



Balancing WTO-TRIP's Standard against Nigeria Counterfeit Regulatory Efforts: a Critique

Ifueko I. Imasuen and Augustine O. Nwajana

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Balancing WTO-TRIP's Standard against Nigeria Counterfeit Regulatory Efforts: A Critique

Ifueko I. Imasuen, University of East London, United Kingdom

Augustine O. Nwajana, University of Greenwich, United Kingdom

Abstract

Recent years has seen the rapid growth and scale of Counterfeit Pharmaceuticals in Nigeria irrespective of the Intellectual Property Right (IPR) standard provided by the World Trade Organisation-Trade Related aspect of Intellectual Property Right (WTO-TRIPS) Agreement. The effect of the WTO-TRIPS protection of Intellectual Property Rights creates the problem of access to medicine for developing countries. This has provoked counterfeit pharmaceutical activities worldwide and prevalently in Nigeria. The aim is to ascertain, by way of analytical framework the viability of the WTO-TRIPS agreement for addressing the scourge of counterfeit pharmaceuticals in Nigeria. The concept of counterfeit pharmaceuticals will be explored, and its parameters defined as a premise for testing the viability of the WTO-TRIPS and the Nigerian Counterfeit regulatory framework.

Introduction

“The tremendous increase in IP application in recent years reflects the growing importance of technology and innovation in a global economy and our daily lives”¹ (WIPO, 2019)

The relevance of innovation or novelty today is so essential a complementary right is created to protect its advancement. It is a way of thinking outside the present rather it is a future based insight. Innovation compares past and future ideas to solve a future problem². Innovation is usually linked to creativity, in the words of Tienken *creativity is new, unique and creates innovations in countries*³ 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. Having established the fact that IP is a unique value-adding creation,⁴ which generates a legal right when the due process of registration and grant of according right is established, thus it creates an entitlement to creativity.

However, the question of 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

¹ 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, Available https://www.wipo.int/wipo_magazine/en/2019/03/article_0002.html Accessed (27 December 2019)

² Anneli Stenberg, What does Innovation mean – a Term Without a clear definition

³ Christopher H. Tienken "International Comparisons of Innovation and Creativity."(2013), Vol 49 No 4 *Kappa Delta Pi Record*, PP 153-155.

⁴ Christopher M. Kalanje, "Role of intellectual property in innovation and new product development." 2006, World *Intellectual Property Organization*

supported by scholarly evidence advocating clarity in the interpretation of what a right to property means. Secondly, it is right to understand the nature of TRIPS protection and the strategy preferred for the utilization of this protection especially in developing countries (Nigeria) for if the protection authorized by the World Trade Organisation established any discrepancy in its application will be underlined and questioned in resolving Nigeria counterfeit drug problem.

The nature of Intellectual Protection

The subject of Intellectual Property is unknown and side-lined in the 1960s but over time it has gained widespread acceptance as a viable instrument for economic growth and development. States have come to recognise and see IP as a new form of 'resource' which can foster innovation, development, and shape economic relations. In today's conditions, an intellectual resource is an intangible right to a creative outcome, be it scientific, industrial or any creative step new to mankind is deemed a resource worthy of protection. In this note, any unauthorized use of IP resources is tantamount to stealing a creator's legal authority over his goods. To safeguard against unauthorized use, states approve legal protection on IP to encourage new technological inventions, artistic expression, and creativity with the sole objective of preventing others from benefiting from the sweat of another and to encourage 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 right, two key issue needs further clarification, these includes:

- 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 the strategy adopted by TRIP integral for innovative growth in developing countries.

On the first issue, it is already established that IP is a form of property granted by national law of a state and governed within the exclusive jurisdiction of that state, the law in that jurisdiction determines the time frame, limitation, minimum requirement, and usage of such right⁵. However, *Lemley* believes that it is rather absurd to associate IP with real property (propertization⁶) 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, this 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 what is a right and the type of property instead it looks at the ordinary meaning of terms⁷. Given this argument, IP is a recognised right that is knowledge-based given to a private individual or party to control information accruing from creative ability or outcome⁸. It is also quite clear that intellectual property rights are territorial, and it is different from tangible property.

Following the idea established earlier, on delineating IP from tangible property, *Easterbrook* equated both regimes and concluded that IP and property are similar,

⁵Jonathan M W 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 -345

⁶Michael A. Carrier "Cabining intellectual property through a property paradigm. (2004), 54 *Duke Law Journal* 1. The context of IP over the years have 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 have limited the expression of IP for instance 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.

⁷Mark A .Lemley "Property, intellectual property, and free riding.(2004) 83, *Texas Law. Review*, 1031

⁸Harry Surden, 'Technological Cost as Law in Intellectual Property' (2013) 27, No 1 *Harvard Journal of Law & Technology* 135-202

for example, the framework of the invention improves with time resulting in a new and better product, which inadvertently means more financial gains, this is similar to developing a property to secure more profit. Another connection is the issue of monopoly, a patent or copyright entitles a right holder to control its output to the exclusion of all others, also IP rights holders have the right of exclusion same as a tangible property right holder⁹. Importantly, research proves that IP and property rights are intricately connected but the true nature of this relationship needs clarification in a bid to correctly contextualise IP, IP pertains to the right to abstract ideas¹⁰ so it justifies suggesting 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 nature of the principle of an agreement is tedious, and can cause ambiguity in its interpretation if an ordinary approach is adopted then an intellectual question on its nature might seem unanswered because the more abstract it is, the more difficult it will be to analyse¹¹. But without dissipating ambiguity, the existing principle cannot be disputed or probed this is the case of the WTO-TRIPs agreement. The nature and purpose of TRIPS can only be understood within a wider context of the WTO agreement. The WTO agreement is all-encompassing and unique in all facets but scholars have argued that the WTO IP rules in developing countries are detrimental to fundamental health and life and if possible

⁹ Frank H. Easterbrook, "Intellectual Property Is Still Property," (1990) 13, Harvard Journal of Law and Public Policy 108.

