking at this information begs the question of the feasibility of this data. Most pharmaceutical companies do not disclose data on the cost of production of medicines publicly, thus reducing the powers of price in medicines. The only available tool to reduce drugs' monopoly price is by generic competition[362], such as the ones used in South Africa and India during the HIV crisis.

There is no doubt that producing drugs is expensive, but there should be a balance between the initial and total cost of a drug to reach a fair price acceptable for consumers. Without the right price, access to medicine will be impossible, leaving room for counterfeit, especially in developing countries like Nigeria. The high cost of drugs, coupled with inaccessibility, triggers the surge of counterfeit medicine. Often supplied through an authorized and unspecified distribution network to an unsuspecting willing consumer, counterfeit medicine is welcomed as a cheaper alternative to brand known overpriced drugs[363]. Nigeria needs to adopt a strict standard for regulating and distributing drugs, for it is hailed as Africa's biggest economy and a frontier for pharmaceutical growth in Africa. Setting a precedent for

[360] Cost to Develop New Pharmaceutical Drug Now Exceeds $2.5B, and A benchmark report estimates that the cost of bringing a drug to market has more than doubled in the past ten years, By Rick Mullin, Chemical & Engineering News on November 24, 2014, Available, https://www.scientificamerican.com/article/cost-to-develop-new-pharmaceutical-drug-now-exceeds-2-5b/Accessed (April 8, 2019)

[361] Forbes- The Cost Of Developing Drugs Is Insane. That Paper That Says Otherwise Is Insanely Bad, by Matthew Herper Availablehttps://www.forbes.com/sites/matthewherper/2017/10/16/the-cost-of-developing-drugs-is-insane-a-paper-that-argued-otherwise-was-insanely-bad/#38fa21c2d459 Accessed (April 9, 2019)

[362] Andrew M Hill, Melissa J Barber and Dzintars Gotham, 'Estimated Costs of Production and Potential Prices for the WHO Essential Medicines List',2018;**3** BMJ Global Health**:** e000571

[363] Chinwe Obuaku,' Essential Medicines in Nigeria: Foregrounding Access to Affordable Essential Medicines.' (2014) b Vol 18. Issue 2: African Sociological Review pp. 42.

other African nations should be the key objective of its government. Instead, it is marred with large-scale counterfeit drugs' consumption despite its government preventive steps to reduce counterfeit. Deaths caused by counterfeit drugs have soared steadily over the years in Nigeria, with deaths mostly undocumented[364], which affects data accuracy on the scale of counterfeit medicines. One of the first documented cases of counterfeit death is the paracetamol syrup disaster of 1990, where 109 children died from consuming fake paracetamol syrup produced with the toxic substance diethylene glycol instead of propylene glycol[365]. Another similar death recorded in 2008, killing over 80 babies caused by contamination of *my pikin Baby teething power* with engine coolant diethylene glycol[366].

To effectively address the issue of counterfeit pharmaceuticals, it is pertinent to discuss the legal and institutional framework in Nigeria, for, without clarification, the reorganization will be impossible to achieve. Nigeria's anti-counterfeit procedure is not specific; it is subdivided into different rules and policies and border measures to fit a particular purpose, which applies to an IP right holder. Counterfeit pharmaceutical is a global issue. Counterfeit has eaten so deep into the structure of Nigeria's health and pharmaceutical sector, to the point of attaching more importance to profit than human life. For instance, the standard organization of Nigeria (SON) estimates that the federal government loses around #15 Billion annually to counterfeiters' activities, with 80% of counterfeit products originating from Asia and other countries around the world.[367] It makes Nigeria the largest market for drugs in Africa. With such a unique position, the

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[364] Paul N Newton, and others' Murder by Fake Drugs: Time for International Action.' (2002): 800-801.

[365] S. Ogoh Alubo. 'Death for Sale: A Study of Drug Poisoning and Deaths in Nigeria.' (1994) Vol 38. Issue 1 *Social Science & Medicine*. PP97.

[366] Olusegun Akinyandenu.' Counterfeit drugs in Nigeria: A threat to public health.' (2013) Vol 7, Issue 36: African Journal of Pharmacy and Pharmacology, pp. 2571.

[367] The Leadership, Nigeria loses #15 billion annually to fake products annually, Available https://leadership.ng/2018/02/07/nigeria-loses-n15bn-fake-products-annually/ Accessed (February 9, 2019)

World Health Organisation survey found that over 64% of Nigeria's antimalarial drugs are fake or counterfeit[368].

4.2 An Introductory Overview of Nigeria

A booming economy, diverse people, and immense economic potential sum up the country called Nigeria. It is known as the giant of Africa for its strength and might in the economic, technological, educational, cultural and industrial prowess in the continent of Africa. To discuss Africa without mentioning Nigeria is tantamount to considering global issues without the United States of America. Therefore, to analyse the viability of TRIPs in relation to counterfeit in Nigeria, it is pertinent to look at the institutional, geographical, legal and economic framework of Nigeria to ascertain if the rules formulated by TRIPS undermines the surge of counterfeit drugs in Nigeria.

Geographically, Nigeria is in Western Africa, bordering the Gulf of Guinea, between Benin, Ghana, Togo and Cameroon, with a total mass of land measuring around 910,768 sq. km and water estimated around 13,000 sq. km as delimited by international boundaries and coastlines. Nigeria is endowed with abundant natural resources such as natural gas, tin, coal, iron ore, lead, zinc, limestone, niobium, arable land and most importantly, petroleum[369]. The oil and gas sector is the primary source of export, with over 83% of total export revenue and 10% of the country's gross domestic product[370]. Nigeria's oil reserve is estimated to be around 23 billion barrels, and the gas reserves are estimated to be 160 Trillion cubic meters. Regardless of such

[368] The Economist, fake medicine bad medicine available https://www.economist.com/international/2012/10/13/bad-medicine accessed (February 9, 2019)
[369]Central Intelligence agency, (CIA)world Fact book : Nigeria , Available https://www.cia.gov/library/publications/the-world-factbook/geos/ni.html Accessed (15 January 2019)
[370] Organisation of Petroleum Exporting Countries (OPEC) Nigeria Fact sand Figures , Available https://www.opec.org/opec_web/en/about_us/167.htm Accessed(10 April 2019)

vast natural resources, Nigeria is classified as a developing country, with over 70% of its population living in abject poverty.

Despite the abundant resource highlighted above, it can be argued that these resources can be referred to as a curse rather than a blessing. For instance, Obaje addresses the notion of a resource curse, indicating that the term emerged in the 1980s. They assert that states with vast natural resources are beleaguered with undesirable economic output[371] as a consequence of inflation, high unemployment level, terrorism, kidnapping, protests and negative political turmoil. These factors have invariably been affecting the utilization of natural resources. This is a typical example of Nigeria's situation whose natural resources is perceived as a curse in disguise, as they are a constant source of hardship, death, pain and conflict in Nigeria although it is a limited perception to classify a country based on a single variable rather than other determinant factors.

4.2.1 History of Nigeria

Historically, Nigeria is a former protectorate of the British Empire, and most of its laws and policies emanate from the British Empire and influence. Scholars like Toyin Falola believe Nigeria's British occupation in early 1900 created enabling conditions for force, undue nationalism, political instability, corruption, and power tussle amongst the ruling elite. Maybe it was a way to resist colonialism or might be a precondition for the country called Nigeria[372]. These issues have eaten deep into the fabric of Nigeria, with Nigeria

[371] Nuhu George Obaje, *Geology and Mineral Resources of Nigeria* Vol. 120 (Springer, 2009)
[372] Toyin Falola, *Colonialism, and Violence in Nigeria*, (Indianan University Press, 2009)

rated as one of the most corrupt countries in the world[373]. An apple does not fall far from a tree; corruption is an integral part of colonialism, with the colonial masters bribing chiefs and elders with gifts to oppress Nigerians. Steven traced the current corrupt practices in Nigeria to the British colonial regime[374]. The leaders have failed Nigerians right from the beginning with the help of colonialism.

Nigeria finally gained its independence from Britain in 1960, hoping that the country will be the giant of Africa. Unfortunately, the country experienced various military coups and countercoups, with different regimes struggling to rule the country. From 1960 till 1999, Nigeria had long spells of military rule, precisely between 1966 to 1979 and between 1984 and 1999. The Nigerian government continues to face the daunting task of institutionalizing democratic principles of good governance in a system encumbered with corruption. However, this thesis will not dwell too much on the historical issues of Nigeria.

4.2.3 Population

Modernization and technological advancement enabled people to live longer and healthy, resulting in the world population's unprecedented growth. Nigeria is one of such countries regarded as the fastest and most populated African country. Its last census in 2006 projected the population to be around 140 million people[375]. By 2013, the estimated population projection for Nigeria was 169.7 million, and by 2019 it was

[373] Transparency international –Nigeria is regarded as 144 least corrupt nation out of 180 countries, according to the 2018 Corruption Perceptions Index reported by Transparency International. With the Corruption Rank in Nigeria averaged to be around 121.48 from 1996 until 2018, reaching an all-time high of 152 in 2005 and a record low of 52 in 1999.Available https://www.transparency.org/country/NGA Accessed (3 February 2019)

[374] Steven Pierce,' Looking like a State: Colonialism and the Discourse of Corruption in Northern Nigeria.' (2006) 48.4 Comparative Studies in Society and History 887.

[375] Toyin Falola and Matthew M. Heaton, *The History of Nigeria* (Cambridge University Press, London 2014)

over 200 million people making it the 7th largest country in the world[376]. The United Nations projects that by 2050, the Nigerian population will surpass that of the United States and maybe the third most populous country in the world behind India and China [377]. The consequence of population growth is multidimensional economically[378]. It has led to an increase in the labour force and per capita income of a state. Pikett supports this view that population growth is a contributing factor for economic growth in per capita GDP[379]. The consequence of unregulated population growth transcends economic problems such as inflation and debt. It reduces development in low-income countries.

4.2.4 Nigeria Trade Alliances

No country is an island; every country has trade ties with other counties, coupled with trade liberalization policies. This has made trade easy and efficient, for trade is an engineer of growth, development, and a means of integration. Theoretically, two benefits of trade have been identified by international trade scholars. Firstly, trade allows specialized gains from trading activities, and the overflow from trade is profit[380]. However, the benefits of free trade to developing countries are multifaceted. According to the International Monetary Fund (IMF), liberalization has increased the wealth of

[376]Eli H Tartiyus, Mohammed Inuwa Dauda, and Peter Amade,' Impact of population growth on economic growth in Nigeria, (2015)20.4: *IOSR Journal of Humanities and Social Science (IOSR-JHSS)* 115.

[377] The Guardian Newspaper Nigeria expected to have a larger population than the US by 2050 UN predicts that Africa – and Nigeria in particular – will be at the forefront of substantial global population rise over the next century Available, https://www.theguardian.com/global-development/2013/jun/13/nigeria-larger-population-us-2050 Accessed (15 January 2019)

[378] Derek D Heady and Andrew Hodge' The Effect of Population Growth on Economic Growth: A Meta-Regression Analysis of the Macroeconomic Literature' (2009) 35, Population and Development Review, 221

[379] Thomas Piketty, Capital *in the Twenty-First Century* (Cambridge, MA: Belknap Press of Harvard University Press, 2014)

[380] Andrés Rodríguez-Pose and Javier Sánchez-Reaza 'Economic Polarization through Trade: Trade Liberalization and' (2005) *Spatial Inequality and development*. 237

nations, leading to enhanced export and import, increased income, manufacturing[381], and technological Proficiency amongst nations, particularly in developing countries.

Nigeria is a member of various international, regional, and national trade organizations. For this research, a few of these organizations will be discussed briefly. Starting from International organizations, Nigeria has been a member of the WTO since 1990 and a GATT member since 1960. Nigeria has actively participated in the activities of the WTO. It has ratified most of the WTO trade rules which cover goods, services, and IP into its legal system, in addition to WTO permitted exceptions. Recently, Nigeria signed the trade facilitation agreement, which is expected to reduce the cost of trade by an average of 14.3%, with developing countries like Nigeria having the most gain. This agreement will ensure that import time is reduced, with an estimated average reduction time of 47% and 91% and the capacity to increase global merchandise export by over $1 trillion[382]. The WTO revised its implementation mechanism to reflect each member country's ability to achieve a desirable outcome.

The benefit of being a member of the WTO is remarkable. Adejuwon, Nigeria Ambassador to the WTO. Has commented that Nigeria's economy has a lot to gain from its membership of the WTO, such as increased technical support for its developmental and infrastructural growth, easy flow of FDI, improved foreign exchange and earnings, elimination of technical and non-technical barriers to trade. It ensures free market access for local manufacturers in the international trade forum[383]. However, some scholars believe that WTO rules on trade liberalization favoured

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[381] International Monetary Fund IMF, Global Trade Liberalization and Developing Countries, Available https://www.imf.org/external/np/exr/ib/2001/110801.htm Accessed (29 April 2019)

[382]WTO Nigeria Ratifies the Trade Facilitation Agreement Available https://www.wto.org/english/news_e/news17_e/fac_20jan17_e.htm Accessed (06 May 2019)

[383]The Nations, What Nigeria Stands To Gain From the WTO, availablehttps://thenationonlineng.net/what-nigeria-stands-to-gain-from-wto/ Accessed (06 May 2019)

developed countries, which had established a trading system rather than developing countries and LDCs, and its policies have increased the poverty and inequality ratio[384]. Since the WTO is a rule-based organization founded on negotiations (all-inclusive principal rule), it would seem plausible to suggest that developing countries may not have adequate negotiating skills to obtain agreement favourable to their national interest, which appears defensive rather than offensive. Developing countries tend to accept most conditions offered in the negotiating table instead of picking and choosing. Developed countries, have cutting-edge negotiators for every agreement ratified by their government and negotiate as a Bloc rather than individual member countries.

Nigeria is a member of the Africa Union (AU)[385], formerly the Organisation of African Unity (OAU)[386]. It was established based on the existing legal and institutional framework, with the sole objective of ensuring unity amongst African nations, defence of its sovereignty, political and economic integration to guarantee free trade amongst African states. Also, included in its objectives is that it provides for International corporations to promote sustainable development and harmonize regional economic policies to increase the living standard of all Africans[387]. The AU has endorsed different health initiatives during the HIV crisis, on peacekeeping from regional conflicts in states like Libya, Mali, Congo, Sudan, and Somali war. It can be said that the AU is a

[384]Andrew K Rose.' Do WTO Members have more Liberal trade Policy' 2004 Vol 63 Issue2: Journal of International Economics 209 The notion of free trade, liberalization championed by the WTO has not been measured to check if its policies favour other developing countries. However, she proposed that liberalization can be measured under the following heading firstly Openness (e.g., the ratio of trade or imports to GDP), 2. Trade flows adjusted for country-characteristics (outcome-based), 3. Tariffs. 4. Non-tariff barriers 5. Informal or qualitative measures, 6 Measures based on price outcomes

[385] Konstantinos D Magliveras, and Gino J. Naldi' The African Union—A New Dawn for Africa?' (2002) Vol 51, Issue 2: International & Comparative Law Quarterly, 415.
After a meeting by the head of states of African countries, the AU is created to establish a body solely for Africans called the African Union on 26 May 2006. With the sole responsibility of ensuring a legal and institutional framework for economic integration, military might, social and cultural integration amongst African states.

[386]Colin Legum, 'The Organisation of African Unity-Success or Failure' (1975*)* Vol 51, issue 2, International Affairs (Royal Institute of International Affairs: PP 208-.

[387]African Union, AU in a Nutshell, Available https://au.int/en/au-nutshel Accessed (27 May 2019)

true testament to cooperation amongst African nations. One would wonder if AU's stated objectives can be achieved given the peculiar circumstance in Africa. The competence of AU can be compared to the likes of the European Union (EU), can AU deliver more for Africa like the EU is doing for Europe. Okhonmina highlights the importance of regional hegemony, linking it to regional power with significant influence on regional subjects for which the AU ought to be, to effectively deal with rapidly changing global issues[388].

Some issues have been identified that could potentially inhibit the success of AU. For instance, the AU is structurally incompetent in its operation due to the poverty ratio in Africa. The AU lacks a concise administrative capability to run the organization's activities and ideology to fulfil its stated objectives, so it can be said to be structural inadequate even though this argument is said to be speculative. Nevertheless, it is pragmatic in the way AU has handled issues. For example, one of its objectives is the free movement of people and goods. However, actualizing this objective is marred by unending corruption and a lack of cooperation amongst African states.

In West Africa, Nigeria is a founding member of the Economic Community of West African States (ECOWAS) [389] and has championed this organization's cause over the years for the harmonization of trade, finance, and investment amongst the 16 member nations of ECOWAS. Nigeria has actively participated in many negotiations. One such agreement entered into force in 2017 is the negotiation of the Continental Free Trade

[388] Stephen Okhonmina, 'The African Union: Pan-Africanist aspirations and the challenge of African Unity' (2009) Vol3, Issue 4 The Journal of Pan African Studies PP 85.

[389] The Economic Community of West African States (ECOWAS) Available https://www.ecowas.int/ecowas-law/treaties/ Accessed (15 May 2019) is a multilateral agreement signed by the member states that made up the Economic Community of West African States. 16 member states signed the first agreement in 1975 in Lagos, Nigeria, and a revised treaty was signed in 1993 in Cotonou, Benin Republic in July 1993 by the heads of states and government of West African countries, some of the countries include Nigeria, Ghana, Mali, Niger, Senegal, Serra Leone, Benin, Togo, Cape Verde Cameroon, and Gambia ETC.

Area (CFTA) under the African union free trade area for preferential trade access[390]. Article 3 of ECOWAS *provides for "the removal, between the Member States, of obstacles to the free movement of persons, goods, services, and capital, and to the right of residence and establishment"* [391].

