



**UNIVERSITY OF
KWAZULU-NATAL**

**INYUVSEVI
(YAKWAZULU-NATALI)**

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2012.

**THE WORLD TRADE ORGANIZATION'S TRADE AGREEMENTS: A LEGAL ANALYSIS OF
THEIR IMPACT ON ACCESS TO ANTIRETROVIRAL DRUGS AND THE HUMAN RIGHT TO
HEALTH/LIFE IN ZAMBIA.**

A Thesis

Submitted to the School of Law, in complete fulfilment of the requirements for the Degree of Masters
of Laws (LLM)

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Declaration statement

I, Christine Mabvuto Pemba, hereby declare that this dissertation is a product of my own work except where otherwise stated and expressly acknowledged, and that it has not been previously presented either in part or in its entirety at any other university for the award of a degree.

Signature.....Student N°.....

**Dated.....at.....Faculty of law University of KwaZulu-Natal Howard College
Campus. Durban 2012.**

Quote

"It is my aspiration that health finally will be seen not as a blessing to be wished for, but as a human right to be fought for."

United Nations former Secretary-General

Kofi Annan

Dedicated

To my late sister Priscilla Mukuka Pemba-Zwane who passed away at the tender age of 26 years on the 23rd of January 1996. Priscilla, although it has been 17 years since your premature death shattered our family, your life was a blessing; your memories a treasure you are loved beyond words and sadly missed beyond measure.

This is definitely for you and may your soul rest in eternal peace you forever remain in our hearts until we meet again.

Acknowledgements

First and foremost, I would like to thank my Lord God Jehovah Almighty through whom all things are possible including this dissertation.

The process of writing this dissertation could not have been successfully completed without the assistance and inspiration from the following people:

I am deeply indebted to my Supervisor Dr. Edith Mneney for her invaluable support, insightful supervision, unwavering patience and critical analysis of the content that went in to this dissertation which assisted me to eventually complete this work.

To my mother Miss Christine Mutale, words cannot describe how thankful and appreciative I am for your advice, spiritual teachings and values that you instilled in me at a tender age of which have groomed me into the woman that I am. May the good Lord keep you for a long time you will always be my inspiration.

My utmost appreciation goes to my two sisters and five brothers and all my nieces and nephews whose unique love and support inspired me to ascend to higher heights in my studies. Special thanks to my young brother Elias Pemba, for your constant encouragement especially when I felt like giving up.

Special thanks to two of the most important people in my life my fiancé Sunday Mwanga and our daughter Neema-Grace, your love, support and presence in my life keeps me striving to be a better daughter, sister, cousin, aunt, friend, partner, mother and person. God Bless you.

I would specifically like to thank Mr and Mrs Ndlovu, Fr. Peter Lafferty and Mr George Augustine for their morale and financial support, Professor Alan Rycroft for initiating this whole process and Dr. Caroline Goodier for her editorial contribution which not only refined my researching and writing skills but also gave me focus and the ability to improve this paper.

Finally, I would like to thank all my friends especially Carol Anne Epstein for her morale support throughout the entire process of researching and compiling this dissertation, and the entire School of

Law at the University of KwaZulu-Natal for granting me this opportunity to research on this interesting and very close to home topic.

ABSTRACT

This dissertation has been motivated by the prolonged deficiency of access to advanced regimens of Antiretroviral drugs (ARVs) and efficient health services by people living with HIV/AIDS (PLWHA) in Zambia, a least developed Member of the World Trade Organisation (WTO). Zambia's reality of dire provision of health services particularly essential medicines persists despite the urgent need for sustainable access to ARV drugs in poor African countries worst affected by HIV/AIDS, having been accentuated in the international declaration on Trade Related Aspects on Intellectual Property Rights (TRIPS) and Public Health.

Furthermore, under international human rights law of treaties, access to medicines including ARV drugs, has been recognised as a core component of the right to health and or life which needs to be progressively realised by governments, even in the advent of globalisation of domestic health services including provision of medicines.

Whilst the Zambian government has highlighted lack of funds as the foremost impediment to efficient supply of health services particularly essential medicines. Conversely the WTO has pronounced lack of legal adoption of a plethora of flexibilities envisaged in its relevant international agreements by most poor Members, as the foremost impediment to fostering efficient public health service delivery including access to ARV drugs and therapy for PLWHA.

Thus to assist in ascertaining whether the issue of deficient access to ARV drugs as a health service is as a result of legal unpreparedness in poor countries specifically Zambia; or whether it is due to provisions in the WTO trade agreements that foster globalisation of health services through liberalised trade in services and pharmaceutical patent protection of essential drugs. This dissertation will analyse the WTO's multilateral trade agreements and their legal impact on access to ARV drugs as a health service and a human right to health in Zambia.

The foregoing analysis will be conducted through a desk review of literature on the subject, making use of paper and electronic sources.

LIST OF ACRONYMS

AGOA	:	African Growth and Opportunities Act
AIDS	:	Acquired Immune deficiency syndrome
ARIPO	:	African Regional Industrial Property Organisation
ART	:	Antiretroviral therapy
ARV DRUGS	:	Antiretroviral drugs
BI	:	Boehringer Ingelheim
BMS	:	Bristol-Myers Squibb
CBOH	:	Central Board of Health
CCP	:	Competition and Consumer Protection Act of 2010
CCPC	:	Competition and Consumer Protection Commission
CESCR	:	Committee on Economic Social and Cultural Rights
CHAZ	:	Christian Association of Zambia
CL	:	Compulsory Licenses
COMESA	:	Common Market for Eastern and Southern Africa
CSO	:	Central Statistical Office
EAC	:	Eastern African Community
EC	:	European Commission
EPAs	:	Economic Partnerships
FDI	:	Foreign Direct Investment
FTAs	:	Free Trade Agreements
GATS	:	General Agreement on Trade in Services

GDP	:	Gross Domestic Product
GFATM	:	Global Fund for HIV/AIDS TB and Malaria
GRZ	:	Government of the Republic of Zambia
GSK	:	GlaxoSmithKline
HIPC	:	Heavily Indebted Poor Countries
HIV	:	Human Immune Virus
ICPRS	:	International Covenant on Civil and Political Rights
IESCR	:	International Covenant on Economic Social and Cultural Rights
IMF	:	International Monetary Fund
IP	:	Intellectual Property
IPRs	:	Intellectual Property Rights
KIP	:	Kenyan Industrial Property Act
KIPI	:	Kenyan Industrial Property Institute
LDCs	:	Least Developed Countries
MDGs	:	Millennium Development Goals
MFN	:	Most Favoured Nation
MMD	:	Movement for Multi-Party Democracy
MNCs	:	Multi-National Companies
MOCTI	:	Ministry of Commerce Trade and Industry
MOFNP	:	Ministry of Finance and National Planning
MOH	:	Ministry of Health (Zambia)
MTCT	:	Mother to Child Transmission of HIV/AIDS
NAC	:	National AIDS Council

NASA	:	National Spending Assessment
NDP	:	National decentralisation Programme
NGOs	:	Non-Governmental Organisations
NHSA	:	National Health Services Act
NHSF	:	National Health Strategic Framework
NT	:	National Treatment
PACRO	:	Patents and Companies Registration Office
PEPFAR	:	United States President's Emergency Plan for HIV/AIDS Relief
PLWHA	:	People Living With HIV/AIDS
R&D	:	Research and Development
RSA	:	Republic of South Africa
SAALP	:	South African AIDS Law Project
SACU	:	Southern African Customs Union
SADC	:	Southern African Development Committee
SAPS	:	Structural Adjustment Programmes
TAC	:	Treatment Action Campaign
TALC	:	Treatment Advocacy and Literacy Campaign
TB	:	Tuberculosis
TRIPS	:	Trade Related Aspects on Intellectual Property Rights
UDHR	:	Universal Declaration on Human Rights
UK	:	United Kingdom
UNAIDS	:	United Nations Joint Programme on HIV/AIDS
UNIP	:	United Nations Independent Party

UNZA	:	University of Zambia
USA	:	United States of America
VL	:	Voluntary License
WORLD BANK	:	International Bank of Reconstruction and Development
WHO	:	World Health Organization
WIPO	:	World Intellectual Property Organisation
WTO	:	World Trade Organization
ZCCM	:	Zambia Consolidated Copper Mines
ZDHS	:	Zambia Demographics Health Survey
ZPA	:	Zambia Privatisation Agency
ZRA	:	Zambia Revenue Authority

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CHAPTER ONE: INTRODUCTION

1.1. BACKGROUND

This dissertation comprises an analysis of the World Trade Organization's Agreements on Trade Related Aspects on Intellectual Property Rights (TRIPS) and the General Agreement on Trade in Services (GATS) and their legal impact on access to antiretroviral drugs (ARVs) as a human right to health/life in Zambia. An appreciation of the historical socio-economic background of access to health services in Zambia in relation to the current challenges of sustained access to ARV drugs in the Zambian health system is however pertinent and sections 1.2; 1.2.1 and 1.2.2 will present an account of this background.

1.2. SOCIO-ECONOMIC BACKGROUND OF ACCESS TO HEALTH SERVICES IN THE ZAMBIAN HEALTH SYSTEM

The Republic of Zambia is a least developed (LDC) sub-Saharan African country¹. It is a former British protectorate that was called Northern Rhodesia and subsequently adopted its current name after receiving its independence on October 24th 1964.² In 1968³ the then newly elected government embarked on implementing national economic reforms aimed at nationalising the copper mines which formed the basis of Zambia's major economic sector.⁴ The nationalisation of copper mines permitted the Zambian government to control the economy which resulted in inter alia, the subsidisation of core government sectors pertinently health and the abolition of user fees of health services improving access thereto.⁵

However between the 1980's and 1990's the fall in the global price for copper due to diminished world-wide demand affected the Zambian economy adversely,⁶ this propelled the government into

¹ Least developed countries (LDCs) United Nations (UN) Classification (2012). Available on line at: <http://data.worldbank.org/country/zambia>. Accessed on 26/04/2012.

² CIA the World Fact book Zambia (23rd August 2011). Available online at: <https://www.cia.gov/library/publications/the-world-factbook/geos/za.html>. Accessed on 08/09/2011.

³ Ibid.

⁴ Republic of Zambia *The nation is You: Addresses to and Resolutions of, the National Independence Party at Mulungushi Hall* (1972) 23.

⁵ M. Eklund, *The cases of Botswana And Zambia : A Comparative Study in to the Cases of Corruption* (1999)22.

⁶ The Impact of Structural Adjustments in Zambia (AFRODAD 2007). Available online at: <http://www.ukzn.ac.za/Homepage.aspx>. Accessed on 02/05/2012. Hereinafter referred to as, AFRODAD (2007).

chronic external borrowing of loans from financial institutions chiefly the International Monetary Fund (IMF) and the World Bank, to finance its state funded social services.⁷ Regrettably, these loans came with the Structural Adjustment Programmes (SAPs)⁸ which were the World Bank's conditions for loan repayment for Heavily Indebted Poor Countries (HIPC), Zambia included.⁹

For purposes of this research the main condition envisaged in the SAPs that Zambia adopted was, "cutting back on government expenditures mainly subsidies."¹⁰ This condition compelled Zambia to cut-back on subsidies to most of its government funded institutions which inevitably led to the denial of basic social services, inter alia health.¹¹ This lack of basic social services triggered massive riots country wide between 1986 and 1990 which resulted into Zambia's first democratic parliamentary and presidential elections in 1991.¹²

The coming into power of the first democratic government¹³ not only brought about a new political regime but also a new economic trade policy of fully liberalising Zambia's state controlled economy.¹⁴ The liberalisation of state entities yielded Zambia strong economic growth between the periods of 1994 and 2004 and facilitated its qualified debt relief under the Highly Indebted Poor Country Initiative (HIPC).¹⁵ However, socio-economic poverty levels still remained high as the negative effects of the privatization process continued to be experienced throughout varying sections of society.¹⁶ The two main negative effects of privatization in the health sector related to national health

⁷ Ibid.

⁸ J. K Mapulanga-Hulston, The implementation of structural adjustment programmes in sub-Saharan Africa: An Infringement of state sovereignty? *Zambian law Journal* Vol.35 at 1, 1-19 (2003).

⁹ P. Marren Zambia and The Enhanced HIPC Deal: A Lasting Solution To The Debt Problem?(2001)11.

¹⁰ "The loans or credits carried other conditions including; removal of trade barriers, currency devaluation, raising interest rates and tight monetary control". These conditions proved to be unfriendly and dangerous to economic health of the borrowing nations in Africa. This was because the prescribed standard conditions did not take in to account the political, economic and social conditions prevailing in the subject countries." AFRODAD (2007) Note 6 above. See also A. Thomson, *An Introduction to African Politics*, Second Edition (London: Routledge, 2004) JQ18 72 THO at173.

¹¹ Ibid.

¹² L. Rakner, Political and Economic Liberalisation in Zambia 1999-2001(2003) 2.

¹³ Ibid. "The immediate issue confronting the Movement for Multi-party Democracy (MMD) government in 1991 was the external financial situation. Due to the withdrawal of the IMF and World Bank credits, Zambia had incurred arrears on its debt to the multilateral financial lending institutions. Zambia's financial credibility was at a low-point as the country was ineligible to draw on IMF funds as well as the World Bank and Bilateral balance of payments support grants. The need to restore international confidence and to increase the level of donor funding was therefore of paramount importance for the government."

¹⁴ N. Ndumingu, *More on: All you need to know about privatization in Zambia (June/July 2000): More on all you need to know about privatization in Zambia*. Lusaka: Post Privatization Department, Privatization News. 13.

¹⁵ International Monetary Fund Press Release for April 8, 2005, "IMF and World Bank Support \$3.90 billion in Debt Service Relief for Zambia". Available online at: <http://www.imf.org/external/np/sec/pr/2005/pr0580.htm>. Accessed on 05/12/2011.

¹⁶ Privatization AFP, "Zambia's privatizations a total failure, says unions", January 19, 2004. Available online at: <http://www.eprop.co.za/news/article.aspx?idArticle=3039>. Accessed on 15/12/2011.

programs on access to ARV drugs treatment discussed below, were; substantial curtailment of government subsidies and the introduction of a two-tier national health system.

1.2.1. The substantial curtailment of government subsidies

Under privatization policies the IMF and World Bank's conditions demanded further substantial reductions of government subsidies to Zambia's core Ministries including the health sector.¹⁷ This minimal government funding towards the health sector brought changes in the provision of public health services for instance; the introduction of user fees, whilst health worker incentives, salary increments and housing allowances were halted and recruitments of new health workers were abolished despite their scarcity.¹⁸ The lack of incentives for health workers, as discussed later in this chapter, engendered migration of skilled professionals such as doctors and nurses to industrialised countries that offered better working conditions.¹⁹ Thus the delivery of health services including national health programmes on ARV drugs and therapy was disrupted.²⁰ The substantial curtailment of government subsidies was coupled with the introduction of private health services, to create a two tier national health system discussed below.

1.2.2. The introduction of a two tier health system and decentralised health services

Health services in Zambia as previously mentioned were provided free of charge. This was due to the fact that public health services were entirely government funded and private services were forbidden under the Medical Aid Societies and Nursing Homes (Dissolution and Prohibition) Act of 1975.²¹ However, post 1991 economic liberalisation health sector reforms were carried out to restructure the

¹⁷ E. Makasa 'The Human Resource crisis in the Zambian Health Sector – A Discussion Paper' (*Medical Journal Of Zambia* (2009 MJOZ), Vol. 35 No. 3 Pages 82-86. Available online at: <http://ajol.info/index.php/mjz/article/view/46522/32917>. Accessed on 11/10/2010. Hereinafter referred to as Makasa. "The World Bank and IMF through their heavily Indebted Poor Countries (HIPC) initiative in November 2000, Zambia's public sector wages were not to exceed 8% of the Gross Domestic Product (GDP) in order for the country to qualify for a relief of about half of its \$6.8 billion debt."

¹⁸ D. Goldsbrough Does the IMF Constrain Health Spending in Poor Countries? Centre for Global Development Brief (2007). Available online at: http://www.cgdev.org/files/14104_file_IMF_and_Health_Spending.pdf. Accessed on 24/05/2012. Hereinafter referred to as Goldsbrough (2007). See also Brook K. Baker *Further Debate on the International Monetary Fund and Health* the Impact of the International Monetary Fund's Macroeconomic Policies on the Aids Pandemic (2010). Available online at: http://people.pwf.cam.ac.uk/ds450/details/40_3p.pdf. Accessed on 24/05/2012 Hereinafter referred to as, Baker (2010). See also Mail and Guardian online.com, "Downturn costs 8,200 mining jobs in Zambia", March 2, 2009. Available online at: <http://www.mg.co.za/article/2009-03-02-downturn-costs-8nbsp200-mining-jobs-in-zambia>. Accessed on 20/11/2012.

¹⁹ Makasa. Note 17 above.

²⁰ Ibid.

²¹ Government of Zambia (1975) *Medical Aid Societies and Nursing Homes (Dissolution and Prohibition) Act*. Government of Zambia: Lusaka. Available online at: http://www.saflii.org/zm/legis/consol_act/masanhapa619/. Accessed on 21/02/2012. Hereinafter referred to as the Medical Aid Societies and Nursing Act.

national health system. Thus the two major changes brought about by the health reforms post 1991 pertinent to health service delivery and access to ARV drugs were; the establishment of private health services and the legal restructuring of the functions of the Ministry of health. These are now deliberated below.