¹⁰ Milkhalien Du Bois, Justification theories for Intellectual Property Viewed Through the Constitutional Prism, (2018) ,No 1, *Potchefstroom Electronic Law Journal/Potchefstroomse Elektroniese Regsblad* 21

¹¹ John P .Humphrey, "On the definition and nature of laws, (1945) Vol 8, issue 4 *The Modern Law Review* 194-203.

an absolute nightmare for developing countries¹² prompting various debates on the suitability of having a uniform standard in a diverse world¹³. This begs the question of the nature of what TRIPS aim 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 collectively¹⁴ and 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 rights¹⁵. 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 a legal mandate, that's not the case of TRIPS. It is an annexe of the WTO i.e. a *de jure standards* thus a legal requirement is already created by the WTO¹⁶. TRIPS require all members to adapt their laws to fit into the minimum required standard of IPR protection even though it will have a great impact on access to medicine and the pharmaceutical sector¹⁷, this standards or obligation is mandatory for all members in respect of their development position.

¹² Peter K. Yu, The Objectives and Principles of the TRIPS Agreement, (2009), 46 Houston Law Review .979 (2009). Available at: <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 stifle the development of IP.

¹³ 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)

¹⁴ Peter K. Yu, The Objectives and Principles of the TRIPS Agreement, (2009), 46 Houston Law Review .979 (2009). Available at: <https://scholarship.law.tamu.edu/facscholar/457>

¹⁵ Taubman, A., Wager, H., & Watal, J. (Eds.). (2020). *A handbook on the WTO TRIPS agreement*. Cambridge University Press.

¹⁶ Steven M. Spivak , *Standardization Essentials : Principles and practice* 2001 (CRC Press, New York)

¹⁷ 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)

No proof increasing standards increases economic welfare instead 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 process¹⁸ even though the term was shorter in most developing countries resulting in the rise of counterfeit pharmaceuticals. Essentially TRIPS ought to set applicable standards, not a one size fits all approach but permit diverse standards¹⁹ that the state can efficiently utilize.

The compulsory license right on pharmaceuticals in Nigeria and the 'generics'

This section will look at the provision and operation of the phrase '*other use without authorization of the right holder*' otherwise known as a compulsory license. It is not explicitly found in the TRIPS Agreement²⁰ but it is inferred into the agreement by its purposed use that is, striking a balance between research and development in new drugs and promoting unlimited access to drugs. To developing countries, it is a welcomed idea, but it still illustrates the existing inequality operating within the multilateral trade regime of the WTO. Therefore, a detailed analysis of how compulsory licence is interpreted and utilized will be examined in a bid to

¹⁸ 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 for the protection of industrial property, the 1971 Berne convention for protection of literary and Artistic work.

¹⁹ Steve Charnovitz, "International Standards and the WTO,(2005)George Washington University Law School, Legal Studies Research Paper 394, http://scholarship.law.gwu.edu/faculty_publications/394

²⁰ WTO- 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 and this means or includes use of any patent right by the government for their own purposes without getting formal authorization from the right owner especially if voluntary licence application has failed but if compulsory licences is granted the right holder is adequately remunerated.

demonstrate the silent problems associated with its application especially in the aspect of Nigerian counterfeit drug problems.

A compulsory licence 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 consent of a right owner²¹. Regardless of the foregoing, compulsory license is deemed an exception to the bold expression of the right to intellectual property, as the consent of the right owner is not demanded, In order words, it takes away the right conferred on a right owner which is the right of acceptance or refusal, this is an infringement to ownership. Nevertheless, a Compulsory license is valuable, as a means of saving lives, a government can authorise the use of a pharmaceutical patent for its use in a bid to address public health problems.

The idea behind compulsory licence originates from the lack of access to essential medicine, particularly in developed and LDC often because these pharmaceuticals are unaffordable²². This concern was 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 Doha declaration of TRIPS agreement²³. This declaration affirmed that the TRIPS agreement should be implemented in such a way that it is not detrimental to Public

²¹ 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)

²² Ellen F.M Hoen, Jacquelyn Veraldi, Brigit Toebe, & Hans V. Hogerzeil, Medicine procurement and the use of flexibilities in the Agreement on Trade-Related Aspects of Intellectual Property Rights, 2001–2016, (2018) , Vol 96, Issue 3 ,*Bulletin of the World Health Organization*,doi:10.2471/BLT.17.199364

²³ Carlos M. Correa, World Health Organization, *Implications of the Doha Declaration on the TRIPS Agreement and public health*, No. WHO/EDM/PAR/2002.3. Geneva: World Health Organization, 2002

Health in respect to its scope, implication, implementation and application, whilst still recognising the importance of intellectual property to the advancement of new drugs²⁴.

Article 31 of the TRIPS Agreement provides for a compulsory license, it 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'*²⁵.

In retrospect, the Doha Declaration further simplified 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 a commitment*

²⁴ Ibid Ellen F.M Hoen, Jacquelyn Veraldi, Brigit Toebes, & Hans V. Hogerzeil, Medicine procurement and the use of flexibilities in the Agreement on Trade-Related Aspects of Intellectual Property Rights
²⁵TRIPS 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 individual merits;

(b) such use may only be permitted if, prior to 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 of time. 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 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 search, 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 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 legitimate interests of the persons so authorized, to be terminated if and when the circumstances which 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, taking into account 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 other independent review by a distinct higher authority in that Member

to patent protection 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 all²⁶. 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 case of market failure (patented pharmaceuticals)²⁷. Article 31 clearly instructs that a compulsory licence must be issued principally for the supply and utilization by the domestic market of the TRIPS member granting the licence. However, countries without a substantial pharmaceutical sector have not been able to utilize the compulsory licensing provisions of TRIPS²⁸.

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 be able to oppose the production and distribution of the generic version of the pharmaceutical. This 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 whereas in developing countries such as India it cost \$539, this is exceedingly expensive the Malaysian government issued a compulsory licence for this drug²⁹, thus reducing the earning powers of the patent holder.