ECOWAS guarantees a regional economic corporation and integration amongst West African states. Removing any impediment to trade promotes trade liberalization and the total removal of customs duties amongst member states. On the other hand, free movement has contributed to the surge of counterfeit, even though it is meant to transit original products. Furthermore, the essence of being a part of an international and local trade organization is to strengthen trade bonds, but with a negative turnout such as counterfeit, it is impossible to reconcile the positive objective of partaking in this organization, thus defeating the theoretical standpoint for the association.

4.2. 5 Economic Viewpoint

Nigeria's economy was known to be viable after independence with the per capita income in 1960- 1970 estimated to be around US$1,113 up until US$1,084 in 2000. However, recent figures show that Nigeria's economy and currency are among the world's 15 most impoverished nations [392]. Despite this, Nigeria is not classified as a Least Develop Country (LDC) but a developing Country. Nigeria's economy facilitates integration and increased productivity supported by a viable service sector. The most enormous contribution to Nigeria's economy is from its natural resources, mostly from

[390] WTO summary, WT/TPR/S/356 • Nigeria Availablehttps://www.wto.org/english/tratop_e/tpr_e/s356_sum_e.pdf Access (04 May 2019)
[391] ECOWAS Revised Treaty Available http://www.ecowas.int/wp-content/uploads/2015/01/Revised-treaty.pdf Accessed (15 May 201
[392] Xavier Sala-i-Martin and Arvin Subramanian 'Addressing the natural resource curse: An illustration from Nigeria,' 2013 Vol.22 issue 4 Journal of African Economies PP 570

crude oil exportation. As of 2018, Nigeria produced around 2.16 million barrels per day[393] of petroleum. The sale of Oil and gas production is the backbone of Nigeria's economy, and it has greatly benefitted the country. It accounts for 70% of the total government revenue[394].

Nonetheless, oil production's negative impact led to environmental degradation and social deprivation of economic welfare in oil-producing communities[395]. Aside from the ecological and humanitarian effects of oil production, Nigeria has witnessed a steady decline in its foreign reserve due to its persistent deterioration in global oil prices. For instance, the Nigerian foreign reserve as of 2008 is estimated to be around $53.6 billion, but by 2016 it dropped to $24.74 billion, which has weakened the naira's value against other currencies less dependent on petroleum. Nigeria inflation rate in 2016 is estimated to be 17.69% [396]. It is predicted that the inflation rate will increase in 2019 to around 13.5% for goods and services. According to the latest data obtained from the central bank of Nigeria (CBN), Nigeria's foreign exchange reserves now stand at $36.57 billion, having increased sharply from $33.42 billion as of April 29, 2020, which shows a gain of $3.15 billion in 33 days, the naira is still weak in comparison other non-oil dependent currencies.

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[393] Femi Asun, 'Nigeria Daily Oil Production Rises to 2.16 Million Barrel' Available https://punchng.com/nigerias-daily-oil-production-rises-to-2-16-million-barrels/ Punch Newspaper, October 2018 Accessed (February 3, 2019)

[394] Augustine Ikelegbe, 'The Economy of Conflict in the Oil Rich Niger Delta Region of Nigeria.' 2005 14.2 Nordic Journal of African Studies 208

[395] Gbadebo Olusegun Odularu, 'Crude oil and the Nigerian Economic Performance' *Oil and GasBusiness* (2008)https://www.researchgate.net/publication/228627073_Crude_Oil_and_the_Nigerian_Economic_Performance/citation/download

[396] Agya Adi Atabani and Friday Udo' The Impact of Oil Shock on Nigeria Economy: Asymmetry Effect Analysis." 2017, 6 (1) Journal of Social & Economic Statistics

60 http://search.ebscohost.com/login.aspx?direct=true&db=bth&AN=125409055&site=ehost-live

The fall of global oil prices has significantly affected the Nigerian economy due to over-reliance on petroleum[397]. The government has overlooked other key non-oil tradable revenue sources[398], such as agriculture, textile etc. Nigeria used to be heavily dependent on agriculture as its primary source of export, with products such as cocoa, palm oil and cotton before the advent of petroleum. However, farmers had fewer incentives or contributions from the government, and competitiveness towards agriculture is reduced. Neither were farmers willing to take advantage of new farming techniques after the oil boom. The passion for going into agriculture further declined with the mass emigration of potential labourers to the cities seeking white-collar jobs resulting in reduced labour availability[399]. Pinto has criticized government policies on agriculture for failing to provide adequate finance mechanisms for farmers, and neither is there any support system for training nor educating farmers on new farming techniques[400]. Overall, oil discovery is one of the most significant problems for the non-oil tradable sector's fundamental growth in Nigeria.

The steady decline in the rate of production is another major issue affecting Nigeria's economy. Production is linked to human capital and a significant determinant of economic growth [401]if harnessed. Nigeria is known to have a large population to sustain increased output. Despite being rich in human capital, the Nigerian government has not harnessed this resource but depends on foreign goods and services. Ojo suggests Nigeria ought to be a developed country if it maximizes its

[397] Nigeria is the 6th largest producer of petroleum in the world and a member of OPEC

[398] Brian Pinto, 'Nigeria During and After the Oil Boom: A Policy Comparison with Indonesia, (1987) Vol 1, No 3 The World Bank Economic Review, Pg. 419. The comparison illustrates the setback witnessed in the agricultural sector in Nigeria after the discovery of Oil. The government withdrew all the subsidies and special assistance to farmers, failing to provide long term effect of weak oil prices.

[399] Sara J Scherr, 'Agriculture in an Export Boom Economy: Comparative Analysis of Policy and Performance in Indonesia, Mexico, and Nigeria." 1989 Vol 17, Issue 4, *World Development* 543.

[400] IBID

[401] Robert E Lucas Jr. 'On the Mechanics of Economic Development.' 1988 Vol 22. Issue 1 Journal of Monetary Economics,) pp 3

human and natural resources towards production instead of being a consumer-centred economy[402]. In broad terms, investing in human capital sustains economic growth and ensures long term returns for any country. The Nigerian economy is persistently deteriorating[403], coupled with risky government expenditure on infrastructures and development. The situation requires a broad institutional and economic transformation different from the deformed structural adjustment program [404]. The factors that are militating against the Nigerian economy's growth include growing government expenditure, a decrease in export, a rise in unemployment, an inadequate taxation system, lack of infrastructure, and corruption.

I. ***Increased Government Expenditure*** is a viable tool used to influence economic growth and national income[405]. However, Nurudeen and Usman think that the government's primary function is to provide security and public services such as infrastructures, education, health, power, and defence. It will stimulate economic growth. However, a different view proposed by some scholars believes that increased expenditure weakens the performance of an economy and subsequently leads to higher borrowing[406], high cost of production, reduced market access, break-in trade relationships, and will increase the value of goods and services. Another scholar, Wagner, posited *in the law of increasing*

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[402] Johnson Ojo Adelakun, "Human Capital Development and Economic Growth in Nigeria" (2011): 3.9 European Journal of Business and Management 29.
Developing human capital is a means of economic growth, for it turns economic surplus into investment. Nigeria should empower its people to achieve a desirable outcome economically. It can be attained by maintaining a high level of education and training in various fields, especially technology.
[403] Michael Watts, '*State, Oil, and agriculture in Nigeria*,' Institute of International Studies, (University of California, 1987) also in 1988 Volume 70, Issue 1*American Journal of Agricultural Economics*, Pages 215 https://doi.org/10.2307/1242009
[404] Oluremi Ogun, 'Real Exchange Rate Movements and Export Growth' Nigeria, 1960-1990.' Africa Portal (1998).
[405] Ibi S Ajayi, 'Macroeconomic Approach to External Debt The case of Nigeria." Africa Research Consortium
(1991). https://opendocs.ids.ac.uk/opendocs/bitstream/handle/20.500.12413/2074/No%208.pdf?sequence=1&isAllowed=y
[406] Abu Nurudeen and Abdullahi Usman, 'Government Expenditure and Economic Growth in Nigeria, 1970-2008: A Disaggregated Analysis,', (2010) Volume 4 Business and Economic Journal, 237

state activity that increasing state spending and activity inadvertently leads to economic and state development. Although the new function of government will be capital intensive, in the long run, it will stimulate economic productivity[407]. The provision of infrastructure increases business prospects, and the lack of it is a significant drawback to Nigeria's economic development. Compared with other developed countries, for instance, the UK, which invested £19.7 billion in 2017 on infrastructural development, it is a determinant for productivity, reducing the barrier to trade and open markets[408] in Nigeria. Consequently, Okoro recommends that to improve Nigeria's economic situation, the government ought to invest in infrastructures such as roads and electricity, for it increases productivity and employment, which will advance the economy[409]

II. ***A decrease in export***-Indeed, the issues articulated above on the state of Nigeria's economy is worrisome. However, the World Trade Organisation (WTO) trade liberalization policies guarantee the reduction of any restriction to trade and advocates for the free exchange of goods and services with moderate tariffs. Nigeria is a WTO member state; thus, it is entitled to reduce surcharges and duty charges for all imports and export. Nigeria is known to export mainly crude oil, petroleum gas, cocoa beans, and sugar to India, Spain, the United States of America, the Netherlands, etc. It is estimated that in 2017, Nigeria exported over $46.8 billion worth of goods, which is a sharp contrast from previous export figures with a deficit of -17% reduction[410], due to a decline in

[407] Ram Rati. 'Wagner's Hypothesis in Time-Series and Cross-Section Perspectives' (1987) vol. 69(2) *The Review of Economics and Statistics* 194
[408] The Office of National Statistics, Developing new Statistics of infrastructure: August 2018, Available http://www.ons.gov.uk Accessed (18 April 2019)
[409] A .S Okoro, "Government spending and economic growth in Nigeria (1980-2011)." (2013). Global Journal of Management And Business Research PP 15
[410] OEC, Nigeria Available https://atlas.media.mit.edu/en/profile/country/nga/ Accessed (19 April 2019)

oil prices after the global financial crisis [411]which accounts for 90% of Nigeria export. Unlike in the 1960s, Nigeria exported mainly agricultural products such as cocoa, palm oil, nuts. This sector was neglected after the discovery of crude oil. Neither did the government provide an incentive to farmers nor stimulate farming inputs, thus reducing potential yield[412]. Another issue highlighted for the fall of the agricultural sector in Nigeria is the negative influence of liberalization. Global change in agricultural policies creates unfair competition, an increase in farm products, protectionism, and unfavourable institutional policies, which limit the final output.

III. ***Inadequate taxation system***- Taxation is the live wire of every country; its effect is so significant that without taxation, state expansion is impossible. The revenue accrued from tax is used for security and infrastructural development. States have developed effective structures supported by binding rules to collect and generate income used to improve the economy. For example, tax in the UK is the largest government revenue source with a functioning decentralized system of collection at national and local levels. Although every tax collected is supported by formal legislation of government in Nigeria, the taxation system is flawed from uneven data, ineffective tax administration, regulatory challenges, the difficulty of tax laws, and the multiplicity of tax[413], and corruption[414]. Nigeria

[411] The financial crisis first started in the USA in 2007, from the sub-prime mortgage market to a global banking crisis due to excessive risk taken by banks resulting in a massive bailout to prevent the collapse of financial institutions

[412]Nahanga Verter N., and Vera. Bečvářová "Analysis of Some drivers of Cocoa Export in Nigeria in the era of Trade Liberalization" *Agris on-line Papers in Economics and Informatics* 6.665-2016-45040 (2014): 208

[413]Micah, and others' Tax system in Nigeria–challenges and the way forward' (2012) 3.5*Research Journal of Finance and Accounting*): 9 Solutions proposed to tackle these problems in the administration of tax in Nigeria includes tax education, the public needs to be educated on the importance of paying taxes and the right form of payment. Equally, the tax policy should be modified in simple terms to ensure ease of payment and fairness.

[414] Adeleke Salami. 'Taxation, Revenue Allocation, and Fiscal Federalism in Nigeria: Issues, Challenges, and Policy Options.' (2011) 56189. *Economic Annals* 27

is still plagued by persistent tax issues even after various policy change, introduced to ease the tax system, including the e-payment system[415]. Okoye and Ezejiofor propose the following recommendation: the re-organization of the tax structure, modification of outdated rules, policies, and strict sanctions for failure to pay tax[416]. Moreover, if these recommendations are adopted, they will reduce over-reliance on crude oil to run the country's affairs.

IV. ***Unemployment***- Unemployment is a significant problem in Nigeria. It is estimated by the Nigerian Bureau of Statistics (NBS) that over 23.10% [417]of Nigerians are unemployed, i.e., people who have no job compared to the labour force[418]. Unemployment is so pervasive that it is challenging to tackle at the moment. Nigeria is endowed with human resources, but unemployment undermines the growth of industries/economic growth in Nigeria. With over 18 million people without a job, this suggests that 1 in every five youth is unemployed. According to Okafor, despite the large turnout of graduates, the street of Nigeria is littered with unemployed youth seeking employment, which can lead to a hostile environment and socioeconomic problems in the country[419]. There seems to be a correlation between unemployment, poverty, and criminal actions, combined with the fact that nearly 80% of the 180 million people live on less than 2 dollars a day[420]. The zeal

[415] Kingsley N. Ashibogwu and Kayode. O. Bankole 'Comparative Study of Nigeria and the United Kingdom Tax System,' (2018) Vol 5, No6 International Journal of Research in Business and Social studies and Management, pp31
[416] Pius VC Okoye, and Raymond Ezejiofor' The impact of e-taxation on revenue generation in Enugu, Nigeria' (2014): 2.2 International of Advanced Research 449
[417] Nigeria Bureau of statistic available https://www.nigerianstat.gov.ng/ Accessed (27 April 2019)
[418] Trade and Economics. Nigeria Unemployment rate,
Available https://tradingeconomics.com/nigeria/unemployment-rate accessed (27 April 2019)
[419] Emeka Emmanuel Okafor. 'Youth Unemployment and Implications for Stability of Democracy in Nigeria' (2011) 13.1 Journal of sustainable development *in Africa*: 35
[420] Punch newspaper, Available https://punchng.com/152-million-nigerians-live-on-less-than-2day-afdb/ accessed (27 April 20

to make money through other means will be on the increase, including crime. What exacerbates the situation is that the few employed people are underemployed, impacting the general output or work ethics. Having looked at the challenges restricting economic and social growth in Nigeria, it is worth noting that Nigerians' problem is burdensome. Practically, all the sectors from health, education, legal, developmental needs reform to increase the country's growth level.

4.3 Introduction to Nigerian Legal system

As noted above, Nigeria is a former British colony[421] , and by legal transplant, it has adopted the British legal system which includes the British common law, doctrine of equity and statute of general application along with its customary law which is not repugnant to natural justice[422]. This is provided for in "Section 45 (1) of the Interpretation Act which provides among other things that, the common *law of England and the doctrines of equity and the statutes of general application which were in force in England on 1 January 1900 are applicable in Nigeria, only in so far as local jurisdiction and circumstances shall permit"*[423] . *This provision explicitly stipulates that the English legal system will be operative in Nigeria as it pertains to any legal issues without consultation or legislation from Nigeria houses of parliament*.

British law was not necessarily welcomed by the ethnic groups that came to constitute Nigeria. Instead, acceptance was at the point of the sword with Nigeria accepting British rule and its laws on account of Britain's military might. It is quite understated that the colonized state assimilated the legal system of its oppressors for fear of

[421] Emmanuel Okonkwo. 'An Appraisal of Nigerian Legal System in the Light of Savigny's Philosophy of Law.' (2014) 1.9 International Journal of Research 371.
[422] Alan Cuthbert Burns, *History of Nigeria*, (George Allen and Unwin Limited, London, 1929).
[423] Derek Asiedu-Akrofi, 'Judicial Recognition and Adoption of Customary Law in Nigeria' 1989 vol. 37, no. 3, *The American Journal of Comparative Law*, pp. 571–*JSTOR*, www.jstor.org/stable/840092

prosecution (British colonial system), and in the words of Gower, ' *English law was applied without consideration of its suitability to local conditions* [424]. Colonial rule in Nigeria used intimidation, threat, infiltration, and treaty protection to ensure the occupation of territory without regard for the people's existing customs and traditions. Okeke suggests that international law was used as an instrument of intimidation to enhance Nigeria's colonial subjugation [425]. Notwithstanding these arguments on colonialism, its merit shaped a structured legal system in Nigeria irrespective of its source.

Source of Nigerian Law-The constitution contains the fundamental law of any country. The rules, provisions, and policies in the Constitution are supreme over any law. All laws must be compatible with the provisions contained in the Constitution. Section 1(1) of the 1999 constitution of Nigeria provides that "*this Constitution and its provisions shall have binding force on all authorities and persons throughout the Federal Republic of Nigeria."*[426] In addition to this, Section 1(3) states that "*if any other law is inconsistent with the provisions of this Constitution, the constitution shall prevail and that other law shall to the extent of the inconsistency be void*[427]. This provision solidifies the Constitution's supremacy and renders any other law inconsistent except that which is provided for in the Constitution. The Nigerian Constitution's preamble essentially promotes good governance and the welfare of all persons in Nigeria under

[424] Gower, Laurence Cecil Bartlett. *Independent Africa: The Challenge to the Legal Profession*. (Cambridge, Mass.: Harvard University Press, 19670.
[425] Christian N. Okeke' International Law in the Nigerian Legal System' (1996) 27, California Western International Law Journal 311
[426] The 1999 Constitution of the Federal Republic of Nigeria , Section 1(1) Availablehttps://publicofficialsfinancialdisclosure.worldbank.org/sites/fdl/files/assets/law-library-files/Nigeria_Constitution_1999_en.pdf Accessed (29 May 2019)
[427] The 1999 Constitution of the Federal Republic of Nigeria , Section 1(3) Availablehttps://publicofficialsfinancialdisclosure.worldbank.org/sites/fdl/files/assets/law-library-files/Nigeria_Constitution_1999_en.pdf Accessed (29 May 2019)

the principle of equity and justice. The next source of law is statutory law; under the provisions of the 1999 constitution in section 4(2)*,' The National Assembly shall have the power to make laws for the peace, order and good government of the Federation or any part thereof* ". It constitutes a body of law enacted by the legislature's express will as a binding legal order such as decrees and edits[428].