Firstly, the health reforms established the operation of certified private health institutions subject to conditions.²² Thus today the main providers of health services in Zambia are either private hospitals or government health institutions.²³ Public health institutions provide health services at a fee for most of the country's poor population²⁴, whilst private clinics cater for the affluent population²⁵ as they remain unregulated and under developed to benefit wider sections of society.²⁶ This has created an unequal delivery of health services as liberalisation of health services has placed the burden of medical costs on individual citizens making access to what used to be affordable health services, including ARV drugs and therapy unaffordable and out of reach for most Zambians.²⁷ The ultimate result of this is a high disease burden, due to re-occurrence of formerly eradicated or regulated diseases including HIV/AIDS.²⁸

²² Ibid. "To be approved, all private hospitals must provide a minimum level of facilities, including: a) emergency and casualty services (b) operating theatre facilities (c) laundry facilities (d) kitchen and catering facilities (e) ambulance service (f) laboratory and blood bank services (g) mortuary and incinerator services (h) pharmacy."

²³ Republic of Zambia Ministry of Health (MOH) National Health Strategic Plan "Towards Attainment of Millennium Development Goals and National Health Priorities" herein after referred to as the (NSHP 2006 - 2010). Available online at: http://www.who.int/nha/country/zmb/Zambia_NH_Strategic_plan,2006-2010%20.pdf. Accessed on 21/02/2012. Hereinafter referred to as the NHSP 2006-2010. "The Public health facilities in Zambia operate under the Ministry of health (MOH).facilities under the Ministry of Defence, including clinics and one hospital in Lusaka; clinics under the Ministry of Home Affairs; Mine hospitals and clinics; Mission hospitals and clinics, which are coordinated by the Churches Health Association of Zambia (CHAZ). Whilst Private hospitals and clinics operate Non-Governmental Organizations (NGOs) and foreign investors."

²⁴ A. H Mabika & L. London Zambia: The right to health and international trade agreements Southern and Eastern African Trade, Information and Negotiation Institute (SEATINI), School of Public Health and Family Medicine, University of Cape Town (UCT) Regional Network for Equity in Health in east and southern Africa (EQUINET) Paper produced as part of an EQUINET Capacity building programme (January 2007) With support of the University of Free State Law Faculty and the Ford Foundation available online at: <http://www.equinet africa.org/bibl/docs/CBP14tradeZAMBIA.pdf>. Accessed on 06/04/2009. Hereinafter referred to as Mabika & London.

²⁵ Zambia Demographic and Health Survey (ZDHS) Central Statistical Office(CSO), Ministry of Health(MOH), Tropical Diseases Research Centre(TDRC), University of Zambia(UNZA) and Marco International Inc. (2009). Available online at: <http://www.measuredhs.com/pubs/pdf/FR211/FR211%5BRevised-05-12-2009%5D.pdf>. Accessed on 05/03/2010. Hereinafter referred to as the ZDHS (2009). "More than 40 per cent of the Zambian population is resident in the urban areas and the remaining 60 per cent is scattered around the rural sections of the country, indicating a marked disparity between the rural and urban areas. Which raises particular varying needs and problems for the health sector in Zambia, for example, more than 1 in 10 children born in rural areas die within their six days of life, twice as much as in urban areas. Moreover, only 30 per cent of their mothers were assisted during birth by a skilled person, whilst the figure rises to over 80 per cent in urban areas."

²⁶ M. Ndulo 'An Assessment of Trade in Services in Zambia' University of Zambia (2001). Available online at: <http://www.archipress.org/capas/docs/pdf/ndulo.PDF>. Accessed on 22/05/2010 hereinafter referred to as Ndulo (2001).

²⁷ Privatization AFP, "Zambia's privatizations a total failure, says unions", January 19, 2004. Note 16 above.

²⁸ World Food Program, "Executive Brief-Zambia, Effects of the Financial crisis on Vulnerable Households", May 26, 2009. Available online at: <http://home.wfp.org/stellent/groups/public/documents/communications/wfp203545.pdf>. Accessed on 04/12/2011. See also S. L Kongwa 'Privatisation and Its Impact on Human Rights: A case study of the

Secondly, the government as part of its economic liberalisation health reforms restructured the functions of the Ministry of health (MOH), by decentralising health services from provincial level to district level.²⁹ This resulted in the establishment of the central board of health (CBOH) which was in charge of implementing health policies. The CBOH was regulated by the National Health Services Act of 1995.³⁰ However, due to a replication of functions between the MOH and the CBOH,³¹ the CBOH was disbanded and the National Health Services Act was repealed.³² In spite of this, legislature has failed to replace this lacuna with the relevant health services Act to assist in the implementation of health policies including the provision of medicines under the Zambian patent Act³³ of which and as contended below is also in desperate need of legal transformation if access to medicine is to drastically improve.

Thus today the MOH is responsible for the implementation of policies on primary health care as a health system in Zambia, whilst district hospitals are in charge of funding and regulation of finances.³⁴ This has had negative implications on the administration of national health services delivery with regard to “planning, resource allocation, human resource management and accountability”.³⁵ This as shall be investigated later in this chapter is particularly the case in the implementation of HIV/AIDS programmes on ARV drug roll out and access thereof as these programmes are externally funded.

Against this background of health services provision in Zambia, the current challenges related to health service delivery and principally access to ARV drugs and treatment in Zambia will be discussed below. This is in order to contextualize the aspects of legal health policy formulation that Zambia’s adoption of the neo-economic trade policies under the GATS and TRIPS Agreements, discussed in chapters two and three of this dissertation, are likely to legally impact on.

Zambian Privatisation Programme(1991-2001) LLM Thesis in International and African regional law in the faculty of Law(2006).

²⁹ Ndulo (2001) Note 26 above.

³⁰ Government of the Republic of Zambia (1995) National Health Service Act No 22 of 1995. Hereinafter referred to as the National Health Service Act. See also Mabika & London Note 24 above.

³¹ NHSP 2006-2010 Note 23 above. “The other major challenge was the CBOH’s failure to delink health professional staff from public service to the health boards.”

³² University of Zambia Department of Economics, Ministry of Health Zambia, TARSC: Equity Watch: Assessing Progress towards Equity in Health in Zambia, (EQUINET 2011), Lusaka and Harare: available online at: <http://equinetafrica.org/bibl/docs/Zambia%20EW%20Aug%202011%20web.pdf> accessed on 20/01/2012. Hereinafter referred to as, EQUITY WATCH: Assessing Progress towards Equity in Health in Zambia, (EQUINET 2011).

³³ The Zambian Patents Act statutory instrument No. 54. (CAP400) of 1958). Available online at: http://www.saflii.org/zm/legis/consol_act/pa109/. Accessed on 23/02/2012. Hereinafter referred to as the Zambian Patents Act.

³⁴ Ibid.

³⁵ National Health Accounts 2004–2006, Report(2008), MOH, Lusaka. Available online at: http://www.who.int/nha/country/zmb/zambia_nha_report_2003-2006.pdf. Accessed on 21/01/2012.

1.3. THE CURRENT CHALLENGES IN THE DELIVERY OF HEALTH SERVICES IN ZAMBIA

The main challenges in the delivery of health services in Zambia include inter alia; a defective and out-dated Patent Act³⁶, scarcity of health workers, a high rate of HIV/AIDS due to lack of equal delivery of health services including access to ARV drugs, and uncoordinated funds for HIV/AIDS programmes. These challenges are now discussed as follows:

1.3.1. Defective and out-dated Patent legislation

1.3.1.1. Background: Zambia's legal regulation of medicines and adoption of colonial patent legislation and access to medicine

In Zambia's context, historically the legal regulation of medicines had been long established in 1941 when the Pharmacy and Poisons Act³⁷ was first enacted alongside the Pharmacy and Poisons Board (PPB) an institution which was established under the Pharmacies and Poisons Act to afford the overall management of the pharmaceutical industry as a profession and a trade in drugs and poisons.³⁸ Furthermore and much recently the Pharmaceutical Act³⁹ which came into force in November 2004, established the Pharmaceutical Regulatory Authority an independent body corporate, which is responsible for inter alia:

The registration and regulation of pharmacies; registration and regulation of medicines, herbal medicines and allied substances intended for human use and for animal use; regulation and control of the manufacture, importation, exportation, possession, storage, distribution, supply, promotion, sale and use of medicines, herbal medicines and allied substances.⁴⁰

³⁶ The Zambian Patents Act Note 33 above.

³⁷ Pharmacies and Poisons Act Chapter 299 of the Laws of Zambia. Available online at: http://zamlaws.zambia.co.zm/laws_view.php?chapter=299. Accessed on 03/01/2013. Hereinafter referred to as the Pharmacies and Poisons Act.

³⁸ Zambia Assessment of pharmaceutical data disclosure Status of pharmaceutical sector data part of Component 1 of the MeTA Baseline Assessments ZAMBIA June 2010. The Medicines Transparency Alliance Zambia. Available online at: http://www.medicinestransparency.org/fileadmin/uploads/Documents/countries/Data_disclosure_PDFs/MeTA_Zambia_Data_Disclosure_Survey.pdf. Accessed on 03/01/2012. Hereinafter referred to as Zambia Assessment of pharmaceutical data disclosure Status of pharmaceutical sector data part of Component 1 of the MeTA Baseline Assessments ZAMBIA June 2010.

³⁹ Pharmaceutical Act (No. 14) of 2004. Available online at: <http://www.parliament.gov.zm/dmdocuments/The%20Pharmaceutical%20Act,%202004A.PDF>. Accessed on 03/01/2013. Hereinafter referred to as the Pharmaceutical Act.

⁴⁰ Zambia Assessment of pharmaceutical data disclosure Status of pharmaceutical sector data part of Component 1 of the MeTA Baseline Assessments ZAMBIA June 2010. Note 38 above.

Conversely, the Pharmaceutical Act does not encompass regulation of practitioners in the pharmaceutical industry⁴¹, this area as discussed under chapter two has the potential and in certain instances actual negative impact on the affordability of medicines by the Zambian population currently infected with HIV/AIDS⁴². This is due to the fact that non-regulation of pharmaceutical practitioners poses a threat to the regulation of price mark ups for essential medicines especially ARV drugs whether provided in the public, private or non-governmental institutions⁴³.

Correspondingly the Zambian Patent Act⁴⁴ which forms the focus of this research as it stands today is as was inherited or imposed by the colonial powers⁴⁵. According to Thorpe⁴⁶ the historical imposition of patent legislation in many African countries in different regions has remained unchanged and until recently patent protection in over 1/5th of African countries could be obtained merely by the local registration of a grant in the United Kingdom.⁴⁷ Despite the latter practice having been replaced by new provisions or pieces of legislation in most African countries, it is still possible in a few WTO African countries Zambia included⁴⁸. This could adversely affect efficient access to medicines as it signifies that the Zambian Patent Act⁴⁹ encompasses defective and outdated provisions that give effect to a limited number of the vast TRIPS flexibilities which could protect the Zambian public from over-priced medicines. For instance and as discussed in detail under chapter three of this dissertation, currently the Zambian Patents Act under Section 29(a) provides patent protection for pharmaceutical products for a period of 16 years and this period is subject to an extension of up to a maximum of 20 years patent protection on a specification.⁵⁰

⁴¹ Ibid.

⁴² Ibid

⁴³ Ibid.

⁴⁴ See Note 33 above.

⁴⁵ Workshop on flexibilities in International Intellectual Property Rules and Local Production of Pharmaceuticals for Southern, Central and West African Region 7 – 9 December, 2009 Cape Town, South Africa Registration of Medicines: Zambian Experience Presented by Ms Esnat Mwape, Director General Pharmaceutical Regulatory Authority, Zambia. Available online at: http://unctad.org/sections/dite_totip/docs/tot_ip_0015_en.pdf. Accessed on 03/01/2013.

⁴⁶ P. Thorpe Commission on Intellectual Property Rights Study Paper 7 Study on the Implementation of the TRIPS Agreement by Developing Countries. Commission on Intellectual Property Rights Study Paper 7 Available online at: http://www.iprcommission.org/papers/pdfs/study_papers/sp7_thorpe_study.pdf. Accessed on 12/11/2. Hereinafter referred to as Thorpe.

⁴⁷ Ibid.

⁴⁸ See also Section 29(c) of the Zambian Patent Act which provides that: “in the case of a patent registered under the Registration of United Kingdom Patents Act, Chapter 205 of the 1957 Edition of the Laws, the term of the relevant United Kingdom patent...;”

⁴⁹ Ibid.

⁵⁰ Sections 30 and 10A of the Zambian Patents Act. Note 33 above.

Moreover and as discussed in detail in chapter three of this dissertation, Zambia is a Member of ARIPO⁵¹ and a signatory of the Harare Protocol which was adopted in 1982 and entered into force in 1984⁵². The corollary of this is that the Zambian government has empowered the ARIPO Office to obtain and process patent and industrial design applications on its behalf⁵³. This could potentially restrict access to ARV drugs even though currently Zambia as a least developed Member of the WTO is permitted under Article 66 of the TRIPS Agreement, to defer compliance with the TRIPS Agreement until at least 1 January 2013⁵⁴.

Furthermore and following the Doha Ministerial meeting of 2001, Least Developed Members of the WTO have a 10 year transition period until at least 2016⁵⁵ before having to provide patent protection for pharmaceutical products and to safeguard against unmerited exploitation of pharmaceutical allied information acquiesced to a respective Members regulatory authority for registration approval⁵⁶.

However, as already noted above and as discussed in detail in chapter three of this dissertation the considerable majority of LDCs, at least in Africa, Zambia included, already provide patent protection for pharmaceutical products despite having severed ties with colonial powers post political independence⁵⁷. Thus against this backdrop and as discussed below Zambia's current restricted supply of ARV drugs is most likely to be compounded inter alia by the governments' tepid approach to transform its legal frameworks domestically to fully exploit TRIPS flexibilities for the benefit of people living with HIV/AIDS.

⁵¹ African Regional Intellectual Property Organization ARIPO. Available online at: <http://www.aripo.org/>. Accessed on 03/01/2012. Hereinafter referred to as ARIPO.

⁵² Harare Protocol on Patents and Industrial Designs within the Framework of the African Regional Intellectual Property Organization (1982). Available on the world Intellectual Property Organization (WIPO) web-page at: http://www.wipo.int/clea/docs_new/pdf/en/ap/ap006en.pdf. Accessed on 27/10/2010. Hereinafter referred to as the Harare Protocol (1982).

⁵³ Thorpe Note 46 above.

⁵⁴ TRIPS Council Decision of 29 November 2005 extended the period by which LDCs were to be TRIPs compliant (with the exception of pharmaceutical patents) from 1 January 2006 to 1 July 2013 or until the LDC status was no longer valid. The statement extending the exemption period for LDCs. Available online at: http://www.wto.org/english/news_e/pres05_e/pr424_e.htm. Accessed on 23/02/2012. Hereinafter referred to as the TRIPS Council Decision of November 2005.

⁵⁵ The full legal text of Agreement on Trade Related Aspects on Intellectual Property Rights (TRIPS) WTO 1994 Annexure 1 C of the Marrakesh Agreement. Available online at: http://www.wto.org/english/docs_e/legal_e/27-trips.doc. Accessed on 04/01/2012. Hereinafter referred to as TRIPS Agreement.

⁵⁶ Ibid.

⁵⁷ Thorpe Note 46 above.

1.3.2. The scarcity of professional health workers in the public health system

Due to the Zambian government's longstanding limited financial support to its public health system as discussed above, professional public health workers have become scarce creating a major challenge to the delivery of public health services.⁵⁸ This scarcity of health workers has been due to migration of Zambian health professionals to developed economies or local exits in to the private health sector since the early 1990's.⁵⁹ This internal and external movement of professional skilled workers also known as the brain-drain⁶⁰ is driven by the following factors⁶¹:

Low remunerations; poor working conditions absence of career development schemes; civil strife and political instability; fear of contact diseases such as HIV; and; country policies that encourage labour export as an area of relative benefit for their economies. For example India, Mexico and the Philippines already receive over \$5 billion per year each in workers' remittances while in countries such as Tonga, Lesotho and Jordan, workers' remittances represent over 20% of national GDP.⁶²

Accordingly in Zambia individual doctors and nurses have been emigrating to both developed and developing countries within and outside of Africa for economic reasons such as those identified above. However the Zambian government does not have the legal frameworks to regulate the migration of its professional health workers and so it has failed to benefit from these migrations through remittances.⁶³ For example:

In 2009 the doctor and nurse population ratios stood at 1 to 15,000 and 1 to 1,500 respectively. This was far lower than the world health organization's (WHO)

⁵⁸ Ibid.

⁵⁹ D. Lusale Why do Zambian health workers migrate abroad? The brain drain of Zambian Health workers. *Medicus Mundi Switzerland* No.104, May 2007. Available online at: http://www.medicusmundi.ch/mms/services/bulletin/bulletin104_2007/chapter0705168999/bulletinarticle0705162432.ht. Accessed on 01/03/2010.

⁶⁰ Ibid.

⁶¹ Taking stock: Health worker shortages and the response to AIDS. Available online at: <http://www.who.int/hiv/toronto2006/takingstocktr.pdf> . Accessed on 19/05/2012. See also Health workers: A Global Profile' World health organization (WHO) world health report (2006). Available at: <http://www.who.int/whr/2006/chapter1/en/index.html>. Accessed on 28/10/2010.

⁶² Makasa Note 17 above. See also Joint Submission to the World Health Assembly. (WHA.2003). The GATS Threat to Public Health (endorsed by Equinet, International People's Health Council, Medact, People's Health Movement, Save the Children UK, Wemos, and World Development Movement. Available online at: <http://www.equinet africa.org/bibl/docs/RES2003trade.pdf>. Accessed on 04/01/2012. Hereinafter referred to as (WHA 2003).