²⁶ 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

²⁷ 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

²⁸ 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

²⁹ Ooms, G., Forman, L., Williams, O. D., & Hill, P. S. (2014), Could international compulsory licensing Reconcile tiered pricing of pharmaceuticals with the right to health? *BMC international health and human rights*, 14(), 37

To developing countries, the compulsory licence is a welcomed development to solving public health crises such as tuberculosis, malaria, Ebola and HIV Aids crisis³⁰ 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* failed³¹. However, the emergency is not limited to just these diseases but covers any public health concern, to health advocates, a compulsory license can lead to low priced drugs in cases of national crisis³². Consequently, compulsory license repels the standards of intellectual protection dictated by TRIPS and it guarantees access to essential medicine making it a legal exception to the TRIPS directive.

With regards to Nigeria, the compulsory license is enshrined in the Nigerian patent and design act, particularly in section 11, which states as follows. That *the provisions of the First Schedule to this Act shall have effect concerning compulsory licences 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 certain categories thereof) declared by the order to be of vital importance for the defence or the economy of Nigeria or public health, compulsory licences may be granted before the expiration of the period mentioned in*

³⁰ Hestermeyer, Holger. *Human rights and the WTO: the case of patents and access to medicines*. (Oxford: Oxford University Press, 2007)

³¹ Eric Bond, 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 the price of efavirenz, even after the price reduction (30%). The government issued a 5 year compulsory license but still the local company for the production of efavirenz, did not have the manpower or technology.

³² 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

*paragraph 1 above and may permit importation*³³. The provision of this act allows a government agent or minister to adopt compulsory license on any ancillary matter with access to patented medicine, although it is not automatic. Only the court can authorize the grant if the following conditions have been established (i) inability to obtain patented licence (ii) parties cannot agree on terms (iii) patentee will be adequately remunerated (royalty or otherwise) taking into account the relevant invention to be worked(iv) it will be contrary to the public interest if not granted. Once all these conditions have been established a compulsory license will be authorized. These conditions, however, can be waived in the case of extreme emergency or national emergency termed government use³⁴. In principle, the compulsory licence is a welcomed development giving that in the past, most developing countries and developed countries did not permit patents on pharmaceutical products³⁵. It is a vital government tool for exemption of liability especially in the context of pharmaceuticals, even if the rights of a patent holder are undermined, the zeal to save the public comes first.

For a country like Nigeria, a compulsory licence seems to be a viable option for its failing public health. In the words of Winslow "*Public health is the science and art of preventing disease, prolonging life and promoting physical health and efficacy through organized community efforts for the sanitation of the environment, the control of communicable infections, the education of the individual in personal hygiene, the*

³³ Patents and Designs Act, Chapter 344 Laws of the Federation of Nigeria 1999, Cap C23 Laws of Federation of Nigeria

³⁴ Jerome H. Reichman "Comment: compulsory licensing of patented pharmaceutical inventions: evaluating the options." (2009) Vol 37.2 *the Journal of Law, Medicine & Ethics* PP 247-263. 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 won't be the case if the WTO had not increase its minimum standard of patent protection without underpinning effect on developing countries.

³⁵Ibid, Hestermeyer, Holger *Human rights and the WTO: the case of patents and access to medicines*

*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 birthright and longevity.*³⁶ 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 is relatively a new diseases³⁷. Faced with this growing threat a state must ensure the best possible health care, for this, the Nigerian government is expected to seek the best possible option available (compulsory license) especially with regards to increasing the cost of producing drugs and the new problem of pharmaceuticals counterfeit.

The Nigerian government is saddled with challenging issues underpinning its pharmaceutical sector. Reports have shown that counterfeit still subsist regardless of measures put in place by both state and international authorities. Counterfeit pharmaceutical as the name implies is 'a drug which is deliberately and fraudulently mislabelled concerning identity and source'³⁸ resulting in high morbidity, mortality and damage to public health structure.³⁹ Also, 'counterfeit drug' can be regarded as 'any drug or medical product, which is not what it purports to be, coloured, coated or polished to which the damage it creates is far greater than the therapeutic value' it

³⁶ Koplan, Jeffrey P., T. Christopher Bond, Michael H. Merson, K. Srinath Reddy, Mario Henry Rodriguez, Nelson K. Sewankambo, and Judith N. Wasserheit. "Towards a common definition of global health" *The Lancet* 373, no. 9679 (2009): 1993-1995 citing Winslow Charles-Edward. "The untilled field of public health" *Mod Med* 2 (1920).183-91

³⁷ Rosen, George. *A history of public health*, (John Hopkins University Press: New York, 2015)

³⁸ WHO Guidelines for the development of measures to combat counterfeit drugs

³⁹ Robert Cockburn, Paul Newton, E. Kyeremateng, Dora Akunyili, Nicolas J. White , The Global Threat of Counterfeit Drugs : and Why Government Must Communicate the Dangers, (2005) PLoS Medicine Vol. 2 (4) e100

purports to resolve.⁴⁰ It undermines the stated provision of the Nigerian constitution, which guarantees the right to health for its citizen and it can be said to destabilize the right of Nigerians to quality medicine needed for the treatment of disease⁴¹

The problem of counterfeit Pharmaceuticals 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 in Africa provided evidence to support the claim of counterfeit pervasiveness in Africa. It is estimated by the World Health Organisation (WHO) that 10% of drugs sold globally are counterfeit. It also reveals that out of this 10%, 30% is sold in Africa⁴². 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 result is an indicator that most drugs consumed by Africans are either counterfeit or fake.

The consequence of counterfeit has resulted in over 700,000 death from counterfeit consumption annually in Africa, with most of the drugs originating from china, India, Mexico and Brazil.⁴³ An example is the discovery of a lethal amount of melanin in baby formula and the sale of pharmaceutical with little or no active ingredient⁴⁴. The Nigerian Government is inundated with the task of providing essential medicine and proper health facilities for its citizen despite the prevalence of counterfeit medicine. The issue of counterfeit remains of great importance to the Nigerian government and

⁴⁰ Section 12 of the Nigerian counterfeit and fake Drugs (Miscellaneous provision) Act, Cap C34, Laws of the federal republic of Nigeria (LFN)2004

⁴¹ The Constitution of Nigeria 1999, CAP 23 LFN

⁴² 33BBC NEWS, Counterfeit Drugs 'may Kill You or cause Superbugs' September 2013 Available <http://www.bbc.co.uk/news/health-24270737> Accessed (16 May 2016)

⁴³ Jeremy M. Wilson, Roy Fenoff, The Health and Economic Effect of Counterfeit Pharmaceuticals in Africa

(2011) A-CAPPP Background, Available <http://a-capp.msu.edu/sites/default/files/files/africabackgroundfinal.pdf> Accessed (25 April 2016)

⁴⁴ International Standard Organisation (Jan 2014) Crackdown on counterfeiting , Elizabeth Denis Available <http://www.iso.org/iso/news.htm?refid=ref1809> Accessed (30 March 2016)

most pharmaceutical products in Nigeria may be fake, substandard or counterfeit.⁴⁵

Counterfeit medicines and other public health issues greatly affect people's health in Nigeria.

