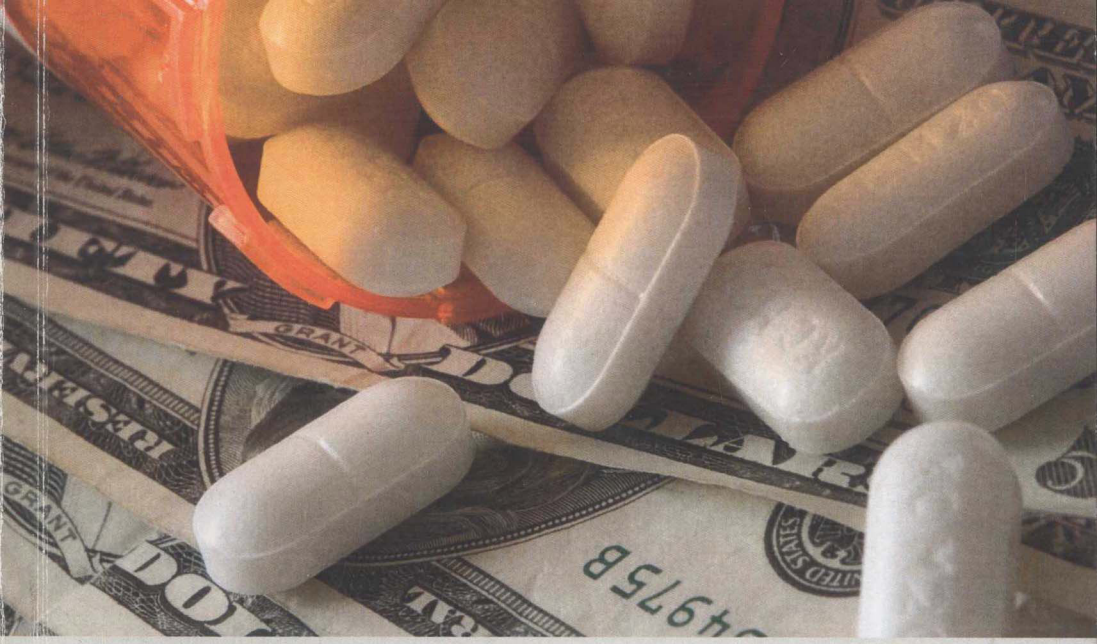

Ebenezer Durojaye

TRIPS, HUMAN RIGHTS AND ACCESS TO MEDICINES IN AFRICA

A POST DOHA ANALYSIS

VDM
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LISTS OF ABBREVIATIONS

ACHPR	African Charter on Human and Peoples' Rights
AIDS	Acquired Immune Deficiency Syndrome
ARIPO	African Regional Intellectual Property Organisation
ARVs	Anti Retrovirals
AU	African Union (formerly the Organisation of African Unity – OAU
AZT	Zidovudine (formerly Azidothymidine)
CEDAW	Convention on Elimination of All Forms of Discrimination Against Women
CERD	Convention on Elimination of All forms of Racial Discrimination
CESCR	Committee on Economic, Social and Cultural Rights
CRC	Convention on the Right of the Child
EPC	European Patent Convention
EU	European Union
GATT	General Agreement on Trade and Tariffs
HDR	Human Development Report
HIV	Human Immuno-Deficiency Virus
ICCPR	International Covenant on Civil and Political Rights
ICESCR	International Covenant on Economic, Social and Cultural Rights
ICJ	International Court of Justice
IP	Intellectual Property

IPRs	Intellectual Property Rights
LDC	Least Developed Countries
MSF	Medecins Sans Frontieres
NAFTA	North American Free Trade Agreement
NGO	Non-Governmental Organisation
OAPI	African Intellectual Property Organisation
OECD	Organisation for Economic Co-operation and Development
PLWHA	People Living with HIV/AIDS
R & D	Research and Development
TAC	Treatment Action Campaign
TB	Tuberculosis
TRIPS	Agreement on the Trade Related Aspects of Intellectual Property Rights
WHO	World Health Organisation
WTO	World Trade Organisation
UDHR	Universal Declaration on Human Rights
UK	United Kingdom
UN	United Nations Organisation
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNDP	United Nations Development Programme
UNHCHR	United Nations High Commissioner for Human Rights
USA	United States of America
VCLT	Vienna Convention on the Law of Treaties

