April 2015 Vol. X No. 1 ISSN (PRINT) : 0973-4503 ISSN (ONLINE) : 2454-1702 RNI : UPENG 2006/17831

http://EconPapers.repec.org/RePEc:jct:journl:v:10:y:2015:i:1:p:7-19
https://ideas.repec.org/a/jct/journl/v10y2015i1p7-19.html

Pages 7-19

Assessing the Role of TRIPS Agreement for Inaccessibility and Un-affordability of Essential Medicines in Nigeria

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Abstract

Intellectual property rights (IPRs) protection was not recognised in Nigeria and essential medicines were accessible and affordable to all but reverse is the case with the implementation of TRIPS agreement on IPRs. This resulted in inordinate policy formulation and implementation that exacerbates the public health care despite Nigeria's endowment with enormous human and natural resources. This paper argues that patents protection hinders access and affordability to essential medicines in Nigeria. It also argues that pharmaceutical companies prevent developing countries from utilising the TRIPS flexibilities to access essential medicines for their citizens. It concludes that access and affordability to essential medicines are additional challenges to Nigeria.

The paper is based on the anti-corporate globalisation movement theory. The theory advocates for a world structured by human values other than greed and domination, one less dominated by the culture and values of global capital. The economic, political, and cultural interconnectedness signified by globalisation is irreversible and possibly a good thing, this interconnection, could potentially serve the interests of people and the earth, not just the elites. Although the rich and powerful have shaped globalisation in their interest, the anti-globalisation theory is a counter-movement that seeks to reshape the interconnected world in the interests of people and the planet.

Keywords: *Anti-Globalisation, Pharmaceutical Corporations, Patent, Essential Drugs, Nigeria.*

1. INTRODUCTION

The aim of this paper is to assess the role of trade related aspects of intellectual property agreement (TRIPS) for inaccessibility and un-affordability of essential medicines in Nigeria. Access to essential medicines is difficult and is increasingly so for many of those who need them most, thus hindering the realisation of right to public health in many developing countries. It is neither the TRIPS agreement nor the World Trade Organisation (WTO) alone that is responsible for this situation, rather multinational pharmaceutical companies or the governments of industrialised countries, acting on their behalf.[1]

The TRIPS agreement came into effect in January 1995, alongside the creation of the WTO, to facilitate trade through the creation of a comprehensive multilateral agreement on intellectual property rights (IPRs) including patents, trademarks and copyright, etc. Prior to its implementation, IPRs protection was unevenly recognised in many countries. On patents, TRIPS extended minimum standards of protection for any inventions, whether products or processes, in all fields of technology without discrimination, subject to the normal tests of novelty, inventiveness and industrial applicability. This includes the requirement by all WTO members to make patents available for pharmaceutical innovations. TRIPS also establish procedures and remedies for patent holders to enforce their rights.[2] This however makes drugs protected by patents more expensive and accessible to fewer consumers than similar drugs produced in a competitive environment without patent protection.[3]

The ethical problems brought up by IPRs are most pertinent when, for instance, socially valuable

products like life-saving medicines are given IPRs protection. While the application of IPRs can allow companies to charge higher prices than the marginal cost of production in order to recoup the costs of research and development (R&D), the price may exclude from the market anyone who cannot afford the cost of the products.[4]

Within the TRIPS framework, flexibilities exist which gives governments of WTO member countries room to fulfill the public health obligations to their citizenries. However, the pressure from some industrialised countries has made it almost impossible for developing countries to exploit these flexibilities. This is reflected in the outright threat of an imposition of trade sanctions on countries that have adopted measures to promote public health under the IPRs regime.[5]

In response to the agitations of developing countries for the failure of the TRIPS regime to protect access to essential medicines, the Doha Declaration[6] affirms that the TRIPS agreement does not and should not prevent members from taking measures to protect public health.[7] However, soon after the Doha Declaration, the implementation of the statement failed as the United States (US) and the European Community (EC) have taken a harder line in order to protect their pharmaceutical exporters. While solutions are urgently needed, evidence shows that progress to achieve the health-related issues has been slow.[8]

Hence, access and affordability of essential medicines became a subject of public discourse, raising serious concerns about the negative effects of the WTO agreement on TRIPS.[9] Voices of resistance materialise in the form of street demonstrations and protests against organisations such as the International Monetary Fund (IMF), the WTO, the World Bank, and the G8 heavily industrialised nations. While these undemocratic organisations zealously attempt to permeate the globe, their overwhelming power remains off the radar for most of the world population. In the theoretical context of global economy, they will neither be satisfied by certain wealth or power, nor will they sacrifice much for actual development of developing countries.[10]

The key challenges confronting Nigeria's pharmaceutical market include counterfeit medicines, poor healthcare infrastructure and limited spending power of citizens. Despite government efforts to promote domestic manufacturing, Nigeria remains heavily reliant on imported pharmaceuticals, although there are large volumes of underutilised manufacturing capacity which could be applied to produce new products upon demand.[11]

In view of the foregoing, should social products like life-saving drugs be subjected to IPRs protection? The paper will attempt to provide an answer to this question by first discussing the theoretical framework, TRIPS agreement and its flexibilities as well as access to essential medicines as global priority. It concludes by making observations and recommendations.