Counterfeit stifles the economic growth of countries for it can reduce economic incentives, technological know-how and it can decrease product value in Pharmaceuticals⁴⁶. The WHO projected that economic loss as a result of counterfeit drugs will amount to over \$75 billion. Which is a significant loss to pharmaceutical companies.⁴⁷ Consequently, the economic effect of counterfeit pharmaceuticals can lead to loss of legitimate drugs sale. As Peter Bloch, Ronald Bush and Leland Campbell point out that, a high percentage of producers of legitimate goods face damages to brand reputation due to counterfeit. Hence producers in a bid to save brand names fail to inform consumers of the potential existence and consequence of counterfeit pharmaceuticals this has further increased the growth of counterfeit.

The plague of counterfeit pharmaceuticals especially in Nigeria is now regarded as a global phenomenon with far-reaching effects. For example, consumption of counterfeit led to the death of 2,500 children in the Niger republic from vaccines donated by the Nigerian government. As well as the death of 109 children reported in southern Nigeria following the consumption of counterfeit paracetamol found to contain toxic ethylene glycol solvent instead of propylene glycol⁴⁸. Factors attributed for the prevalence of counterfeit pharmaceutical includes ineffective drug supply, high rate of infectious

⁴⁵ Ohuabunwa ,M, Health care Delivery in Nigeria, Past Present and the Future, Nigerian Journal of Pharmacy Vol.31 (2002) pp15-17

⁴⁶ Jeremy M. Wilson , The Health and Economic effects of counterfeit Pharmaceuticals in Africa 2011 A- CAPPP Available a-capp.msu.edu/sites/default/files/files/africabackgroundfinal.pdf

⁴⁷ WHO 2006

⁴⁸ Dora Akunyili, Fake and Counterfeit Drugs in the Health Sector: The Role of Medical Doctors, Annals of Ibadan Postgraduate Medicine Vol.2 No.2 (2004) PG 19-22

diseases like as malaria, HIV, Tuberculosis and tropical diseases, irrational use of drugs, poor database and ineffective alliance between government agencies and other professional bodies responsible for the control of pharmaceuticals. It is imperative to examine the drug situation in Nigeria, starting from the pharmaceutical market⁴⁹.

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 per cent yearly to reach US\$ 717 million by 2019. Despite the Nigerian Government efforts to promote domestic production of pharmaceuticals, Nigeria remains largely dependent on imported pharmaceutical products. 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%⁵⁰.

Essentially the delivery of drugs in Nigeria is chaotic; drugs are sold everywhere from sale in an open market, patent medicine stores, wholesalers and pharmaceutical manufacturers. There is no proper mechanism in place to make checks and balances on the inflow of drugs in the health sector in Nigeria. It is a common occurrence to see public displays 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^{51,52}. From the stated facts above, it is evident that Nigeria's health care system

⁴⁹ Bale.H.E , 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)

⁵⁰ Okoli, S Pharma Industry in Distress , Pharma news Vol22 Issue 3 (2000) pp 1

⁵¹ Adelusi Adeluyi , Drug Distribution : Challenges and Effects on the Nigerian society, Keynote speaker at the

⁵² rd Annual National Conference of the Pharmaceutical Society of Nigeria , November 2000

is poorly organised and mismanaged. To the extent that counterfeiters are so skilled in making counterfeit medicine authentic⁵³. It is so appalling that a 2018 Lancet study ranked Nigeria health care quality 142nd out of 195 countries⁵⁴, which is extremely low compared to other countries. 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 expectancy is estimated to be about 55 and 50 years⁵⁵. This is expected from a country where infectious disease, malaria, diarrhoea, river blindness, tuberculosis, and ultimately HIV etc is part of the everyday life of Nigerians. Unfortunately, the problem of counterfeit drugs and lack of essential medicine such as Antimalarial and HIV drugs have enhanced the prevalence of counterfeit. As indicated by a recent review of the chemical components of some Antimalarial drugs. The review confirms that over 36% of the drugs tested failed the chemical analysis.⁵⁶

Another problem recognised for 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 ideal 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 cost of research and development (R&D). In this light, IP is a justification for the economic exploits of Pharmaceutical products. But this absolute right gives rise to

⁵³ BBC New, 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 (18 June 2020)

⁵⁴ Fullman, N., Yearwood, J., Abay, S. M., Abbafati, C., Abd-Allah, F., Abdela, J., ... & Abraha, H. N. (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. *The Lancet*, 391(10136), 2236-2271

⁵⁵ WHO Mortality Fact Sheet 2006

⁵⁶ WHO, Malaria rapid Diagnostic test performance Available, http://whq.who.int/publication/2010/9789241599467_eng.pdf Accessed (23 May 2016)

counterfeit which is an infringement of IP. Thus, the act of counterfeiting amounts to theft for it misleads the consumers and it can damage the goodwill of manufacturers. The WTO–TRIPS framework created a stronger patent protection regime by restricting statutory monopoly to an inventor, to solely enjoy the right of its invention. This protection with regards to pharmaceuticals implies that it enabled pharmaceutical companies to manipulate the price and supply of medicines, inadvertently making them inaccessible and extremely expensive to the public, especially in developing countries. The menace of counterfeit pharmaceuticals in Nigeria can be traced from 1985 to 2000 and the situation has not changed to date⁵⁷. On the whole, the limitation that is, the protection between IPR and the quest to have access to medicine, over and above the protection of IPR, introduced the element of counterfeit pharmaceuticals within the Nigerian system.