⁶³ Makasa Note 17 above.

recommendations on doctor population ratio of one doctor to 5,000 and a nurse to a population ratio of 700⁶⁴. And:

According to the National Human Resources for Health Strategic Plan 2011 – 2015, by all metrics, Zambia suffers from a shortage of clinical health staff within its public health sector: The current number of doctors, clinical officers, midwives and nurses of 12,786 is only 43.0% of the WHO recommended staffing level of 2.28 health workers per 1,000 population.⁶⁵

Furthermore about “1,198 Zambian nurses are working in seven European countries (equivalent to 5% of the total number of nurses in Zambia, and out of 1,200 doctors trained in Zambia since the late 1960s only 391 are practicing in the public sector today”.⁶⁶ Accordingly Makasa⁶⁷ has argued that:

The scarcity of health workers has contributed to the high patient burden of PLWHA in public health institutions. This increased demand for HIV/AIDS related services amidst reduced supply of services, increased costs and lack of subsidies for the health sector, if unresolved, is likely to negatively affect the performance of the health system leading to its total collapse⁶⁸.

1.3.3. The increase in HIV/AIDS patients

At present the annual infection rate of HIV/AIDS stands at 80,000 and out of a population of approximately 13 million people, over 1000,000 people are living with HIV/AIDS (PLWHA)⁶⁹. There

⁶⁴ Ibid.

⁶⁵ Republic of Zambia Ministry Of Health National Human Resources For Health Strategic Plan 2011 – 2015. Available online at: http://www.who.int/workforcealliance/countries/ccf/HRH_plan_zambia2011-2015.pdf. Accessed on 09/01/2013. See also World Health Organization, "Ranking of Medical Care Systems," 2000. Available online at: <http://www.photius.com/rankings/healthranks.html>. Accessed on 11/12/201

⁶⁶ Makasa Note 17 above.

⁶⁷ Ibid.

⁶⁸ Ibid.

⁶⁹ Republic Of Zambia National Aids Council Zambia Country Report Monitoring the Declaration of Commitment on HIV and AIDS and the Universal Access Biennial Report Submitted To The United Nations General Assembly Special Session ON HIV AND AIDS Reporting period: January 2010 – December (2011). March 31st 2012. Available online at http://www.unaids.org/en/dataanalysis/knowyourresponse/countryprogressreports/2012countries/ce_ZM_Narrative_Report.pdf. Accessed on 12/01/2013.

See also Republic of Zambia(Biennial Report) Submitted to the United Nations General Assembly Special session on AIDS declaration of commitment reporting period: January 2008 – December 2009 (March 31st 2010 Ministry of health National AIDS Council. Available online at:www.unaids.org/.../2010progressreportssubmittedbycountries/zambia_2010_country_progress_report_en.pdf. Accessed on 22/11/2011. Hereinafter referred to as UNGASS (2010). Central Statistics Office (CSO) Lusaka. Available online at: http://www.zamstats.gov.zm/media/chapter_3_population_comp_size_and_growth_final.pdf. Accessed on 21/01/2012.

are 75,000 HIV/AIDS related deaths annually,⁷⁰ making Zambia the home of 800,000 orphans and vulnerable children.⁷¹ It is important to note that out of the 1,000 000 PWLHA in Zambia, only 285, 000 are receiving ARV drugs and treatment.⁷² This is for a variety of reasons,⁷³ including the limited number of health workers discussed above and the unavailability of ARV drugs and treatment.

The HIV/AIDS statistics stated above rank Zambia as number seven among the countries worst affected by HIV/AIDS in sub-Sahara Africa.⁷⁴ Thus HIV/AIDS is one of the main challenges to the current socio-economic development plans including delivery of health services in Zambia.⁷⁵ Accordingly the Zambian government developed various legal and policy frameworks on HIV/AIDS between 2002 and 2010⁷⁶ to be implemented by government Ministries of health (MOH) and Finance and National Planning (MOFNP).

However donor funding underwrites a significant portion of HIV/AIDS funding in Zambia to help the core Ministries implement various policy frameworks on HIV/AIDS including the roll out of ARV drugs. Thus the United States President's Emergency Plan for AIDS Relief (PEPFAR) and Global Fund for Aids Tuberculosis and Malaria (GFATM) are the organizations that have "continued to fund HIV/AIDS programmes in Zambia through the joint arrangement financing (JAR). For this reason PEPFAR donates monetary aid directly in to the National AIDS Council's coffers as part of its budget on HIV/AIDS, whilst the Global fund channels its aid money in to the government Ministries of health and finance and other co-recipient organizations such as Christian association of Zambia (CHAZ)".⁷⁷ However donor funding may not be a sustainable way of increasing access to ARV drugs in the near

⁷⁰ World Health Organization, "Zambia Mortality Country Factsheet for 2006". Available online at: http://www.who.int/whosis/mort/profiles/mort_afro_zam_zambia.pdf. Accessed on 04/12/2010. See also CIA World Fact Book on Zambia (2011) Note 2 above.

⁷¹ UNGASS (2010) Note 69 above.

⁷² United Nations Joint Programme on HIV/AIDS (UNAIDS REPORT 2008) Zambia Country Situation (2008) .Available online at: http://data.unaids.org/pub/FactSheet/2008/sa08_zam_en.pdf. Accessed on 11/10/2010.

⁷³ "The high poverty levels, currently standing at 68 per cent; illiteracy levels and; lack of information about the disease" NHSP 2006-2010 Note 23 above.

⁷⁴ UNGASS (2010) Note 69 above.

⁷⁵ ZDHS (2009) Note 25 above.

⁷⁶ The National HIV and AIDS/STD/TB Act (2002); National HIV and AIDS/STI/TB Policy (2005), Reproductive Health Policy (2008), National Health Strategic Frameworks and National HIV/AIDS Strategic Frameworks instituted between (2006-2010 and 2011-2015); National Decentralization Policy (NDP 2003 and 2007); Fifth and Sixth National Development Plan (NDP 2006-2010 and (2011-2015); UNGASS(2010) Note 69 above.

⁷⁷ Government of the Republic of Zambia and the Ministry of Finance and National Planning and The Ministry of Health and the Government of the United States of America to Support the Implementation of the Zambian National Response to HIV/AIDS from 2011-2015. Available online at: [http:// www.pepfar.gov/frameworks/zambia/158525.htm](http://www.pepfar.gov/frameworks/zambia/158525.htm). Accessed on 20/10/2012. Hereinafter referred to as GRZ and USG (2011-2015). "Other Cooperating Partners participating in the HIV group include: Canada, European Union, Germany, Japan, the Netherlands, Norway, Sweden, the United Kingdom and members of the UN family."

future as the public health financing in Zambia is fragmented as discussed below. Implementation of alternative strategies such as TRIPS flexibilities is critical in sustaining access to ARV drugs.

1.3.4. Uncoordinated health funds

Zambia's previous restructuring of the public health system has impacted on the current health system's financing of health services.⁷⁸ The nation-wide accounting exercises and expenditure tracing assessments has indicated that "health financing in Zambia is complex and fragmented".⁷⁹ This has created difficulties for health policy makers to "calculate the funds available, direct them to where they are essentially needed and circumvent duplication";⁸⁰ and has led to an upsurge of mismanagement of funds in relevant co-recipient ministries.⁸¹

Accordingly, recent reports indicate that between 2009 and 2011 there had been mismanagement of funds which had resulted in erratic ARV drug supply in various public clinics and hospitals. Moreover, during the ARV drug stock outs⁸² there were no alternative sources of medicines for the patients who were in urgent need of treatment.⁸³ These interruptions have restricted access to ARV drugs including advanced ARV drug regimens resulting in either ARV drug resistant cases in need of switching over to a third line ARV drug regimen⁸⁴ or deaths.⁸⁵

Thus urgent government action is required through its Ministries of health and finance to prioritise programmes on health worker retention, financing and access to ARV drugs and therapy (ART). These programmes require regulation through national health legislation principally, a new national health services and Patent Act, especially in the advent of Zambia's adoption of GATS and the

⁷⁸ EQUITY WATCH: Assessing Progress towards Equity in Health in Zambia, (EQUINET 2011). Note 32 above.

⁷⁹ Ibid.

⁸⁰ Ibid.

⁸¹ A statement released by the Auditor General (AG) for the Global Fund revealing that "more than seventy two million United States dollars (\$72, 000000), of which approximately 5% of the amount in question came from the Global Fund had been misappropriated. Consequently the fund taking strict action against the two Ministries by putting a halt to funding intended for use by the Ministry of health in HIV/AIDS programmes from August 2009 till mid-2011 when funding was resumed". ZAMBIA: Corruption Scandal Rocks ARV Programme: JOHANNESBURG, 14th March 2011 (PlusNews Global) available online at: <http://www.irinnews.org/report.aspx?ReportID=92191>. Accessed on 08/09/2011.

⁸² ZAMBIA: 'Third-Line ARVs Available Soon'. (PlusNews/IRIN) AfricaFiles 7th MARCH 2011. Available online at: <http://www.plusnews.org/report.aspx?reportid=92124>. Accessed on 31/08/2011.

⁸³ Ibid.

⁸⁴ Ibid.

⁸⁵ Treatment Advocacy Literacy Campaign (TALC. Available online at: <http://internationalbudget.org/wp-content/uploads/Profile-of-TALC-Zambia-2011.pdf>. Accessed on 11/01/2013. "The TALC is an HIV/AIDS Activists Organization that is involved in country wide campaigns for the efficient and effective provision of ARV and TB drugs in Zambia. Hence since the stock outs the "TALC, PLWHA, and other HIV/AIDS organizations launched an aggressive campaign to have a portion amounting to \$5million (USD) set aside for the procurement of AIDS drugs in this year's national budget allocated to third-line drugs."

pending adoption of TRIPS' provisions on pharmaceutical patents and test data, to assist in circumventing any adverse effects that these trade agreements are likely to have on the structure of the national health system and the future of access to ARV drugs in Zambia which is to be seen as not only a health service but also a human right.

1.4. CONCLUSION

This chapter has demonstrated that Zambia's adoption of the economic trade policies on SAPs and privatization did not only have the impact of legally altering the structure of the national health system from a completely government subsidized sector to a minimally funded sector, but also impacted negatively on the socio-economic affordability of health services including access to ARV drugs. This change has weakened the public health sector's capacity to deliver quality health services including the current supply of ARV drugs as a health service.

It thus emerges that in the absence of legal frameworks such as a new national health services Act and Patent Act to deal with the issues of; medical staff retention, public health financing, suspension of registration of pharmaceutical patents until at least 2016 the issue of disease pandemics and grim statistics notwithstanding the policy objectives of the MOH, will continue to deteriorate health service delivery in Zambia. Poor access to health services, including ARV drugs, is likely to be further fuelled by the effect of neo-economic trade policies on liberalised health services and patent protection on pharmaceutical drugs as envisaged in the GATS and TRIPS Agreements respectively.

Hence the aim of this dissertation is to analyse the actual or potential legal impact that the latter two agreements have or are likely to have on access to ARV drugs as a human right in Zambia taking into account its current domestic legal frameworks on health. This analysis is approached according to themes arranged within the following chapters:

1.4.1. OUTLINE OF CHAPTERS

Chapter two: Is an assessment of the potential or actual impact of the GATS agreement on any current and or future formulation of health policies aimed at improving the delivery of health services in the Zambian public health system.

Chapter three: Is a survey of the impact of the TRIPS agreement on access to medicines in developing and least developed WTO Members. Comparative case studies on Kenya and South

Africa will be used as yard sticks to determine the degree to which WTO Members specifically Zambia can use TRIPS flexibilities to access ARV drugs, counting the interpretations of the flexibilities in the Doha declaration and the WTO Council's 30th of August, 2003 decision. Subsequently, Zambia's legal adoption and use of viable TRIPS flexibilities in its intellectual property laws, specifically the Patents Act (CAP 400) of 1958, will be investigated.

Chapter four: Explores the legal duty to observe the right to health specifically its component of access to medicines by nations that have endorsed international human rights, which includes Zambia, in the advent of the TRIPS and GATS agreements being translated in to national laws.

Chapter five: Comprises the conclusion of the dissertation summarising the discussion on the issues raised by the research topic; and recommendations which might assist the Zambian government to legally balance its trade and public health policies, so as to advance the right of access to ARV drugs in future.

CHAPTER TWO: THE GENERAL AGREEMENT ON TRADE IN SERVICES AND ITS IMPACT ON THE DELIVERY OF HEALTH SERVICES IN ZAMBIA

2.1. INTRODUCTION: BACKGROUND AND PURPOSE OF THE GATS AGREEMENT

The establishment of the General Agreement on Trade in Services (GATS)⁸⁶ on January 1st 1995 was as a result of the 1986–94 Uruguay round of trade negotiations.⁸⁷ Its conception was mainly inspired by the objectives of the General Agreement on Tariffs and Trade (GATT)⁸⁸ which specialized in merchandise trade from 1947. Accordingly as of 24th August 2012 there were approximately 157 economies that had membership to the WTO's GATS Agreement, including Zambia.⁸⁹

The purpose of the GATS Agreement essentially is to consolidate international rules on trade in services in a much more credible and reliable manner.⁹⁰ The consolidation is in response to the growing understanding that, most domestic services have become international activities⁹¹ through use of technologies that transmit vital national public services inter alia health, banking, agriculture, education, electricity, water and transportation between nations creating a global economic village.⁹²

Thus in terms of Article 4 and as discussed at a later stage in this chapter, one of GATS's main objective is the most favoured nation which aims to promote "the progressive liberalization of trade in services".⁹³ This is a WTO concept operating on the principle of non-discrimination and transparency that aspires to create freer markets that are more attractive to foreign direct investors (FDIs) and

⁸⁶ World Trade Organization (WTO 1994) General Agreement on Trade in Services (GATS) Agreement Annex 1 B of the Marrakesh Agreement Establishing the WTO. Available on the WTO official web-page at: http://www.wto.org/english/docs_e/legal_e/legal_e.htm. Accessed on 26/05/2010.

⁸⁷ WTO legal texts. Available online at: http://www.wto.org/english/docs_e/legal_e/legal_e.htm accessed on 22/03/2012.

⁸⁸ WTO 1994) GATS Agreement: Objectives, Coverage and Disciplines. Available online on the WTO-webpage at: http://www.wto.org/english/tratop_e/serv_e/gatsqa_e.htm. Accessed on 26/05/2010.

⁸⁹ World Trade Organization understanding the WTO: Members and Observers. Available online at: http://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm. Accessed on 22/12/2012.

⁹⁰ General Agreement on Tariffs and Trade GATT (1947). Available online at: http://www.wto.org/english/docs_e/legal_e/gatt47_01_e.htm Accessed on 20/12/2012.

⁹¹ GATS Agreement Note 86 above. Preamble states: "Members, recognizing the growing importance of trade in services for the growth and development of the world economy".

⁹² R. Chanda *Trade in Health Services. Bulletin of the World Health Organization*(2002); 80(2): 158-163. Available online at: [http://www.who.int/bulletin/archives/80\(2\)158.pdf](http://www.who.int/bulletin/archives/80(2)158.pdf). Accessed on 20/01/2012. Herein after referred to as, Chanda (2002) See also R. Chanda *Commonwealth TRADE HOT TOPICS July 2008 Issue No.49 Services Trade and Domestic Regulation: Issues for Developing Countries*. Available online at: <http://www.thecommonwealth.org/files/184137/FileName/THT49servicestradeanddomesticregulation.pdf>. Accessed on 20/03/2012. Hereinafter referred to as Chanda (2008)

⁹³ See Article 4 of the GATS Agreement Note 86 above.

encourages global participation in trade of services from diverse Member economies.⁹⁴ Whilst paying attention to the needs of the LDCs such as Zambia, which require support from industrialized nations to facilitate the expansion of their domestic services and enhance service exports.⁹⁵

Accordingly GATS proponents have argued that trade liberalisation of health services will allow Members to choose how much and which services sectors to open up for investment under the multilateral trading system.⁹⁶ This in turn, it is claimed, will allow Members to enjoy certain benefits such as; efficient production and delivery of domestic services, increase in export earnings and far-reaching market access to imported inputs.⁹⁷

GATS opponents on the other hand argue that even though the Agreement does offer opportunities for Members that have implemented its provisions on freer domestic markets. It nevertheless presents difficult challenges for developing Members that could negatively affect the following facets of legal policy formulation, in the health sector⁹⁸:

The substance of health policies; as the GATS Agreement imposes restrictions on Member's capacity to formulate health policies which compel national health services regulators to allocate identical or even superior magnitude to trade liberalisation targets than the protection of human health.

The structure of the health systems Members; as the adoption of progressive liberalisation of health encourages private health care facilities preventing Members from gaining any form of returns from their provision of public health services. As most of their monetary resources are fuelled into experimenting on the viability of privatization as an economic policy meant to assist health services development.

⁹⁴ Mabika & London Note 24 above; Chanda (2008) Note 92 above.

⁹⁵ C. Joy & P. Hardstaff "Whose Development Agenda? An Analysis of the European Union's GATS Requests of Developing Countries. London: World Development Movement." (2003). See also the Preamble of the GATS Agreement Note 86 above. See also Least Developed Countries (LDCs) United Nations (UN) Classification (2012): Note 1 above.

⁹⁶ R. Adlung & A. Carzaniga (2003) Trade in Health Services Under GATS. Revised version of Adlung and Carzaniga 2001, dated June 5, 2003. WTO working paper series (Geneva, WTO, 2003). Available online at: http://www.unescap.org/esid/hds/pubs/2449/2449_ch6.pdf. Accessed on 04/01/2012. Herein after referred to as, Adlung & Carzaniga.