Customary law- Apart from the common law and statutory law, there is the established law and indigenous legal system binding and accepted by a particular group of people to regulate its daily activity. It must not be repugnant to natural justice, equity, and good conscience nor incompatible directly or by implication with any written law in force at that time[429]. This provision is otherwise known as the repugnancy doctrine. Different scholars have debated the rationale behind this doctrine. While some scholars perceive it as a form of the statute of limitations [430], others view it as a prerequisite for customary law recognition[431], in order words. The different meanings attributed to the repugnancy doctrine are superficial, and it does not affect the court's use and recognition. Hence, a country's legal system determines if the rule of law is effective or undermined in the resolution of a dispute, managing contractual rights, protection of public goods, and policies put forward before it[432]. Moreover, the Nigerian legal system's efficacy will be tested against the pervasiveness of counterfeit pharmaceuticals to determine if the rule of law is operational in tackling counterfeit drugs.

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[428] Charles Mwalimu, 'The Nigerian legal System'*:* 2005 Vol. 1. *Public law*.
[429] Derek Asiedu-Akrofi, 'Judicial Recognition and Adoption of Customary Law in Nigeria' 1989. vol. 37, no. 3, *The American Journal of Comparative Law*, pp. 571–593. *JSTOR*, www.jstor.org/stable/840092
[430] Benjamin Obi Nwabueze, *The Machinery of Justice in Nigeria* (No.8, Butterworth, 1963)
[431] Onyeka Igwe, 'Repugnancy Test and Customary Criminal Law in Nigeria: A Time for Re-Assessing Content and Relevance.' *Available at SSRN 2528497* (2014)
[432] Stephen Knack, and Philip Keefer's Institutions and economic performance: cross-country tests using Alternative Institutional Measures." (1995) Vol 7. No 3 *Economics & Politics* pp. 207

4.4 Nigeria Intellectual Property Model

It is pertinent to examine the intellectual property framework in Nigeria for IP is the bedrock of human welfare[433]. Broadly speaking, it is paramount to harness and regulate this newfound sphere's economic benefit within viable legal parlance for the actual value of IP is strategic to growth and increased revenue of states. This is particularly important as counterfeit drugs fall within the patent law of states. Therefore, it is essential to study the IP history, laws, rules, policy operating in Nigeria as well as its limitation. Other aspects of assessment include its contractual management rights, and the protection of public goods, which is intricately related to counterfeit drugs.

Historically, the national laws governing the protection of IPR in Nigeria is derived from its colonial past and modelled per the British IP regime. The IP system did not exist in Nigeria before the advent of colonialism. To assert British control over its colony, the colonial office, in a bid to maintain order and protect people and property, adopted the indirect rule system with the colonial masters delegating power to traditional rulers to act on its behalf [434]still maintaining sole authority. Given this situation, the English statute of 1900 had both positive and negative outcomes[435] in its colonies.

[433] Christopher M Kalanje, 'Role of intellectual property in innovation and new product development.' *World Intellectual Property Organization* (2006) The true value of the patent to small scale industries is strategic to growth, increased revenue

[434] Nigeria: History, Commonwealth, Available, http://thecommonwealth.org/our-member-countries/nigeria/history Accessed (02 September 2019)

[435] Ogba Chidinma Onwuchekwa' Archiving in Nigeria: Relevance for Legal Education' (2017) Vol9 Issue 2 International Journal of Library and Information Science PP 7

Historical evidence substantiates that around 1861, Britain annexed Lagos' colony; it introduced its patent law applicable in England through the patent proclamation ordinance No. 27 of 1900 to north and southern Nigeria. Nigeria repelled the 1900 patent ordinance in 1916 and further amended it by the new patent ordinance No. 6 of 1925. It had its limitations, such as obstruction of local innovation and research, cumbersome registration requirement for the indigenous patent, and little recognition in the UK[436]. "*Yankey also affirms this position that the introduction of the patent administrative institution was "never meant to encourage either inventive indigenous activity, local research, and development, innovation or to accomplish an effective transfer of technology. Instead, it works towards protecting property rights in machinery technology relevant to the exploitation of gold and other mineral and human resources in the Colonies"[437].*

Although the British IP system is unique, it is deemed inadequate to meet Nigeria's unstructured legal system, thus integrating the British IP rule proved rather cumbersome for a young state. Even at that, the IP structure operative in Nigeria is outdated, for example, the current patent and design act of 1971 has not been reviewed or amended to bring it in harmony with contemporary IP improvement neither is there an established administrative mechanism for IP to be fully operational in Nigeria. Instead, it is saddled with corrupt practices such as counterfeit, piracy, and ineffective legal tool. Therefore, the wholesome adoption of an established IP system undermines the developmental trajectory of IP in Nigeria. It needs to abolish the part

[436]Shafiu Adamu Yauri, The Patent system in Nigeria' (2012) Vol 34, Issue 3 World Patent Information 213

[437]George M Sikoyo, Elvin Nyukuri, and Judi W. Wakhungu' Intellectual Property Protection in Africa Status of Laws, Research and Policy Analysis in Ghana, Kenya, Nigeria, South Africa, and Uganda' (2006) Africa Portal

of its rigid patent system to bring it in line with the modern IP system, and have a Nigerian patent system, which is unique to Nigeria circumstances.

Another issue with the Nigerian IP model is the inconsistency in the definition of counterfeit pharmaceuticals. These conflicting definitions have opened a wide array of terminologies and definitions such as substandard, falsified, piracy, fake, spurious and counterfeit drugs. These terms are interconnected but have different connotations, however, if a unified definition is accepted, this will positively impact the prevalence of counterfeit drugs. Nigerian IP model ought to address the legal and institutional inconsistency in its IP Laws. If it remains unresolved proffering solutions to counterfeit will prove unattainable.

Another issue is the administrative part of IP in Nigeria. It is grossly inefficient to the extent that the trademarks, patent, and designs registry operated a manual recording system until recently when an electronic filling platform [438]created with a commitment to delivering prompt, excellent, and consistent services in the area of modern technology and innovation consistent with best practices obtained globally. Upon completion and verification of novelty, a certificate is issued but territorially limited to Nigeria. But

Nwabueze thinks that patent and trademark protection should be subject to different legal regimes. For instance, Cameroon, Chad, Niger, and Benin are members of Organisation Africaine de la propriété Intellectuelle (OAPI), an African IP organization for the protection of IP in Francophone countries [439]. However, its protection

[438] Trademark, patent and design registry commercial law Department
Available http://www.iponigeria.com/#/
Accessed (01 September 2019)

[439] Caroline Nwabueze, 'Challenges of Transnational Trademark Law Practice: The Case of Nigerian Companies' (2015) 45.1, Brands in the OAPI States." *Revue générale de Droit* 321.

supersedes patent and trademark matters in Nigeria, explaining the importance of joining a regional IP organization.

4.4.1 The Nigerian Patent Act and Design Act of 1970

The legal and institutional mechanism for the regulation and enforcement of IP in Nigeria falls under these acts, but for the sake of clarity, only the patent and design act and the copyright act will be examined in detail.

Copyright Act (as amended), Cap. C28, Laws of the Federation of Nigeria 2004

Nigerian copyright act is the primary legislation for the regulation of copyright in Nigeria. Part 1, section 1, provides literary work, musical work[440], artistic work, cinematography, and sound recording is eligible for protection under the act. The Nigerian copyright-based industry is estimated to be worth around $7.5 Billion. However, the accruing potential of this industry is underutilized due to widespread piracy and copyright infringement. There is no viable enforcement mechanism or effective sanctions to deter the problems associated with piracy. Many issues have militated against the growth of copyright in Nigeria. For example, improved technology allowed rampant digital knowledge theft, which is against the Nigerian copyright act. The act guarantees protection for copyright owners to benefit from their inventive steps following the TRIPS agreement provision.

To ensure clarity, in the fight against piracy and infringement, extrajudicial measures ought to be utilized, such as social, judicial, and technological approaches as judicial measures have proved inadequate considering their magnitude, especially in developing countries. Similarly, Lemley and Reese suggest that the issue of

[440] Includes books, novels, stories, plays, stage direction, letters, reports, essays, articles, histories, and films.

infringement should not solely be on infringers but equally on third parties aiding and abetting the work of digital infringers for indirect liability can eradicate the entire network of infringers[441].

The courts hardly recognize an indirect liability, but under the doctrine of vicarious liability (holding someone in authority accountable for the actions of another) and contributory negligence, a third party can be judicially liable for infringement. However, the court's interpretation of these provisions is a restrictive approach[442]. Copyright is from creative knowledge; it is intangible; it is a special right, worthy of protection by the law to reward originality and imagination. Furthermore, in *Adenuga V. Ilesanmi press and sons Ltd*[443], the court held that copyright is the right exclusively restricted to the creator of the copyright[444]. The law ought to be effective in protecting copyright as the impact of piracy on any state's economy can deter creativity and inventive steps.

4.4.2 The Patent Registry System

The need for a reliable system to regulate, protect, and guarantee the efficient utilization of the rights accrued to the owner of an inventive step falls within the scope of an operational patent registry. To an economist, innovators can be rewarded in two ways. Firstly, by allocating IP rights (monopoly) to the invention, and secondly by

[441] Mark A Lemley & R Anthony Reese, 'Reducing Digital Copyright Infringement Without Restricting Innovation,' (2003) Vol 56
Stan Law Review pp. 1345 Prosecuting third-party infringers has its unique advantages, for it can discourage illegal trading of digital materials. Another solution to deter infringement is taxation, making the infringers pay tax towards the stolen digital content.
[442] Douglas Lichman & Williams Landes, 'Indirect Liability for Copyright Infringement: An Economic Perspective,' (2003) Vol 16 Number 2, Harvard Journal of Law and Technology, PP395
[443] 5bNigerian Weekly Law Report (NWLR) part 189, page 82
[444] Mary Nwogu, 'Copyright Law and the Menace of piracy in Nigeria,' (2015) Vol 34 Journal of law, policy and Globalisation pp. 2224

outright ownership by the state, otherwise known as compulsory license [445]. However, how do we determine how much reward should be given, and what rubric should be used to resolve it? A competent patent registry can only determine this. The patent and design act of 1970 regulates patent registration and other ancillary matters.

In Nigeria, the patent and design registry under the federal ministry of trade and commerce administers the protection of patents, trademarks, and designs to ensure consistent delivery and registration of modern innovation consistent with the best practices across the globe[446]. The patent registry primarily protects ideas. It begs the question: What idea can be registered since not all ideas are valuable or patentable. In Jonson's words, ideas are necessary elements of thought that can either be visual, concrete, or abstract[447]. The idea is free and unique but must be backed up by manifestation or methodology to warrant legal protection. According to the Nigerian patent registry, only a statutory inventor has the legal right to claim patent protection even if he is neither the true inventor nor the first to apply, but as far as there is sufficient proof to establish that he is the statutory inventor[448] right will be issued.

The patent and design act provided the conditions needed for the registration of a patent in Nigeria's patent registry. This act determines patentable ideas, qualification, prohibition, exception, right accorded, timeline, and protection type. The following essential conditions must be met to be eligible for patent protection:

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[445]Steven Shavell & Tanguy Van Ypersele,' Reward Versus Intellectual Property Right,' (2001), Vol 42 Issue 2 The Journal of Law and Economics PP 525

[446]Nigerian Patent Registry, Available http://www.iponigeria.com/#/About Accessed (05 October 2019)

[447] Ben Jonson. 'Design Ideation: The Conceptual Sketch in the Digital Age.' (2005) Vol 26. issue 6 *Design Studies* pp 613

[448] Shafiu Adamu Yauri' The Patent System in Nigeria' Vol 34. issue 3 (2012): World Patent Information PP 213

Qualification- To qualify for registration, a prospective patent application must meet the following conditions.

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 is new, results from inventive activity and capable of industrial application.

(2) For subsection (1) of this section— (a) an invention is new if it does not form part of state of the art; (b) an invention results from an inventive activity if it does not follow from state of the art, either as to the method, the application, the combination of methods, or the product it concerns or the industrial result it produces; and (c) an invention is capable of industrial application if it can be manufactured or used in any industry, including agriculture. (3) In subsection (2) of this section, "the art" means the art or field of knowledge to which an invention relates, and "state of the art" means everything concerning that art or field of knowledge which has been made available to the public.

Prohibition-The Nigerian patent and design act prohibits the registration of Patents for the following.

(4) Patents cannot be obtained in respect of- (a) plant or animal varieties, or essentially biological processes for the production of plants or animals (other than microbiological processes and their products); or (b) inventions the publication or exploitation of which would be contrary to public order or morality (for this paragraph that the exploitation of an invention is not contrary to public order or morality merely because its exploitation is prohibited by law) (5) Principles and discoveries of a scientific nature are not inventions for this Act.

A right accorded- after fulfilling the requirement, this section provides for the right specified to a prospective applicant.

Right to patent (l) Subject to this section, the right to a patent in respect of an invention is vested in the statutory inventor, that is to say, the person who, whether or not he is the true inventor, is the first to file, or validly to claim a foreign priority for, a patent application in respect of the invention. (2) The true inventor is entitled to be named in the patent, whether he is also the statutory inventor, and the entitlement in question shall not be modifiable by contract.

Prohibition –once the right is conferred, a patentee can do the following according to section 6 of the patent and design act.

(1) A patent confers upon the patentee the right to preclude any other person from doing any of the following acts---(a) where the patent is granted in respect of a product, the Act of making, importing, selling or using the product, or stocking it for sale or use; and (b) The patent has been granted in respect of a process, the Act of applying or the process of doing, in respect of a product obtained directly through the process, any other acts mentioned in paragraph (a) of this subsection.

Lapse of patent -A patent will be nullified where the description of the invention does not conform to the provision of the law

Duration and lapse of the patent (1) Subject to this Act; a patent shall expire at the end of the twentieth year from the date of the filing of the relevant patent application.

(2) A patent shall lapse if the prescribed annual fees are not paid in respect of it: Provided that- (a) a period of grace of six months shall be allowed for the payment of the fees; and (b) if the fees and any prescribed surcharge are paid within that period, the patent shall continue as if the fees had been duly paid. (3) The expiration or lapse of a patent shall be registered and notified.

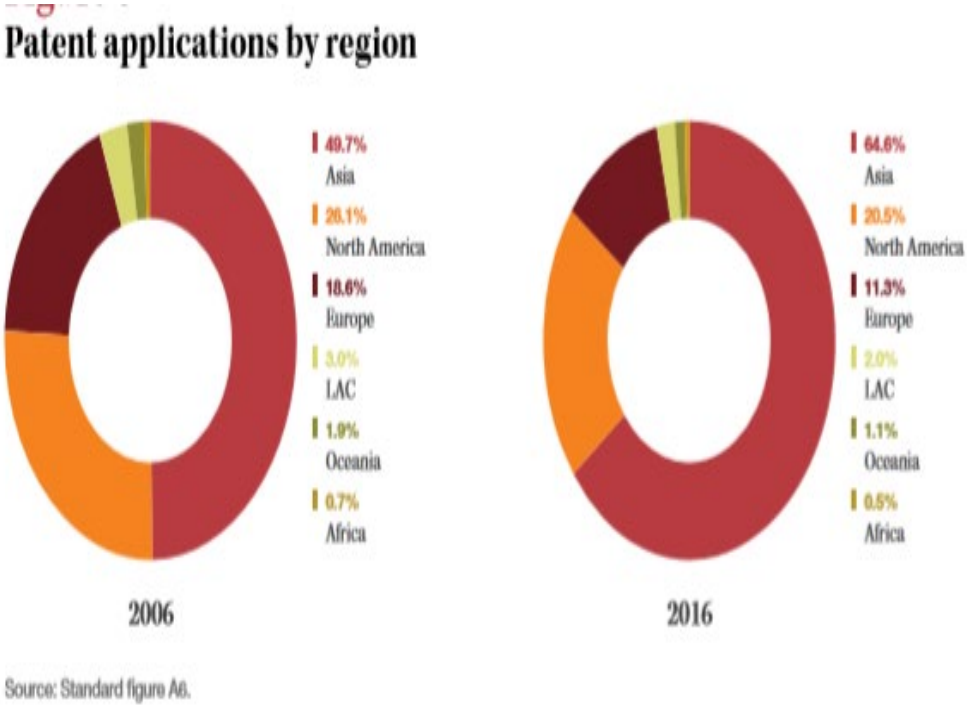

Figure 3 patent application by region

Source WIPO[449]

Following the review, the Nigerian patent registry mandated the requirement for the grant of patent. A patent is a viable tool for economic growth, and it ought to be utilized in full capacity. Nigerians ought to be enlightening on the benefits the law provides to inventions in all fields of technology. It appears to be underutilized. For example, WIPO indicators show over 3 million patent applications were submitted globally, with China leading with over 236,600 applications, 98% of global applications, followed by the USA with 16, 200 addition filling while the rest of the world accounted for 0.2%. This statistic shows that there has been a gradual decrease in filing for a patent in

[449] WIPO Indicator , Available https://www.wipo.int/edocs/pubdocs/en/wipo_pub_941_2017-chapter2.pdf Accessed (12 October 2019)

developing countries, which limits growth and may have allowed counterfeit to exist in a bid to evade the law.