The scourge of counterfeit and substandard drug is contrary to the goal of ensuring safe cost-efficient pharmaceutical that meets the national health needs. The capacity to meet this stated need seem unrealistic in the face of Nigeria failing developmental and medical agenda. It is 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, UK. The country lacked viable local industry to produce drugs (process or product) neither was patent rule acceptable nor practised; therefore, TRIPS standard on drugs seems unlikely.

Although, a Compulsory license is an all-encompassing solution to the TRIP tough patent defect in developing countries. Certain concerns have been raised that there is a possibility that compulsory license seems to have an adverse influence on the

⁵⁷ W.O.Erhun, O.O .Babalola, M.O. Erhun, Drug regulation and control in Nigeria: the challenge of counterfeit drugs, *Journal of Health and Population in Developing Countries* Vol.4, Issue 2. (2001) pp 23-34

increasing level of counterfeit pharmaceuticals for example it allows unapproved generic drugs to be manufactured and distributed, this raises a safety issue⁵⁸, that counterfeit drugs can be possibly manufactured instead of the original drugs, moreover, developing countries with a large population like Nigeria (lax immigration) can be used as dumping ground for unwanted generic irrespective of its source or dangerous impurities utilized.

In conclusion, the compulsory license is an all-important administrative right bestowed on the government for the protection of public health, but for developing countries, effective utilization seems to affect the use of this right, joint harmony amongst stakeholders of developing countries can effectively be used to reduce the price of medicine, without actively relying on compulsory license, it should be a last resort to unforeseen emergencies.

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 cell⁵⁹ 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 subsequent death for use. Therefore, existing strategies ought to be critically examined in a bid to draw a contrast if, existing IP rules authorized by TRIPS stifle the availability of pharmaceuticals in

⁵⁸ Muhammad Zaheer Abbas, Pros and Cons of Compulsory Licensing: An Analysis of Arguments (2013) Vol 3, No3 International Journal of Social Science and Humanity PP254-258

⁵⁹ 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

Nigeria. One such adopted option available to developing countries is the parallel import option.

Although the Nigerian National Drug Control Master Plan (NDCMP) offers an integrated and comprehensive approach towards tackling the issue of pharmaceuticals for 2015-2019. The plan includes regulation of counterfeit drug supply and distribution following international regulatory authority on drug control and use. It is established that a viable drug plan does exist that recognise international authority for pharmaceutical regulation. However, the paramount goal of this drug plan is the eradication and reduction of counterfeit to the barest minimum. The plan is strategic, for it links rule of law to public health whilst 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 criminalising the production and distribution of counterfeit or illicit drugs. To sustain this approach, Nigeria ratified both regional and international agreements on anti-drug initiatives and programmes in a bid to control 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 drug counterfeit or illicit drugs. The law enforcement agency is considered obsolete and not proactive in intelligence collection and analysis. It lacks professionalism, unlike other recognised 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 the operations of law enforcement agencies at the federal and state level for both levels lacked corporation in strategic drug issues⁶⁰. Perhaps the shortcoming of this plan is, it is keen on curtailing drug trafficking and use of Narcotic substances for medical and scientific purposes⁶¹, instead of solving the problems of counterfeit pharmaceuticals, counterfeit is a core problem affecting both public health and the economy if till now no adequate drug plan has not been proposed, then how will this new drug plan be proficient. Nigeria needs to develop a viable drug policy for example in Malawi, interested parties in the supply and distribution of drugs gathered to form a proficient drug policy from collaboration⁶². The latter issue is relevant and ought to be taken seriously by the Nigerian government policies formation to control the increasing rate of pharmaceutical counterfeit.

Another relevant narrative on drugs is the Nigerian National Drug plan supported and promoted by the World Health Organisation (WHO) point out that, as far back as 2003 a drug plan existed for Nigeria. Though obscure it serves as a precedent to develop a valid efficient plan considering the counterfeit issue. The background of the drug plan states that” *no matter how vibrant a health policy is, without the availability of good*

⁶⁰ 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](file:///C:/Users/ugo/AppData/Local/Packages/Microsoft.MicrosoftEdge_8wekyb3d8bbwe/TempState/Downloads/ndcmp-2015-2019%20(1).pdf) Accessed (25 January 2020)

⁶¹ United Nation Office on Drug and Crime (UNODC) Nigeria takes lead, rolls out policy documents to improve availability and access to controlled medicines and improve drug treatment standards Available <https://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 the recognition of 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 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.

⁶² Ransome O .Kuti, National Drug Policy in Nigeria , (1992), Vol 13 ,No 3 Journal of Public Health Policy, pp. 367-373

quality and affordable medicines, that policy will be sterile” therefore affordable and safe medicine is an essential goal of an innovative drug plan. The goal of the national drug policy 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 system, promoting rational use of drugs, control and regulate the importation, distribution sale of medicines and to increase research on alternative medicine⁶³.

Following the establishment of the potential existence of a national drug plan in Nigeria, the next step is to examine the core issue of this section which is the applicability of parallel import on the Nigerian national drug plan. Parallel import otherwise known as (PI) is a very controversial topic amongst IP scholars and commentators who have a diverse perspective on its significance in the global trading regime. Strong IP advocate support banning PI, arguing that it reduces profit incentive in the pharmaceutical industry and can undermine the growth capacity of the research in pharmaceuticals. But this school of thought contravenes the interest of developing /underdeveloped countries, which places a high value on the affordability of medicine rather than supporting a strong IP regime⁶⁴. Thus, a strong patent invariably leads to high drug price which is at variance with access to affordable medicine⁶⁵.

⁶³WHO Nigerian National Drug Policy 2003 Available <https://apps.who.int/medicinedocs/documents/s16450e/s16450e.pdf> Accessed (25 January 2020)

⁶⁴ Maskus, Keith E. "Parallel imports in pharmaceuticals: implications for competition and prices in developing countries." *Final Report to World Intellectual Property Organization* 13 (2001), Available https://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.

⁶⁵ Danzon, Patricia M., 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 183-205.