2. THEORETICAL FRAMEWORK

The paper is based on the anti-corporate globalisation movement theory. The theory advocates for a world structured by human values other than greed and domination, one less dominated by the culture and values of global capital.[12] The economic, political, and cultural interconnectedness signified by globalisation is irreversible and possibly a good thing, this interconnection, could potentially serve the interests of people and the earth, not just the elites. Although the rich and powerful have shaped globalisation in their interest, the anti-globalisation theory is a counter-movement that seeks to reshape the interconnected world in the interests of people and the planet.[13]

The theory is critical of the policies of economic neo-liberalism that has guided international trade and development since the closing decades of the 20th century. It advocates that the policies of neo-liberalism have exacerbated global poverty and increased inequality. It constituents include trade unionists, environmentalists, anarchists, land and indigenous rights activists, organisations promoting human rights and sustainable development, opponents of privatisation, and anti-sweatshop campaigners. They connect their actions with wider efforts against the international, national and local consequences of neoliberal policies.

Internationally, they held protests outside meetings of transnational actors such as the WTO, the IMF, the World Bank, the World Economic Forum, and the G8.[14]

The single integrated global economy is largely an ideological construct, a political instrument and economic weapon deployed by the stronger economies and governments in support of the global operations and requirements of their transnational corporations.[15] The overwhelming power of these actors implies that the only possibility of effective challenge must involve organisations and movements that can counter them at the scale at which they operate. It is believed that such movements must necessarily be global in their vision and scope if they are to be successful. Indeed, many argued that the anti-capitalists globalisation movement (ACGM) is the most significant left movement of the new Millennium.[16]

The movement is not organised around a single issue or identity based. On the contrary, it directly attacks capitalist global economic and political infrastructure with a radical strategy of confrontation.[17] The protests and clashes between demonstrators and police outside the WTO meeting in Seattle, US is a harbinger of things to come. This reveals the explosiveness of the social tensions building up within capitalism and the American people. Those who came to Seattle in their thousands raised a myriad of issues related to the environment, public health and exploitation of child labour and workers in the developing countries. But their major source of unification was the concern over the growing social inequality and hostility to the domination of the transnational corporate giants over working people, not just in America but all over the world.[18]

In Nigeria, a group of non-governmental organisations (NGOs) and other organisations came together to form the coalition of civil society groups on access to essential drugs.[19] The group took up a campaign designed to mobilise volunteers and people who support the vision of improving public health of the population. The coalition encourages all activities that bring this message to policy makers as well as the general public so as to ensure access to essential medicines including issues of affordability, financing, and health systems.[20] This theory is directly related to the Nigeria's pharmaceutical patent regime.

3. TRIPS AGREEMENT AND ITS FLEXIBILITIES

The TRIPS agreement is contained in Annex 1C of the agreement establishing the WTO signed in Marrakesh, Morocco, on April 15th, 1994. Almost all developing countries have incorporated the TRIPS agreement and the extent of its actual use for public health purposes into legislation.[21] It is a multilateral international treaty introduced by the WTO that came into effect on June 1st, 1995. It establishes minimum standards for the regulation of IPRs within member countries of the WTO.[22] The TRIPS Agreement covers seven types of IP: copyright and related rights;[23] trademarks;[24] geographical indications;[25] industrial designs;[26] patents;[27] layout-designs (topographies) of integrated circuits;[28] and undisclosed information, including trade secrets.[29]

The TRIPS agreement is designed to reduce distortions and impediments to international trade through the promotion of effective and adequate protection of IPRs by ensuring that protection measures do not become barriers to trade. It preserved the national treatment and most-favoured nation treatment.[30] Members are obliged the treatment meted to nationals of other member states. This is to be done by an appropriate method of implementation within a member's legal system and practice. Existing obligations under the Paris, Berne and Rome Conventions are preserved. Developed country members are obliged to provide technical and financial assistance to developing country members. Developing countries are afforded one year period of transition to bring their laws into conformity with TRIPS. Members trying to establish a market economy are allowed four years to implement all provisions on TRIPS except on most-favoured-nation treatment and national treatment.[31]

Other concessions granted to developing countries include a grace period of five years to apply the patent provision of TRIPS unprotected areas of

trade like pharmaceuticals and agricultural chemical products. Least developed countries (LDCs) have maximum of ten years within which to apply all provisions of TRIPS except for the most-favoured – nation and national treatment rule which have immediate application[32] . Of fundamental import is the provision that compels members to cooperate to eliminate international trade in goods infringing IPRs. [33]

Developing countries find themselves in a difficult situation, balancing the demand for cheap medicines and protecting the patent rights of multinational pharmaceutical companies.[34] However, the TRIPS agreement provides certain health exceptions or flexibilities necessary to support the principles and objectives of the agreement particularly, guaranteeing access to medicines and reducing the effect of monopoly as an instrument for profiteering to the detriment of public health.[35] These flexibilities are: compulsory licenses, parallel imports, importation pursuant to paragraph 6, bulk purchasing, etc.