⁹⁷ World Trade Organization. (2002). Director-General of WTO and Chairman of WTO Services Negotiations Reject Misguided Claims that Public Services are under Threat. Press Release 299, June 28, 2002. Available online at: http://www.wto.org/english/news_e/pr299_e.htm. Accessed on 05/12/2011.

⁹⁸ S. Sinclair & J. Grieshaber-Otto (2002). Facing the Facts: A Guide to the GATS Debate. Ottawa: Canadian Centre for Policy Alternatives. Available online at: http://www.policyalternatives.ca/sites/default/files/uploads/publications/National_Office_Pubs/facing_facts.pdf. Accessed on 04/01/2012. Hereinafter referred to as, Sinclair & Grieshaber-otto. See also WHA (2003) Note 39 above.

Finally, the procedure; here the process of formulating national health policies is restricted to the system in the general obligations and specific commitments operational in the GATS Agreement.⁹⁹

In light of the above divergent arguments, this chapter's substantive analysis of the GATS Agreement will commence with an effort to create an understanding of the scope and applicability of GATS to public health services in general and specifically in Zambia.¹⁰⁰

It will, then examine the potential impact of the general obligations and specific commitments on Zambia's legal health policy formulation, taking in to account the existing challenges posed by HIV/AIDS on the delivery of public health services.¹⁰¹

2.2. GATS SCOPE AND APPLICABILITY TO THE PUBLIC HEALTH SERVICES SECTOR IN WTO MEMBER COUNTRIES

2.2.1. The scope of the GATS Agreement

Article I:1 of GATS provides that this Agreement applies to "*Measures by Members affecting trade in services.*" The italicised phrases¹⁰² confirm GATS's wide-ranging scope and application.¹⁰³

2.2.1.1. "Measures by Members"

These have been defined in the GATS Agreement to include, all those measures taken at different levels of government such as central, regional, and local, counting any delegated measures from any

⁹⁹ D. P. Fidler C. Correa & O Aginam. (November 2005) Draft Legal Review of the General Agreement on Trade in Services (GATS) from a Health Policy Perspective PREPARED BY THE GATS LEGAL REVIEW TEAM FOR THE WORLD HEALTH ORGANIZATION Globalization, Trade and Health Working Papers Series. Available online at: http://www.who.int/trade/resource/GATS_Legal_Review_15_12_05.pdf. Accessed on 23/11/2011. Hereinafter referred to as, Fidler, Correa & Aginam. Alternatively as the GATS review team.

¹⁰⁰ Member Information on Zambia and the WTO. Available online on the WTO webpage at: http://www.wto.org/english/thewto_e/countries_e/zambia_e.htm. Accessed on 22/02/2012. See also: Mabika & London Note 24 above; Ndulo (2001) Note 26 above.

¹⁰¹ NHSP 2006-2010 Note 23 above; UNGASS 2010 Note 69 above. See also section 1.3 in chapter one of this dissertation.

¹⁰² Article I (PART I) Scope and Definition of the GATS Agreement states that 1: "This Agreement applies to measures by Members affecting trade in services." Emphases in italics are the authors own.

¹⁰³ Fidler, Correa & Oginam Note 99 above.

government level to non-governmental bodies exercising regulatory powers delegated by any level of government.¹⁰⁴

In addition the term “*Measures by Members*” embraces measures in terms of Article XXVIII (a) of GATS: “whether in the form of a law, regulation, rule, procedure, decision, administrative action, or any other form, even unwritten practice.” These provisions give the phrase “*Measures by Members*” an all-encompassing definition. This means that Article XXVII (a) could be interpreted as having the potential to render ineffective any laws that Members and in this instance Zambia may possibly aspire to enact to ensure equal and universal access to health services for its vulnerable population especially those infected with HIV/AIDS.¹⁰⁵

2.2.1.2. “Affecting”

The word “*Affecting*” also has a broad interpretation which means that regulation of laws specifically designed to sustain merchandise as catered for under the sister Agreement of GATS namely GATT, may nevertheless have an effect on services and fall well within the ambit of Article I: 1 of GATS. Thus the review panel of the GATS Agreement concluded the following:

At issue in both *EC—Bananas III* Sept. 9, 1997, WT/DS27/AB/R and *Canada—Periodicals* (1997) Feb. 11, 2000, WT/DS139/R and WT/DS142/R, was whether measures could fall within the scope of both GATT (trade in goods) and GATS (trade in services). In both cases, the WTO Dispute Settlement Body held that a measure could fall within the scope of both agreements, which is further evidence of the broad scope of GATS.¹⁰⁶

2.2.1.3. “Trade in Services”

In terms of Article I:2 GATS has four modes of service supply:

(a) mode one - Cross-border supply from the territory of one Member into the territory of any other Member;

¹⁰⁴ Article I: 3 (a) of the GATS Agreement states that: For the purposes of this Agreement: (a) “measures by Members” means measures taken by: (i) central, regional or local governments and authorities; and (ii) non-governmental bodies in the exercise of powers delegated by central, regional or local governments or authorities.

¹⁰⁵ Mabika & London Note 24 above.

¹⁰⁶ Fidler, Correa & Aginam Note 99 above.

(b) mode two - Consumption abroad in the territory of one Member to the service consumer of any other Member;

(c) mode three - Commercial Presence by a service supplier of one Member, through commercial presence in the territory of any other Member;

(d) mode four - Presence of natural persons by a service supplier of one Member.

However the above provisions in Article I: 2 of the GATS Agreement do not offer Members a definition of the words “*trade in services*”. This has been evidenced in the number of cases brought to the WTO’s dispute settlement body involving the issue of whether certain economic practices amount to “*services in trade*”.¹⁰⁷ Thus GATS applicability to public health services emerges as a point of discussion and is examined below.

2.2.2. Applicability of the GATS Agreement to Public Health Services

The GATS Agreement¹⁰⁸ is applicable to all services sectors with the exception of two services supplied by government.

Article I:3 (b) and (c) of GATS Scope and Definition state: For the purposes of this Agreement...

(b) services include any service in any sector except services supplied in the exercise of governmental authority;

(c) a service supplied in the exercise of governmental authority means any service which is supplied neither on a commercial basis, nor in competition with one or more service suppliers.¹⁰⁹

Although the above provisions in Article I:3 (b) state that the GATS Agreement excludes; “services supplied in the exercise of governmental authority” they become contradictory when applied to Members that charge user fees for public health services as part of their health policies. According to Mabika and London, at this point the GATS Agreement would apply because in terms of Article I: 3

¹⁰⁷ Ibid.

¹⁰⁸ GATS Agreement Note 86 above.

¹⁰⁹ Ibid..

(c) the public services in question are being offered on a commercial basis irrespective of whether competition is absent or present.¹¹⁰

The provisions of Article I:3 (b) raise the issue of the extent to which GATS is likely to exclude health related services supplied by public authorities in Member nations. The WTO Secretariat has in the past contended that “the provision of medical and hospital treatment directly through the government, free of charge” would be protected by Article I:3 (c).¹¹¹

Nevertheless it appears that the provision in Article I:3 (c) would not be applicable to a health system in which public and private health care providers co-exist. This is because the GATS Agreement has left the phrase “*neither on a commercial basis nor in competition with one or more service suppliers*” subject to interpretation.¹¹² Thus authors Sinclair and Grieshaber-Otto have argued that “the provisions under Article I: 3 (c) are too contracted making public health services subject to GATS.”¹¹³ Whilst the WTO secretariat¹¹⁴ Adlung and Carzaniga¹¹⁵ have argued that Article I:3 (c) leaves out public health services.

Public health services supplied on a strict “commercial basis” on the other hand, are encompassed by the GATS Agreement.¹¹⁶ These are services offered in exchange for money and are supplied in competition with other suppliers of the same services in a particular sector. The service suppliers in question must be engaged in the supply of “like” or “substitutable” services.¹¹⁷

This means that service suppliers must be targeting the same consumers, or wanting to realize the same profit as the other suppliers and those consumers must be able to utilize such services as alternatives.¹¹⁸ The services in question must be comparable and offer the same outcome.¹¹⁹ For

¹¹⁰ Ibid.

¹¹¹ WTO Director-General of WTO and Chairman of WTO Services Negotiations Reject Misguided Claims that Public Services are under Threat. Press Release 299, June 28, 2002. Available online at: http://www.wto.org/english/news_e/pres02_e/pr299_e.htm. Accessed on 22/02/2012.

¹¹² Fidler, Correa & Aginam. Note above. 99 above. Emphasis in Italics are the authors own.

¹¹³ S. Sinclair & Grieshaber-Otto. Note 98 above.

¹¹⁴ World Health Organization/World Trade Organization. (2002). WTO Agreements & Public Health—A Joint Study by the WHO and the WTO Secretariat. Geneva: World Trade Organization. Available online at: <http://www.who.int/mediacentre/news/releases/who64/en/> See also http://www.wto.org/english/res_e/booksp_e/who_wto_e.pdf Accessed on 04/01/2012. Hereinafter referred to as WHO&WTO (2002).

¹¹⁵ Adlung & Carzaniga Note 96.

¹¹⁶ Fidler, Correa & Aginam. Note 99 above.

¹¹⁷ Ibid.

¹¹⁸ Ibid.

¹¹⁹ Ibid.

example in the instance of HIV/AIDS public health services such as CD4 counts and other blood tests offered at a fee may well be substituted for those offered in the private sector as they involve the same suppliers and service. However in another example where:

The provision of public health service of polio immunizations offered at a minimal fee in local clinics cannot be regarded as an identical or a substitute service for a hi-technology health service such as bone-marrow transplant procedures offered in the private sector.¹²⁰

It is important to note that “public services” differ according to countries or should be interpreted on a case by case basis.¹²¹ For instance:

Some countries base the definition of the provision of public services, if there is some form of tax or mandatory insurance payments involved, whilst others like the United States of America (USA) have certain services such as health that are generally regarded as public services being predominantly supplied by the private sector.¹²²

The uncertainty indicated above regarding the possible meanings of the provision under Article I:3 (c) makes it an unclear provision. Thus the WTO Member complaining about the applicability of GATS and the possible violation of Article I:3 (b) bears the responsibility to prove that a government-supplied service conflicts with the criteria found in Article I: 3 (c) of GATS.¹²³

For example the US bore the Burden of proof In *US—FSC* (2000) in United States—Tax Treatment for “Foreign Sales Corporations,” the WTO Appellate Body Report, Mar. 20, 2000, WT/DS108/AB/R [*US—FSC*]. The United States unsuccessfully bore the burden of proof as defendant that of the Agreement on Subsidies and Countervailing Measures (SCM Agreement) provided an exception to the general definition of “subsidy” in Article 1.1 of the SCM Agreement.

¹²⁰ Ibid.

¹²¹ D. N. Drager & D. P. Fidler GATS AND HEALTH RELATED SERVICES MANAGING LIBERALIZATION OF TRADE IN SERVICES FROM A HEALTH POLICY PERSPECTIVE (2004). Available online at: http://www.searo.who.int/LinkFiles/Global_Trade_and_Health_GTH_No6.pdf. Accessed on 24/01/2012. Hereinafter referred to as, Drager & Fidler.

¹²² M. Krajewski, “Public Services and the Scope of the General Agreement on Trade in Services (GATS).” Research Paper for the Center for International Environmental Law(2001). Available online at: <http://www.ciel.org/Publications/PublicServicesScope.pdf>. Accessed on 23/0/2010. “Cases in point are social security schemes and any other public service, such as health or education that is provided at non-market conditions.”

¹²³ Ibid.

In other words, the general definition of “subsidy” applied to the U.S. action, forcing the United States to justify its behaviour under an exception to the general rule. Using this case’s analysis, one could argue that (1) Article I: 3(c) of GATS is an exception to the comprehensive scope of GATS defined by the rest of Article I; and (2) because Article I:3(c) is an exception, the defendant WTO Member bears the burden of proof that the conditions of Article I:3(c) have been met.¹²⁴

Consequently, it can be argued that there is a rebuttable presumption that government provided services (Article I:3(b)) fall outside the scope of GATS unless a complaining WTO Member invalidates this presumption by establishing that services in questions do not in actual fact meet the tests provided in Article I:3 (c).¹²⁵

The above discussion illustrates how the all-encompassing definition of “trade in services” covered by the GATS Agreement under Article 1:3 (b) and (c) tends to create an overlap with legal health policy.¹²⁶ That is why as discussed below, it is crucial to establish whether the wide-ranging scope of “trade in services” under GATS encompasses public health services here, mainly access to ARV drugs in Zambia; and the implications arising from its general and specific obligations.

2.2.2.1. The applicability of GATS to health services: Implications on public health service delivery in Zambia

Owing to Zambia’s previous adoption of health reforms discussed previously in chapter one, which constituted a problematic government exercise that created a two-tier structure comprising private health service providers as an alternative to public provision of health services which are also provided at a fee.¹²⁷ This has had the inevitable result of GATS provisions being applicable to public health services in Zambia Article I:3 (c).¹²⁸

Thus, any health policies formulated by the Zambian government in response to the current challenges in its public health system, such as the scarcity of health workers previously discussed in chapter one, will risk violation of the most critical provisions under GATS namely; the general obligations of most favoured nation (MFN) and specific commitments on national treatment (NT),

¹²⁴ Fidler, Correa & Aginam. Note 99 above.

¹²⁵ Ibid.

¹²⁶ Ibid.

¹²⁷ Refer to discussion under item 1.2.2 on page 4 in chapter one.

¹²⁸ Mabika & London Note 24 above.

market access and progressive liberalisation of trade in services including health services.¹²⁹The latter general obligations and specific commitments are subject of the next legal analytical step in order to determine their impact or potential legal impact on health policy formulation in relation to access to ARV drugs in Zambia.

2.3. APPLICABILITY OF THE GENERAL OBLIGATIONS TO TRADE IN HEALTH SERVICES

The general obligations are applicable to 'all measures affecting trade in services' within the GATS Agreement. In terms of the jurisprudence on GATS the general obligations of MFN are either referred to as horizontal disciplines in that they encompass all service sectors and measures affecting trade in services among investors horizontally; or as top-down disciplines, in that there are mandatory obligations imposed vertically by the WTO on its Members.¹³⁰ The general obligations of MFN and their potential to affect public health policy formulation in Zambia are investigated below.

2.3.1. Most favoured nation as a mandatory duty for WTO Members and its potential impact on public health policy formulation in Zambia

Article II:1 "Most-Favoured-Nation Treatment (MFN)" states that:

With respect to any measure covered by this Agreement, each Member shall accord immediately and unconditionally to services and service suppliers of any other Member treatment no less favourable than that it accords to like services and service suppliers of any other country.

The provisions of Article II:1 require recipient WTO Members of foreign services and service suppliers to accord equal or non-discriminatory treatment of foreign nations competing and willing to invest in their domestic service sectors.¹³¹ Accordingly a Member state would be in violation of the MFN clause if it accords favourable treatment to a service supplier from one nation to the exclusion of others. The less favourable treatment must involve "a measure covered by GATS,¹³² involve like

¹²⁹ Fidler ,Correa & Aginam Note 99 above. See also Mabika & London Note 24 above.

¹³⁰ Fidler ,Correa & Aginam Note 99 above.

¹³¹ Sinclair & Greishaber-Otto at 45-480, Note 98 above.

¹³² See Article I:2 of the GATS Agreement.

services or service suppliers and less favourable treatment of a Foreign Service or service provider from another WTO Member.”¹³³ However, Fidler, Correa and Aginam have argued that:

Less favourable treatment can arise from officially indistinguishable or even dissimilar treatment, what must be examined are the stipulations of competition that effect from the measure. Consequently any modification, irrespective of how insignificant, in the stipulations of competition by the unlike treatment will suffice as less favourable treatment within the meaning of Article II:1. The burden of proof lies with the WTO Member averring that another WTO Member has violated Article II:1 of GATS by establishing that the latter three components required by Article II:1 have been fulfilled.¹³⁴

For example, if Zambia chose to grant a tender to hire health personnel from South Africa on the basis of a ‘good relationship’ between itself and South Africa,¹³⁵ such an exercise of trade in health services would exclude and discriminate other countries which had shown interest in investing their health services in Zambia due to ‘lack of a good relationship’ with the Zambian government.

Consequently in terms of Article II:1 of GATS, Zambia’s actions in the above example, would be in violation of the MFN general obligations as the tender process would be biased and lack objectivity, irrespective of the Zambian government’s policy reasons. Such policy reasons could be inter alia the urgent need to import health services through presence of natural persons at a cheaper cost in order to resolve the issue of external brain-drain of public health workers that has derailed HIV/AIDS programmes including constant supply of ARV drugs and related services previously discussed in chapter one.

However, a WTO Member in violation of the most favoured nation general disciplines is entitled to raise several general exceptions provided for under Article XIV (b) of GATS which permits Members to; “take measures that restrict services and service suppliers for the necessary protection of inter alia human health.”¹³⁶

¹³³ Fidler ,Correa & Aginam Note 99 above.

¹³⁴ Ibid. “WTO case law supports this interpretation of Article II:1. In *EC—Bananas III*, the European Communities argued that Article II: 1 prohibited only *de jure* rather than *de facto* less favourable treatment. The Appellate Body did not agree with this limited interpretation of the MFN principle in GATS: The obligation imposed by Article II is unqualified. The ordinary meaning of this provision does not exclude *de facto* discrimination. The Appellate Body in *Canada Autos* held that a finding of less favourable treatment cannot be based on speculation about possible adverse effects on the conditions of competition.”

¹³⁵ In terms of GATS service supply (mode 4) See Note 86 above.