The concept of PI is important 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 of exchange of 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 the valuable commodity⁶⁶. In contemporary society, much value is placed on Pharmaceuticals for it is essential to both public health and economic development. It is like a double-edged sword, on one hand, is the impact of price on access and affordability and on another hand 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 company⁶⁷.

The pharmaceutical industry is said to be one of the most successful industries accounting for the high profit margin necessary for its rapid growth. To Kyle, the price of pharmaceuticals is found to be very important 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 revenue⁶⁸. With much revenue generated it can be implied that these companies may exploit the need of consumers particularly the most vulnerable in the society for higher returns on investments. Although monopoly stimulates innovation the dire consequences of this on middle-

⁶⁶ Frank A. Fetter, The Definition of Price, (1912) Vol. 2, No. 4 ,The American Economic Review pp. 783-813

⁶⁷ Dos Santos, Maria Angelica Borges, Leticia Lucia dos Santos Dias, Cláudia Du Bocage Santos Pinto, Rondineli Mendes da Silva, and Claudia Garcia Serpa Osorio-de-Castro. "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

⁶⁸ Kyle K. Margaret. "Pharmaceutical price controls and entry strategies. (2007),Vol 89 Issue 1 *The Review of Economics and Statistics* 89.1 (2007): pp. 88-99.

income countries cannot be determined due to inaccurate recording systems thus price undermines the total utilization of drugs prompting the rise of generic medicine.

Global sale of generic pharmaceuticals has increased drastically, although a source of controversy amongst brand own pharmaceutical thus altering the competitive dynamics in the pharmaceutical market. Grabowski and Vernon observed a price correlation between generic and branded pharmaceuticals, as generic price reduced, the price of branded medicine increased leading to a substantial shift in the pharmaceutical market⁶⁹. Gibson, Ozminkowski, and Ron Goetzel believe that generic is a form of cost-sharing but hold reservations on its therapeutic value⁷⁰. Hence, it can be concluded that generic rivalry reduced the prices of pharmaceuticals but the contradictory effect in less-regulated regimes can be challenging and result in a different option.

One such option available to developing countries endorsed by the 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 "that welfare implications of allowing parallel imports is ambiguous"*⁷¹. However parallel imports are genuinely patented and trademarked goods still having subsisting Intellectual property protection, placed into circulation in one market, but imported into a second market without due authorization from the license right holder. This product is not different from the original product although may be packaged differently, without the original licence owner warrant. It is important to note that the product is presumed to be

⁶⁹ Frank, Richard G., and David S. Salkever "Generic entry and the pricing of pharmaceuticals" (1997) Vol 6 issue 1 *Journal of Economics & Management Strategy* PP 75-90.

⁷⁰ Gibson, Teresa B, 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.

⁷¹ Keith E. Maskus, Yongmin Chen. "Vertical price control and parallel imports: theory and evidence."(2004) Vol 12, Issue 4 *Review of International Economics* pp551-570.

genuine, not counterfeit. However, PI is legal (international exhaustion) but contravenes the principle standpoint of intellectual property⁷².

Developing countries are keen on availability rather than 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 a prerogative individual states can exercise, though states can choose any form of exhaustion. The policy on Exhaustion comprises of three distinct concepts, the first is national exhaustion here the holder of IP right to a product is exhausted when the product is placed in the national territory, whilst regional exhaustion is when IP holder product is placed in a regional province, for instance, the African union regional market in this note "Parallel imports" will only be permitted, but only with regards to goods initially placed on the market within a regional territory. Whereas "international" exhaustion policy, makes the IPR holder's right extinguished when a protected product is placed 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 world⁷³.

Nevertheless, to WIPO, exhaustion is a limitation to IP rights, as the name implies it simply means the exhaustion of IP right in a product after the sale. This means the

⁷²Keith E. Maskus, Parallel Imports in Pharmaceuticals: Implications for Competition and Prices in Developing Countries (2000) Vol 23, Issue 9 *the world economy* pp1269-1269. PI of pharmaceuticals can be observed to restrict the incentive to produce new pharmaceuticals, IP supporter have argued for states to desist from using PI for it slows down innovation and creativity. However, developing countries and public health advocates have argued that availability of pharmaceuticals is far more vital than the source of the pharmaceutical.

⁷³ Abbott, Frederick M. "Parallel Importation: Economic and social welfare dimensions." *International Institute for Sustainable Development (IISD), Swiss Agency for Development and Cooperation (SDC)* (2007), Countries tend to pick and choose exhaustion policy to adopt to fit its peculiar circumstance, for instance a country may adopt regional exhaustion policy for goods protected by patent, and will adopt national exhaustion policy for copyright protected product.

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 owner⁷⁴. The Doctrine of exhaustion provides a legal base for PI, certain factors can influence PI such as price: It plays a key role in the Parallel trade of pharmaceuticals, a high price can prompt competition between the original producer and parallel importers⁷⁵. 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 pharmaceuticals⁷⁶.

The salient idea on PI from a developing country perspective is, PI ensure 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 rates or subsidised, this can set a standard for negotiations amongst pharmaceutical importers to dictate the basis of sale 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 by been a member of the Economic Commission of West African States (ECOWAS). ECOWAS rules do not support regional exhaustion neither has its competition rule been domesticated in its regional states. In practice, national exhaustion ought to be applicable but the supreme court in Nigeria deliberated on the issue of *consent* and protection in the case of *Dyktrade v. Omnia, on IP protection the*

⁷⁴ WIPO, International Exhaustion and Parallel Importation, Available https://www.wipo.int/sme/en/ip_business/export/international_exhaustion.html Accessed (09 February 2020)

⁷⁵ 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

⁷⁶ 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. Law Journal*10 (1999): 185

court contended that the registered owner of a product can institute actions against trademark infringement but the court goes further to clarify who is entitled to protection to include the owner, importer and exporter⁷⁷. Whereas on the subject matter of consent the supreme court in *Ferodo Ltd v. Ibeto Ind. Ltd* held that “ A proprietor has the exclusive 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 goods⁷⁸.”

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 Motors⁷⁹ 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 Limited⁸⁰*, here the court held that parallel importation is a foreign doctrine, which is not actionable under Nigerian Law⁸¹. This means for PI to be applicable in Nigeria, it is by way of international exhaustion, but no rule suggest 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 make applicable the WTO binding rules in its domestic legal system⁸².