4.5 National Agency for Food and Drug Control-NAFDAC

During the pre-colonial period, Nigeria rarely had issues with counterfeit drugs, but the drug problem escalated in the 80s and 90s when "briefcase importers" [450] of drugs and the influx of unregulated pharmaceutical imported by indigenous and foreign firms saturated the local market with counterfeit drugs causing devastating health problems, increased morbidity, drug resistance and subsequently death. Economically, the influx of unregulated medicines is associated with economic globalization and free trade. Although the government heavily promotes domestic manufacturing of pharmaceuticals to ensure sustainable economic growth, it is yet to attain its full potential of producing affordable drugs, neither is there any incentive to make high-quality drugs. The gap created from the absence of genuine pharmaceuticals and the need for the establishment of a viable industry to regulate the production of pharmaceuticals resulted in the surge of counterfeit pharmaceuticals. One of the initiatives to curb the surge of counterfeit by the Nigerian government is the establishment of the National Agency for Food and Drug Administration and Control (NAFDAC) created by Law from the *NAFDAC ACT cap N.1 LFN 2004, Counterfeit and fake drugs and unwholesome processed food (miscellaneous provision) Act Cap*

[450]NAFDAC the 21st Annual National Conference of Association of Industrial Pharmacists of Nigeria (NAIP)held on 18 April 2018 at Kwara hotels, Ilorin, Kwara state Available https://www.nafdac.gov.ng/imperatives-for-national-drug-security/ Accessed (23 October 2019)

34LFN 2004[451]*, the food and drug Act Cap F 32 LFN*[452] *and the food drug and related Product (Registration) Act*[453]. NAFDAC's vision is to *safeguard public health,* complemented with a mission statement *to ensure that only the right quality drugs, food, and other regulated products manufactured, imported, distributed sold, and used in Nigeria*. The vision and mission statement summarises the purpose and goal of the agency. NAFDAC objective is to prohibit the sale and distribution of fake, banned, substandard or expired drugs. It is recognised as a global pacesetter in diligence, innovation, and a subsistent interdisciplinary organisation, an excellent case study for Africa's growth. Therefore, it is pertinent to examine the stated vision of NAFDAC for any variation.

The first line of the NAFDAC vision statement, the phrase "*safeguarding public health,"* is not specific neither does it provide a degree of flexibility to literarily interpret the meaning of public health protection. For instance, the term public health is not well specified. It could mean the quality of health, quality of life, preventing diseases, physical and mental health conditions and contrasting it with the US Food and Drug

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[451]Counterfeit and fake drugs and unwholesome processed food (miscellaneous provision) Act Cap C. 34LFN 2004 Available https://www.nafdac.gov.ng/wpcontent/uploads/Files/Resources/Regulations/NAFDAC_Acts/COUNTERFEIT-AND-FAKE-DRUGS-AND-UNWHOLESOME-PROCESSED-FOODS-Cap.-C.34.pdf Accessed (16 October 2019) Section 1 and 2 of this act prohibits the sale of any fake substandard pharmaceutical product and specified penalties ranging from N500,000 or imprisonment for a term of not less than five years or more than fifteen years. It also made provision for penalties for corporations by holding defaulting companies accountable for actions of members of the company and actions can be instituted in the federal high court.

[452] The food and drug Act Cap F 32 LFN Available https://www.nafdac.gov.ng/wp-content/uploads/Files/Resources/Regulations/NAFDAC_Acts/FOOD-AND-DRUGS-ACT.pdf Accessed (16 October 2019) This act prohibition the sale of certain food , drug and cosmetics that contains harmful substances that is against stipulated safety requirement

[453] Food, Drugs And Related Product (REGISTRATION, Etc) ACT Cap F.33 LFN 2004,Available https://www.nafdac.gov.ng/wp-content/uploads/Files/Resources/Regulations/NAFDAC_Acts/FOOD-DRUGS-AND-RELATED-PRODUCTS-REGISTRATION-ACT-Cap.F.33.pdf Accessed (16 October 2019) Relates to prohibits the manufacture of unregistered drugs and food production in Nigeria. Unless it is duly registered before any drug or food can be imported, exported, advertised, sold or distributed in Nigeria. However a sample of the food or drug clinically tested to ensure it meets the required standard provided by Law. When the agency is satisfied that all the required standards have been established, a certificate of registration is issued to show compliance.

Admiration (FDA) mission statement which seeks *to ensure the safety, efficacy and security of human and veterinary drug and national food supply*[454]. It is glaring that there is a clear delimitation of objective; it is specific, not vague.

Secondly, NAFDAC seeks to regulate the manufacture and import of drugs and food into the country. However, Akinyandenu careful observed that achieving this criterion by NAFDAC, means the placement of health inspectors at airports and seaports, but how practicable is this vision in tackling counterfeit (lack of funding/manpower). He suggests that local manufacturing should be encouraged with added incentives by the government. Instead, local manufacturers have less favourable conditions for the production of drugs. For instance, obtaining registration is cumbersome, starting with initial analysis, drug testing and safety requirement, which can take months to get registration[455]. In addition, the Law that created NAFDAC has not been reviewed since its formation like other similar organisations with the same mandate to bring it to conformity with modern standards acceptable standards.

Despite NAFDAC's best efforts to tackle counterfeit drugs, the problem seems unabated. Statistics from the National Agency for Food and Drug Administration and Control revealed that 70% of drugs sold in Nigeria are fake. That means 7 in 10 drugs sold are counterfeit. Recently, NAFDAC raided 5 locations in Nigeria (Abuja, Shagamu, Ogun, Kaduna and Gombe) and destroyed counterfeit drugs worth over #4.7million[456]. It is also reported that NAFDAC seized 80 truckloads of counterfeit medicines[457] during the same raid? Be that as it may, counterfeit drugs are

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[454] US food and drug Administration Available https://www.fda.gov/home Accessed (21 October 2019)
[455] Olusegun Akinyandenu, 'Counterfeit drugs in Nigeria: A Threat to Public Health.' (2013): 7.36 *African Journal of Pharmacy and Pharmacology* 2571.
[456] Leadership, Curbing incidence of fake drug in Nigeria Available https://leadership.ng/2019/07/29/curbing-incidences-of-fake-drugs-in-nigeria/ Accessed (21 October 2019)
[457] John Spink, Douglas C. Moyer, and Michael Rip, 'Addressing the risk of product fraud: a case study of the Nigerian Combating Counterfeiting and Sub-standard Medicines Initiatives' (2016): 4.2 Journal of Forensic Science & Criminology 1

responsible for nearly 450,000 preventable deaths from fake anti-malarial drugs taken by unsuspecting victims, making Nigeria one of the highest countries with the most counterfeit drug incidence. As such, Counterfeit is still a threat to global public health, and it undermines the whole system of drug regulation and control[458].

4.5.1 NAFDAC Securing Nigeria's Medicine Security

Life without health is unattainable as health is necessary to fulfil life. In recognition of this stated importance, the 1948 Universal Declaration of Human Right guaranteed the right to health for all people found in *Article 25 and read as follows that everyone has a right to a standard of living adequate for the health and well-being of himself and family which includes food, clothing, housing, and medical care*"[459] . Also, the World Health Organisation made a similar provision for the right to health. Its preamble states that "*the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being, without distinction of race, religion, political belief, economic or social condition.* It is an inclusive right that encompasses freedom, entitlement, good quality healthcare, and access to essential medicine[460].

[458]Kaliyaperumal Karunamoorthi. 'The Counterfeit Anti-Malarial is a Crime Against Humanity: A Systematic Review of the Scientific Evidence; 2014, 13 Malar Journal, 13:20910.1186/1475-2875-13-209. PMID: 24888370; PMCID: PMC4064812.

[459] Universal Declaration of human right, Available httpwww.un.org/en/universal-declaration-human-rights/ Accessed (22 October 2019Article 25 Right to health*, (1) Everyone has the right to a standard of living adequate for the health and well-being of himself and his family, including food, clothing, housing, and medical care and necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in the circumstances beyond his control*. This declaration was reached after the traumatic events of the 2nd world war, which created a need to safeguard human existence and foster international peace amongst conflicting nations. It resulted in the establishment of the United Nations in 1945 with 50 initial member states. To engrave this unity, a list containing human rights necessary for peaceful coexistence was devised and accepted by the UN General assembly and enshrined in the ratifying state constitution.

[460] World Health Organisation Right to Health, Factsheet No 31, Available https://www.ohchr.org/Documents/Publications/Factsheet31.pdf Accessed (22 October 2019)

Ratifying states to the World Health Organisation (WHO) made significant efforts by making health care a paramount concern, especially in developing countries like Nigeria. Remarkably, Nigeria's constitution affirms that the government must uphold the standards of social justice, equity, welfare, and human right to quality healthcare and develop and implement a national policy for controlling medicine. However, various setbacks ranging from lack of coordination, resources, adequate human resources, decaying infrastructures, bias resource distribution[461], and essential medicine have delayed the attainment of the standard mandated by the WHO. Sustainable healthcare seems unattainable even though the WHO identifies the importance of medicine by stating that the "*Lack of access to medicines is one of the most complex and disturbing problems that stand in the way of better health*' [462]' If there is no adequate medicine, life cannot be sustained. On this premise, the Nigerian government developed a series of initiatives and proposals to attain the best possible health care for its people, and one of such initiatives is the creation of NAFDAC.

NAFDAC's sole objective is the safety, security, and equitable provision of medicine to all. Adeyeye recently noted that the problems facing drugs are non-availability, which negatively compromises drug security. In his words, drug security is the standard " *medicines produced in facilities must meet the right standards and that the integrity of such medicines should not compromise stated rules and regulations, during its production and distribution along the supply chain from the manufacturers down to the consumers."* Therefore, if a drug standard is compromised, it will undermine medicine's effectiveness on an unsuspecting consumer. It is imperative to have a

[461] Menizibeya Osain. 'The Nigerian Health Care System: Need for Integrating Adequate Medical intelligence and surveillance systems.' (2011) Vol. 3, 4 Journal of Pharmacy & Bio Allied Sciences 4708doi:10.4103/0975-7406.90100

[462] WHO, Availablehttps://www.who.int/publications/10-year-review/chapter-medicines.pdf?ua=1 Accessed(22 October 2019)

significant national drug security policy that is sustainable and covers essential medicine access. For example, recently, the statehouse medical centre in Aso Rock recorded an incident of non –availability of drugs. If the presidency lacks essential drugs, what happens to other vulnerable Nigerians in rural areas. Cooperation is needed amongst stakeholders to establish a structure or network backed by strict legal sanctions.

4.6 Infringement and enforcement of IP under Nigerian Laws

This section aims to discuss the place of IP enforcement in Nigeria's legal system by examining some reported cases on IP violation and the attitude of the Nigerian court to ascertain if it meets the international standard required by local, regional and international law. The court plays a vital role in the interpretation and development of IP laws in Nigeria. It is undoubtedly significant in the current dynamics of IP practice and application. IP protection creates commercial value for ideas and innovative steps in all fields of technology. It is therefore paramount to protect IP, especially in this era of globalisation, which has integrated different economies[463]. IP is a contemporary issue in the emergent knowledge economy[464]. It is interesting to note that intellectual property laws in Nigeria present a pattern and shortcoming in the law from which it may be possible to highlight some discernible attributes or characteristics in the development of some aspects of the law.

[463] Eswar Prasad and others. 'Effects of Financial Globalisation on Developing Countries: Some Empirical Evidence.' (2003) Vol. 38, No. 41 Economic and Political Weekly, pp.4319-4330.
[464] Michael W Carrol. 'One for All: The Problem of Uniformity Cost in Intellectual Property Law' (2006) Vol 55 No 4 American University Law Review, pp.845-900.

Laws for the protection of IP is an exclusive right that excludes a 3rd party from exercising the right to IP without the express authorization of the right owner. This right is transposed into Nigeria's legal system from the English legal system. It forms the bedrock to bring actions against infringement of IP rights. However, despite the international development of IP and Nigeria's membership of the WTO-TRIPS agreement, IP is relatively an obscure issue of contention in the Nigerian courts: the case law is rare, and litigation is slow-paced, neither has there been any law reform or revision, all of which have considerably impacted the judicial trend of IPR. Until now, only the Federal high courts have exclusive jurisdiction to hear and determine disputes about the infringement of IP. The provision is found in Section 251(1) of the constitution of the Federal Republic of Nigeria which *states as follows ''Notwithstanding anything contained in this Constitution and in addition to such other jurisdiction as may be conferred upon it by an Act of the National Assembly, the Federal High Court shall have and exercise jurisdiction to the exclusion of any other court in civil causes and matters subsection.''*

(f) any Federal enactment relating to copyright, patent, designs, trademarks and passing-off, industrial designs and merchandise marks, business names, commercial and industrial monopolies, combines and trusts, standards of goods and commodities and industrial standards'[465]*'*

The provision of the section above shows that in respect to patents and any form of IP in Nigeria, jurisdiction lies only with the federal high court. As seen in *Arewa Textile Industries. V.Finetex Limited* (2003) [466], the court held that on the issue of jurisdiction, it is fundamental for the adjudicating court and it is crucial to determine the issue of

[465] Section 251(1)(F) Constitution of the Federal Republic of Nigeria 1999.1.
[466] *Arewa Textile Industries. V.Finetex Limited* (2003) 7 Nigerian Weekly Law Report.

jurisdiction in order not to waste the time of the court. The position of the court is similar, in the case of *Dyketrade Ltd. v. Omina (Nig.) Ltd*[467]. One of the issues submitted before the judge was that of jurisdiction. The Federal High Court is said to lack jurisdiction to entertain claims of unregistered trademark. To support the argument on competency, the appellant relied upon the case of *Madukolu v. Nkemdilim (1962)* [468]. The court held that under section 251, the Federal High Court is conferred with jurisdiction to hear and determine not only on matters stipulated in subsection (f) but other jurisdictions as may be conferred upon it by an Act of the National Assembly. Given this, in Nigeria, it is accepted legal practice to bring all IP related matters to the Federal High Court, or else the issue would not be resolved. This requirement may be cumbersome for IP litigants. This exclusivity of the Federal High court has not significantly helped to shift the frontiers of scientific and technological development such that it is difficult to assert the accuracy of the adjudicating system in Nigeria.

Similarly, the role of the Nigerian court is questioned in terms of the quality of adjudication required for the advancement of IP. The standards set by the court will determine protection. For instance, if a penalty meted out for infringement of IP is stiff, infringement will decrease. However, if infringement gains surpass, the penalty IP violation will surge. This is the typical situation of Nigeria as seen in the following cases, Barewa *Pharmaceutical Limited. v. The Federal Republic of Nigeria*[469]. This is the famous case of 'My Pikin' teething powder, which made over 111 children sick, three-quarters of whom have died. The mixture is believed to have been tainted with a high concentration of diethylene glycol, which is linked to poisoning cases. At the

[467] *Dyketrade Ltd. v. Omina (Nig.) Ltd* 43 NIPJD (SC 2000) 57/1995.
[468] *Madukolu v. Nkemdilim (1962) 2 NWLR.*
[469] Barewa Pharmaceutical Limited.v. The Federal Republic of Nigeria, (2019) LPELR-47385 (SC).

end of the trial, the court found the appellant and the two other accused persons guilty of the offence, and they were convicted accordingly. The appellant, being a company, was ordered to be wound up, with its assets forfeited to the Nigerian government while the two other convicts were each sentenced to seven years imprisonment, for which the sentences were ordered to run concurrently. On the other remaining counts, the accused persons were discharged and acquitted. This case is a typical example of how the Nigerian court has missed the opportunity to advance the jurisdiction of the court about matters of IP infringement. Adequate enforcement of IP will deter infringement. The approach of the Nigerian courts in respect to IP matters is unconstitutional, IP is as much a right as the right to tangible property. Although IP is an intangible right, infringement of this intangible right can be resolved in both civil and judicial Courts. Also, right holders should be allowed to bring IP matters to any court in Nigeria. The provision that restricts IP matters to just the Federal High Court in Nigeria should be declared null and void. To this end, IP rights holders should be given the means to get redress in any court in Nigeria, by so doing reduce infringement.

Conclusion

This chapter examined the Nigerian situation using historical evidence to demonstrate that Nigeria is a country with immense wealth both in human and natural resources. Nigeria, from its inception, was a British colony, and it adopts the English legal system. Its laws modelled the law existing in England, including Nigeria IP Law. Nigeria is a member of the WTO, AU, ECOWAS to increase trade and development, but the promised benefit from membership to these organizations negatively impacted trade in Nigeria, which can be attributed to the increase of counterfeit. To reduce the incidence of counterfeit pharmaceuticals, Nigeria, created NAFDAC. Although it has been relatively successful in tackling counterfeit, counterfeit pharmaceuticals is still on

the increase. It is, therefore, imperative to develop an overarching framework with specific objectives, which tally with the need to have affordable medicine and an effective facilitation mechanism that ensures even distribution and control of pharmaceuticals.

Chapter 5 Balancing TRIPS Standard against Nigeria Counterfeit Regulatory Efforts: A Critique

5.1 Introduction

'*The tremendous increase in IP application in recent years reflects the growing importance of technology and innovation in the global economy and our daily lives."* [470] Today's relevance of innovation or novelty is so essential that a complementary right is created to protect its advancement. It is a way of thinking outside the present; instead, it is a future based insight. Innovation compares past and future ideas to solve a future problem[471]. Innovation is linked to creativity. In Tienken's words, *creativity is new, unique and creates innovations in countries*'[472].Many innovations can only be protected by intellectual property to generate economic value with an established competitive advantage to guarantee commercial control and use. IP is reward-based; the reward is an incentive for creativity. It established the fact that IP is a unique value-adding creation,[473] which generates a legal right when the due process of registration and grant of according right is established. It creates an entitlement to creativity.