4. COMPULSORY LICENSE

Compulsory license is one of the flexibilities on patent protection included in the WTO's agreement on intellectual property. It is when a government allows someone else to produce the patented product or process without the consent of the patent owner. This is however, subject to exceptions; where the patent lapses, is surrendered or is declared a nullity by a Court of competent jurisdiction.[36] According to the TRIPS agreement, compulsory license should only be granted in specific circumstances, including public health crises, for instance, if the population of a particular country needs a potentially life-saving invention as quickly as possible and the patent holder is unable or unwilling to meet the demand.[37]

The TRIPs agreement provides that contacting parties are allowed to grant the use of patents to third parties without the authorisation of the right holder, provided that such a grant does not unreasonably prejudice the legitimate interests of the patent owner, while taking cognisance of legitimate third party interests.[38] Among other conditions, a compulsory license must be non-exclusive, non-assignable, be considered on their individual merits, compensation to be paid to the right holder, and the legal validity of the decision to grant such a license and the decision on remuneration to be subject to judicial review. In addition, it has to be established that the proposed user would have sought the license on reasonable commercial terms from the right holder and has failed to get a positive response within a reasonable time. This may be waived in cases of national emergency for non-commercial use of the patent.[39]

Some developing countries were able to exploit these flexibilities in order access essential medicines for their inhabitants. For instance, the Indian patents law contains a number of significant safeguards, including: strict patentability criteria to limit the number of patented products, automatic compulsory licensing for generic drugs brought to market between 1995 and 2005, and the possibility for anyone to oppose the granting of a patent. However, this law was challenged by *Novartis* after it was denied patent on its cancer drug *imatinib mesylate*, but, it has been upheld and has set an important example for other countries wishing to build more flexibilities into their national patent laws.[40]

In some cases, developing countries are often been intimidated by the "behind-the-scenes" influence of the multinational pharmaceutical companies and their political allies, who often use public and private threats to convince nations to abandon a right they might need to provide their citizens with affordable medicines. These tactics prevent developing countries from using that right effectively. Where developed countries finally acknowledged that the right to compulsory licensing was binding, the multinationals went around the barn to convince some developing countries to publically pledge not to exercise that right.[41]

A classic example of the pharmaceutical corporation's opposition to the exercise of the flexibilities TRIPS offers is manifested in a lawsuit filed by 41 pharmaceutical corporations against the government of South Africa. The suit challenged a law seeking to provide access to drugs for the people in the country. The suit led to a mobilisation of advocacy groups against the pharmaceutical corporations. The

Treatment Action Campaign (TAC) is a renowned South African Civil Society Organisation working with and for People Living with AIDS. TAC applied to the Court and was granted leave to file briefs as an *amicus curie*.[42]

In other cases, developing countries were unable to use the TRIPS flexibilities to access lower-priced generic drugs. For instance, Cipla tried to sell a generic version of the AIDS drug Combivir to health officials in Ghana. India has no patent protection for Combivir, a GlaxoSmithKline product, and produces a generic version for about one-tenth of the price. GlaxoSmithKline negotiates patents in some African countries through a regional organisation that it believes extends to Ghana. When the company discovered that the sale was taking place, it warned Cipla of a possible patent infringement, and the transaction was halted.[43]

In Nigeria, the Patents and Designs Act (PDA)[44] provides for the grant of compulsory license respecting a patent in deserving cases. The PDA seems to create a dichotomy in the grant of the license. It provides that compulsory license will be granted to a person who makes an application to Court after the expiration of four (4) years from the date the patent application concerning the invention was lodged or at the expiration of three (3) years from the date of the actual grant of the patent, whichever is applicable.[45] However, in granting the license, one or more of the following conditions must have been established before the Court:

(a) that the patented invention being capable of being worked in Nigeria has not be so worked;

(b) that the existing degree of working of the patented invention in Nigeria does not meet on reasonable terms the demand for the product;

(c) that the working of the patented invention in Nigeria is being hindered or prevented by the importation of the patented article;

(d) that, by reason of the refusal of the patentee to grant license on reasonable terms, the establishment or development of industrial or commercial activities in Nigeria is unfairly and substantially prejudiced.

It is to be noted that the patentee may apply to Court to cancel a compulsory license if the licensee fails to comply with the terms of the license or if the conditions that necessitated the grant of the license have ceased to exist.[46]

The PDA[47] further provides for compulsory license and use of patents for the service of government agencies. It makes extensive provision for use of patent by government which offers the statute-based mechanism or framework to address the needs of public health through necessary arrangements to provide the needed medicines for the health needs of its population. The use of patent for service of government agencies issued by a Ministerial Order offers a more pragmatic way for addressing access to medicines because the provision specifically empowers the minister of commerce to declare by order in public interest.

(a) For the maintenance of supplies and services essential to the life of the communities; or

(b) For securing sufficiency of supplies and services essential to the wellbeing of the community, and or

(c) For ensuring that the whole resources of the community are available for use and are used in a manner best calculated to serve the interest of the community.