¹³⁶ Article XIV General Exceptions in the GATS Agreement states that: “Subject to the requirement that such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries

Nevertheless, Fidler, Correa and Aginam have argued that; “the burden imposed by the ‘necessity test’ in Article XIV (b) is substantial and difficult and as such, Article XIV cannot be easily relied on by poor nations defending non-compliant regulations”¹³⁷ For example if Zambia decides to implement the previously cited national health policies to hire foreign health services suppliers from South Africa to resolve its issue of brain-drain of health workers such regulations could be construed as ‘unnecessary’ if the WTO resolved that there are alternative approaches of attaining the same public health goals.

The above discussion illustrates how health services in Zambia might suffer the brunt of the MFN discipline, even in situations where the policies behind discriminatory treatment of foreign services or service suppliers were driven by justifiable health policy in particular access to ARV drugs or other social objectives. This illustrates that the MFN obligations do not give independent domestic regulation of services by Members,¹³⁸ making formulation of regulatory domestic legal frameworks inevitable, if local citizens are to benefit from the GATS Agreement.

In addition to the general obligations are GATS’ provisions on specific commitments on national treatment, market access and progressive liberalisation of trade in services which give WTO Members discretion to choose which sectors to commit to and how much they are willing to open up to foreign investors. The specific commitments will now be examined in order to ascertain their impact on Zambia’s health policy formulation and subsequent delivery of quality health services for its HIV/AIDS infected population.

2.4. GATS SPECIFIC COMMITMENTS AND REGULATION OF PRIVATE HEALTH SERVICES IN ZAMBIA

The second set of rules of trade in services is the specific commitments to be made by WTO Members in terms of Part (III) of the GATS Agreement. It is crucial to note that Members are given the discretion whether or not to make specific commitments on market access or national treatment (NT) in service sectors which they propose to liberalise.¹³⁹ However, once a Member resolves to

where like conditions prevail, or a disguised restriction on trade in services, nothing in this Agreement shall be construed to prevent the adoption or enforcement by any Member of measures: ... (b) necessary to protect human, animal or plant life or health.”

¹³⁷ WHA (2003). Note above 62 above.

¹³⁸ Mabika & London Note 24 above.

¹³⁹ Drager & Fidler Note 121.

make specific commitments on market access and NT; by detailing them in the schedule of commitments annexed to GATS,¹⁴⁰ they become part of the mandatory Agreement.¹⁴¹ The trade rules on specific commitments are often called bottom-up rules because they are instigated by the WTO Members, in contrast to the top-down provisions that are mandatory general obligations imposed by the WTO on its Members.¹⁴²

In Zambia's context, despite having fully liberalised health services, it has not placed any NT or market access restrictions in the schedule of commitments annexed to GATS.¹⁴³ Nevertheless, this does not mean that GATS provisions on market access or NT are not applicable to Zambia's health policies. These are now discussed in order to illustrate how they are likely to affect health policies aimed at regulating private health services in Zambia.

2.4.1. Market Access and regulation of private health services in Zambia

Article XVI:1 requires the following:

With respect to market access through the modes of supply identified in Article I, each Member shall accord services and service suppliers of any other Member treatment no less favourable than that provided for under the terms, limitations and conditions agreed and specified in the Schedule of specific commitments.¹⁴⁴

The above provisions in Article XVI:1 require, WTO Members to positively specify the service sector and mode of supply for which they are making market access commitments. If they do not, the GATS provisions on market access will not apply. On the other hand Article XVI: 2 requires that; WTO Members schedule restrictions on market access that they either will or intend to adopt.¹⁴⁵ This means that foreign investor service supply, in this instance health services, is conditional on the

¹⁴⁰ Article XX: 1 and 3 of the GATS Agreement.

¹⁴¹ Drager & Fidler Note. 121 above.

¹⁴² Ibid.

¹⁴³ Ndulo 2001 Note 26 above.

¹⁴⁴ Fidler, Correa & Aginam Note 99 above explain that "If a Member undertakes a market-access commitment in relation to the supply of a service through the mode of supply referred to in subparagraph 2(a) of Article I and if the cross-border movement of capital is an essential part of the service itself, that Member is thereby committed to allow such movement of capital. If a Member undertakes a market-access commitment in relation to the supply of a service through the mode of supply referred to in subparagraph 2(c) of Article I, it is thereby committed to allow related transfers of capital into its territory."

¹⁴⁵ Article XVI:2 of the GATS Agreement provides that : "In sectors where market-access commitments are undertaken, the measures which a Member shall not maintain or adopt either on the basis of a regional subdivision or on the basis of its entire territory, unless otherwise specified in its Schedule, are defined as:"...

limitations inscribed by a particular Member. These provisions require of WTO Members to 'remove trade barriers to foreign services'.¹⁴⁶

However the Medical Aid Societies and Nursing Act, requires that privately owned health institutions must be 'Zambian-owned'.¹⁴⁷ Despite there being no evidence of Zambia scheduling restrictions on market access in the schedule on specific commitments annexed to the GATS Agreement. Thus it could be interpreted that foreign health service investors are only allowed to invest in the Zambian private health sector if they are willing to relinquish most of their ownership rights to the Zambian local investors despite the foreign investors being the main funders and owners of the institutions. This could amount to a violation of market access provisions as the Medical Aid Societies and Nursing Act could be found to be restricting market access of foreign investors in the absence of scheduled restrictions.¹⁴⁸ Notwithstanding the policy intentions of the legislature at the time the Medical Aid Societies and Nursing Act was amended. These policy intentions could have been to encourage the retention of local health workers, mainly doctors, by allowing them to set up private practices as another way of diversifying health service delivery and supplementing the low salaries offered in public health institutions.

However if the Zambian government did not undertake any commitments in the health sector such as liberalisation of its health services this would also limit market access but would not violate any rights of foreign investors wanting to invest in the country as the health sector would not be liberalised to invite investors in the first place. On the other hand such a situation would disadvantage the entire Zambian population from seeking alternative health care services within the country as there would be limited suppliers.

Hence the government's liberalisation policy of health services under GATS could achieve substantial results if more health services principally from private investors both local and foreign are encouraged but on condition that their supply of services compliment the delivery of health services in the overburdened public health sector especially in the area of HIV/AIDS. Some of the conditions that could be placed on foreign health service suppliers by the Zambian government to facilitate public health service delivery are discussed later in this chapter. However this adoption of conditions

¹⁴⁶ Drager & Fidler Note 121 above.

¹⁴⁷ Refer to Note 22 above. See also Mabika & London Note 24 above.

¹⁴⁸ Fidler, Correa & Aginam Note 99 above. See also Ndulo 2001 Note 26 above.

requires legal regulatory frameworks to be devised or revised to be legally enforceable against investors in the private sector this issue has also been deliberated below.

2.4.2. National treatment provisions and public health finance in Zambia

Article XVII:1 States the following:

In the sectors inscribed in its Schedule, and subject to any conditions and qualifications set out therein, each Member shall accord to services and service suppliers of any other Member, in respect of all measures affecting the supply of services, treatment no less favourable than that it accords to its own like services and service suppliers.

In light of the above provision, national treatment requires that:

First, there must be an exercise of a measure affecting the supply of services. Second, such exercise of a measure must occur in a sector sheltered by a national-treatment commitment; third; the conditions or qualifications in the national-treatment commitment related to the applied measure must be non-existent. Fourth; like foreign and domestic services or service suppliers must be in attendance. Fifth; that there must be evidence that less favourable treatment was accorded to the Foreign Service or service supplier. This means that complaining Member has to demonstrate that the less favourable treatment either immediately advantages the local investors or is most likely to advantage such investors in the future to the disadvantage of foreign investors, as long as such allegations are not based on mere conjecture.¹⁴⁹ In this instance intention to accord less favourable treatment to a foreign investor is irrelevant.¹⁵⁰

Thus, Mabika and London have argued that the provisions on NT have the potential to halt any government subsidies available for public health institutions in Zambia. As the government subsidies would alter Zambia's conditions for fully liberalising its health sector under the GATS by favouring public health institutions. Such an exercise might amount to a violation of the NT clause.¹⁵¹ Hence in

¹⁴⁹ Article XVII:(2)of the GATS Agreement states that: "A Member may meet the requirement of paragraph 1 by according to services and service suppliers of any other Member, either formally identical treatment or formally different treatment to that it accords to its own like services and service suppliers."

Article XVII: (3) states that: "Formally identical or formally different treatment shall be considered to be less favourable if it modifies the conditions of competition in favour of services or service suppliers of the Member compared to like services or service suppliers of any other Member."

¹⁵⁰ Fidler, Correa & Aginam Note 99 above.

¹⁵¹ Article XVII: 1 of the GATS Agreement.

order to avoid violation of the discipline of national treatment the Zambian government would also have to subsidize private health care facilities owned by both foreign and local investors in order to afford equal national treatment to both sectors.¹⁵² This would have adverse effects on the delivery of health services, as the Zambian government would have to further extend its already fragmented and limited public health funds in order to subsidize the health service delivery in the private health sector.¹⁵³

Mabika and London have reasoned that, considering Zambia's weak economic standing it would be impossible for the government to fund two separate health sectors¹⁵⁴ in the wake of the much needed financial assistance to foster policy frameworks presently in place in order to halt and reverse the spread of HIV/AIDS.¹⁵⁵

Thus in light of the above the Zambian government has two options, the first one would be the complete abolition of subsidies to the public health sector to avoid violation of the GATS Agreement. The second option would be continued government subsidisation of public health sector to such an extent that public health institutions virtually offer free basic health services to patients of which would not be remotely in competition with services supplied in the private health sector. This means that the Zambian government may simply select those areas of health care, including ARVs, where it wants to provide subsidies and thus ensure that in those areas there is no competition as envisaged in the GATS Agreement.¹⁵⁶ The latter option would not only prevent the possibility of the Zambian government extending its limited resources for the public health sector to the private health institutions it would also prevent violation of the GATS Agreements' NT clause.

Furthermore, Ndulo has asserted that the policy of the Medical Council of Zambia (MECZ), which offers favourable treatment to locally qualified doctors by requiring them to pay lower license fees than their foreign counterparts, amounts to Zambia's complete violation of the NT clause.¹⁵⁷ Hence, it is important to note that WTO Members and Zambia in particular must select service sectors they

¹⁵²Mabika & London Note 24 above.

¹⁵³ Ibid.

¹⁵⁴ Mabika & London Note 24 above.

¹⁵⁵ For current policy frameworks on HIV/AIDS in Zambia. See UNGASS 2010 Note 69 above.

¹⁵⁶ See text to footnote 120 on page 21 of this chapter.

¹⁵⁷ Ndulo (2001) Note 26 above.

will accord NT restrictions to¹⁵⁸ in their schedule of commitments¹⁵⁹ to avoid violation thereof. On the other hand Fidler, Correa and Aginam have warned that:

Restrictions on national treatment may not automatically be used as legal regulatory policy frameworks for the health sector. Hence certain WTO Members when signing the GATS and or other international trade agreements that encompass trade liberalisation of trade in services have explicitly removed health services from the national treatment principle.¹⁶⁰

However in Zambia's context, Ndulo has argued that, having fully liberalised its public health services discussed below, Zambia needs to make restrictions on market access and NT as legal regulatory frameworks required for regulating private health services have not been developed.¹⁶¹ Hence Zambia could adopt new legislation or amend existing legislation envisaging provisions of trade in services including the Medical Aid Societies and Nursing Act to include some of the suggested conditions¹⁶² for private health service operation. This will facilitate domestic regulation of private health services in a manner that these services help to improve the general provision of health services on access to ARV drugs. Some of the suggested conditions include;

(a) requiring foreign private health services suppliers to take up a certain measure of pro-bono health care to the underprivileged particularly HIV/AIDS patients. For example private hospitals could reserve a few beds for the treatment and admission of severe cases of sick people.

¹⁵⁸ Fidler, Correa & Aginam Note 99 above. "highlighted some of the National Treatment Restriction Examples such as inter alia "(i)Subsidy measures Only nationals can receive government subsidies (ii)Tax measures Taxes applied to premium payments made to non-resident insurance companies (iii) Other financial measures Higher license fees are charged for non-residents (iv) Nationality requirements Services may only be provided by nationals (v) Residency requirements Services may only be provided by individuals resident for a specified period of time (vi) Licensing and qualification requirements Licenses or qualification exams limited to residents or nationals (vii) Registration requirements Foreign service suppliers have to have registered office in the country (viii) Authorization requirements Foreign service suppliers face extra authorization requirements (ix)Technology transfer/training requirements Foreign service suppliers are required to transfer technology or train local workers (x) Local content requirements Priority shall be given to local service providers (xi) Ownership of property/land Foreign nationals may not purchase real estate or face additional requirements to purchase."

¹⁵⁹ Article XX Schedules of Specific Commitments States that: 1."Each Member shall set out in a schedule the specific commitments it undertakes under Part III of this Agreement. With respect to sectors where such commitments are undertaken, each Schedule shall specify: (a) terms, limitations and conditions on market access; (b)conditions and qualifications on national treatment; (c)undertakings relating to additional commitments;(d)where appropriate the time-frame for implementation of such commitments; and (e)the date of entry into force of such commitments."

¹⁶⁰ Fidler, Correa & O. Aginam Note 99 above have noted as example of : "Canada's exclusion of health services from NAFTA's national treatment principle."

¹⁶¹ Ndulo (2001) 26 above.

¹⁶² WHA (2003) Note 62 above.

(b) on the other hand the government may seek levy on private hospital amenities and cross-subsidise the revenue to public health services and incentive programmes for retention of health workers and;

(c) in order to prevent the national brain-drain of public professional health workers, WTO governments may request that private health institutions supply rural dwellers with basic medical services and or offer advanced training to old and newly employed professional public health workers.¹⁶³

Additionally Mabika and London have concurred with the above reasoning that it is imperative that Zambia adopts certain regulations for private health services and restrictions on national treatment and market access benefits to protect its local investors as it will assist the government to avoid leaving its health services sector wide open to abuse by Foreign Service suppliers, through the disregard of national laws and regulatory frameworks by adopting tactics that advance private services. This is especially so as the public-private dimension of health service delivery expands in view of the GATS' provisions on progressively liberalising health services¹⁶⁴ discussed below.

2.4.3. Progressive liberalisation of trade in health services a solution for effective public health services in Zambia?

Article XIX:1 and 2 require WTO Members to:

(1) ...Enter into successive rounds of trade negotiations...with a view to achieving a progressively higher level of liberalization...

(2) The process of liberalisation shall take place with due respect to national policy objectives and the level of development of individual Members both in overall and in individual sectors.

The above provisions on progressive liberalisation require Members to engage in various trade negotiations with the aim of liberalising trade in health services. This is because progressive liberalisation has been described by GATS proponents to bring about "better quality, affordable, and

¹⁶³ Ibid.

¹⁶⁴ Mabika & London Note 24 above.

effective health-related services, leading to greater equity in health outcomes”¹⁶⁵ by offering WTO Members enough flexibility to select what services sectors to liberalise and to what degree.¹⁶⁶

On the other hand GATS opponents have argued that liberalisation of health services does not automatically bring about the aforementioned health benefits, as a particular Member’s potential to benefit from liberalised health services is contingent on inter alia, “the structure of the health sector, and the existing legal regulatory and policy environment affecting all the participants, domestic and foreign.”¹⁶⁷

Thus in countries where the regulations of private health services is limited or even non-existent for example in Zambia liberalised health services is likely to result in “reduced affordability of healthcare to the poor, and worsening of existing inequities and shortages in the sectors selected for liberalisation.”¹⁶⁸ Therefore bearing in mind the above arguments for and against GATS provisions on progressive liberalisation, Zambia’s full liberalisation of health services under GATS¹⁶⁹ is analysed to determine their impact on health service delivery.

At present Zambia is one of the few countries in the sub-Saharan African region that have made full commitments on trade in health services by not placing “any restrictions on market entry and operations in its services sector”.¹⁷⁰ However, health services, including those in respect of HIV/AIDS, remain underdeveloped. This underdevelopment is due to lack of domestic legal regulatory frameworks such as a new National health Services Act¹⁷¹ to regulate private health services,¹⁷² so that they operate a complementary role to public health programmes on access to ARV drugs to lessen the burden of patients on public hospitals.

¹⁶⁵ Drager & Fidler 121 above.

¹⁶⁶ Ibid.

¹⁶⁷ Chanda (2008) Note 92 above.

¹⁶⁸ A.M Pollock & D. Price (2000). “Rewriting the Regulations: How the World Trade Organisation Could Accelerate Privatisation in Health-Care Systems.” *The Lancet*; 356: 1995-2000). Available online at: [www.lancet.com/journals/lancet/article/PIIS0140-6736\(00\)03317-1](http://www.lancet.com/journals/lancet/article/PIIS0140-6736(00)03317-1). Accessed on 21/01/2012.

¹⁶⁹ “The Zambian government has also liberalised; “business services, construction and related engineering services, and tourism and travel related services.” WTO PRESS RELEASE: PRESS/TPRB/319: 27 and 29 JULY TRADE POLICY REVIEW: ZAMBIA ‘Diversification of the economy and structural reforms essential for continuing stability and growth’. Available online at: http://www.wto.org/English/tratop_e/tp_r/_/219-03_e.doc. Accessed on 05/09/2010. Hereinafter referred to as, the WTO Trade Policy Review on Zambia (2009).

¹⁷⁰ Ndulo(2001) Note 26 above.

¹⁷¹ See Discussion under item 1.2.2 on page 4 of chapter one of this dissertation.

¹⁷² Ibid.