However, intellectual protection granted by a state is limited in scope as there is a delimitation between international and national intellectual protection. The first part will attempt to rectify this issue by examining the meaning of property supported by scholarly evidence advocating clarity in interpreting what a right to property means. Secondly, it is right to understand the nature of TRIPS protection and the strategy

[470] WIPO, Harnessing the Benefit of IP for Development Keynote Address by **Ambassador Amina C. Mohamed**, Cabinet Secretary of the Ministry of Sports, Culture and Heritage of the Republic of Kenya, Availablehttps://www.wipo.int/wipo_magazine/en/2019/03/article_0002.html Accessed (27 December 2019)

[471] Anneli Stenberg, 'What does Innovation mean – a Term Without a Clear Definition' Available https://www.diva-portal.org/smash/get/diva2:1064843/FULLTEXT01.pdf

[472] Christopher H. Tienken' International Comparisons of Innovation and Creativity' (2013), Vol 49 No 4 *Kappa Delta Pi Record*, PP 153

[473] Christopher M. Kalanje, 'Role of Intellectual Property in Innovation and New Product Development.' 2006, World *Intellectual Property Organization*

preferred for the utilization of this protection, especially in developing countries such as Nigeria, for if the protection authorized by TRIPS is established, any discrepancy in its application will be underlined and questioned in resolving Nigeria counterfeit drug problem.

5.2 The nature of Intellectual Protection

The subject of Intellectual property was unknown and mostly overlooked in the 1960s. Recently, it has gained widespread acceptance as a viable instrument for economic growth and development. States have come to recognize and see IP as a new form of 'resource' which can foster innovation, development and shape economic relations. An intellectual resource is an intangible right to a creative outcome in today's conditions, be it scientific, industrial, or any inventive step new to humankind; it is deemed a resource worthy of protection. Because of this, any unauthorized use of IP resources is tantamount to stealing a creator's legal authority over his goods. States approve legal protection on IP to safeguard against unauthorized use and to encourage new technological inventions, artistic expression, and creativity with the sole objective of preventing others from benefiting from the creativity of another. It promotes fair trading. With this authority, a right holder can bring actions in a civil or criminal proceeding to enforce IP rights.

Given the peculiar nature of intellectual property rights, two key issues need further clarification. These include:

- Understanding what delineates IP from other forms of property that ensure global recognition and protection
- Secondly, what is the nature of TRIP protection and how is TRIP's strategy integral for innovative growth in developing countries.

On the first issue, it is established that IP is a form of property protection granted by the national law of a state and governed within that state's exclusive jurisdiction. The law in that jurisdiction determines the time frame, limitation, minimum requirement, and usage of such rights [474]. However, *Lemley* thinks it is absurd to associate IP with real property (propertization)[475], especially in terms of its economic importance and profitability. With this noted association, the IP regime appears to be modelled around property laws even though both regimes are different. It will inevitably affect the balance of both paradigms.

Therefore, it may seem appropriate to adopt a utilitarian approach to delineate both regimes because it does not attempt to strike a balance between a right and the type of property; instead, it looks at the ordinary meaning of terms[476]. Given this argument, IP is a recognized right that is knowledge-based given to a private individual or party to control information accruing from the creative ability or outcome[477]. It is also quite clear that intellectual property right is territorial and is different from physical property. Following the idea established earlier, on delineating IP from the property, *Easterbrook* equated both regimes and concluded that inventive property is similar. For example, the invention framework improves with time, resulting in new and better products, which inadvertently means more financial gains. It is similar to developing a property to secure more profit. Another connection is the issue of

[474]Jonathan M W. Chu, 'When Property Does Not Mean Property: An Analysis of the Existence of International Intellectual Property' (2011) 39 International law Journal of Legal Info, 328

[475] Michael A. Carrier "Cabining intellectual property through a property paradigm. (2004), 54 *Duke Law Journal* 1. Over the years, the context of IP has been revolutionized to fit into the discourse of real property as such, narrowing its essence as an intangible right worthy of protection. Although using this context has limited IP expression, the unlimited duration and scope of the previous IP right resemble the unlimited duration and scope of property rather than the finite regime of protection that the creators proposed

[476] Mark A Lemley' Property, Intellectual Property, and Free Riding. (2004) 83, *Texas Law. Review,* 1031

[477] Harry Surden, 'Technological Cost as Law in Intellectual Property' (2013) 27, No 1 Harvard Journal of Law & Technology 135-202

monopoly. A patent or copyright entitles a right holder to control its output to the exclusion of all others. The IP rights holder has rights of exclusion, the same as the property rights holder[478]. Importantly, finding proves that IP and property rights are intricately connected, but this relationship's true nature needs clarification to contextualize IP correctly. IP pertains to the right to abstract ideas[479], so it is justifiable to suggest the establishment of a distinct theory to meet its peculiar needs.

Secondly, what is the nature of TRIP protection, and how is the strategy adopted by TRIP integral for innovative growth in developing countries.

To determine the principle of an agreement is tedious and can cause ambiguity in its interpretation. If a common approach is adopted, then the philosophical question on its nature might seem unanswered because the more abstract it is, the more difficult it will be to analyse [480]. However, without dissipating ambiguity, the existing principle cannot be disputed or probed, which is the case of the WTO-TRIPs agreement. The nature and purpose of TRIPS can only be understood within a broader context of the WTO agreement. The WTO agreement is all-encompassing and unique in all facets. However, scholars have argued that the WTO IP rules in developing countries are detrimental to fundamental health and life and, if possible, an absolute nightmare for developing countries,[481] prompting various debates on the suitability of having a

[478] Frank H. Easterbrook, "Intellectual Property Is Still Property' (1990) 13, Harvard Journal of Law and Public Policy 108.
[479] Milkhalien Du Bois, 'Justification Theories for Intellectual Property Viewed Through the Constitutional Prism, (2018), No 1, *Potchefstroom Electronic Law Journal/Potchefstroomse Elektroniese Regsblad* 21
[480] John P. Humphrey, 'On the Definition and Nature of Laws, (1945) Vol 8, issue 4 *The Modern Law Review* 194
[481] Peter K. Yu, 'The Objectives and Principles of the TRIPS Agreement' (2009), 46Houston Law Review .979. Available, https://scholarship.law.tamu.edu/facscholar/457 To developing and least developing countries, the implementation of TRIPS minimum standards demands more protection than can be provided by these countries. TRIPs is perceived to have ignored the local needs of the people, such as medical, legal, and technological needs, and it may have stifled the development of IP.

uniform standard diverse world. [482]It begs the same question of the nature, and what TRIPS aims to protect in the first instance; is it health or wealth?

In the context of TRIPS, it is designed to protect all forms of IP collectively[483], and it is regarded as the most comprehensive international treaty for the protection of IP rights, with mandatory minimum standards for the protection and enforcement of IP provided by each member with specified terms of protection, for a given subject matter within a definite period covered by permissible exceptions of those rights[484]. It is a standard-setting agreement intended to be a rational process for intending members to boost efficiency and economic growth. This standard ought to be voluntarily accepted without questioning the authority of TRIPs. However, this is not the case with TRIPS. It is an annexe of the WTO, i.e., a *de jure standard*; thus, a legal requirement is created under the WTO[485].TRIPS requires all members to adapt their laws to fit into the minimum required standard of IPR protection, even though it will significantly impact access to medicine and the pharmaceutical sector[486]. These standards or obligations are mandatory for all members concerning their development position.

No proof that increasing standards increases economic welfare. On the contrary, excessive standards can stifle economic development. In the case of pharmaceuticals, TRIPS Standard mandates patent protection for a minimum term of 20 years for product and process[487] even though the time was shorter in most developing

[482]Thomas Cottier 'The Doha Waiver and its effects on the nature of the TRIPS system and on competition law: the impact of human rights' (2006) NCCR Trade working papers, Available www.nccr-trade.org Accessed (29 December 2019)

[483]Peter K. Yu, 'The Objectives and Principles of the TRIPS Agreement'(2009), 46 Houston Law Review 979. Available, https://scholarship.law.tamu.edu/facscholar/457

[484] WTO-TRIPS, Overview: The TRIPS Agreement

[485] Steven M. Spivak*, Standardization Essentials: Principles and Practice* (CRC Press, New York.2001)

[486] WHO-Essential Medicine and Health Product, the WTO and TRIPS Agreement, Available https://www.who.int/medicines/areas/policy/wto_trips/en/ Accessed (30 December 2019)

[487] WHO-Essential Medicine and Health Product, the WTO and TRIPS Agreement, TRIPS also mandates members to adhere to some listed provisions such as the 1967 Paris convention to protect industrial property, the 1971 Berne Convention for the protection of literary and artistic work.

countries, resulting in counterfeit rise pharmaceuticals. Essentially, TRIPS ought to set applicable standards, not a one size fits all approach but permit various measures[488] which the state can efficiently utilize.

5.2.1- Compulsory license right on pharmaceuticals in Nigeria and the 'generics.'

This section will look at the provision and operation of the phase '*other use without authorization of the right holder*' otherwise known as a compulsory license. It is not found in the TRIPS Agreement[489]. It is inferred into the agreement under the guise of its purposed use, in a bid to strike a balance between R&D in drugs and to promote unlimited access to drugs. To developing countries, it is a welcomed idea, but it still illustrates the existing inequality operating within the WTO's multilateral trade regime. Therefore, a detailed analysis of how compulsory licenses can be interpreted and utilized will be examined to demonstrate the salient problems associated with its application, mainly in the aspect of Nigerian counterfeit drug problems.

A compulsory license is a legal flexibility permissible within the WTO but granted to a state to permit the production of a patented product or process without the right owner[490]. Regardless of the foregoing, compulsory license is deemed an exception to the bold expression of the right to intellectual property, as the right owner's consent was not sorted. In order words, it takes away the right conferred on the right owner,

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[488] Steve Charnovitz, 'International Standards and the WTO' (2005)*George Washington University Law School, Legal Studies Research Paper* 394, http://scholarshiplaw.gwu.edu/faculty_publications/394

[489] WT0- Factsheet: TRIPS and Pharmaceutical Patent, Obligations and Exceptions, Available http://www.wto.org/english/tratop_e/trips_e/factsheet_p Article 31 provides for other use. This means or includes the use of any patent right by the government for their purposes without getting formal authorization from the right owner, mostly if voluntary license application has failed but if compulsory licenses are granted the right holder is adequately remunerated.

[490] WTO-compulsory Licencing of Pharmaceuticals and TRIPS
available https://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm , Accessed (2 January 2020)

which is the right of acceptance or refusal, which is an infringement of ownership. Nevertheless, the compulsory license is valuable as a means of saving lives, for a government can authorize the use of the pharmaceutical patent to address public health problems.

The idea behind compulsory license originates from the lack of access to essential medicine, particularly in developed and LDC, often because these pharmaceuticals are unaffordable[491]. This concern further intensified during TRIPS negotiation, particularly the patent provision within TRIPS. In response to this foreseeable problem, the World Trade Organisation (WTO) Doha Ministerial conference of 2001 adopted the TRIPS agreement[492]. This declaration affirmed that the TRIPS agreement should be implemented, and it should not be detrimental to Public Health as per its scope, implication, implementation, and application, while still recognizing the importance of intellectual property to the advancement of new drugs[493].

Article 31 of the TRIPS Agreement provides for a compulsory license, which can be summarized as follows (*section A-F) 'That authorization can only be granted based on the individual merit of each application, however, permission is granted based on the previous refusal from the right holder within a period, but this requirement can be waived in the event of a national emergency, public non-commercial use after due notification to the right holder'*[494]. In retrospect, the Doha Declaration further simplified

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[491] Ellen F.M Hoen and others, 'Medicine procurement and the use of flexibilities in the Agreement on Trade-Related Aspects of Intellectual Property Rights,' (2018), Vol 96, Issue 3, *Bulletin of the World Health Organization*, 2001–2016 DOI:10.2471/BLT.17.199364

[492] Carlos M. Correa, 'Implications of the Doha Declaration on the TRIPS Agreement and Public Health,' 2002 Geneva: World Health Organization, No. WHO/EDM/PAR/2002.3.

[493] IBID Correa

[494] TRIPS Agreement- Article 31
Available https://www.wto.org/english/res_e/publications_e/ai17_e/trips_art31_oth.pdf Accessed(2 January 2020)(A.)authorization of such use shall be considered on its merits;
(b) such use may only be permitted if, before such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period. This requirement may be waived by a Member in the case of a national emergency or other circumstance of extreme urgency or in cases of

Article 31 of the TRIPS agreement, to Gathii the "*Doha Declaration captures the middle ground between the positions adopted by developing and developed countries. It embodies the commitment to protect patent for the development of new drugs and the availability of these drugs, in addition, it can be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all*[495]. Ultimately, it is a freely granted right decided on merit, otherwise known as government use. This right given can be assigned to a government entity or non-government entities as an alternative measure in market failure (patented pharmaceuticals)[496]. Article 31 clearly instructs that a compulsory license must be issued principally for the supply and utilization by the TRIPS member's domestic market granting the license. However, countries without a substantial

public non-commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable.
In the case of public non-commercial use, where the government or contractor, without making a patent research, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly;
(c) the scope and duration of such use shall be limited to the purpose for which it was authorized, and in the case of semi-conductor technology shall only be for public non-commercial use or to remedy a practice determined after the judicial or administrative process to be anti-competitive;
(d) such use shall be non-exclusive.
(e) such use shall be non-assignable, except with that part of the enterprise or goodwill which enjoys such use.
(f) any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use.
(g) Authorization for such use shall be liable, subject to adequate protection of the persons' legitimate interests so authorized, to be terminated if and when the circumstances that led to it cease to exist and are unlikely to recur. The competent authority shall have the authority to review, upon motivated request, the continued existence of these circumstances.
(h) the right holder shall be paid adequate remuneration in the circumstances of each case, considering the economic value of the authorization.
(i) the legal validity of any decision relating to the authorization of such use shall be subject to judicial review or another independent review by a distinct higher authority in that Member

[495] James Thuo Gathii, 'The Legal Status of the Doha Declaration on TRIPS and Public Health under the Vienna Convention on the Law of Treaties' (2002) Vol 15, No2 Harvard Journal of Law and Technology PP 301

[496] Kyung-Bok Son, 'Importance of the Intellectual Property System in Attempting Compulsory Licensing of pharmaceuticals: a Cross-Section Analysis,' 2019 Vol 42, Global Health, DOI:10.1186/s12992-019-0485-7

pharmaceutical sector have not utilized the compulsory licensing provisions of TRIPS[497].

In practice, it can be argued that compulsory license is inconsistent with the statutory right accruing to a patent holder to recoup the cost and benefit of research and development. Neither will the patent holder oppose the production and distribution of the generic version of the pharmaceutical. It can stifle the incentive to innovate new essential medicines. A typical example of this highlighted point is the case of sofosbuvir used in the treatment of hepatitis C, and in the USA, it cost $64 per treatment. In contrast, in developing countries such as India, it cost $539, this is exceedingly expensive; the Malaysian government issued a compulsory license for this drug[498], thus reducing the earning powers of the patent holder.

To developing countries, compulsory licencing is a welcome development to solving public health crisis such as tuberculosis, malaria, Ebola and HIV Aids problems[499] needing extreme urgency as seen in the case when Brazil issued a compulsory license for the patented drug *efavirenz* (*patented HIV Medicine*) after negotiation with the patent holder *Merck* failed. However, the emergency is not limited to just these diseases, but it covers any public health concern to health advocates. A compulsory license can lead to low priced drugs in cases of national crisis[500]. Consequently, compulsory license repels the standards of intellectual protection

[497] Alexandra G. Watson' International Intellectual Property Rights: Do Trips' Flexibilities Permit Sufficient Access to Affordable HIV/AIDS Medicines in Developing Countries (2009), Vol 32, Issue 1, *Boston College International law & Comparative law review* (2009): 143

[498]Gorik Ooms and others Could International Compulsory Licensing Reconcile Tiered Pricing of Pharmaceuticals with the Right to Health? (2014),*14* BMC International Health and Human Rights, 37

[499] Holger Hestermeyer, *Human Rights, and the WTO: The Case of Patents and Access to Medicines*. (Oxford: Oxford University Press, 2007)

[500] James Thuo Gathii, 'The Legal Status of the Doha Declaration on TRIPS and Public Health under the Vienna Convention on the Law of Treaties' (2002) Vol 15, No2 Harvard Journal of Law and Technology 291

dictated by TRIPS, and guarantees access to essential medicine, making it a legal exception to the TRIPS directive.

Regarding Nigeria, the compulsory license is enshrined in the Nigerian patent and design act, particularly in section 11, which states as follows. That t*he provisions of the First Schedule to this Act shall affect compulsory licenses and the use of patents for the service of government agencies, the* first schedule explicitly explains compulsory license provision, specifying that *Section 13 of the first schedule permits a state minister by order in the Federal Gazette to authorize, certain patented products and processes (or for specific categories thereof) declared by the order to be of vital importance for the defence or the economy of Nigeria or public health, compulsory licenses may be granted before the expiration of the period mentioned in paragraph 1 above and may permit importation*[501]*.* The provision of this Act allows a government agent or minister to adopt compulsory license on any ancillary matter concerning access to patented medicine, although it is not automatic. Only the court can authorize the grant if the following conditions have been met.

(I) Inability to obtain a patented license

(ii) Parties cannot agree on terms

(iii) The patentee will be adequately remunerated (royalty or otherwise) considering the relevant invention to be worked

(iv) It will be contrary to the public interest if not granted.