However, there are many reasons why countries should think twice before granting a compulsory license. Patent protection and the commercial opportunity it presents are intended to compensate the patent holder for their investment in R&D, which is likely to have taken a number of years. If countries grant compulsory licenses too freely, innovators are deprived of the full benefit of their monopoly rights. As a result, pharmaceutical companies could be discouraged from investing in developing

countries and such countries could become isolated, with less control over drugs that may be needed to treat their populations in the future.[48]

4. PARALLEL IMPORTATION

Parallel importation is an unauthorised import into a country. It refers to non-counterfeit goods imported from one country to another without the express permission of the patent owner. It also refers to gray market goods. The parallel part of the import involves a patented, copyrighted or trademarked product brought into a country at a reduced price by a distributor, wholesaler or retailer where the product is already marketed. With lower prices, it creates a more competitive landscape, forcing authorised firms to do a better job serving local customers and offering greater customer service satisfaction.[49]

Parallel importation ensures access to medicines legitimately put on the world market, at the best price. For instance, if a drug is marketed in New zealand at US$ 1 and in Russia at US$ 20, Nigeria can buy this drug from New Zealand.[50] Although piracy and counterfeiting constitute a burden for pharmaceutical companies in developing countries, and in particular, Nigeria, it appears that little or no attention is paid to the importation of grey goods and its impact on licensed users.[51]

However, the doctrine of exhaustion is potentially applicable to all categories of IPRs, although its operation can and does differ across IP subject matter. It determines the point at which a IPRs holder's control over protected goods or services expires. The typical point of exhaustion for present purposes is the first sale, that is, the placing of the product in the market.[52]

The TRIPS agreement[53] states that: 'for the purposes of dispute settlement under this agreement, subject to the provisions of Articles 3 and 4, nothing in this agreement shall be used to address the issue of the exhaustion of intellectual property rights.' This implies that no violation or limitation of a TRIPS obligation beyond national treatment[54] and most favored nation (MFN)[55] may be invoked to challenge the treatment of parallel imports. However, there is legal debate about this interpretation. Overall, it seems that Article 6 preserves the territorial prerogative to regulate parallel trade. This flexibility was important in gaining the acceptance of TRIPS by many developing countries.[56]

Nigeria applies the national exhaustion doctrine, at least in relation to patents by virtue of Section 6.[57] The PDA[58] provides in effect that rights under a patent 'shall not extend to acts done in respect of a product covered by the patent after the product has been lawfully sold in Nigeria.' The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of IPRs is to leave each member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions..

However, some amount of caution is called for. First, the provision has not been fully tested for judicial confirmation of whether it does indeed obligate a national exhaustion doctrine in respect of patents. Second, the provision obviously only concerns patents specifically and does not extend to other forms of IP such as trademarks or copyright. Third, proposed new legislation is expected to see the replacement of the provision with one that is thought to clearly provide for international exhaustion in that rights under which a patent will not extend to acts done in respect of a product covered by the patent 'after the product has been lawfully sold in any country.[59]

As a general rule, it is difficult to prevent parallel importation in Nigeria. However, in view of the absence of a national exhaustion regime, there are certain measures that parties can take:

(a) Both foreign patent holder and local representative can ensure that pre- contractual rights are well documented and consents explicitly withheld or waived, in order to ensure effective enforcement of IPRs.

(b) Action against a parallel importer if it is shown that there is a legal interest, which is sought to be protected, and that the licensee has suffered an injury or damage as a result of the importers acts of interfering with its rights, privilege and

benefits conferred on him by law. Injunction may be sought to restrain an offender from further interfering with the legal or economic interest of the patent owner, and an order of court for the delivery or destruction of the marked goods. The patent owner or licensee could also seek monetary damages or compensation for loss of profit as far as can be established.

(c) There should be enforcement of terms of any agreement between the parties. There is a growing acknowledgement by national governments and international organisations that appropriate structure and vigorous enforcement of contracts between the parties can promote international trade.[60]

A patent owner or licensee can approach the court to restrain parallel importation on grounds that such importation is in breach of his contractual right. The Nigerian court has recognised and protected the right of a patent owner or licensee to the exclusive distribution of its goods in Nigeria.[61]

In *Pfizer Limited v. Tyonex Nigeria Limited and Ebamic Pharmacy Limited,*[62] a patent was found to be valid and infringed. This case involves a Pfizer patent claiming amlodipine besylate, which was being sold in Nigeria under the brand name "NORVASC." The defendants imported a generic version of this drug from Turkey and marketed it as "AMLOVAS." Pfizer lodged a complaint with the appropriate regulatory authority in Nigeria, which moved swiftly to de-register the generic product, arrest the Managing Director of the first defendant company, and seal the premises of both defendants for one week. In addition, the Federal High Court considered the validity and infringement of Pfizer's patent and decided in favour of Pfizer, granting an injunction and damages, accordingly.