Moreover, as highlighted in chapter one of this dissertation, the Pharmaceutical Act does not regulate the activities of pharmacists thus prices charged in the public, non-governmental and private sectors determine the affordability of essential medicines. For example even though provision of medicines in the public health facilities in rural areas in Zambia is free of charge, user fees are charged for medicines provided in urban health facilities and these prices can be unaffordable. Furthermore, as medicines proceed through the private sector there are no regulation of the original prices or mark ups charged by manufacturers. This means dispensing pharmacies are free to set whatever prices they deem tally with their pharmaceutical products including ARV drugs.¹⁷³

Above and beyond, there has not been significant foreign private investment in the health sector post liberalisation of trade in services in Zambia,¹⁷⁴ due to poor economic standing, evidenced in its high poverty levels currently standing at 68.0%, with 87.2% of the general population living on less than \$2 dollars a day.¹⁷⁵ According to Aart van Os¹⁷⁶ these economic challenges have further affected social benefits linked to the delivery of health services as currently:

The Zambian private health sector is one of the smallest in the world with no more than 10 - 15% of total health care services (Os, 2009). In 2009 there no more than 70 registered pharmacy retail outlets, 80 pharmaceutical importers/wholesalers, 300 private (dispensing) clinics (1 to 2 doctors), private health insurers with no more than 30.000-50.000 people privately insured, six officially registered manufacturers of which only 3 were operational with a very limited product portfolio.

Correspondingly, the provision of primary health services was described as follows by the US State Department's travel advisory for Zambia:

Government hospitals and clinics are often understaffed and lack supplies. Private medical clinics in major cities can provide reasonable care in many cases, but major medical

¹⁷³ Zambia Assessment of pharmaceutical data disclosure Status of pharmaceutical sector data part of Component 1 of the MeTA Baseline Assessments ZAMBIA June 2010. Note 38 above.

¹⁷⁴ Ndulo (2001) Note 26 above. See also Mabika & London Note 24 above.

¹⁷⁵ UNDP, "2007/08 Human Development Report for Zambia," September 2008. Available online at: http://hdrstats.undp.org/en/countries/data_sheets/cty_ds_ZMB.html. Accessed on 04/01/2012. "Zambia is number 163 out of the 179 countries and regions in the UNDP human development index."

¹⁷⁶ Aart van Os. 2009. Private Sector Mapping Report. 2009.

emergencies usually require medical evacuation to South Africa, Europe, or the United States. Basic medical care outside of major cities is extremely limited.¹⁷⁷

Thus it is submitted that, post liberalisation of trade in health services under GATS, the Zambian health system is still undergoing the same challenges inherited from the privatisation policies.¹⁷⁸ Although the privatization of health services is not linked to liberalisation of trade in services in terms of GATS, it could be argued that it sets the background for progressive liberalisation of inter alia health services under GATS.¹⁷⁹ For this reason, Zambia should have prepared itself with legal regulatory frameworks such as a National health services Act and further revised the Medical Aid Societies and Nursing Act as well as the fairly recent Pharmaceutical Act to regulate the current private health services according to its national policy objectives on HIV/AIDS.

It is key to note that liberalisation provisions under GATS remain untested in Zambia,¹⁸⁰ however once the latter provisions take effect, private health care providers and formulation of legal health policy will remain contingent on the provisions under GATS' general obligations and specific commitments. This has the potential to affect the right to health for the vulnerable groups of society who are currently not protected from any possible adverse effects arising from measures on trade liberalisation of services above all health services by any domestic laws in Zambia.¹⁸¹

2.5. CONCLUSION

This chapter has demonstrated that the wide-ranging scope of GATS encompasses public health services in Zambia and thus its general obligations and specific commitments could create challenges to the provision of public health services especially in the absence of regulatory frameworks for both local and foreign private health services providers.¹⁸² On the other hand, this chapter has also demonstrated that GATS could bring about benefits in the provision of public health services in Zambia as its provisions on liberalisation have due regard to poor nations and their

¹⁷⁷ US State Department, "Travel Advisory for Zambia" for January 23, 2009. Available online at: http://travel.state.gov/travel/cis_pa_tw/cis/cis_1062.html. Accessed on 21/01/2012.

¹⁷⁸ Ndulo (2001) Note 26 above.

¹⁷⁹ Ibid.

¹⁸⁰ Mabika & London Note 24 above.

¹⁸¹ Ibid.

¹⁸² Drager & Fidler Note 121 above.

national policy objectives.¹⁸³ Thus, since Zambia's full liberalisation of its health services under GATS provisions remain untested in its two-tier provision of health services,¹⁸⁴ Zambia's adoption of regulatory frameworks for private health services and their implementation will determine whether the GATS Agreement benefits or further deteriorates the current provision of health services, particularly with regard to the equitable distribution of and access to ARV drugs and treatment. How this state of affairs is affected by the imminent adoption of TRIPS provisions on pharmaceutical patents and test data is discussed in the next chapter.

¹⁸³ Article XIX:2 of the GATS Agreement.

¹⁸⁴ Ndulo (2001) Note 26 above.

CHAPTER THREE: THE TRADE RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS (TRIPS) AGREEMENT AND ITS IMPACT ON ACCESS TO ARV DRUGS IN ZAMBIA.

SUMMARY

This chapter will analyse the legal impact of TRIPS on the price of ARV drugs and access thereto by developing and least developed WTO countries with specific focus on Zambia.

It begins by giving a brief synopsis of the background and purpose of the TRIPS Agreement to illustrate how this Agreement has intensified IPRs by requiring WTO Members to adhere to its provisions on pharmaceutical patent rights protection.

It will also analyse select viable TRIPS flexibilities counting their interpretation in the Doha Declaration on TRIPS and public health and relatively recent implementation of Paragraph 6 of the 30th August 2003/ 6th December 2005 decision.

Furthermore Zambia's utilization of TRIPS flexibilities to access ARV drugs will be reviewed in order to ascertain if there are any other viable options of TRIPS flexibilities that Zambia could exploit in the not so distant future to increase access to advanced regimens of ARV drugs.

Comparative studies of the use of TRIPS flexibilities in Kenya and South Africa will be conducted amidst various country experiences. To determine the expediency of various TRIPS flexibilities in the area of access to ARV drugs in different economic environments.

In conclusion, the emergence of TRIPS-Plus free trade agreements will be scrutinised to determine their potential impact on the future of access to ARV drugs in WTO African Member countries principally Zambia.

3.1. INTRODUCTION: BACKGROUND AND PURPOSE OF THE TRIPS AGREEMENT

The establishment of the WTO¹⁸⁵ Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS), like the GATS Agreement, was as a result of the Uruguay trade negotiations from 1986 to 1994.¹⁸⁶ Thus due to the intensification of economic globalization of intellectual property rights,¹⁸⁷ as of August 24th 2012, there were 157 countries across the globe that formed TRIPS' official Member list.¹⁸⁸

In terms of Article 7, the purpose of the TRIPS Agreement is primarily to enforce minimum standards on intellectual property rights (IPRs),¹⁸⁹ those pertinent to this study being, patent rights over essential drugs specifically ARV drugs owned by pharmaceutical drug companies in WTO Members.¹⁹⁰ The minimum standards on IPRs are based on two fundamental obligations provided by TRIPS Agreement; these are the most favoured nation (MFN) and national treatment (NT).¹⁹¹ Thus the adherence of WTO Members to the MFN and the NT obligations are prerequisite under TRIPS, as their provisions are enforceable through the WTO's dispute resolution mechanisms under which non-compliant Members are likely to suffer inter alia the penalty of trade sanctions if found in violation.¹⁹²

¹⁸⁵ WTO, 'What is the World Trade Organisation,' Available online at: http://www.wto.org/english/thewto-e/whatis_e/tif_e/fact1_e.html last. Accessed 3/03/ 2010. "The WTO is an organization that creates an environment which facilitates the free flow of multinational commercial activities including the enforcement and protection of all facets of intellectual property rights globally through the TRIPS Agreement".

¹⁸⁶ TRIPS Agreement See Note 55 above.

¹⁸⁷ C .M Correa "Intellectual Property Rights and Inequalities in Health Outcomes (2008): WHO Commission on Social Determinants of Health." Available online at: <http://infojustice.org/download/gcongress/ipandhumanrights/Correa%20article.pdf>. Accessed on 21/10/2011. Hereinafter referred to as Correa (2008).

¹⁸⁸ WTO Official Members (as of August 24th 2012). Available online at: http://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm. Accessed on 04/01/2012.

¹⁸⁹ In terms of 'PART I General Provisions and Basic Principles' of the TRIPS Agreement "TRIPS, protects other forms of intellectual property rights including copy rights, trademarks, circuit diagrams."

¹⁹⁰ TRIPS Agreement Article 7 'objectives' state as follows: "The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations." See also C. Fink "Intellectual Property Rights: Economic Principles and Trade Rules" (Revised version 2007). Available online: http://siteresources.worldbank.org/INTRANETTRADE/Resources/InternalTraining/1_Carsten_Main_Module_IPRs.pdf. Accessed on 04/01/2012. Hereinafter referred to as, Fink (2007).

¹⁹¹ TRIPS Agreement Article 4 is the 'most favoured nation (MFN) clause' and Article 3 of TRIPS is the 'national treatment (NT) clause'. The MFN and NT disciplines are also found under GATS and have been extensively deliberated in chapter two thus they will not be discussed in depth in this chapter.

¹⁹² TRIPS Agreement 'Enforcement of intellectual property rights' Section 1: General Obligations. Article 41 paragraphs 1-5. See also Article 68 'Council for Trade-Related Aspects of Intellectual Property Rights' states that: "The Council for TRIPS shall monitor the operation of this Agreement and, in particular, Members' compliance with their obligations hereunder, and shall afford Members the opportunity of consulting on matters relating to the trade-related aspects of intellectual property rights. It shall carry out such other responsibilities as assigned to it by the Members, and it shall, in

On the other hand, in terms of the principles of TRIPS envisaged in Article 8(1),¹⁹³ the protection of patent rights owned by pharmaceutical companies have to be balanced with the broader public health and human rights interests of consumers in WTO Members worldwide.¹⁹⁴ This provision might be interpreted to the advantage of WTO LDCs as they need to employ various mechanisms in their domestic intellectual property legal frameworks mechanisms to override the patents rights awarded to pharmaceutical companies by TRIPS so as to gain access to medicines, in this instance, patented ARV drugs in the near future.¹⁹⁵

Furthermore the TRIPS Agreement in terms of Article 66.1 awarded LDCs including Zambia transitional arrangements that legally exempt these countries from enforcing minimum standards on pharmaceutical patent protection and test data protection until 1st January 2006 a date which was extended under the Doha negotiations to 2016. The Doha declaration will be discussed later in this chapter. Additionally LDCs are exempt from implementing TRIPS provisions on IPRs until 1st July 2013.¹⁹⁶

Article 66.1 “least developed countries” states that:

In view of the special needs and requirements of least-developed country Members, their economic, financial and administrative constraints, and their need for flexibility to create a viable technological base, such Members shall not be required to apply the provisions of this Agreement other than Articles 3, 4 and 5, for a period of 10 years from the date of application as defined under paragraph 1 of Article 65.¹⁹⁷ The Council for TRIPS shall, upon duly motivated request by a least-developed country Member, accord extensions of this period.

particular, provide any assistance requested by them in the context of dispute settlement procedures...” See also Fink Note 190 above.

¹⁹³ TRIPS Agreement Article 8 (1) ‘Principles of TRIPS’ state that: “Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.”

¹⁹⁴ WTO Official website on Members See Note 188 above: “The African Member States of the WTO who are LDCs are: Angola, Burkina Faso, Burundi, Central African Republic, Chad, Democratic Republic of Congo, Djibouti, The Gambia, Guinea, Guinea-Bissau, Lesotho, Madagascar, Malawi, Mali, Mauritania, Mozambique, Niger, Rwanda, Senegal, Sierra Leone, Tanzania, Togo, Uganda and Zambia. The African Members States of the WTO who are not LDCs are: Benin, Botswana, Cameroon, Egypt, Gabon, Kenya, Mauritius, Morocco, Namibia, Nigeria, South Africa, Swaziland, Tunisia, and Zimbabwe.”

¹⁹⁵ S.F Musungu and C. Oh (South Centre & World health organization 2006) ‘The Use Of Flexibilities In Trips By Developing Countries: Can They Promote Access To Medicines? Available online at www.equinet africa.org/bibl/docs/POLBRF16trade.pdf. Accessed on 15/10/210. Hereinafter referred to as, Musungu & Oh.

¹⁹⁶ TRIPS Council Decision of November 2005 Note 54 above.

¹⁹⁷ TRIPS Agreement Article 65(5) ‘Transitional arrangements’ under TRIPS states that “A Member availing itself of a transitional period ... shall ensure that any changes in its laws, regulations and practice made during that period do not result in a lesser degree of consistency with the provisions of this Agreement...”

Accordingly, the 2016 and 2013 deadlines are subject to extension.¹⁹⁸ This is as a result of the TRIPS council's decision of June 27th 2002 which implemented Paragraph 7 of the 2001 Doha Declaration on the TRIPS Agreement and Public Health.¹⁹⁹ Paragraph 7 of the Doha declaration states that LDC Members:

Will not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under these Sections until 1 January 2016, without prejudice to the rights of least-developed country Members to seek other extensions of the transition periods as provided for in Article 66.1 of the TRIPS Agreement.

In spite of the above provisions exempting LDC's from implementing intellectual property rights provisions and the protection of pharmaceutical patents and of test data in their national patents legislation until 2013 and 2016 respectively, most, LDCs currently offer patent protection to pharmaceutical products in their domestic patent legislation.²⁰⁰

Correspondingly Zambia awards patent protection through national law in form of the *Zambian Patent Act's*,²⁰¹ Section 29(a) which provides that: "Patent protection in Zambia is granted for a period of 16 years commencing from the date of lodging and complete specification of a patent at the patents office".

¹⁹⁸ WTO: 2011 NEWS ITEMS 17 November 2011 INTELLECTUAL PROPERTY: FORMAL MEETING Draft decisions agreed on poorest nations' and intellectual property and 'non-violation. Available online at: http://www.wto.org/english/tratop_e/trips_e/ldc_e.htm. Accessed on 04/01/2012. "WTO Members meeting as the TRIPS (intellectual property) Council have reached consensus agreement on two draft decisions for their ministers to adopt in the 15-17 December 2011 Geneva Ministerial Conference. Ministers are now expected to ask the council to consider extending the mid-2013 deadline for least developed countries to implement intellectual property protection under the WTO agreement. They are also expected to agree that their countries will continue to refrain from bringing "non-violation" cases to the WTO dispute settlement system for another two years."

¹⁹⁹ The TRIPS Council's Decision of 27 June 2002 (WTO document IP/C/W/25). Available online at: http://www.wto.org/english/tratop_e/trips_e/art66_1_e.htm. Accessed on 02/02/2012.

²⁰⁰ T Avafia, J Berger & T Hartzenberg: "The ability of select sub-Saharan African countries to utilise TRIPs Flexibilities and Competition Law to ensure a sustainable supply of essential medicines: A study of producing and importing countries" tralac Copyright © ICTSD, UNCTAD and tralac, (2006). Available online at: http://www.givengain.com/unique/tralac/pdf/20061002_Avafia_TRIPsandCompetitionLaw.pdf Accessed on 15/10/2010. Hereinafter referred to as Avafia & Berger & Hartzenberg. See also Thorpe Note 46 above. See also Musungu & Oh Note 195 above.

²⁰¹ The *Zambian Patent Act* Note 33 above.

Furthermore Zambia awards 20 years patent protection through its membership to the African Regional Industrial Property Organisation (ARIPO).²⁰² Section 10A of the Zambian Patent Act encompasses ARIPO provisions on the protection of patents and it states as follows:..

- (2) Where a patent has been granted by ARIPO under section 3 (7) of the ARIPO Protocol and the Registrar has not objected, under section 3 (6) of the Protocol, to the patent having effect in Zambia, the patent shall for all purposes be deemed to have been granted under this Act.
- (3) A patent shall not be deemed to have been granted under this section if, under section 3(6) of the ARIPO Protocol, the Registrar objects to its having effect in Zambia. (As amended by Act No. 26 of 1987).

Hence it emerges that the Zambian Patent Act is flawed and should be legally transformed urgently²⁰³ to ensure that Zambia utilises the leeway granted to LDCs under TRIPS' provisions on transition periods to legitimately exempt pharmaceutical patent protection of certain essential medicines to help improve access thereof before the 2016 deadline.²⁰⁴ Predominantly in light of the current challenges in the Zambian national health system related to the erratic health service supply of ARV drugs discussed respectively in chapter one and two of this dissertation,²⁰⁵ as well as the impact of pharmaceutical patent protection on the prices of ARV drugs which is usually high and restricts affordability and access thereto discussed next in this chapter.

²⁰² See Harare Protocol (1982) Note 52 above.

²⁰³ According to the (WTO) Trade Policy Review on Zambia: (2009) Note 169 above : "Intellectual property laws (IP) in Zambia have not had any substantial changes made to them since Zambia received its independence from its colonial government, to warrant rationalized reviews. Essentially, Zambia domestic legal frame work patent cannot be pronounced to be TRIPS compliant yet. However the Zambian government has embarked on the legal transformation of its IP laws including its patents Act of which upon amendment should require a 20 year period of patent protection."

²⁰⁴ S. O'Carroll 'Importing Indian Generic Drugs Following TRIPS: Case Studies from Zambia and Kenya' (2009). Available online at: http://www.law.utoronto.ca/documents/ihp/HIV_Ocarroll.doc. Accessed on 12/03/2010. Hereinafter referred to as, 'O' Carroll.