Once all these conditions are established, a compulsory license will be authorized. However, these conditions can be waived in the case of extreme emergency, or

[501] Eric Bond and Kamal Saggi, 'Compulsory Licensing, Price Controls, and Access to Patented Foreign Products, (2014)109, *Journal of Development Economics* 217-228. After Brazil triggered the first compulsory license to make Merck reduce efavirenz's price, even after the price reduction (30%). The government issued a 5-year compulsory license; still, the local company for efavirenz production did not have the workforce or technology. Patents and Designs Act, Chapter 344 Laws of the Federation of Nigeria 1999, Cap C23 Laws of Federation of Nigeria

national emergency *termed government to use*[502]. In principle, the compulsory license is a welcomed development given that in the past, most developing countries and developed countries did not permit patents on pharmaceutical products[503]. It is a vital government tool for exemption of liability, especially in the context of pharmaceuticals. Even if the rights of a patent holder is undermined, the zeal to save the public comes first.

For a country like Nigeria, compulsory license seems to be a viable option for its failing public health. Winslow suggests that' *Public health is the science and art of preventing disease, prolonging life, and promoting physical health and efficacy through organized community efforts for the environment's sanitation. The control of communicable infections, the education of the individual in personal hygiene, the organization of medical and nursing services for the early diagnosis and preventive treatment of disease, and the development of social machinery which will ensure every individual in the community a standard of living adequate for the maintenance of health; so organizing these benefits in such a fashion as to enable every citizen to realize his birth right and longevity[504]*." Similarly, Rosen emphasized that the scope of public health has evolved as society developed to not only include prevention and control of diseases as earlier stated but now include new emerging communicable diseases, for example, HIV, AIDS, Anthrax, and Ebola, which are relatively new diseases.[505] Faced

[502]Jerome H. Reichman' Comment: compulsory licensing of patented pharmaceutical inventions: evaluating the options." (2009) Vol *37.2* The Journal of Law, Medicine & Ethics PP 247. This comment traced the history of TRIPS in a bid to discover the legality of the all-encompassing compulsory license provision and its relative effect on developing countries' essential medicine problems without undermining the right guaranteed as a member of the WTO or face unilateral sanctions from patent right holders. It wouldn't be the case if the WTO did not increase its minimum patent protection standard without an underpinning effect on developing countries.

[503] IBID Reichman

[504] Jeffrey Koplan and others, 'Towards a common definition of global health' (2009) no. 9679 *The Lancet* 373: 1993-1995 citing Winslow Charles-Edward. "The untilled field of public health" *Mod Med* 2 (1920).183-91

[505] George Rosen, *A History of Public Health*, (John Hopkins University Press: New York, 2015)

with this growing threat, a state must ensure the best possible health care. Given this, the Nigerian government is expected to seek the best viable option available (compulsory license), especially regarding the increasing cost of producing drugs and the new problem of pharmaceuticals counterfeit.

The Nigerian government is facing challenging issues underpinning its pharmaceutical sector. Amongst the problems is the scourge of counterfeit and substandard drugs, which is contrary to ensuring safe and cost-efficient pharmaceuticals that meet the national health needs. The capacity to meet this stated need seems unrealistic in Nigeria's failing developmental and medical agenda. It has been observed that not until the early 1970s, Nigeria was solely dependent on finished drugs such as syrups, tablet suspensions imported from developed countries such as the USA and UK. The country lacks a viable local industry to produce drugs (process or product) neither was patent rule acceptable nor practised; therefore, having a TRIPS standard on drugs seems unlikely.

Although compulsory license is an all-encompassing solution to TRIP Agreement, the stringent patent is defective in developing countries. Specific concerns have been raised on compulsory license, which seems to encourage the increase of counterfeit pharmaceuticals. For example, it allows unapproved generic drugs to be produced and distributed. It raises a safety concern[506]that counterfeit drugs can be possibly manufactured instead of the original drugs. Moreover, developing countries with a large population like Nigeria (with lax immigration laws) can be used as dumping ground for unwanted generic irrespective of its source or dangerous impurities utilized

[506] Muhammad Zaheer Abbas, 'Pros and Cons of Compulsory Licensing: An Analysis of Arguments' (2013) Vol 3, No3 International Journal of Social Science and Humanity PP254

in making it. In conclusion, compulsory license is an all-important administrative right bestowed on the government to protect public health. Still, developing countries, effective utilization seems to affect the use of this right. Communal harmony amongst stakeholders of developing countries can effectively reduce the price of medicine, without actively relying on the compulsory license. It should be a last resort to unforeseen emergencies.

5.2.2 The Impact of Parallel importation on counterfeit on Nigeria national drug plan

The need to have a sustainable drug plan is the foremost goal of any government, especially the Nigerian government, particularly in the face of its current health care situation with life expectancy at birth estimated to be 54 years and the infant mortality ratio around 86 per 100 births. The death toll from preventable diseases such as tuberculosis, HIV, malaria, asthma, and sickle cell[507] is alarming; still, the gap between the health care value and the current pharmaceutical reality is changing given the perversity of counterfeit drugs production, trafficking, and use which subsequently could result to death. Therefore, existing strategies ought to be critically examined in a bid to draw a contrast with current IP rules authorized by TRIPS. This is intending to find out if the rules stifle the availability of pharmaceuticals in Nigeria. One such adopted option available to developing countries is the parallel import option.

The Nigerian National Drug Control Master Plan (NDCMP) offers an integrated and comprehensive approach towards tackling pharmaceuticals from 2015-2019. The plan includes counterfeit drug supply and distribution following international regulatory

[507] Muhammad, Faisal, Jamil Hassan Abdulkareem, and ABM Alauddin Chowdhury 'Major Public Health Problems in Nigeria: A review' (2017) Vol 7, issue 1 *South East Asia Journal of Public Health* pp.6-11.

authority on drug control and use. It is established that a viable drug plan does exist that recognizes international authority for pharmaceutical regulation. However, this drug plan's paramount goal is the eradication and reduction of counterfeit to the barest minimum. The plan is strategic, for it links the rule of law to public health while canvassing for a viable criminal justice system in place to prohibit the surge and usage of counterfeit drugs. Essentially it is a rule-based system that upholds criminalizing the production and distribution of counterfeit or illicit drugs. To sustain this approach, Nigeria ratified regional and international agreements on anti-drug initiatives and programs to control the counterfeit drug surge.

To implement this initiative, stakeholders consulted local authorities, ministers, and heads of ministries to formulate plans and find ambiguities in existing rules. One such gap identified is the inefficiency of Nigerian Law Enforcement agencies in tackling the surge of counterfeit drugs or illicit drugs. The law enforcement agency is considered obsolete and not proactive in intelligence collection and analysis. It lacks professionalism, unlike other recognized law enforcement agencies. Also, unethical practices within the agency and the adverse effect of inadequate policy and a non-operative legal framework inhibit how it is dealing with counterfeit Issues. Similarly, the most obvious gap is the lack of synergy between law enforcement agencies' operations at the federal and state level for both levels lacked corporation in strategic drug issues[508]. Perhaps the shortcoming of this plan is that it is keen on curtailing drug trafficking and the use of narcotic substances for medical and scientific purposes[509] instead of solving the problems of counterfeit pharmaceuticals.

[508]Nigerian National Drug Control Master Plan (2015-2019) Available file:///C:/Users/ugo/AppData/Local/Packages/Microsoft.MicrosoftEdge_8wekyb3d8bbwe/TempState/Downloads/ndcmp-2015-2019%20(1).pdf
Accessed (25 January 2020)

[509]United Nation Office on Drug and Crime (UNODC) Nigeria takes the lead, rolls out policy documents to improve availability and access to controlled medicines and improve drug treatment standards

Counterfeit is a core problem affecting both public health and the economy. If up till now, no adequate drug plan has been proposed, then how will this new drug plan be effective.

Nigeria needs to develop a viable drug policy. For example, in Malawi, interested parties in the supply and distribution of drugs came together to form a proficient drug policy from collaboration[510]. The latter issue is relevant and ought to be taken seriously by the Nigerian government policy formation to control the increasing pharmaceutical counterfeit rate. Another relevant narrative on drugs is that the Nigerian National Drug plan is supported and promoted by the World Health Organisation (WHO). It is worth pointing out that as far back as 2003, a drug plan has been in existence for Nigeria. Though obscure, it serves as a precedent to develop a useful, efficient strategy to tackle the counterfeit problem. The drug plan background states that" *no matter how vibrant a health policy is, without the availability of good quality and affordable medicines, that policy will be sterile*." Therefore, affordable and safe medicine is an important goal for an innovative drug plan. The national drug policy's goal is to ensure the availability of good quality safe medicine in Nigeria and the expansion of local production of medicine. Amongst the objective provided by the drug policy includes ensuring access to safe and affordable medicine, the provision of a drug management

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Availablehttps://www.unodc.org/nigeria/en/nigeria-takes-lead--rolls-out-policy-documents-to-improve-availability-and-access-to-controlled-medicines-and-improve-drug-treatment-standards.html Accessed (25 January 2020)
The initiative and development of a National Policy for Controlled Medicines is anchored on recognizing individual needs and the best interest of human development. The National policy elaborates and presents a practical approach to ensure the availability and accessibility of medicines. It addresses a barrier to essential medicine to prevent abuse and overdose. The government hopes to provide the best health care based on internally accepted practice to ensure safe ace, to quality and affordable medicine.

[510] Ransome O. Kuti, 'National Drug Policy in Nigeria' (1992), Vol 13, No 3 Journal of Public Health Policy, pp. 367

system, promoting rational use of drugs, regulation of the import, distribution sale of medicines and increasing research on alternative medicine[511].

Having established the potential existence of a national drug plan in Nigeria, the next step is to examine this section's core issue, which is the applicability of parallel import on the Nigerian national drug plan. Parallel import, otherwise known as (PI), is a controversial topic amongst IP scholars and commentators who have diverse views on its significance in the global trading regime. Strong IP advocates support banning PI, arguing that it reduces profit incentives in the pharmaceutical industry and can undermine the growth capacity of the research in pharmaceuticals. Conversely, this school of thought contravenes the interest of developing /underdeveloped countries, which places a high value on medicine's affordability rather than supporting a robust IP regime[512]. Thus, strong patent invariably leads to high drug prices, which is at variance with access to affordable medicine[513].

The concept of PI is essential in a discussion of access to medicine. It is pertinent to examine what parallel import means, for without meaning. Elucidation is pointless. Price is money worth for the right to exchange an article, or it is a measure of value placed on a commodity. To Fetter, value is deemed more subtle than the word money; it is all-encompassing and can reflect the energy utilized in creating a valuable

[511] WHO Nigerian National Drug Policy 2003
Available https://apps.who.int/medicinedocs/documents/s16450e/s16450e.pdf Accessed (25 January 2020)

[512]Keith E Maskus, 'Parallel imports in pharmaceuticals: implications for competition and prices in developing countries.' *Final Report to World Intellectual Property Organization* 13 (2001), Availablehttps://www.wipo.int/export/sites/www/about-ip/en/studies/pdf/ssa_maskus_pi.pdf Accessed (27 January 2020) Most developing countries do not have research capacity to develop their own medicine, so reliance on cheaper medicine is essential for the treatment of disease. To demonstrate how important price is, South Africa resorted to using PI after exhausting other remedies to reduce the excessive price of HIV drugs protected by patent.

[513] Patricia M Danzon and Adrian Towse, 'Differential Pricing for pharmaceuticals: Reconciling access, R&D and patents (2003) Vol3, Issue 3 International *journal of health Care Finance and Economics* PP 183

commodity[514]. In contemporary society, much value is placed on pharmaceuticals because it is essential to public health and economic development. It is like a double-edged sword. On the one hand, there is the impact of price on access and affordability, and on the other hand, there is the incentive to create new drugs. Monopolistic profit is a driving factor in the pharmaceutical industry due to the high investments required to start-up and run a pharmaceutical company[515].

The pharmaceutical industry is one of the most booming sectors accounting for the high-profit margin necessary for its rapid growth. To Kyle, the price of pharmaceuticals is paramount in terms of the quantity and quality of drugs. For instance, the United States has the largest single market on pharmaceuticals estimated annually, generating revenue of around $97 Billion, followed by Europe, making over $51 billion annual revenue[516]. With much revenue generated, it can be implied that these companies may exploit the need of consumers, particularly the most vulnerable in society, for higher returns on investments. Although monopoly stimulates innovation, the dire consequences of this on middle-income countries cannot be determined due to inaccurate recording systems. Thus, price undermines the total utilization of drugs prompting the rise of generic medicine.

The global sale of generic pharmaceuticals has increased, although it is a controversy amongst its brand pharmaceuticals, thus altering the competitive dynamics in the pharmaceutical market. Grabowski and Vernon observed a price correlation between generic and branded pharmaceuticals. As generic medicine prices reduced, branded

[514] Frank A. Fetter, 'The Definition of Price,' (1912) Vol. 2, No. 4, The American Economic Review pp. 783-813

[515] Dos Santos and others' Factors Influencing Pharmaceutical Pricing- A Scoping Review of Academic Literature in Health Science'. (2019) Vol 12, No 1 Journal of Pharmaceutical Policy and Practice pp 1-12

[516]Margaret K Kyle, 'Pharmaceutical Price Controls and Entry strategies.' (2007), Vol 89 Issue 1 *The Review of Economics and Statistics* 89.1 (2007): pp. 88.

medicine's price increased, leading to a substantial shift in the pharmaceutical market[517]. Gibson, Ozminkowski, and Ron Goetzel believe that generic is a form of cost-sharing but holds reservations on its therapeutic value[518]. Hence, it can be summarized that generic rivalry has reduced pharmaceuticals' prices, but the contradictory effect in less-regulated regimes can be challenging and result in a different option.

One such option available to developing countries and endorsed by TRIPS Agreement is parallel import (PI). The significance of permitting PI is a contentious issue amongst IP scholars and advocates. For instance, Maskus and Chen *speculate, "those welfare implications of allowing parallel imports is ambiguous"* [519]. However, parallel imports are genuinely patented, and trademarked goods that still have existing intellectual property protection, placed into circulation in one market but imported into a second market without due authorization from the license holder. This product is not different from the original product, although it may be packaged differently without the original license owner warrant. It is important to note that the product is presumed to be genuine, not counterfeit. However, PI is legal (international exhaustion), but it contravenes the intellectual property's principle standpoint [520].

[517] Richard G Frank and David S. Salkever' Generic entry and the pricing of pharmaceuticals' (1997) Vol 6 issue 1 *Journal of Economics & Management Strategy* PP 75-90.

[518] Teresa B Gibson, Ronald J. Ozminkowski and Ron Z. Goetzel, 'The effects of prescription drug cost-sharing: a review of the evidence.' (2005) , Vol.11 Issue11 *American Journal Management Care* PP 730-740.

[519] Keith E. Maskus and Yongmin Chen. 'Vertical price control and parallel imports: theory and evidence.' (2004) Vol 12, Issue 4*Review of International Economics* pp551

[520] Keith E. Maskus, 'Parallel Imports in Pharmaceuticals: Implications for Competition and Prices in Developing Countries' (2000) Vol 23, Issue 9 The World Economy pp1269. PI of pharmaceuticals can be observed to restrict the incentive to produce new pharmaceuticals. IP supporters have argued for states to desist from using PI, for it slows down innovation and creativity. However, developing countries and public health advocates have argues that pharmaceuticals' availability is far more vital than the source of the pharmaceutical.

Developing countries are keen on availability rather than the source. Therefore, PI is a vital territorial tool used in the regulation of the price of pharmaceuticals. It is rather disturbing that price stands in the way of good health, but this is the reality most developing countries like Nigeria encounter daily. PI is an individual prerogative state can exercise, though states can choose any form of 'exhaustion.' The policy on exhaustion comprises three distinct concepts. The first is national exhaustion. Here, the holder of IP right to a product is exhausted when the product is sold in the national territory, while regional exhaustion is when the IP holder product is sold in a regional province, for instance, the African Union regional market. In this case. "Parallel imports" will only be permitted, but only regarding goods initially placed on the market within a regional territory. Whereas the "international" exhaustion policy makes the IPR holder's right extinguished when a protected product is sold in any global market. States can pick and choose what form of PI to adopt based on the condition that it pertains to goods or services lawfully first placed on the market anywhere in the world[521].

Nevertheless, to WIPO, exhaustion is a limitation to IP rights, as the name implies, it merely means the exhaustion of IP right in a product after the sale. This means the product can be resold in a different jurisdiction without the authority of the IP owner. This product can be parallel imported outside the distribution channel contractually negotiated by the right owner[522]. The doctrine of exhaustion provides a legal base for PI. Certain factors can influence PI, such as price. Price plays a vital role in the parallel

[521] Frederick M Abbott, 'Parallel Importation: Economic and Social Welfare Dimensions.' International Institute for slowing Development (IISD), Swiss Agency for Development and Cooperation (SDC) (2007), Countries tend to pick and choose exhaustion policy to adapt to fit its peculiar circumstance. For instance, a country may adopt a regional exhaustion policy for goods protected by patent and adopt a national exhaustion policy for copyright-protected products.

[522] WIPO, International Exhaustion and Parallel Importation, Available https://www.wipo.int/sme/en/ip_business/export/international_exhaustion.htmlAccessed (09 February 2020)

trade of pharmaceuticals: high prices can prompt competition between the original producer and parallel importers[523]. It may be possible that excess price competition in the pharmaceutical sector can potentially result in over-investment in research and development or excessive duplication ideal, and it may reduce the incentive to produce new pharmaceuticals[524].

The salient idea on PI from a developing country perspective is thus: PI ensures expensive patented drugs from another country can be sold at a lower price, inadvertently competing with a similar product having similar IP protection in that region. If PI is implemented in Nigeria, drugs can be sold at cheaper or subsidized rates. This can set a standard for negotiations amongst pharmaceutical importers to dictate the basis of sales with multinational pharmaceutical companies. However, for PI to be applicable in Nigeria, it can only be under international exhaustion of rights, for regional exhaustion will not be applicable for being a member of the Economic Commission of West African States (ECOWAS).