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CHAPTER 1

INTRODUCTION

> Globally trade policy provisions need to be used more effectively to increase access to care. The availability of low-cost generic drugs needs to be expanded, in accordance with national laws and international trade agreements and with a guarantee of their quality. The relevance of compulsory licensing and the development of national manufacturing capacities need further expansion. We need to find ways of more effectively using trade policy provisions, such as compulsory licensing or parallel importation, to increase access to care. The availability of low-cost generic drugs needs to be expanded, in accordance with national laws and international trade agreements and with guarantees of their quality.[1]

1.1 **Introductory remarks**

The Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement of 1994, an outcome of the Uruguay Round negotiations, radically altered the role of international trade law in promoting and enforcing intellectual property protection around the globe.[2] This important, yet controversial, international agreement requires members of the World Trade Organisation (WTO) to implement strong intellectual property protections in their domestic law. Prior to 1994, countries of the world were not obligated to grant patent rights for pharmaceutical products, but with the signing of the TRIPS agreement this changed. Along with this change, patent protection for pharmaceuticals, and the impact that such patent protection is likely to have on access to medicines for the world's poor, have become a major source of conflict between rich and poor nations.

African countries remain particularly worst affected by this development. This is a continent that is grappling with various problems including poverty, conflicts and devastating diseases such as HIV/AIDS, tuberculosis and malaria. While Africa

[1] Report of the UN Secretary General to the UN General Assembly meeting issued on 16, February 2001 document A/55/779.

[2] The TRIPS Agreement was part of the Final Act establishing the WTO commonly referred to as the 'Marrakech Agreement' attached as Annex 1C to the WTO Agreement.

constitutes about ten percent of the world's population it is home to over 70 percent of people living with HIV. In 2008 alone approximately 2 million people were reported to have lost their lives as a result of HIV/AIDS related illness, 80 percent of which were from sub-Sahara Africa.[3] Women have been the worst affected by the epidemic, constituting about 50 percent of the world infection rate and 60 percent of the rate in Africa.[4] The problem is not limited to HIV/AIDS alone. Other diseases such as tuberculosis and malaria continue to pose great threats to lives in Africa.

1.2 **Statement of the problem**

In many developing countries, particularly those in Africa, people are dying needlessly of diseases, which are easily treatable in developed countries. This situation is further aggravated when a country spends little or nothing on the health of its people which is the case in many African countries. It must be observed that poverty can hardly be separated from poor health. Poverty may restrict access to healthcare by weakening infrastructures, limiting number of health care personnel and even reducing access to drugs. Little wonder then that preventable and treatable diseases such as HIV/AIDS, tuberculosis and malaria are most prevalent in poor countries of the world.

Experience has shown that in the world only a handful of people living with HIV currently have access to life saving medication known as antiretroviral drugs (ARVs). Although these drugs are not a cure for HIV/AIDS, it has been shown that they have dramatically improved the rates of mortality and morbidity, prolonged lives, improved quality of life, revitalised communities and transformed perceptions of HIV/AIDS from a plague to a manageable chronic disease.[5] This has led to improved increase in antiretroviral coverage from 7% in 2003 to 42% in 2008. In Africa the percentage of those accessing treatment is put at 40% of about 3 million people in need. However, this percentage varies among sub-regions For instance, while the percentage of those

[3] UNAIDS *Report on the Global AIDS epidemic* December 2009.
[4] *Ibid.*
[5] World Health Orgamization (WHO) *Scaling up anti-retroviral Therapy in resource-limited Settings Guidelines for a Public Health Approach* April (2002).

receiving treatment in Southern African is 48% that of Western and Central Africa is 30%.[6]

One needs to point out here that recent developments in the world seem to show that cheaper drugs are being made available in developing countries due to a series of international initiatives and support from developed countries such as the Global Fund and the United States government's President Emergency Plan Fund for AIDS Relief (PEPFAR). More importantly, one must commend the initiatives and efforts of the Clinton Foundation for being able to strike some deals with pharmaceutical companies to sell HIV/AIDS drugs at a cheaper price in some developing countries.[7] However, drugs made available under these initiatives are reaching very few people. There are better opportunities for developing countries to scale up treatment for their citizens if they are allowed to effectively invoke the flexibility provisions contained in the TRIPS Agreement particularly compulsory licensing. But with limited resources and high cost of drugs, particularly for second- line drugs for HIV/AIDS treatment, just a handful of people can at present be reached.