²⁰⁵ See ZAMBIA: Corruption Scandal Rocks ARV Programme: JOHANNESBURG, 14th March 2011 (PlusNews Global) Note 81 above. See also ZAMBIA: 'Third-Line ARVs Available Soon'. (PlusNews/IRIN) AfricaFiles 7th MARCH 2011 Note 82 above. See also Treatment Advocacy Literacy Campaign (TALC) Note 85 above.

3.2. PHARMACEUTICAL PATENT PROTECTION UNDER TRIPS: IMPACT ON PRICES FOR MEDICINES AND ACCESS TO ARV DRUGS IN DEVELOPING COUNTRIES

3.2.1. Patent rights under TRIPS

In terms of Article 27 of TRIPS to be discussed later in this chapter, only new, non-obvious and commercially applicable inventions qualify for patents.²⁰⁶ Thus, in terms of Article 28²⁰⁷ of the TRIPS Agreement, a patent confers certain exclusive rights on originator pharmaceutical companies; “to produce, use, sell and import patented medicines, for a patent term of 20 years after which the patent expires.”²⁰⁸ In other words during the existence of the patent, patent owners can legally exclude others in this instance generic drug producers²⁰⁹ and governments from “making, using or selling the patented products.”²¹⁰

Although the above provisions in the TRIPS Agreement which award innovators in this instance originator pharmaceutical drug companies exclusive rights over the production and sale of medicines in order to enable them to realize profits to research and develop (R&D) new and improved medicines²¹¹ appear to be reasonable, especially in the wake of global pandemics such as HIV/AIDS that require new drugs in case of drug resistant cases. t’Hoen²¹²; Drahos and Mayne²¹³ have nevertheless argued that TRIPS’ patent system is often abused by originator pharmaceutical drug companies, who set high prices for medicines which restrict access to essential drugs in least developed and developing African countries.

²⁰⁶ TRIPS Agreement Article 27 ‘Patentable Subject Matter’ states that: “(1.) Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application...”

²⁰⁷ TRIPS Agreement Article 28 ‘Rights Conferred’ state that: “1.A patent shall confer on its owner the following exclusive rights: (a) where the subject matter of a patent is a product, to prevent third parties not having the owner’s consent from the acts of: making, using, offering for sale, selling, or importing²⁰⁷ for these purposes that product; (b) where the subject matter of a patent is a process, to prevent third parties not having the owner’s consent from the act of using the process, and from the acts of: using, offering for sale, selling, or importing for these purposes at least the product obtained directly by that process. 2. Patent owners shall also have the right to assign, or transfer by succession, the patent and to conclude licensing contracts.”

²⁰⁸ TRIPS Agreement Article 33 ‘Term of Protection’ states that: “The term of protection available shall not end before the expiration of a period of twenty years counted from the filing date.”

²⁰⁹ K.A Jaktar ‘Compulsory Licensing and the Anti-Competitive Effects of Patents for Pharmaceutical Products: From A Developing Countries’ Perspective.’ Available online at: http://www.idra.it/garnetpapers/C14A_Kaushik_A_Jaktar.pdf. Accessed on 04/01/2012.

²¹⁰ See Article 28 Note 207 above.

²¹¹ J. Hughes (1998). *The Philosophy of Intellectual Property*. George. Law J. 77(287): 299-330,1998; See also John Locke. *Two Treatises of Government*, Second Treatise, Cambridge University Press, England.

²¹² P. Drahos and J Mayne(ed) *Global Intellectual Property Rights: Knowledge access and development* (2006). Hereinafter referred to as Drahos & Mayne.

²¹³ E.F. M t’Hoen (2009). “The Global Politics of Pharmaceutical Monopoly Power”, *Drugs Patents, Access, Innovation and the application of the WTO Doha declaration on TRIPS and Public health*(2009) AMB Publishers. Hereinafter referred to as t’Hoen.

3.2.2. The impact of TRIPS on the prices of medicines and access to ARV drugs in developing countries

According to t'Hoen, multinational research based drug companies (MNCs) abuse their dominant position in multifaceted ways, including the following;

The espousal of devices to frustrate the premature entry of generic rivals through 'ever-greening'; including excessive pricing; premeditated constricted market access to create space for high price fixing and applying discriminatory marketing principles that compromise access.²¹⁴

The aforesaid patent abusive techniques employed by drug companies, consequently prevent generic drug producing companies from using the patented information to produce economical generic products²¹⁵ leading to originator drug companies retaining high prices on patented products.²¹⁶ Whilst these high prices yield great amounts of profits for originator drug companies²¹⁷ to conduct R&D of advanced medicines this process ultimately leaves developing countries with restricted or absolutely no access to essential medicines for those in desperate need of them, chiefly PLWHA ²¹⁸.

²¹⁴ Ibid. t'Hoen sets out a few scenarios to illustrate how pharmaceutical companies misuse of their dominant positions for instance; "In the 2003, South African Competition Commission case in which GlaxoSmithKline (GSK) South Africa and Boehringer Ingelheim (BI) had been found guilty of contravening the Competition Act 1998 by abusing their dominant positions in the anti-retroviral (ARV) drug market. This case has been extensively later in this dissertation.' In another example, "in 2007, certain US pharmaceutical retailers accused drug maker Abbott Laboratories of leveraging its monopoly position over an HIV drug patent called Norvir, to inflate the cost of the drug by almost 400 per cent for a period of last four years to offset losses due to increased competition for another HIV-related drug it produces ." t'Hoen explains that 'Patent holders could also abuse their rights to block dynamic or downstream innovation, or entry of generic rivals.' For example, 'in June 2005, the European Commission (EC) imposed a 60-million euros fine on AstraZeneca for misusing national patent systems and national procedures for marketing pharmaceuticals to block or delay market entry for generic competitors to its ulcer drug Losec"

²¹⁵ Yousouf. A Vawda 'Access to life saving medication in South Africa: The case for legislative reform' PHD thesis (2010) available in the GMJ SWEENEY Faculty of Law Library University of Kwazulu-Natal (UKZN) Howard College Campus, Durban. "A Generic drug- is an identical copy or bioequivalent of the patented product. In other words generics are exactly the same as patented drugs in dosage safety strength quality and efficacy. Usually the only difference between patented drugs and generic is that generics are cheaper."

²¹⁶ Ibid.

²¹⁷ Source: Equal Treatment (TAC Magazine) Issue 14-November (2011) pages 6-7. Available online at: <http://www.tac.org.za/community/files/file/etmag/ET41/ET41English.pdf> accessed on 07/03/2012. Hereinafter referred to as, the Equal Treatment TAC (2011). Total revenue in billion Rands of the top five originator pharmaceutical companies by March 2010 according to Equal Treatment TAC (2011); "Johnson & Johnson R452.77 million, Pfizer R343.99 million, Roche R325.7 million, GlaxoSmithKline R315.24 million and Novartis R304.51million. These profits have ranked the pharmaceutical industry to be the second largest profit making sector in the world economy". See also Correa (2008) Note 187 above.

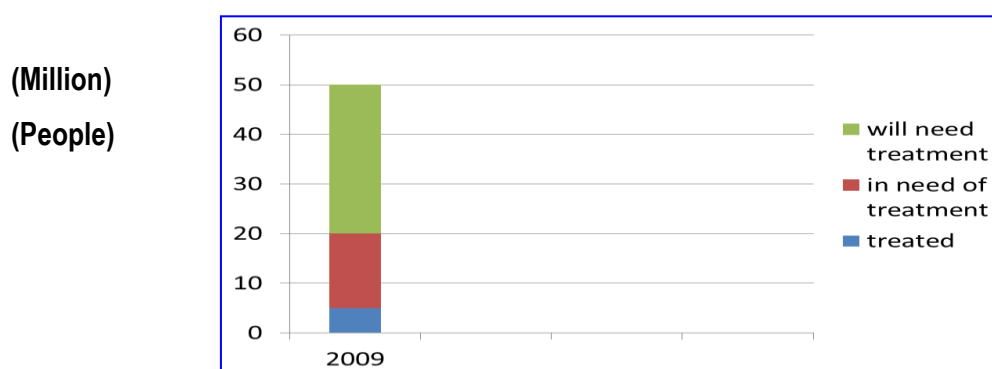
²¹⁸ W. New "UN Agencies Encourage Use of WTO Measures to Lower HIV Medicines Costs" Published on 15 March 2011. Available online at: <http://www.ip-watch.org/2011/03/15/un-agencies-encourage-use-of-measures-to-lower-hiv-medicine-costs/>. Accessed on 28/03/2012.

The strong and direct impact of the TRIPS Agreement on the high prices and availability²¹⁹ of ARV drugs was recently confirmed in the report of a statement by the World Health Organization (WHO) Director General Margaret Chan:

The price has a decisive impact on access to medicines, together with the remoteness of the services, lack of staff, poor procurement practices and delivery systems and the absence of health insurance schemes. But price can be an absolute barrier to poor countries' ability to access medicine. Furthermore, that 90 per cent of poor countries in the developing world have to purchase medicines from their out of pocket payments, making their expenditure on medicines the highest after food.²²⁰

Table 3.1 below illustrates the number of PLWHA in developing countries that were in need of ARV drugs by 2009 and that will need ARV drugs in future globally in developing countries:

Table 3.1. People living with HIV/AIDS in Developing Countries



Source: World Health Organization. Towards Universal Access: Scaling up priority HIV/AIDS interventions in the health sector. Available online at: http://www.who.int/hiv/pub/2010progressreport/summary_en.pdf. Accessed on 03/04/2012.

The information in the table above was interpreted at the 2009 WHO-WIPO-WTO symposium as follows:

5.2 million People in developing countries were on ART by end of 2009 but a further 10 million people are in urgent need of treatment as per WHO guidelines. An additional 18

²¹⁹ The Millennium Development Goal (MDG) Gap Task Force Report of 2009. Available online at: http://www.un.org/millenniumgoals/pdf/MDG_Gap_%20Task_Force_%20Report_2009.pdf. Accessed on 29/03/2012. "Shows that the availability of essential selected medicines in developing countries was low – access in the public sector was 38.1 per cent while in the private sector it stood at 63.3 per cent – yet the majority of citizens used public health facilities for their healthcare." See also allAfrica.com: 'Africa: Intellectual Property Rights Remain a Barrier to Drugs' (2010). Available online at: <http://allafrica.com/stories/201007200830.html>. Accessed on 04/01/2012.

²²⁰ The Symposium on 'Access to Medicines' held on June 16th 2010: Available online at: http://www.wto.org/english/news_e/news10_e/trip_16jul10_e.htm. Accessed on 29/03/2012.

million people are HIV positive and will need treatment, whilst 1.2 million were new people on treatment in 2009, but 2.6 million new infections.²²¹

It is crucial to note that sub-Saharan and East African regions have been worst afflicted by the HIV/AIDS pandemic, currently accounting as they do for at least 60% of the global HIV/AIDS infection rates²²² and making Africa the global epidemic centre.²²³ HIV/AIDS related diseases account for 500 million or more illnesses and 6 million deaths every year due to the fact that most of the African countries in the aforesaid regions including Zambia, cannot afford to purchase essential drugs offered at the patented price.²²⁴ As a result, patients have to purchase these high priced medicines on an out of pocket basis when unavailable in public hospitals a situation that has exacerbated an unequal global health system.²²⁵

Thus TRIPS's impact on the price of medicines raises questions as to whether there is really an immediate need for strong patent protection in resource-challenged African countries such as Zambia. This is because premature patent protection means pharmaceutical companies could use their devices discussed above, to maintain the exorbitant pricing of medicines and this has human rights implications²²⁶ predominantly through the limitation of national state sovereignty to ensure

²²¹ Presentation by E.F. M 't Hoen "The Medicines Patent Pool Understanding the Patent Status of Antiretroviral Drugs. Medicines Patent Pool WHO-WIPO-WTO Symposium": February 18, 2011. Available online at http://www.wto.org/english/tratop_e/trips_e/techsymp_feb11_e/t_hoen_18.2.11_e.pdf. Accessed on 02/04/2012. Hereinafter referred to as t'Hoen Medicines Patent Pool WHO-WIPO-WTO Symposium (2011).

²²² Global Report on HIV/AIDS Regions. Available online at: <http://www.unaids.org/en/regionscountries/regions/easternandsouthernafrika/>. Accessed on 23/02/2012. Hereinafter referred to as Global Report on HIV/AIDS Regions (UNAIDS).

²²³ Ibid.

²²⁴ WHO global price reporting mechanism report,(May 2010). Available online at <http://www.who.int/hiv/amds/en/>. Accessed on 24/04/2012 . See also Untangling the web of antiretroviral price reductions. Geneva, Medecins sans Frontières. Available online at: <http://utw.msfacecess.org/drugs>. Accessed on 23/02/2012.

²²⁵ ZAMBIA: 'Third-Line ARVs Available Soon'. (PlusNews/IRIN) AfricaFiles 7th MARCH 2011. Note 82 above. See also M. L. Mellino (2010). The TRIPS Agreement: Helping or Hurting Least Developed Countries'Access to Essential Pharmaceuticals? Fordham Intell. Prop. Media. Entertain. Law J. 20:1349-1388.

See also L. O. Gostin, G. Ooms, M. Heywood, J. Ha_eld, S. Møgedal, J. Røttingen, E. A. Friedman, and H. Siem —The Path to Universal Coverage Health Systems Financing World Health Report (2010) Background Paper, 53 The Joint Action and Learning Initiative on National and Global Responsibilities for Health © World Health Organization, 2010. Available online at: <http://scholarship.law.georgetown.edu/facpub/472/> SSRN: <http://ssrn.com/abstract=1714604>. Accessed on 23/02/2012 Hereinafter referred to as World Health Report (2010).

See also Z.A. Zainol1, L. Amin, K. Jusoff, A. Zahid & F. Akpoviri: 'Pharmaceutical patents and access to essential medicines in sub-Saharan Africa'. *African Journal of Biotechnology* Vol. 10(x), pp. 12376-12388, 30 September, (2011) ISSN 1684-5315 © 2011 Academic Journals Available online at <http://www.academicjournals.org/AJB> accessed on 22/01/2012. Hereinafter referred to as Pharmaceutical patents and access to essential medicines in sub-Saharan Africa' (2011).

²²⁶ H. V Hogerzeil. & Mirza. Z GENEVA 2011 WHO/EMP/MIE/2011.2.10. The World Medicines Situation (2011) Access to Essential Medicines as Part of the Right to Health. Available online at: <http://apps.who.int/medicinedocs/documents/s18772en/s18772en.pdf> accessed on 22/01/2012. Hereinafter referred to as Hogerzeil & Mirza (2011).

access to affordable essential medicines.²²⁷ Access to medicine as a human right to health will be discussed at length in the following chapter.

On the other hand and in light of TRIPS' impact on the prices of ARV drugs, the WTO has illustrated its commitment to improving access to patented essential medicines in developing and least developed African nations by promoting the use of TRIPS flexibilities provided for under various provisions inter alia, Articles 7, 8.1, 8.2, 27, 29, 30, 31 and 40.2 of the TRIPS Agreement.

The first category of TRIPS flexibilities to be discussed later in this chapter is known as the post-grant flexibilities and these limit patent rights of patent right holders after a patent has been granted. These are inter alia; limits on data protection or framework²²⁸ exceptions to patent rights, mainly scientific research or experimental use and early working or bolar exception;²²⁹ parallel importation [is a flexibility contingent on the legal adoption into national law of a concept known as exhaustion of rights which has been discussed under item 3.4.2 of this chapter]; competition law and lastly compulsory licensing.

The second category of flexibilities to be discussed later in this chapter is known as the pre-grant TRIPS flexibilities in terms of Articles 27 and 29 of the TRIPS Agreement and these are mechanisms that could be used as exemptions to patentability before patent protection is granted to a particular patent right holder or applicant²³⁰ to allow a third party applicant such as a government or generic

²²⁷ Correa (2008) Note 187 above.

²²⁸ TRIPS Agreement Article 7 Objectives. See Note 190 above. TRIPS aims to enforce measures that promote the protection and enforcement of technological innovation and social-economic welfare. See also TRIPS Agreement: SECTION 7: PROTECTION OF UNDISCLOSED INFORMATION Article 39.3 "requires the protection of such data only from unfair commercial use". See also Musungu & Oh Note 195 above.

²²⁹ TRIPS Agreement Article 30 'Exceptions to Rights Conferred' states that: "Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties". See also *Roche Products Inc. vs. Bolar Pharmaceutical Co.* A733 F.2d 858; 221 U.S.P.Q. 937 Appeal No. 84-560. Available online at: <https://bulk.resource.org/courts.gov/c/F2/733/733.F2d.858.84-560.html>. Accessed on 08/01/2013. This US case dealt with the exception in Article 30 of the TRIPS Agreement, from which the name Bolar exception was extracted. See also IMPROVING ACCESS TO MEDICINES IN THAILAND: The use of TRIPS flexibilities Report of a WHO Mission Bangkok, 31 January to 6 February 2008. Available online at: <http://www.moph.go.th/hot/THAIMissionReport%20FINAL15feb08.pdf>. Accessed on 15/12/2011. Hereinafter referred to as, WHO Mission on the use of TRIPS flexibilities Bangkok, 31 January to 6 February 2008. "...the regulatory review or (Bolar) exception, which allows generic manufacturers to make use of a patented substance before the actual date of expiry of the patent for the sole purpose of obtaining marketing approval for that product."

See also Musungu & Oh *Ibid*, Note 195 above.