ECOWAS rules do not support regional exhaustion; neither did it allow competition rules to be domesticated in its regional states. In practice, national exhaustion ought to be applicable, but the supreme court in Nigeria deliberated on *consent* and protection in the case of *Dyktrade v. Omnia, on IP protection. The court contended that the registered owner of a product could institute actions against trademark infringement. The court went further to clarify who is entitled to protection to include the owner, importer, and exporter*[525]. Whereas on the subject matter of consent, the supreme court in *Ferodo Ltd v. Ibeto Ind. Ltd held that "A proprietor has the exclusive*

[523] Brekke R. Kurt, Tor Helge Holmås, and Odd Rune Straume' Price Regulation and Parallel Imports of Pharmaceuticals (2015) Vol 129, Journal of Public Economics pp. 92-105

[524] Barfield, Claude E., and Mark A. Groom Bridge. 'Parallel Trade in the Pharmaceutical Industry: Implications for Innovation, Consumer Welfare, and Health policy.' Fordham Intellectual. Property Media & Entertainment. 1999 Vol 10, Law Journal 185

[525]DYKTrade Limited(Appellant).V.Omnia Nigeria Limited (Respondent)(2000)AllN.L.R.591

right to use, market and sell goods, without the express consent and use or sale the proprietor can sue for infringement or sue for passing off of goods[526].

The status of parallel import and exhaustion in Nigeria can be deduced from the court's findings in the case of *Honda Place Limited V. Globe Motors*(2005)14 NWLR [527] *Limited, the federal high court upheld* that defendant should cease importing cars from the United States for the plaintiff had the sole right, and that right cannot be contravened by way of parallel import. The *Nigerian Court of Appeal in the case of Pfizer Specialties Limited Vs. Chyzob Pharmacy Limited* [528]*held that parallel importation is a foreign doctrine, which is not actionable* under Nigerian Law[529]. For PI to be applicable in Nigeria, it is international exhaustion, but no rule suggests that all international law must be implemented in the national legal system of states. In this instance, by the WTO legal order, states have ratified a single undertaken to apply the WTO binding rules in its domestic legal system[530].

Perhaps in Nigeria, the PI institution may serve as a myriad or a perfect solution in its struggle with the high cost of pharmaceuticals. Nonetheless, an IP owner's exclusive right is not exhausted; consequently, legal options may seem laudable in some instances to assert ownership especially where international exhaustion supersedes an individual right to IP. The underlying principle interpreted on PI is the availability

[526]Olasupo Shasore , 'Parallel import –How to Manage the Problem,' Availablehttp://www.ajumogobiaokeke.com/wp-content/uploads/2018/01/c930665fe00db0095450d9d46b3e39d6.pdf Accessed (18 February 2020)

[527] (2005)14 NWLR

[528] (LER [2006] CA/L/282/2001)

[529] Banwo and Ighodalo, 'Fair Trade, Monopoly and Competitiveness: Appraising the Legal Rights of Franchisees Against Parallel Imports in Nigeria' Date? Available https://www.banwo-ighodalo.com/assets/grey-matter/0d297c0b10ddcd02b610149391ac60f3.pdf Accessed (18 February 2020)

[530] Pascal Lamy, 'The Place of the WTO and its Law in the International Legal Order, (2006) Vol17, No.5 European Journal of International Law pp. 969 The WTO upholds a principle of equality by making fair rules applicable in all states in respect of the state of development; its rules have developed for over 50 years to become a distinctive legal order containing the body of rules.

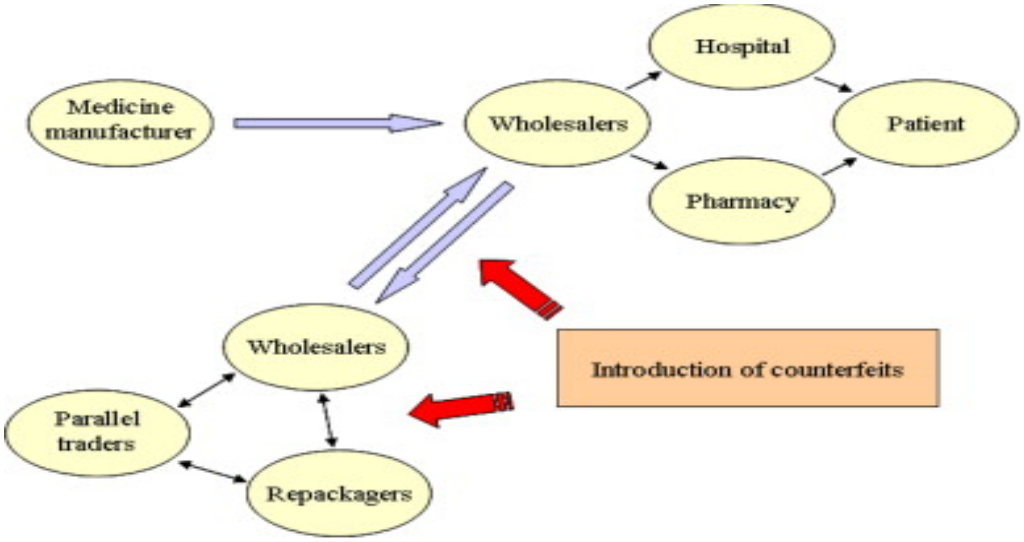
and accessibility of essential pharmaceuticals, but PI may significantly impact the surge of counterfeit drugs. A gap is created when the price of medicine varies in different jurisdictions because of PI. The outcome is the introduction of counterfeit in the supply chain. Equally, the right owner may have lost the IP right to sue for infringement or detect low quality or counterfeit products for PI erodes the legal right to IP.

Liang posits that it is perceived to be a global phenomenon, stating that price differentiation creates an incentive to move medicine from one jurisdiction. Unfortunately, legitimate medicine may be replaced with fake, tainted, expired, or diluted medicine or medicine with ineffective material or counterfeit drug, which can create harm in circulation [531]without arousing suspicion because there is no emphasis on IP nor the existence of a binding legal obligation from the IP owner. Essentially, the distribution of finished medicine is complex and difficult to trace for medicine and might be handled by twenty to thirty intermediaries before reaching a patient[532].

[531] Liang A. Bryan "Parallel trade in pharmaceuticals: injecting the counterfeit element into the public health." (2005), Vol 31 *National California Journal of International Law & Commercial Regucounterfeit medicine*gardin, Klara, Yves Roggo, and Pierre Margo "Understanding and fighting the medicine counterfeit market." *Journal of pharmaceutical and biomedical analysis* 87 (2014): 167.

[532] Dégardin, Klara, Yves Roggo, and Pierre Margo "Understanding and fighting the medicine counterfeit market" *Journal of pharmaceutical and biomedical analysis* 87 (2014), pp.167-175. The distribution of finished medicine can be resold in Europe and America by PI, it is legal by virtue of the EU accepting to utilize regional exhaustion, unlike West Africa where the ECOWAS treaty does not comply with PI directive irrespective of its potential effect in providing access to essential medicine at very low price. The countries in EU have so developed and adopted PI to the point that PI is the largest import market for pharmaceutical, with Britain estimated to have parallel imported 70% of its pharmaceutical supply. But the drawback of PI is in the redistribution network here, drugs can be repackaging and resold, possibly allowing fakes or substandard drugs to infiltrate the distribution network.

Fig.4. Shows the Intricacy of the parallel pharmaceutical trade enabling the introduction of counterfeit pharmaceutical[533]



This diagram shows the intricacy of PI that creates an enabling environment for counterfeit pharmaceuticals to thrive. Medicine manufacturers supply wholesalers' medical products directly who, in turn, distribute to hospitals and pharmacies. These drugs come from authorized licensees who have existing IP rights to sell and distribute. However, if PI is invoked, it may create a break in the chain of distribution and regulation. It can be suggested that PI on genuine patented or trademarked pharmaceuticals in circulation in one jurisdiction can be repackaged and exchanged with counterfeit pharmaceuticals to be supplied to an unsuspecting market, making it difficult to trace the originality of the drug. Thus far, there is little doubt on PI's sustainable objective on pharmaceuticals: it has legal validity under the WTO Legal order. However, its shortcoming outweighs its benefits. PI seems plausible in the Nigerian situation, but its implementation and utilization might be encumbered by the

[533] Jonathan Harper, 'European Alliance for Access to Safe Medicines (EAASM), European Patient Safety and Parallel Pharmaceutical Trade–A Potential Public Health Disaster' *Medicom Group Ltd., Hampton Court, UK* (2007)

weak operating system[534]. In my view, PI ought to be further improved in a bid to close the lacuna caused by PI. However, PI has informed this research by demonstrating how the WTO policy can encourage the surge of counterfeit medicine.

5.2.3 TRIP plus Rules on Counterfeit Pharmaceutical

The TRIPS Agreement reaffirmed its commitment to promote access to essential medicine. This can be perceived from the standard set during the implementation of the Doha declaration. States had the right to utilize any of TRIPS available safeguards such as compulsory license, use exception, and parallel import discussed above to meet its medical needs. Although it is regarded as a breakthrough, the state is obligated by the policy of one size fits all approach undertaken by the WTO. To adopt more stringent patent protection known as TRIPs-Plus, which targets explicitly developing countries to encourage the implementation of stricter patent laws even through it.

It can be inferred from the USA and EU countries' trade deals with developing countries such as the Dominican Republic-Central America FTA (DR-CAFTA), the US-Jordan Free Trade Agreement, and the Trans-Pacific Partnership Agreement (TPP). A typical example of TRIP-Plus provision includes patent linkage, data exclusivity, increased enforcement mechanism, and patent term extension longer than 20 years[535]. TRIP Plus obligation intends to ameliorate the problems of access to medicine in developing countries. However, it has compounded the issue by limiting access to a free alternative source to much-needed medicine. Nigeria and other

[534] Mary Shepherd, 'Beef up International Cooperation on Counterfeits." (2010) Vol16 issue 4 Nature Medicine pp. 366

[535] Jennifer Reid, 'InforJustice.org, The Effect of TRIPS –Plus IP provision on access to affordable Medicine, Available http://infojustice.org/archives/34601Accessed (14 March 2020)

developing countries such as China have modelled their existing IP rules following TRIPs' equivalent obligation[536]. Therefore, this section seeks to examine the influence of TRIP-Plus rules in the surge of counterfeit pharmaceuticals and its relative influence in the developing IP regime.

The use of TRIPs safeguards and flexibility has improved access to medicine and made the IP regime seemly workable in developing countries and LDCs. For instance, the Ecuador IP office used one of TRIPs' flexibility, which is compulsory license in the manufacture of Antiretroviral (ARV) medicine, which is a combination of Lopinavir and Ritonavir. This action informed the reduction of the existing patented HIV medicines. Equally, the Ghana IP authority applied to the government to use the exception to purchase antiretroviral medicine from India, and this reduced the cost of ARV medicine by over 50% in the country. No doubt, TRIPs safeguards have ameliorated the plight of developing countries and remedied the impact of patent protection.

It is useful when implemented into the legal framework of member states. However, developed countries consistently canvassed for more stringent and restrictive IP rules that go beyond TRIPs for developing countries because of the notion that having a higher level of protection outside the framework of TRIPs mandate would increase profit. Developed countries possess the technology, invention, and patent in pharmaceuticals needed by other state members to the WTO. This gave rise to the development of TRIP-Plus. It is a non-technical term, which does not demand an obligation for acceptance by WTO member states. Acceptance of TRIP Plus rules would be considered part of a Free Trade Agreement (FTA)[537] due to fear of trade

[536] Qingjiang Kong, 'A Rising Tide Lifts All Boats, IPR Provision In China's Free Trade Agreement Regional Cooperation and Free Trade Agreements in Asia Edited by Jiaxiang Hu and Matthias Vanhullebusch

[537] Lawrence R. Helfer and Regime Shifting: 'The TRIPs Agreement and New Dynamics of International Intellectual Property Law-Making' (2004) 29 YALE Journal of International Law PP 1

repercussions from developing countries, such as the United States or the European Union. Critics speculate that TRIP-Plus will inhibit the perception of TRIPS flexibilities and safeguards, thus limiting its applicability. It can be suggested that both TRIPS and TRIP Plus create a conflict of relationship. Both forms are valid and applicable but incompatible and left to states to decide which norm should supersede the other[538]. TRIP Plus required states to implement provisions to limit the use of compulsory licenses. Secondly, it supports extending the patent protection term to be increased by more than 20 years. It also includes restrictions for generic competition. However, the most peculiar is data exclusivity. Developed countries knew that the pharmaceutical market is regulated by two laws, IP and laws on drug regulation. If both laws are restricted, for instance, patent, a patent right holder can withhold the right to sell or produce patented medicine if TRIP Plus is applied. Although the drug regulatory system ensures the information on the registration of drug safety, efficacy, and quality submitted by companies for market authorization, this prevents competition and generate high profit. TRIP plus demands that this information should be kept confidential[539]. Therefore, if TRIP Plus rules are affected, the overall impact on access to medicine would be dreadful because the safeguards and minimum standard ought to increase access, not limit access to medicine. This section discussed the

[538] Henning Grosse Ruse-Khan' The International Law Relation between TRIPS and Subsequent TRIPS-Plus Free Trade Agreements: Towards Safeguarding TRIPS Flexibilities' (2010) Vol 18 Journal of Intellectual Property Law 18 (2010)PP 325 To resolve any issue between two international law rules, the Vienna rule of interpretation is the last resort to resolve this issue. *Article 31 (3)(c) state that "relevant" rules of TRIPS "shall be taken into account "because all TRIPS provisions amount to "rules of international law applicable in relations between the parties"* therefore, the rule of treaty interpretation is essential in resolving conflicts but does resolving the conflict supersede the aim of the rules for if attention is paid more to conflict than their stated obligation, then both norms are unreliable.

[539]World Trade Organisation (WTO), Data exclusivity, and other "trips-plus" measures Available file:///C:/Users/ugo/AppData/Local/Packages/Microsoft.MicrosoftEdge_8wekyb3d8bbwe/TempState/Downloads/Data-exclusivity%20(1).pdf Accessed (01 April 2020) The context of data exclusivity prevents competition. It gives pharmaceutical companies a monopoly for 5-10 years before the information is made public. Drugs ought to show its therapeutic effect and safety instead of repeating clinical trials. The pharmaceutical patent owner holds this information until data exclusivity has passed, thus generating higher revenue.

importance of TRIP safeguards concerning access to medicine in both developing and LDCs. The highlighted safeguards have been utilized efficiently and it has a relative impact on the pharmaceutical industry. TRIPS safeguards have ameliorated access to medicine, although complicated in its application and utilization. However, to make progress, proponents called for more robust protection TRIP-Plus, but the adverse effects of TRIP plus rules impede what it intends to protect, resulting in another issue beyond the scope of the WTO-TRIPs Agreement

5.3 Linkages between access to medicine and counterfeit medicine: A critical evaluation

In sections [2.2, 2.2.1], this study discussed the notion of access and counterfeit drugs. However, this part will seek to establish an interaction between these two norms to show a concise analytical summary using identifiable tools to determine the significance of counterfeit pharmaceuticals from a Nigerian perspective. Medicine is a substance administered to treat disease to improve quality of life and be regarded as one of humankind's most important discoveries because it is a preventive and curable measure.[540] This point is rightly observed by Philip Abelson that 'pharmaceutical is responsible for improved health care in this century [541] and attributed to the increase in life expectancy [542] due to its therapeutic effect and safety. However, over time there is a new threat to human health and safety known as counterfeit or substandard medicine ‘’the WHO defines substandard medicine as any *approved medical product that fails to meet quality standards and specifications. At the same time, counterfeit or*

[540]John P Bunker, 'The Role of Medical Care in Contributing to Health Improvements within Societies (2001) Vol 30, Issue 6 International Journal of Epidemiology PP 1260
[541] Philip H. Abelson, 'Improvement in Health Care' (1993) Vol,260 No 5104 'Science, PP11
[542]Sharyl J Nass, Laura A. Levit, and Lawrence O Gostin, 'The Value, Importance, and Oversight of Health Research" in *Beyond the HIPAA Privacy Rule: Enhancing Privacy, Improving Health through Research* (National Academies Press (US), 2009)

falsified medical products are drugs deliberately/fraudulently misrepresented by its identity, composition, or source". However, up till now, there has been no uniform or concise acceptable definition of counterfeit [543]neither does counterfeit and substandard drug have the same meaning. They have different inferences; for instance, substandard means (low-quality medicine)[544] and counterfeit means (outrightly fake in quality and composition), both terms are used interchangeably. [For a detailed discussion on the definitions of counterfeit and substandard pharmaceuticals, see 2.2, 2.4 above]

Although counterfeit is deemed a global problem even in developed countries, the percentage of counterfeit in the American drug market is on the rise through unlawful online sales[545], but there is a presumption that developed countries have smaller incidents of counterfeit compared to developing countries. Correspondingly, many factors have been recognized to cause counterfeit. One example is the technological, economic, social, and financial disparity between the developed and developing /LDCs. Similarly, some of the standards and flexibility required by the WTO-TRIPS agreement have been known to stimulate counterfeit pharmaceuticals, whether directly or indirectly. The flexibilities include trade liberalization policy, compulsory license, parallel import, Doha declaration, TRIP –Plus. The issue that needs to be resolved goes beyond the WTO-TRIPS scope, for the negative impact that arises from using TRIPS flexibilities outweighs its overall utilization. Thus, the issue is the

[543]WHO Substandard and Falsified Medical product, Available https://www.who.int/news-room/fact-sheets/detail/substandard-and-falsified-medical-products Accessed (03 April 2020)

[544]Andrew O'Hagan, April Garlington' Counterfeit drugs, and the online Pharmaceutical Trade, a threat to public safety, (2018) Vol 6 Issue3 Forensic Research & Criminology International Journal PP 151-158

[545]Erwin A., Blackstone, Joseph P. Fuhr Jr, and Steve Pociask, 'The health and Economic Effects of Counterfeit Drugs (2014) Vol 7 Issue 4 American Health & Drug Benefits PP.216

provision of adequate pharmaceuticals for the treatment of disease away from politics, IP, economic considerations to meet the people's needs.