It is also true that for tropical diseases such as tuberculosis and malaria that are killing millions of people, access to medications to reduce their impact is poor despite the fact that these diseases can be cured. Many reasons such as lack of political will or commitment, poor economic conditions and lack of appropriate distribution mechanism have been given as hindering access to life-saving medications in Africa. But aside from these, one of the most crucial factors militating against access to HIV medications in African countries is patent rights enjoyed by pharmaceutical companies on HIV drugs. This is made possible by the WTO's TRIPS Agreement which many have considered a barrier to life-saving medications in Africa.

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[6] UNAIDS (note 3 above) 9.

[7] See L Altman , 'Clinton Group gets discount for AIDS Drugs' *New York Times* 24 0ctober 2003 p 1.Where it was reported that the Foundation has struck a deal with some pharmaceutical companies to sell ARVs at cheaper prices in some countries in Africa and the Caribbean

It is recognised that the TRIPS Agreement contains some safeguard provisions, such as parallel imports, early working exception and compulsory licensing, which African countries can explore to ensure access to life saving medications for their citizens. However, implementation of these provisions in practice has not been as easy as expected. Attempts at invoking these flexibility provisions under TRIPS, especially compulsory licensing, have often met with stiff opposition from developed countries and pharmaceutical companies. Denial of access to life-saving medications is a human rights issue, as it may have direct implications on the enjoyment of an individual's rights to health and life guaranteed in numerous human rights instruments.

1.3 **Focus of the study**

This study focuses on the relevance of the flexibilities of the TRIPS, particularly compulsory licensing for African countries. Many African countries lack the expertise to correctly interpret the TRIPS Agreement or draft protective patent laws that will incorporate the flexibilities into their laws. Those who possess this expertise often lack the technological capacity for local production of drugs even if they invoke the flexibilities provided by TRIPS.

One of the most important and controversial of these flexibilities is the use of compulsory licensing. This is a license issued by a state authority to a government agency, a company or other party to use a patent without the patent holder's consent. Usually royalty is paid to the patent holder as a form of compensation for the use of its patent. Corea has noted that compulsory licensing may constitute an important tool to promote competition and increase the affordability of drugs, while ensuring that the patent owner obtains compensation for the use of the invention.[8] The use of this license, however, has been opposed by pharmaceutical companies from developed countries on the grounds that they discourage research and development (R & D).[9]

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[8] C Corea *Integrating Public Health Concerns into Patent Legislation in* Developing Countries (2000)7.

[9] FM Scherer, 'Comments on intellectual property, technology diffusion, and growth' in R Anderson & N Gallini, (eds) *Competition policy and intellectual property rights in the knowledge-based economy*(1998)104.

Considering the fact that the TRIPS Agreement constitutes a barrier to life-saving medications in Africa, it becomes paramount for African states in line with their obligations under international human rights treaties, to ensure access to life-saving medications for their citizens by making use of the flexibilities of TRIPS.

At the ministerial meeting of WTO members in Doha in 2001, popularly referred to as the Doha Declaration, a glimmer of hope came the way of developing countries as to the use of compulsory licensing. It was resolved at the meeting that the TRIPS Agreement 'can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all'.[10] It was further stated that in order for countries to have flexibility in using the TRIPS agreement, that TRIPS shall be read in light of the object and purpose of the Agreement, found in its Articles 7 and 8. Also, it was reiterated that each member has the right to grant compulsory licences and the freedom to determine the grounds for such a licence.[11] Perhaps the most important aspect of this declaration is found in paragraph 6 where it was recognised 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.' This problem was thus referred to the Council for TRIPS for immediate solution.

It is now more than eight years since the Doha Declaration. Its impact on access to medicines in Africa has remained uncertain. Thus, this study will seek to analysis the flexibilities of the TRIPS Agreement, particularly use of compulsory licensing and their effectiveness in ensuring affordable medicines for Africans using the right to health lens. It will also consider the likely challenges African countries may encounter in invoking these provisions. More importantly it will seek to analyse the events leading to Doha Declaration and the impact, if any, of the declaration on access to medicines for African countries.