It has been argued that the importation of grey goods may positively impact the economy because of increased competition, which in turn increases market efficiency through promotion of free trade. However, it is harmful to consumers and patent proprietors because they may not meet the specific standards for the region into which they are imported not because the goods are sub-standard but mainly because they are not produced and fit for that region. Also, such goods are not eligible for manufacturer's warranty services and refunds.[15] Thus the consumer without knowledge of importation restrictions becomes dissatisfied with the goods which ultimately create distrust for the patent owner.[63]

It is worthy of note however that IP infringement is increasing daily in many parts of the world, particularly in developing countries. This is partly attributable to the fact that many of these developing countries lack the technology to detect and control parallel importation, and partly because parallel importation is negligently encouraged.[64]

Importation Pursuant to Paragraph : Although existing provisions of the TRIPS agreement permit the grant of compulsory licenses to enable generic production of medicines, countries without domestic manufacturing capacity cannot avail themselves of this flexibility. The option of importing generic medicines is hampered by the restriction in the TRIPS agreement that requires production under compulsory license to be predominantly for the supply of the domestic market. Paragraph 6 of the Doha Declaration recognises that "WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector, could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement.' Paragraph 6 is essentially a waiver of the export restriction, thereby allowing the total amount of production under a compulsory license to be exported. The full impact of the August Decision will depend on the extent to which national laws allow for it, and will require specific changes to national laws.[65]

This is a viable option for developing countries because it has the potential of improving the availability of medicine at affordable prices. Since importing and exporting countries under this agreement are likely to be proximately located to one another, the cost of shipment would be minimal such as not to significantly affect the overall cost of drugs. However, this system is not without drawbacks. First, it is administratively complex for developing countries to cope with. It

requires interested countries to take a number of steps in order to benefit from the system. Second, the system effectively limits the validity period of any compulsory license issued to any exporting country to a single-supply basis. This means that in the event that the importing country requires additional quantities of the medicines it had earlier acquired, it must begin the process all over again for subsequent orders.[66]

However, Paragraph 6 is seen as key to improving access to essential medicines in developing countries. It long-term achievement is the refocusing of attention on the potential of other measures that can operate alongside compulsory licensing provisions.[67]

5. BULK/POOLED PROCUREMENTS

This is a cost saving strategy whereby consumers (distributors and hospitals), rather than order for product individually, pool their orders and purchase large quantities from manufacturer. The benefit of this system is that because of the volume of the procurement, the manufacturer is able to give a considerable discount resulting in downward slide of the price, as against when the drugs are purchased on an individual basis. This system has been in use in Nigeria at some level and with outstanding results. The Christian Health Association of Nigeria (CHAN), a non-profit organisation, is engaged in the provision of pharmaceutical products for missionary hospitals, among other things. Its operations are largely on the basis of the bulk procurement strategy whereby the orders of these mission hospitals are pooled and made to the organisation's foreign partner, the IDA in Switzerland. This allows the mission hospitals to access drugs and other pharmaceuticals at cheaper prices, while quality is not compromised.[68]

Pool procurement provides information of updated prices for anti-retroviral medicines, pharmaceutical products and diagnostic tests used to treat a range of opportunistic infections, for pain relief, for use in palliative care, for the treatment of HIV/AIDS-related cancers and for the management of drug dependence. It also provides information on a range of HIV/AIDS test kits for initial diagnosis of the infection, and ongoing monitoring of antiretroviral treatment and drug resistance. In addition, it provides information about registered products included in the survey per country, a pricing guide for developing countries and current discount prices offered by pharmaceutical companies.[69]

The government can equally adopt this strategy for the purchase of drugs and other pharmaceuticals. Indeed it would even be of greater benefit if the government involves itself in the pooled procurement of active ingredients for local manufacture of generic drugs by local pharmaceutical companies. This has the potential of improving Nigeria's manufacturing capabilities in the pharmaceutical industry in addition to making the drugs produced cheaper and easily acceptable by Nigerians.[70]

6. CONCLUSION

An x-ray of the role TRIPS agreement for inaccessibility and un-affordability of essential medicines in Nigeria has been carried out. It appears that if the WTO is going to claim relevance it would to have to embrace global trade diversity. It must move past the one size fits all model. The most-favoured-nation and the national treatment provisions need to be revisited. The WTO should acknowledge the fact that, whatever benefit it may claim for developing countries, imposing restrictive IP measures is not it. If the developed countries hold up their end of the bargain, if technology transfer takes place, developing countries would become industrialised and essential medicines would be accessible and affordable to all and sundry. That is a global goal everyone has aspired for. Social products like life-saving drugs should not be patented.

However, this paper justifies the anti-globalisation social movement theory that globalisation should integrate all. The street protest organised by the coalition group in Nigeria in reaction to unaffordable essential drugs against pharmaceutical companies and policy makers is an off-shoot of the protest in Seattle, US in opposition to the WTO on trade liberalism.