5.3.1 WTO-TRIPS 'Quick fix' Approach

A multilateral trading system is a progressive approach cheered by the WTO, for it encourages openness and fairness in the trading system of the world. More so, it has resulted in the breakdown of barriers between countries, government, and people based on the principles of non –discrimination, national treatment, equality/MFM, and free trade within the well-organized structure of the WTO. The scope of WTO membership encompasses over 164 member states. This serves as proof of WTO's credibility in regulating the growth and development of the world's trading system [546]. Despite the WTO's remarkable success, the organization continued to reform and revise its trade policies, considering changing circumstances around the world.

By this singular mega-regional endeavour, commentators and academics have applauded it as a breakthrough in creating global success in the international Trade system. However, a contrary view to the WTO success maintains that the WTO failing restructuring rounds has resulted in establishing various trade policies to resolve new trade dimensions such as solving protectionism, trade barriers, and violation of IP. Instead of dealing with one issue before another, the WTO adopts a quick fix approach (i.e., utilizing the fastest solution to solve reoccurring problems), leading to the increase of other subsequent unforeseeable issues such as counterfeit. This problem may have been created as a domino effect from the problem of access to medicine.

[546]WTO, Golden Jubilee of the Multilateral-trading system,
Available https://www.wto.org/english/news_e/pres98_e/pr88_e.htm Accessed(April 13 2020)

Without being resolved, the WTO prioritizes other salient issues. An example of this is the collapse[547] of the Doha trade negotiation round[548].

The failure of the WTO as a global trade organization is predictable for its agenda is not explicitly favourable to developing countries, although it arranged some initiatives such as ‘’certain special and differential treatment rights." These provisions are perceived to be inadequate. Even the Ministers at the 4th Doha ministerial conference the Committee on Trade and Development is authorized to examine these special and differential treatment provisions[549]to strengthen and create a more effective and operational system. However, Wallach and James have expressed concern about the text of the Doha development round, stating that the underlying agenda of the round is the expansion of the current scope of the WTO. This expansion will further undermine economic growth in developing countries even though, since its ratification, economic developments have deteriorated with a large percentage of people living on less than $1 a day[550].

Adequate measures have been put in place to shift attention from WTO performance to future gains achievable only from strict adherence to WTO rules and mandates. Using the case study of the WTO-TRIP, the agreement can be considered as the most significant protectionism agreement in the world, which is a direct extension of the

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[547] Popa Diana. 'The Collapse of the Doha Round and a Possible Completion of Negotiations' (2012) Vol 15 Issue 43 *Romanian Economic Journal PP 44*

[548] Peter Halewood, 'Trade Liberalization and Obstacles to Food Security: Toward a Sustainable Food Sovereignty" (2011), Vol 43 Issue 1, The University of Miami Inter-American Law Review 115-136 Pp120

[549]World Trade Organisation(WTO) Special and Differential treatment right provision Available https://www.wto.org/english/tratop_e/devel_e/dev_special_differential_provisions_e.htm Acc essed(April 14, 2020) The special provisions include: Extension of time for adopting and implementing Agreements and commitments, measures to increase trading opportunities for developing countries, provisions requiring all WTO members to safeguard the trade interests of developing countries, adequate support for developing countries to build the capacity to carry out WTO work, handle a dispute and resolve dispute, and implement technical standards, and provisions related to least-developed country (LDC).

[550] Wallach Lori, Deborah James and Public Citizen, 'Why the WTO Doha Round Talks Have Collapsed–and a Path Forward." *Global Policy Forum August 14, 2006*

WTO monopolistic mandate of controlling trade while still advocating for trade liberalization. It also demands states to provide stiff intellectual property protection for drugs without considering the relative impact on drug availability. The WTO ought to fix the multilateral trading system's ills rather than standing back with a quick fix offer. It should be proactive, reflective[551], and deliberate on potential solutions to make it stand out as a world-leading trade organization.

The one size fits all or single undertaken approach utilized by the WTO can be said to be ill-suited in the evolving global trading system, partly as a result of the complex policy obligations such as facilitation of trade-in service[552] and the Trade-related aspect of intellectual property rights (TRIPS). The implication of strengthened protection may have negatively affected developing countries such as high price, product imitation, copying, and drug counterfeit. Besides, most developing countries have changed their legal regime to conform to WTO compatibility standards. Given this situation, it will be unlikely for states to push for more trade rounds or ministerial conferences within the WTO. Instead, states advocate for more plurilateral trade agreements to protect the weak institution.

In conclusion, for the WTO to retain its status as a leading trade organization, it needs to be more proactive towards the issues affecting member states by supporting, encouraging a broad spectrum of plurilateral agreements and extend terms in IP for developing/LDCs. Other steps will be to support non-restrictive measures for the sake of protecting public health[553], reprimand aggressive trade policies offered by

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[551] Rorden Wilkinson, *what is Wrong with the WTO and How to Fix It*, (Polity Press: Cambridge, 2014)
[552] Uri Dadush, William Shaw, 'Rise of Emerging Markets Requires a new WTO, Available https://carnegieendowment.org/2011/09/22/rise-of-emerging-markets-requires-new-wto-pub-45591 Accessed (April 17, 2020)
[553]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?" (2004) Vol 7 Issue 1 Journal of International Economic Law PP 73

developed member states, permit transparency in WTO rules and safeguards and adopt stiff penalties for members flouting WTO rules. Thus, it can be presumed that the WTO, failing rounds, and policy recommendations have influenced the surge of counterfeit in developing countries like Nigeria. Getting solutions will start from the WTO amending and reflecting on proper measures to tackle its discrepancy before member states can implement it. Except there is a rethink in the way the WTO handles problems, solutions may be unlikely.

Chapter 6 Conclusion and Policy Recommendations

I return to this thesis's original question: How does the WTO-TRIPs agreement comport with the regulation of counterfeit pharmaceuticals in Nigeria? The introductory part set out the context to test the viability of the WTO-TRIPs agreement. This thesis demonstrated the importance of protecting IP in a modern economy, for it can encourage innovation and the promotion of technological advancement. IP is a valuable economic and developmental tool both to developing and developed countries. IP can be said to be interrelated to the rise and protection of new medicines and vaccines needed to safeguard public health. This research has shown why protecting IP within the WTO's multilateral trading system is vital for world growth. It started by tracing the WTO's historical development, its ascension over the GATT agreement and negotiations, amendments, reports, and trade rounds till the WTO became the principal legal instrument for the regulation of trade and IP.

Nigeria is a member of the WTO since its inception in 1994. The WTO membership has its benefits such as free trade, liberalization, reduction of tariffs, economic growth, fair trade, fair competition, support for local industry, and movement of technology. All this is promised as a single package deal to members. As a single package deal, members are obliged to bring their laws in conformity with the WTO standards and abide by the rules. Before the negotiation of the TRIPs agreement, IP matters were solely within the jurisdiction of WIPO. However, due to perceived gaps and inconsistencies from developing and developed countries, especially in the area of technology transfer, enforcement, and adequate protection of IP rights, this created the need to incorporate IP within the WTO's scope to provide stringent standards backed up by sanctions.

The WTO-TRIPS agreement is a comprehensive agreement, which allows members to provide extensive protection for IP. It protects all forms of IP rights, including patent, copyright, trademark, geographical indications. However, the TRIP standard is all-encompassing and unique for encouraging IP growth for developing countries such as Nigeria. However, WIPO's low standard may have reduced the burden of tackling counterfeit products due to tough TRIPs IP rules. The perspective that stringent IP laws can enhance IP development in developing countries is vague, for developing countries find it hard to rely on WTO-TRIPS to solve its public health problems, which includes counterfeit pharmaceuticals. The WTO-TRIPS is supportive of developing countries, not the issues that arise from the interpretation of WTO rule in its members' legal system. One such outcome is counterfeit pharmaceuticals.

Stringent IP protection has the potential to lead to the economic exploitation of pharmaceuticals. This thesis has established a link between counterfeit and IP protection, stating that IP is an important economic tool needed to uphold creativity and economic development, nevertheless counterfeit is a product of pharmaceutical patent in terms of pricing and access. Pharmaceutical patent protection can directly limit medicine availability, and subsequently, lead to counterfeit medicine preponderance. Counterfeit is derived from the infringement of IP. It is a targeted threat to the growth of IP and innovative steps.

Proffering a definition of counterfeit seems far-fetched; it is a relative term with a wide array of interpretations. Counterfeit means deceit: a portrayal of goods as what it ought to be instead of what it is, which can undermine its applicability. Till now there is still no concise or uniform definition of counterfeit pharmaceuticals. Reliance on existing definition can lead to different means, attributed to the problem, the definitional question should be resolved as a step towards combating the surge of Counterfeit

pharmaceuticals. The multilateral trade framework of the WTO-TRIPS advocates implementing TRIPS policies and safeguards, which would contribute to eradicating counterfeit pharmaceuticals in Nigeria. Having implemented the slated objectives of WTO-TRIPS, hoping that counterfeit pharmaceutical will reduce, it still on the increase. It proves that TRIPS standards, safeguards, objectives, and all existing legal rules (national and international) proffered for regulating international trade, cannot tackle counterfeit pharmaceuticals.

6.1. Reforms on WTO-TRIPs IP Regulation to Tackle Counterfeit

The WTO-TRIPS Agreement is a legal recognition of the significant link between IP and Trade. It is essential for setting a standard for the regulation and interpretation of IP rights. It has succeeded in harmonizing trade and utilization of creativity, which has enhanced international trade amongst nations. TRIPS is commended for being a catalyst in forcing state members to the WTO to re-evaluate outdated IP laws to bring them in line with modern trade reality and value inventive endeavours. However, TRIPS, in a bid to safeguard creativity, modified the terms of IP, implemented more stringent measures on IP trade, members were not allowed to tailor their approach to IP enforcement and protection outside TRIP set standards. All this extension is to prevent the infringement or abuse of IP; instead, it intensified the problem. TRIPS agreement is pragmatic for achieving some of its stated objectives while still considering alternatives to prevent restrictive IP issues that will negate the maximum utilization of IP standards.

Analysis of the TRIPS agreement revealed that TRIPS' objective supports the development of principles, rules, and discipline dealing in trade in counterfeit goods,

including pharmaceuticals. If the TRIPS standard can regulate Nigeria's counterfeit drug surge, different suggestions and areas for further research have been mentioned. For example, linking the WTO-TRIPS to EU-Acquis is the law of communication for intending member states to examine the pros and cons of membership, especially the provision of special consideration for the transition of intending members legal system. However, the TRIPS agreement allows for a single undertaking that prevents member states from deciding on the favourable aspect of its circumstance. Developing countries must accept the conditions and exceptions without having time to determine what provision in the agreement is useful as picking and choosing is not allowed.

If TRIPS were to be a plurilateral system like GATT, member states would not be stuck to rigid WTO-TRIPS policies. Even with TRIPS safeguards, the period for developing countries to bring their laws in conformity to the TRIPs agreement is too short. It might seem right to suggest that developing countries might succeed in tackling the scourge of counterfeit if they operate outside the WTO framework, but instead, use guidance from the TRIP agreement or revisit the plurilateral system to lead to development. If the last position is adopted, the WTO-TRIPS agreement will still be operating, but from a distance. It will allow developing countries to build a structure that is capable of transitioning into the WTO system smoothly.

Finding from this research so far indicates that the WTO- TRIPS agreement may need to evolve to prioritize developing countries' needs, or its rules will be inadequate to tackle counterfeit pharmaceuticals. The fact stated above indicates that WTO-TRIPS laws and policies do not target Africa's needs in general bearing in mind that it is only when a law is deeply rooted in a country experience can it be workable. So far, the WTO-TRIPS Agreement is not deeply rooted in the counterfeit experience. Although different measures have been proposed, such as parallel import and TRIP plus rules

implemented, it has failed to close the existing gap. The WTO laws ought to be applicable without conformity with existing legislation neither has Nigeria developed a unique framework that can tackle its counterfeit pharmaceutical issues; it solely relies on the WTO-TRIPS.

6.2 Legal Reforms on Nigeria counterfeit Pharmaceutical regulation

Nigeria has witnessed the emergence and proliferation of counterfeit pharmaceuticals since the 1980s, and there is an urgent need to reform the counterfeit drug laws and policy to ensure the swift eradication of counterfeit drugs from Nigeria's pharmaceutical system. The first point of call will be to change the existing laws to reflect new realities to achieve rectification. It is a core value of the rule of law, for law protects, respects, and favours every citizen's rights and liberties during new uncertainties. The quality of laws made and upheld needs to be useful, simplified, modified, and effective. Reforming a law is very important, for it allows a country to keep abreast of current situations by effecting changes to its legal system to become more efficient.

Hence the framework for a good law/policy reform should be clear, positive, inclusive, ratified, and publicized. The overall outcome of law reform should not be *perceived as a tool of domination imposed from the outside or the top but provides valuable tools to live everyday life*. Therefore, it is essential to revise the counterfeit drug laws and policy in Nigeria, for reformation will be perceived as an attempt by the government to take definite steps toward controlling the preponderance of counterfeit drugs.

On this note, the first known decree promulgated by the Nigerian military government to control counterfeit drugs in 1988 is decree No. 21, a miscellaneous provision banning the distribution and sale of counterfeit, fake, and adulterated drugs. This

decree was welcomed as a positive act of the Nigerian government to prevent the surge of counterfeit, but the perversity of counterfeit drugs undermined this degree's capability. Other laws have been implemented, such as *the Poisons and Pharmacy Act, Cap 366 of 1990, Food and Drugs Act Cap 150 of 1990, Counterfeit and Fake Drugs (miscellaneous provisions) Act, Cap 73 of 1990, Drugs and related products (registration) Decree No. 19 of 1993*. Invariably, these laws have been futile in rectifying the counterfeit pharmaceutical problems.

Counterfeit drugs' invisible perversity is more insidious than projected; it created the need to re-evaluate the mediocre laws on counterfeit drugs. One of such significant changes in Nigeria reformation policy came with the enactment of the National Agency for Food and Drug Administration and Control (NAFDAC), established by Decree 15 of 1993, amended by Decree 19 of 1999, Act Cap N1 Laws of the Federation of Nigeria, 2004. It is welcomed as an alternative to the failed counterfeit drug laws and decrees. NAFDAC laws are all-encompassing; its provision is substantive, regulatory, procedural, and specifically designed to criminalize acts connected to the sale and distribution of counterfeit, fake, and substandard pharmaceuticals.

NAFDAC is revered as a regulatory organization, but there seem to be legal gaps in the NAFDAC laws from the previous analysis. The first observation is with NAFDAC's mission statement; it appears vague and needs reform because using the catchphrase' *safe guiding public health,"* undermines its stated purpose. Neither does it provide room to interpret the importance of protecting public health literally. For example, the term public health is not explained in the Nigerian context. It is a relative term: it can mean the quality of health, quality of life, preventing diseases, physical and mental health conditions. Thus, what NAFDAC aims to protect is ambiguous.

Secondly, NAFDAC seeks to regulate the manufacture and import of drugs and food into the country, but this vision is not practicable due to a lack of adequate funding and human resources. Even so, Akinyandenu observed that this criterion makes NAFDAC incompetent in tackling Nigeria's counterfeit pharmaceutical needs. Worse still, the law that created NAFDAC is obsolete, for it has not been reviewed since its formation to bring it in line with current situations and problems, especially the challenges presented from falsified, substandard, and counterfeit drugs threat. This law needs to be reformed so it can be more efficient, accessible and can create a fair system of tackling counterfeit drugs within the purview of the law and sustaining public health at the same time.

Recognizing NAFDAC's flaws is necessary, for this is a direct threat to realizing its aims and objective, it is reasonable to suggest possible ways NAFDAC can reform starting from its goal. NAFDAC must review its goal to be broad or all-encompassing and clear. The *agency function is the "regulation, control and investigation of the importation, exportation, manufacture, advertisement, distribution, sale and use of food, drugs, cosmetics, medical devices, bottled water, and chemicals."* It is not explicit; it looks like a one-size fit- law for everything, which creates doubt on NAFDAC's protection. Is it food, drug, cosmetics, or water? If the function of the agency were specific, the surge in counterfeit drug cases would have subsided.

The pharmaceutical sector's importance to public health cannot be overemphasized; it can make or break nations, but scholars have stressed the need for more regulation and good governance practice to protect this vulnerable sector. In Nigeria, NAFDAC is known to have a culture of transparency in the registration, selection, licensing, and procurement of pharmaceutical products. This task is one of the core functions of

NAFDAC. However, issues have been raised about this function. NAFDAC needs to have a transparent system built on integrity, values, and ethical principles to incorporate institutional confidence in its activities and seek stricter rules when issuing medicine permits and registration in Nigeria.

Another recommendation will be to advise the Nigerian government to reform and review the drug laws to enable the judiciary to apply penalties commensurate to the offences. The issue of interpretation hinders the application of existing laws. The punishment for counterfeit drug offences is not specific, so it tends to encourage counterfeiting. If the penalty is stiff (magnitude of the crime and the intention to commit a crime), the fear of the consequences will reduce counterfeit prevalence. The drug laws conflict concerning scope and application in different counterfeit situations. The government should call for a judicial reform constituting a well-structured approach that brings all the partners and leaders in the pharmaceutical, legal, and economic sectors together to propose a new approach to resolving the surge of counterfeit pharmaceuticals.

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