⁷⁷ *DYKTRADE LIMITED (APPELLANT)V OMNIA NIGERIA LIMITED (RESPONDENT)(2000) All N.L.R. 591*

⁷⁸ Olasupo Shasore SAN, Parallel import –How to Manage the Problem , Available <http://www.ajumogobiaokeke.com/wp-content/uploads/2018/01/c930665fe00db0095450d9d46b3e39d6.pdf> Accessed (18 February 2020)

⁷⁹ (2005)14 NWLR

⁸⁰ (LER [2006] CA/L/282/2001)

⁸¹Banwo and Ighodalo, Fair Trade, Monopoly and Competitiveness: appraising the Legal Rights of Franchisees against Parallel Imports in Nigeria Available <https://www.banwo-ighodalo.com/assets/grey-matter/0d297c0b10ddcd02b610149391ac60f3.pdf> Accessed (18 February 2020)

⁸² 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. 969-984. The WTO upholds a principle of equality by making fair rules applicable in all states in respective of state of development; its rules have developed for over 50 years to become a distinctive legal order containing body of rules.

Perhaps in Nigeria, the institution of PI may serve as a myriad of solutions in its struggle with the high cost of pharmaceuticals, nonetheless, the exclusive right of an IP owner is not exhausted. Consequently, legal options may seem laudable in certain cases to assert ownership excepting where international exhaustion supersedes an individual right to IP. The underlying principle interpreted on PI is availability and accessibility of essential pharmaceuticals, but PI may have a significant impact on the surge of counterfeit drugs. A gap is created when the price of medicine vary in a different jurisdiction as a result of PI, the outcome is the introduction of counterfeit in the supply chain, equally the right owner may have lost IP right to sue for infringement or detect low quality or counterfeit product for PI erode the legal right to IP. To Liang it is perceived to be a global phenomenon, stating that price differentiation creates an incentive to move medicine from one jurisdiction and 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 circulation⁸³ 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 patient⁸⁴.

⁸³ 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 Regulation* PP 847

⁸⁴ Dégardin, Klara, Yves Roggo, and Pierre Margo "Understanding and fighting the medicine counterfeit market." *Journal of pharmaceutical and biomedical analysis* 87 (2014): 167-175. The distribution of finished medicine can be resold in Europe and America by PI, it is legal by virtue of European union accepting to utilize regional exhaustion, unlike west Africa where 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 repackaged and resold ,possibly allowing fakes or substandard drugs to infiltrate the distribution network.

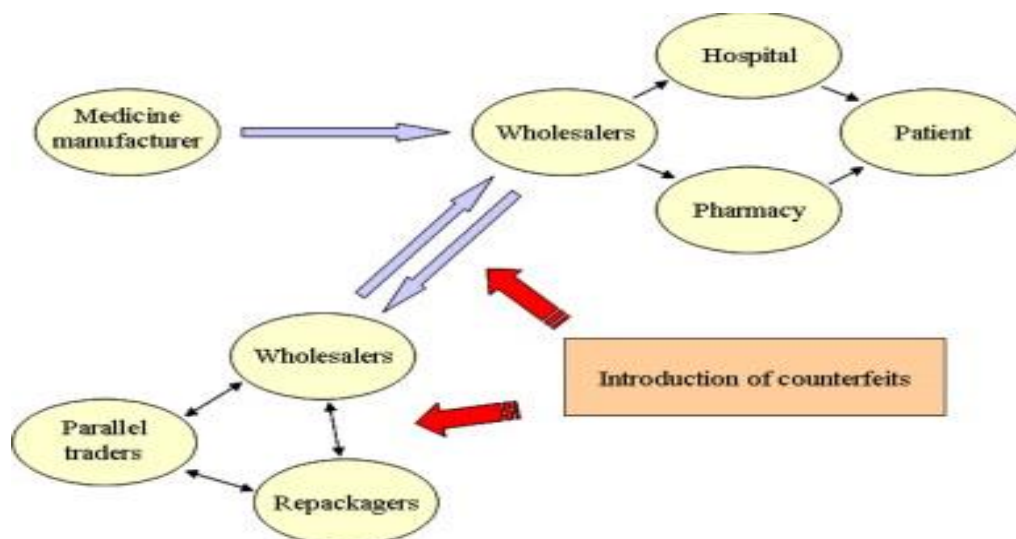


Fig.1. Shows the Intricacy of the parallel pharmaceutical trade enabling the introduction of counterfeit pharmaceuticals⁸⁵.

Thus far there is little doubt on the sustainable objective of PI on pharmaceutical it has legal validity under the WTO Legal order, however, its shortcoming outweighs its benefits, in Nigeria situation PI seem plausible but its implementation and utilization might be encumbered by the weak operating system⁸⁶, in my view PI ought to be further improved in a bid to close the lacuna caused by PI, but PI has informed this research by demonstrating how a WTO policy can encourage the surge of counterfeit medicine.

⁸⁵Jonathan 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)

⁸⁶Mary Shepherd, "Beef up international cooperation on counterfeits." (2010) Vol16 issue 4 *Nature Medicine* pp. 366-366

TRIP plus Rules on Counterfeit Pharmaceutical

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-TRIPS to adopt more stringent patent protection known as TRIP-Plus. Which specifically targets developing countries to encourage the implementation of tougher patent laws even though it is not explicitly stated by the WTO.

It can be inferred from trade deals offered by the USA and EU countries to 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 common example of TRIP-Plus provision includes patent linkage, data exclusivity, increased enforcement mechanism, an extension of patent term longer than 20 years⁸⁷. TRIP Plus obligation intends to ameliorate the problems of access to medicine in developing countries but instead has compounded the issue by limiting access to a free alternative source to much-needed medicine. Nigeria and other developing countries such as China have modelled their existing IP rules per the TRIPs equivalent obligation⁸⁸. Therefore this section seeks to examine the influence

⁸⁷ Jennifer Reid , InforJustice.org, The Effect of TRIPS –Plus IP provision on access to affordable Medicine, Available <http://infojustice.org/archives/34601> Accessed (14 March 2020)

⁸⁸ 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, Matthias Vanhullebusch

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 have improved access to medicine and made the IP regime seemly workable in developing an LDC. For instance, the Ecuador IP office used one of TRIPs flexibility which is compulsory licence in the manufacture of its Antiretroviral (ARV) medicine which is a combination of Lopinavir and Ritonavir; this action informed the reduction of the exiting patented HIV medicines. Equally, the Ghana IP authority applied the government use 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 remedied the impact of patent protection then again, the impact on pharmaceutical companies and patent rights owners is immeasurable.