END NOTES

1. Nwobike, J. C. "Pharmaceutical Corporations and Access to Drugs in Developing Countries: The Way Forward', available at < http://www.surjournal.org/eng/conteudos/artigos4/ing/artigo_nwobike.htm> Accessed on 12/04/2014.
2. Alsegård*, E.* Global pharmaceutical patents after the Doha Declaration – What lies in the future? available at <*http://www.law.ed.ac.uk/ahrc/script-ed/docs/doha.asp*>. *Accessed on 10/04/2013*.
3. Nwobike, J. C. op cit.
4. Ibid.
5. Ibid.
6. The Declaration on TRIPS and Public Health adopted at the Fourth WTO Ministerial Conference, held in 2001 in Doha, Qatar.
7. WTO, "The Doha Declaration on the TRIPS Agreement and Public Health', available at <*http://www.who.int/medicines/areas/policy/doha_declaration/en/*>. Accessed on 29/06/2013.
8. "Swiss Network for International Studies, Examining Global Partnership to Improve Innovation and Access to Medicines on a Sustainable, Priority Needs Basis; MDG8, Target 8,R," available at <*'http://www.snis.ch/call-projects-2011_847_examining-global-partnerships-improve-innovation-and-access-medicines-sustain*>. Accessed on 28/06/2013.
9. WHO, "The Global Politics of Pharmaceutical Monopoly Power, Drug Patents, Access, Innovation and the Application of the WTO Doha Declaration on TRIPS and Public Health", available at <*http://apps.who.int/medicinedocs/en/m/abstract/Js20963en/*>. Accessed on 20/11/2013.
10. Burdacki, S. "Strategy, Tactics and Solidarity: The Anti-Globalisation Movements and its Discontents", available at <*http://bad.eserver.org/issues/2004/65/burdacki.html*> Accessed on 17/05/15.
11. UNIDO, op cit.
12. Burdacki, S. "Strategy, op cit.
13. Globalisation from below
14. Brecher, J., et al, (2000), Globalisation from Below, Cambridge, MA: South End Press, p. 150.
15. "Alternative Regionalisms," available at <*http://www.tni.org/article/alternatives-neo-liberal-globalisation*> Accessed on 18/05/15.
16. Buttel, F. H. "Environmentalism and the Trajectory of the Anti-Corporate Globalisation Movement", available at <http://www.irows.ucr.edu/cd/courses/184/buttelgould.htm> Accessed on 16/05/15.
17. Morse, C. "Theory of the Anti Globalisation Movement", Vol. 2, No. 1, (2003), *New Formulation,* available at <http://www.newformulation.org/1antiglobalization.htm> Accessed on 17/05/15.
18. "The Social Meaning of the Anti-WTO Protests in Seattle", (1999), available at <https://www.wsws.org/en/articles/1999/12/wto-d06.html> Accessed 18/05/15.
19. The coalition includes amongst others: Center for Right to Health, Lifescope Africa, Network Project for the disabled, International Network for Rational Use of Drug, Journalists Against AIDS), Medical Rehabilitation Center for Trauma Victims, Nigeria Aids Alliance, Health Matters, Society for Women and AIDS, National Network of People Living with HIV/AIDS, STOPAIDS, Development of Africa through Law, Project Shield, Social and Economic Rights Action Center, Civil Society Consultative group On HIVAIDS in Nigeria, Access to Justice, Médecins Sans Frontières, etc.
20. 'WTO, "WHO Secretariat Workshop on Affordable Drugs", available at <*http://www.wto.org/english/*

tratop_e/trips_e/tn_hosbjor_e.htm>. Assessed on 01/06/2013.

21. Musungu, S., and Oh, C., "The Use of Flexibilities in TRIPS By Developing Countries: Can They Promote Access To Medicines?, available at < *http://www.who.int/intellectualproperty/studies/TRIPS_flexibilities/en/*>. Accessed on 03/12/14.
22. Satardien, M. Z. "A Critical Analysis of the Trade Related Aspects of Intellectual Property Rights Agreement and has South Africa Complied with this Agreement with Special Reference to Patented Pharmaceuticals," available at <*http://etd.uwc.ac.za/xmlui/handle/11394/2153*> Accessed on 13/05/15.
23. Article 9 – 14.
24. Article 15 – 21.
25. Article 22 – 24.
26. ARTICLE 25 – 26.
27. Article 27 – 34.
28. Article 29.
29. Article 39.
30. Article 3 and 4 of Part 1
31. Ladan, M. T. (2007), *Materials and Cases on Public International Law*, Zaria, ABU Press, p. 353.
32. Article 65 and 66 of Part vi.
33. Article 69, Part vi.
34. Satardien, M. Z. (2014), op cit.
35. JAAids, "Coalition of Civil Society Groups on Access to Essential Medicines in Nigeria", available at <*http://www.nigeria-aids.org/reports.cfm?read=74*>. Accessed on 03/12/14.
36. WTO, "Compulsory Licensing of Pharceuticals and TRIPS", available at <*http://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm*>. Accessed on 03/12/14.
37. Thurston, J., "Compulsory Liceses: Necessity or Threat?", available at <*http://www.rsc.org/chemistryworld/2013/05/compulsory-licence-license-patent-drugs-debate*>. Accessed on 03/12/14.
38. See Article 31 of the TRIPS Agreement
39. See Article 31
40. Thurston, J., op cit.
41. Haddad, W. F., "Compulsory Licensing of Life-Saving Medicines: A Story and A History, A Problem and A Solution", available at < *http://www.equilibri.net/nuovo/articolo/compulsory-licensing-life-saving-medicines-%E2%80%9C-story-and-history%E2%80%9D-%E2%80%9C-problem-and-solution%E2%80%9D*>. Accessed on 03/12/14.
42. The *Medicines and Related Substances Control Act (Medicines Act) No. 90 of 1997.*
43. Schmidt, C. W. 'Drugs as Intellectual Property", available at <*http://pubs.acs.org/subscribe/archive/mdd/v04/i06/html/06rules.html*>. *Accessed on 29/06/2013.*
44. Section 11, First Schedule
45. Part 1 of the First Schedule, PDA
46. Section 9 Part1 of First Schedule PDA