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[10] World Trade Organization, Doha Ministerial Declaration on the TRIPS Agreement and Public Health, para 4, WTO Doc No WT/MIN(01)/DEC/2 (2001)
[11] *Ibid.*

1.4 **Relevance of right to health to the study**

As earlier stated if there is any area of human rights most affected by the discussion on TRIPS Agreement and access to HIV medications it is the right of an individual to the enjoyment of highest attainable standard of physical and mental well being. This right, often regarded as the 'right to health' as a convenient shorthand[12], has long been recognised since 1946 by the World Health Organisation's (WHO) Constitution.[13] The preamble to this Constitution stated that 'the enjoyment of the highest attainable standard of health is a fundamental right' of all.[14] The Universal Declaration of Human Right in its article 25 guarantees the right of every one to a standard of health care adequate for him/her and his /her family including medical care.[15] Though not a treaty by all standards, it has been widely accepted by most nations as binding on them.[16] The most comprehensive provision on the right to health is contained in article 12 of the International Covenant on Economic Social and Cultural Rights (ICESCR). It provides that 'States parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health'. It then proceeds to list other determinants essential for the enjoyment of the right.[17]

At the Alma Ata Declaration on Primary Health Care it was reaffirmed that health, which is a state of complete physical and mental well being and not merely absence of diseases, is a fundamental right of all and that 'the attainment of the highest possible level of health

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[12] V Leary 'The rights to Health in International Human Rights Law' (1994) 1*Health and Human Rights* 24.

[13] 14 UNTS 185 The Constitution of the WHO was adopted by the International Health Conference, New York, 19-22 June, 1945; opened for signature on 22 July 1946 by the representatives of 61 States (Official Records of the World Health Organization, no. 2, p. 100); and entered into force on 7 April 1948.

[14] *Ibid.*

[15] Universal Declaration of Human Rights, G.A. Res. 217 A (III), U.N. Doc. A/810 (10 December 1948).

[16] JP Humphrey 'The Universal Declaration of Human Rights: Its History, Impact and Judicial Character,' in BG Ramcharan (ed) *Human Rights: Thirty Years After the Universal Declaration* (1984).

[17] International Covenant on Economic, Social and Cultural Rights, adopted 16/12/1966; G.A. Res 2200 (XXI), UN. Doc A/6316 (1966) 993 UNTS 3 (entered into force 3/01/1976). Art 12

is a most important world-wide social goal whose realisation requires the action of many other social and economic sectors in addition to the health sector.'[18]

Similarly, the right to health is guaranteed under article 12 of the Convention on Elimination of All Forms of Discrimination against Women (CEDAW)[19], article 24 of the Convention on the Right of the Child (CRC)[20] and article 5 of the Convention on the Elimination of All Forms of Racial Discrimination (CERD).[21] In addition to these provisions Article 16 of the African Charter on Human and Peoples' Rights (ACHPR) guarantees the right of every one to the enjoyment of highest attainable standard of health.[22] It must be noted that states are obligated to respect, protect and fulfill the right to health under international law. The scope and nature of these obligations vis-à-vis the TRIPS Agreement are examined later in this study.

Although the right to health has been widely recognised in so many international and regional human rights instruments, it has like other social and economic rights continued to face the challenge of non justiciability. In particular, the right to health has remained subject of criticism for being vague in content and intersecting with too many rights.[23] It has similarly been held that the right to health is insufficiently precise as to constitute rules of customary international law.[24]

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[18] Article 1 of the *Declaration of Alma-Ata on Primary Health Care*, International Conference on Primary Health Care, 6-12 September 1978, Alma-Ata.

[19]Convention on Elimination of All Forms of Discrimination Against Women GA Res. 54/180 UN GAOR 34th Session Supp No 46 UN Doc A/34/46 1980

[20] Convention on the Right of the Child GA Res. 25 (XLIV), UN GAOR Supp No 49 UN Doc A/RES/44/25 1989

[21] Convention on the Elimination of All Forms of Racial Discrimination, UN General Assembly Resolution 2106 A (XX) (21 December 1965), U.N. GAOR, 20th Session, Supp. No 14, at 47, UN Doc A/6014 (1965), 660 UNTS 195, 222 (entered into force 4 January 1969)

[22] African Charter on Human and Peoples' Rights O.A.U. Doc.CAB/LEG/67/3/Rev.5 Adopted by the Organization of African Unity, 27 June 1981, entered into force 21 October 1986.see also article 11 of Eurpean Charter and article 10 of the Protocol to the American Convention on Human Rights

[23] DP Fidler *International Law and Infectious Diseases* (1999)

[24] *Flores v. Southern Peru Copper Corporation* US Court of Appeal Second Circuit 343 F.3d 140 (2003)