TRIPS minimum standards and safeguards have been effective when implemented into the legal framework of member states. However, developed countries consistently canvassed for more stringent and restrictive IP rules/policy that goes 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 and that 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 obligation for acceptance by WTO member states. Acceptance of TRIP Plus rules would be considered part of a Free Trade Agreement (FTA)⁸⁹ due to fear of trade repercussions from developing countries such as the united states or the European Union, Critics speculate that TRIP-Plus will

⁸⁹ Lawrence R. Helfer, Regime Shifting: The TRIPs Agreement and New Dynamics of International Intellectual Property Law making,(2004) 29 YALE Journal of International Law PP 1

inhibit the perception of TRIPS flexibilities and safeguards thus limiting its applicability. It can be suggested that both TRIPS and TRIP Plus creates a relationship of conflict, both norms are valid and applicable but incompatible and left to states to decide which norm should supersede the other⁹⁰.

TRIP Plus required states to implement provisions to limit the use of a compulsory licence, secondly, it supported the extension of the term of patent protection to be increased more than 20 years, it also includes restriction for generic competition but the most peculiar is data exclusivity. Developed countries had the knowledge 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, whereas 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 generates high profit. TRIP plus demands that this information ought be kept confidential⁹¹. Therefore if, TRIP Plus rules is 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.

⁹⁰ Ruse-Khan, Henning Grosse "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 therefore 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 important 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.

⁹¹ 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](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 give pharmaceutical companies 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 with holds this information till the period of data exclusivity has passed thus generating higher revenue.

This section discussed the importance of TRIP safeguards concerning access to medicine in both developing and LDCs. Trips safeguards can ameliorate access to medicine although complex in its application and utilization. However, to make progress, proponents called for stronger protection TRIP-Plus, but the negative effective TRIP plus Rules impede what it intends to protect resulting in another issue beyond the scope of the WTO-TRIPs Agreement.

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 break-down of barriers between countries, government and people based on the principles of non –discrimination, national treatment, equality/MFM and free trade within the well-organised structure of the WTO. The scope of WTO membership encompasses over 132 member states, this serves as proof of WTO credibility in regulating the growth and development of the trading system of the world⁹².

Despite the remarkable success of the WTO, the organisation continued to reform and revise its trade policy considering changing circumstances around the world. By this singular mega-regional endeavour, commentators and academics have applauded it as a breakthrough in the creation of global success in the international Trade system. However, a contrary view to the WTO success maintains that the WTO

⁹² WTO, Golden Jubilee of the Multilateral-trading system, Available https://www.wto.org/english/news_e/pres98_e/pr88_e.htm Accessed(13 April 2020)

failing restructuring rounds have resulted in the establishment of various trade policies in a bid to resolve new trade dimensions such as solving protectionism, trade barriers, violation of IP etc. Instead of deal with one issue before another, the WTO adopts a quick fix approach (i.e. utilizing the fastest solution to solve reoccurring problems) leading in 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, without been resolved the WTO prioritise other salient issues an example of this, is evident in the collapse⁹³ of the Doha trade negotiation round⁹⁴.

The failure of the WTO as a global trade organisation is predictable for its agenda is not explicitly favourable to developing countries although it arranged certain special and differential treatment rights” these provisions are perceived to be inadequate even the Ministers at the 4th Doha ministerial conference authorized the Committee on Trade and Development to examine these special and differential treatment provisions⁹⁵ to strengthen and create a more effective and operational system. However, Wallach and James 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

⁹³ Popa Diana. "The Collapse of the Doha Round and a Possible Completion of Negotiations"(2012) Vol 15 Issue 43 *Romanian Economic Journal*

⁹⁴ Halewood, Peter. "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

⁹⁵World 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 Accessed(14 April 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 dispute and resolve dispute, and implement technical standards, and provisions related to least-developed country (LDC).

growth in developing countries even though since ratification, economic developments have deteriorated with a large percentage of people living on less than \$1 a day⁹⁶.

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 TRIPS agreement can be considered, the greatest protectionism agreement in the world which is a direct extension of the WTO monopolistic mandate of controlling trade whilst still advocating for trade liberalization then again demanding states provide stiff intellectual property protection for drugs without considering the relative impact on drug availability. The WTO ought to fix the ills of the multilateral trading system rather than standing back with quick fix submissions it should be proactive, reflective⁹⁷ and deliberate on potential solutions to make it stand out as a world-leading trade organisation.

The one size fits 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 service⁹⁸ and trade-related aspects of intellectual property right (TRIPS). The implication of strengthened protection may have created a negative effect in developing countries such as the high price; product imitation, copying, and drug counterfeit. Besides most developing countries, cannot change 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

⁹⁶ 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*

⁹⁷ Rorden Wilkinson What is wrong with the WTO and how to Fix it , (Polity press : Cambridge, 2014)

⁹⁸ 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 (17 April 2020)

conferences within the WTO, instead states advocate for more plurilateral trade agreements to protect their weak institution.

In conclusion, for the WTO to retain its status as a leading trade organisation, it needs to be more proactive towards the issues affecting member states by supporting, encouraging a broad spectrum of plurilateral agreements, extend terms in IP for developing/LDC, support non-restriction measures for the sake of protecting public health⁹⁹, reprimand aggressive trade policies offered by a developed member state, permit transparency in WTO rules and safeguards and adopt stiff penalties for members flouting WTO rules. It can thus 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 a proper measure to tackle its discrepancy before it can be implemented by member states. Except there is a rethink in the way the WTO handle problems solutions may be unlikely.

⁹⁹ Matthews, Duncan. "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 73-107

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