47. Part 2 of the First Schedule
48. Thurston, J., op cit.
49. Delaney, L., "What is Parallel Importation?", available at <*http://importexport.about. com/od/ImportMarketResearch/a/Parallel-Importing.htm.*>. Accessed on 03/12/14.
50. JAAids, (2001), op cit.
51. Adejugbe, A. "Nigeria: Protection of Intellectual Property in Nigeria; Effect of Grey Market Goods; Challenges and Solutions", available at <http://www.mondaq.com/x/307654/Trademark/PROTECTION+OF+INTELLECTUAL+PRO PERTY+IN+NIGERIA+EFFECT+OF+GRAY> . Accessed on 19/05/15.
52. Reichman, J. H., et al, (2014), "The WTO Compatibility of a Differentiated International Exhaustion regime', *International Laboratory for Law and Development,* P. 2.
53. Article 6
54. Article 3
55. Article 4
56. Maskus, K. E., "Parallel Imports in Pharmaceutical: Implications for Competition and Prices in Developing Countries', available at < http://www.wipo.int/export/sites/www/about-ip/en/studies/pdf/ssa_maskus_pi.pdf>. Accessed on 19/05/15, p. 4.
57. The holder cannot use the exclusivity powers conferred by these rights in order to oppose the further commercialisation of genuine products incorporating or protected by such rights once these products have been placed in the market by him or with his consent.
58. Section 6 (3) (b)
59. Philipson Consultancy Blog, "Parallel Imports and the Exhaustion Doctrine: Lessons for Nigeria", available at <*http://phillipsonsconsultancy.com/blog/2013/05/parallel-imports-nigeria/*>. Accessed on 03/12/14.
60. Ukiri, E. O. "Parallel Imports – How to Manage the Problem", available at <*http://www.enownow.com/news/story.php?sno=12295*>. Accessed on 03/12/14.
61. Ibid.
62. Federal High Court, January 23, 2007.
63. Adejugbe, A., op cit.
64. Ibid.
65. WHO, "Essential Medicine and Health Products", available at <http://www.who.int/medicines/areas/policy/wto_impl_para6/en//> Accessed on 23/04/15.
66. Ayodele, A. "Globalisation, (2009), "The TRIPS Agreement and their Implications on Access to Essential Medicine for Developing Countries: A Case Study of Nigeria", Vol. 2, Part 1, *Confluence Journal of Private and Property Law (CJPPL),* Kogi State University, Anyigba, p 109.
67. Matthews, D. "On the TRIPS Agreement and Public Health: A Solution to the Access to Essential Medicines Problem," available at < *http://jiel.oxfordjournals.org/content/7/1/73*> Accessed on 16/05/15.
68. Ayodele, A. (2009), op cit, p. 109.
69. World Health Organisation, "In Vitro Diagnostics and Laboratory Technology", available at <*http://www.who.int/diagnostics_laboratory/publications/procurement/en/*> Accessed on 20/05/15.
70. Ayodele, A. (2009), op cit, p. 109.

REFERENCES

1. Bossche, P. V. (200&), *The Law and Policy of the World Trade Organisation:* Text, Cases and Materials, Cambridge, Cambridge University Press.
2. Brecher, J., et al,. (2000), Globalisation from Below, Cambridge, MA: South End Press.
3. Ladan, M. T. (2007), *Materials and Cases on Public International Law*, Zaria, ABU Press.
4. Ayodele, A. (2009), "Globalisation, The TRIPS Agreement and their Implications on Access to Essential Medicine for Developing Countries: A Case Study of Nigeria", Vol. 2, Part 1, *Confluence Journal of Private and Property Law (CJPPL),* Kogi State University, Anyigba.
5. Reichman, J. H., et al, (2014), "The WTO Compatibility of a Differentiated International Exhaustion Regime', *International Laboratory for Law and Development.*
6. Adejugbe, A. "Nigeria: Protection of Intellectual Property in Nigeria; Effect of Grey Market Goods; Challenges and Solutions", available at <http://www.mondaq.com/x/307654/Trademark/PROTECTION+OF+INTELLECTUAL+PROPERTY+IN+NIGERIA+EFFECT+OF+GRAY> .
7. "Alternative Regionalisms," available at <*http://www.tni.org/article/alternatives-neo-liberal-globalisation*>
8. Alsegård*, E.* "Global pharmaceutical patents after the Doha Declaration – What lies in the future?" available at <*http://www.law.ed.ac.uk/ahrc/script-ed/docs/doha.asp*>.
9. Burdacki, S. "Strategy, Tactics and Solidarity: The Anti-Globalisation Movements and its Discontents", available at <*http://bad.eserver.org/issues/2004/65/burdacki.html*>
10. Buttel, F. H. "Environmentalism and the Trajectory of the Anti-Corporate Globalisation Movement", available at <*http://www.irows.ucr.edu/cd/courses/184/buttelgould.htm*>
11. Delaney, L., "What is Parallel Importation?", available at <*http://importexport.about.com/od/ImportMarketResearch/a/Parallel-Importing.htm.*>.
12. Haddad, W. F., "Compulsory Licensing of Life-Saving Medicines: A Story and A History, A Problem and A Solution", available at < *http://www.equilibri.net/nuovo/articolo/compulsory-licensing-life-saving-medicines-%E2%80%9C-story-and-history%E2%80%9D-%E2%80%9C-problem-and-solution%E2%80%9D*>.
13. JAAids, "Coalition of Civil Society Groups on Access to Essential Medicines in Nigeria", available at <*http://www.nigeria-aids.org/reports.cfm?read=74*>.
14. Maskus, K. E., "Parallel Imports in Pharmaceutical: Implications for Competition and Prices in Developing Countries', available at < *http://www.wipo.int/export/sites/www/about-ip/en/studies/pdf/ssa_maskus_pi.pdf*>.
15. Matthews, D. "On the TRIPS Agreement and Public Health: A Solution to the Access to Essential Medicines Problem," available at < *http://jiel.oxfordjournals.org/content/7/1/73*>
16. Morse, C. "Theory of the Anti Globalisation Movement", Vol. 2, No. 1, (2003), *New Formulation,* available at <*http://www.newformulation.org/1antiglobalization.htm*>
17. Musungu, S., and Oh, C., "The Use of Flexibilities in TRIPS By Developing Countries: Can They Promote Access To Medicines?, available at < *http://www.who.int/intellectualproperty/studies/TRIPS_flexibilities/en/*>.
18. Nwobike, J. C. "Pharmaceutical Corporations and Access to Drugs in Developing Countries: The Way Forward', available at < http://www.surjournal.org/eng/conteudos/artigos4/ing/artigo_nwobike.htm>
19. Philipson Consultancy Blog, "Parallel Imports and the Exhaustion Doctrine: Lessons for Nigeria", available at <*http://phillipsonsconsultancy.com/blog/2013/05/parallel-imports-nigeria/*>.

20. Satardien, M. Z. "A Critical Analysis of the Trade Related Aspects of Intellectual Property Rights Agreement and has South Africa Complied with this Agreement with Special Reference to Patented Pharmaceuticals," available at <*http://etd.uwc.ac.za/xmlui/handle/11394/2153*>

21. Schmidt, C. W. 'Drugs as Intellectual Property", available at <*http://pubs.acs.org/subscribe/archive/mdd/v04/i06/html/06rules.html*>.

22. "Swiss Network for International Studies, Examining Global Partnership to Improve Innovation and Access to Medicines on a Sustainable, Priority Needs Basis; MDG8, Target 8,R," available at <*'http://www.snis.ch/call-projects-2011_847_examining-global-partnerships-improve-innovation-and-access-medicines-sustain*>.

23. "The Social Meaning of the Anti-WTO Protests in Seattle", (1999), available at <https://www.wsws.org/en/articles/1999/12/wto-d06.html>

24. Thurston, J., "Compulsory Liceses: Necessity or Threat?", available at <*http://www.rsc.org/chemistryworld/2013/05/compulsory-licence-license-patent-drugs-debate*>.

25. Ukiri, E. O. "Parallel Imports – How to Manage the Problem", available at <*http://www.enownow.com/news/story.php?sno=12295*>.

26. WHO, "Essential Medicine and Health Products", available at <http://www.who.int/medicines/areas/policy/wto_impl_para6/en//>

27. WHO, "The Global Politics of Pharmaceutical Monopoly Power, Drug Patents, Access, Innovation and the Application of the WTO Doha Declaration on TRIPS and Public Health", available at <*http://apps.who.int/medicinedocs/en/m/abstract/Js20963en/*>.

28. World Health Organisation, "In Vitro Diagnostics and Laboratory Technology", available at <*http://www.who.int/diagnostics_laboratory/publications/procurement/en/*>

29. WTO, "Compulsory Licensing of Pharceuticals and TRIPS", available at <*http://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm*>.

30. WTO, "The Doha Declaration on the TRIPS Agreement and Public Health', available at <*http://www.who.int/medicines/areas/policy/doha_declaration/en/*>.

31. 'WTO, "WHO Secretariat Workshop on Affordable Drugs", available at <*http://www.wto.org/english/tratop_e/trips_e/tn_hosbjor_e.htm*>.