²³⁰ TRIPS Agreement Article 29 'Conditions on Patent Applicants' require that: "Members to provide for sufficiently clear and complete disclosure of an invention when submitting a patent application". Article 29.1, allows "Members to require the applicant to indicate the best mode known to the applicant for carrying out the invention." for a detailed discussion of Article 27 refer to item 3.4.3 of this chapter.

drug producing company to prevent patent registration on products and allow production of pharmaceutical products.

In addition the Doha declaration on TRIPS and public health has elaborated on the use of TRIPS flexibilities and circumstance under which Members may invoke such use with minimal or no opposition.²³¹ Therefore most TRIPS flexibilities can be used in conjunction with other acceptable mechanisms not related to IPRS to improve the availability and affordability of medicines chiefly ARV drugs on condition that such use is not in conflict with the TRIPS Agreement.²³² The WHO Mission on the use of TRIPS flexibilities Bangkok, 31 January to 6 February 2008, suggested some non-patent related cost-effective government mechanisms pertinent to this study. These are as follows:

(a) National/social health insurance and prepayment systems - this could be provided through various models ranging from government funded schemes; to for-profit and private companies provision of health insurance for all. This would have the effect of guaranteeing ordinary citizens sustained access to medicines through health insurance as a distinct facet of the national health system, and as part of the right to health.

(b) Price information - this refers to national procurement of cost-effective medicines through the establishment of transparent pricing information at national level all the way through to the dispensaries.

²³¹ DOHA WTO MINISTERIAL 2001: TRIPS WT/MIN (01)/DEC/220 November 2001 Declaration on the TRIPS Agreement and Public Health adopted on 14 November 2001. Available online at: http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm. Accessed on 23/09/2011. Hereinafter referred to as the Doha declaration.

²³² See Paragraph 4 of the Doha declaration which states as follows: "we agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the 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. In this connection, we reaffirm the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose."

See also Paragraph 5 of the Doha Declaration states as follows: Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include: (a) In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles (b) each member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted. (c) each member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency. (d) the effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4.

(c) Patent pooled purchasing of medicines²³³ - this refers to the purchase of medicines by countries in the same economic bracket and the same needs regarding access to medicines and that have good relations. The patent pool has been endorsed by the WTO as way of reducing the cost of medicines that governments spend individually. ²³⁴

(d) Voluntary licensing - these have been extensively discussed under item 3.4.1.5 below.

(e) Local state production-this refers to the development of government owned pharmaceutical drug manufacturing companies to facilitate low prices for medicine and negotiations with manufacturers of brand names drugs for price discounts.

(f) Government price controls-these have been described as mechanisms that allow the subsidization of essential drugs by charging high on non-essential drugs.

(g) Reduction of import and other taxes for essential medicines, and rational dispensing practices.²³⁵

Thus the Doha declarations' interpretations of TRIPS flexibilities and the non-patent related cost-effective government mechanisms cost effective mechanisms as suggested by the WHO Mission on the use of TRIPS flexibilities Bangkok, 31 January to 6 February 2008, are examined below to ascertain what they entail for Zambia on the issue of accessing patented ARV drugs as discussed in chapter one of this dissertation.

3.3. THE DOHA DECLARATION ON TRIPS AND PUBLIC HEALTH

3.3.1. Background issues that led to Doha

Some of the issues that led to the Doha ministerial conference on TRIPS and Public Health included, for example, controversial global developments such as South Africa's health legislation that

²³³ "An analysis by think tank Results for Development concluded that the Medicines Patent Pool as established by UNITAID could speed up development of fixed-dose combination pills, paediatric medicines and heat stable formulations needed in resource-poor settings, as well as help stimulate generic manufacture of lower cost medicines. And that it will need a critical mass of companies to participate in order to succeed." Results for development: Final report on the Medicines patent pool. Available online at: <http://www.medicinespatentpool.org/results-for-development-final-report-on-patent-pools/>. Accessed on 21/04/2012.

²³⁴ t'Hoen Medicines Patent Pool WHO-WIPO-WTO Symposium (2011) Note 221 above.

²³⁵ WTO Trade Policy Review (2009) on Zambia Note 169 above. "In Zambia's context "a number of goods may be imported into Zambia duty free, including medicines, pharmaceuticals, and medical equipment"

endorses parallel importation of patented drugs,²³⁶ USA²³⁷ governments' sessions initiated with the WTO against Brazil²³⁸, as well as Canada's²³⁹ intentions to supersede Bayer a German pharmaceutical company's patent rights in order to stock-pile on antibiotics used in the treatment of anthrax in the face of fears of a possible outbreak.²⁴⁰ These global developments, inter alia, brought to the fore the world-wide uncertainties about the use of various TRIPS flexibilities, in particular compulsory licensing of which the use of patented medicines produced under these licenses in developing nations was predominantly for the domestic supply Article 31 of TRIPS.²⁴¹ Thus governments' and non-governmental demands in developing countries world-wide for the proper interpretation of TRIPS flexibilities²⁴² resulted in the declaration on TRIPS and Public Health at the WTO's fourth Ministerial Conference held at Doha in Qatar, on 14th of November 2001.²⁴³

3.3.2. Resolutions in the Doha declaration on access to ARV drugs for poor WTO countries

Although the text of the Doha declaration comprises seventeen paragraphs in total, the scope of this chapter is confined to the analysis of paragraphs related to resolving the issues of public health and access to medicines in poor nations.

²³⁶ Medicines and Related Substances Control Amendment Act No. 90 of 1997. Available online at: <http://www.doh.gov.za/docs/legislation/acts/1997/act90.pdf>. Accessed on 27/01/2012. Hereinafter referred to as the South African Medicines Act of 1997 and extensively discussed later in this chapter.

²³⁷ Bradsher. K & Andrews E. L., 'US says Bayer will cut the cost of its anthrax drug.' New York Times 24 October 2001. Available online at: <http://www.nytimes.com/2001/10/24/business/a-nation-challenged-cipro-us-says-bayer-will-cut-cost-of-its-anthrax-drug.html>. Accessed on 24/02/2012. "Although the US government threatened to follow Canada's conduct, it managed to settle a compromise arrangement with Bayer."

²³⁸ Measures Affecting Patent Production- Request for Consultation by the United States WT/DS199/1. See also Brazil- Measures Affecting Patent Protection- Request for the Establishment of a Panel by the United States, WT/DS199/3. Available online at: http://www.wto.int/english/tratop_e/trips_e/ta_docs_e/6_tabledscases_e.pdf. Accessed on 24/02/2012. Hereinafter referred to as USA v Brazil.

²³⁹ A. Harmon & R. Pear, 'Canada overrides patent for Cipro to treat Anthrax,' New York Times 19 October 2001. Available online at: <http://www.nytimes.com/2001/10/19/business/19CANA.html?pagewanted=all>. Accessed on 24/02/2012. "Relying on the anthrax outbreak threats Canada responded by superseding German pharmaceutical company Bayer's patent and ordered a million tablets of the generic version of the anti-biotic in question from a Canadian pharmaceutical company."

²⁴⁰ WTO News, 'Governments share Interpretations on TRIPS and Public Health,' TRIPS Council Wednesday 20 June 2001. Available online at: http://www.wto.org/English/news/etrips_drugs_010620_hm. Accessed on 01/03/2012.

²⁴¹ TRIPS Agreement Article 31 "Other Use Without Authorization of the Right holder" states that: "Where the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected... (f) any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use..."

²⁴² S.R Sekalala. Beyond Doha: 'Seeking Access to Essential Medicines for HIV/AIDS through the World Trade Organization'. Available online at <http://siteresources.worldbank.org/INTRAD/Resources/SSekalala.pdf>. Accessed on 07/09/2010. Hereinafter referred to as Sekalala.

²⁴³ See Note 235 above.

To begin with, Paragraph 3 of the Doha declaration affirmed the TRIPS Agreement's significant impact on intellectual property rights protection and specifically the impact of patent rights on the prices of medicines for the development of new medicines.²⁴⁴ Accordingly the Doha declaration in terms of Paragraph 7 (which has already been discussed in the introductory paragraphs of this chapter) gave leeway to least developed nations such as Zambia to improve access to medicines during the transition periods under Article 66 of the TRIPS Agreement. However, the substantive analysis of the Doha declaration which follows will focus on Paragraphs 4, 5 and 6 to ascertain how these assertions could be used in conjunction with existing patent laws in WTO Members to override patent protection and increase access to ARV drugs.

Paragraph 4²⁴⁵ of the Doha declaration awards wide discretion to countries to take all necessary legal measures to protect public health including the granting of compulsory licensing. Moreover, the phrase "access to medicines for all" in the text of paragraph 4 resolves the conflict of interest between patent protection and access to essential drugs, in that, public health can and will overrule patent protection.²⁴⁶

Paragraph 4 requires that TRIPS should be interpreted and implemented in a manner that respects "Member's rights to protect public health and in particular access to medicine for all". With regard to the latter statement, Sekalala has argued that whilst implementation of TRIPS flexibilities is a national issue, it is not immune from external pressure that could restrict the implementation thereof.²⁴⁷ A good example of external pressure is the TRIPS-plus provisions in free trade agreements devised by the USA government these are discussed later in this chapter.

Paragraph 5 refers to the mechanisms established and elaborated in the Doha declaration. In view of the growing use of compulsory licenses in developing countries,²⁴⁸ Paragraph 5(b) and (c) affirm that

²⁴⁴ Paragraph 3 of the Doha declaration states that: "We recognize that intellectual property protection is important for the development of new medicines. We also recognize the concerns about its effects on prices."

²⁴⁵ Paragraph 4 of the Doha declaration Note 231 above.

²⁴⁶ Sekalala Note 242 above. See also Carlos M Correa, 'Implications of the Doha Declaration on the TRIPS Agreement and Public Health,' World Health Organisation Publications June 2002. Available online at: http://www.who.int/medicines/areas/policy/WHO_EDM_PAR_2002.3.pdf. Accessed on 24/04/2012.

²⁴⁷ Ibid.

²⁴⁸ WTO: 2011 news items 23 November 2011 Intellectual Property: TRIPS and public health 10-year-old WTO declaration has reinforced health policy choices, Lamy tells symposium. Available online at: http://www.wto.org/english/news_e/news11_e/trip_23nov11_e.htm. Accessed on 24/01/2012.

See also Flexibilities in the context of the Development Agenda. Available online at: http://www.wipo.int/ip-development/en/agenda/flexibilities/flex_dev_agenda.html. Accessed on 24/01/2012.

Members have the sovereign right to determine what constitutes a national emergency.²⁴⁹ Thus the Doha declaration broadened the grounds upon which Members may grant compulsory licenses. Some of these broad grounds are extensively deliberated later in this chapter. Finally, Paragraph 5(d) endorses the use of parallel importation for purposes of accessing essential medicines.²⁵⁰

Despite the above elaboration on the use of TRIPS flexibilities in the Doha declaration, Article 31(f) of TRIPS still had a restrictive impact on access to medicine, in that it prohibited the importation of medicines produced under compulsory licensing as they were “predominantly for the domestic supply” of the producing Member.²⁵¹ Thus the Council of Ministers at Doha advised the TRIPS council to find an expeditious solution²⁵² to assist disadvantaged countries with diminutive or no manufacturing capacity to import pharmaceutical drugs produced under compulsory licensing. The result was the adoption of a waiver of the provision in Article 31(f) of TRIPS²⁵³ and the first instance of an amendment of a fundamental WTO Agreement.²⁵⁴ The waiver of Article 31(f) of TRIPS resulting from the decision of the General Council of 30th of August 2003 to implement ‘Paragraph 6’ of the Doha declaration states:

The obligation of an exporting Member under Article 31(f) of the TRIPS agreement shall be waived with respect to the grant by it of a compulsory licence to the extent necessary for the purposes of production of pharmaceutical product(s) and its export to an eligible importing Member(s) in accordance with the terms set out below in this paragraph.²⁵⁵

The waiver of Article 31(f) in the TRIPS Agreement was welcomed by the WTO Director-General (DG) Pascal Lamy²⁵⁶ and by the Kenyan ambassador and the chairperson of the WTO General Council Amina Mohamed.²⁵⁷ However, it has been criticised as being too cumbersome and as having

²⁴⁹ Paragraph 5 of the Doha Declaration Note 231 above.

²⁵⁰ Sekalala Note 242 above.

²⁵¹ See Note 241 above.

²⁵² Paragraph 6 of the Doha Declaration states that: “We recognize 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. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.”

²⁵³ Implementation of Paragraph 6 of the Doha Declaration on TRIPS Agreement and Public health WT/L/540 and Corr.1 1 September 2003. Available online at: http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm. Accessed on 23/08/2011. Hereinafter referred to as the decision of the general council of 30th of August 2003.

²⁵⁴ Members OK amendment to make health flexibility permanent 6 December 2005. Available online at http://www.wto.org/english/news_e/pres05_e/pr426_e.htm. Accessed on 24/02/2012. See also Sekalala Note 242 above.

²⁵⁵ Paragraph 2 of the 30th of August 2003 WTO general council's decision. Note 220 above.

²⁵⁶ WTO: 2005 Press Releases Press/426 of 6 December 2005 on Intellectual Property. Available online at: www.wto.org/english/news_e/pres05_e/pr426_e.htm. Accessed on 01/09/2010.

²⁵⁷ Ibid. Was quoted as follows; “The main benefit of the decision is to ensure that the African nations have access to affordable medicines and that they are able to drive the price of the pharmaceuticals to an even lower level.”

the negative impact of delaying the urgent supply of essential medicines, in LDCs.²⁵⁸ Moreover since 2003 to date, only one LDC country, namely Rwanda,²⁵⁹ has utilised the decision of the General Council to import ARV drugs from Canada.²⁶⁰

Based on this one country experience, Weber and Mills have argued that the decision of the General Council of 30th August 2003 raises issues of practicality in other LDCs and thus most LDCs are reluctant to utilise it to access ARV drugs.²⁶¹ However, it can be argued that the decision of the General Council of 30th of August 2003 might facilitate access to medicines if LDCs use it in relation to the parallel importation provision available under Article 6 of the TRIPS agreement. These possibilities are dealt with later in this chapter.

Following on from the above discussion and in view of Zambia's current protection of patents rights,²⁶² the section below discusses the select 'viable' TRIPS flexibilities that Zambia could use relying on some provisions currently available in its Patent Act and those that it could adapt into its national laws for purposes of increasing its domestic supply of ARV drugs as an important aspect of the human right to health.

It is crucial to note that the use of some of the selected mechanisms have proven to be difficult in reality²⁶³ as will be demonstrated by different country experiences where applicable. However it will

²⁵⁸ A. Weber; L. Mills "A one-time-only combination: Emergency medicine exports under Canada's access to medicine." *Health & human rights an international Journal* Vol. 12(1) 2010 at Available online at: <http://www.hhrjournal.org/index.php/hhr/article/view/209/303>. Accessed on 18/04/2012. Herein after referred to as, Weber & Mills. See also. L. MacInnis (Geneva 2007) 'Rwanda launches key Test of WTO drug waiver' available at <http://www.reuters.com/article/2007/07/20/idUSL20880687>. Accessed on 18/04/2012; See also *Medicins sans frontiers (MSF) 'Amendment to WTO TRIPS Agreement makes access to affordable medicines even more bleak'* (December 6th 2005). Available at: <http://www.doctorswithoutborders.org/press/release.cfm?id=1640> or www.msf.org. Accessed on: 24/04/2012.

²⁵⁹ Notification under Paragraph 2 (c) of the decision of 30th August 2003 on the Implementation of Paragraph 6 of the Doha Declaration on TRIPS and Public Health. IP/N/10/CAN/1 4 October 2007. Available online at www.wto.org/english/news_e/...e/canada_notification_oct_e.doc. Accessed on 03/03/2012.

²⁶⁰ Musungu & Oh Note 195 above.

²⁶¹ Weber & Mills Note 258 above. See also MacInnis Note 258 above. See Also B. K Baker "Athritic Flexibilities For Accessing Medicines: Analysis of WTO action regarding Paragraph 6 of the Doha Declaration on TRIPS Agreement and public health (2004). Available online at: <http://www.healthgap.org/tools/papers.html>. Accessed on 24/04/2012.

²⁶² See text on pages 36-39 of this chapter.

²⁶³ World Health Assembly Resolution 61.21. Geneva, WHO. World Health Organization (WHO) 2008a. Global strategy and plan of action on public health, innovation and intellectual property. Available online at: http://www.who.int/gb/ebwha/pdf_files/A61/A61_R21-en.pdf. Accessed on 04/01/2012 .The World Health Assembly (WHA), guide lines on intellectual property and access to medicine, in resolution WHA61.21, requested the Director-General of the world health organization (WHO): "To provide... in collaboration with other competent international organizations, technical and policy support to countries that intend to make use of the flexibilities contained in the agreement on Trade-Related Aspects of Intellectual Property Rights and other international agreements in order to

be argued that with adequate legal preparation Zambia could use some of the selected flexibilities to its advantage.

3.4.SELECT “VIALE” POST-GRANT AND PRE-GRANT TRIPS FLEXIBILITIES TO IMPROVE ACCESS TO ARV DRUGS IN ZAMBIA

This section’s analysis will focus on the post-grant flexibilities of compulsory licenses and parallel importation and the pre-grant flexibility of exemption to patentability as potential viable flexibilities in LDCs specifically in the current Zambian patent legal system.

Subsequently an account of the external pressures, particularly free trade agreements (FTAs) containing TRIPS-plus provisions which threaten the absolute use of TRIPS flexibilities adopted by WTO Members for purposes of accessing ARV drugs will be given.

3.4.1. Compulsory licenses and grounds amounting to granting thereof

According to the WTO, “compulsory licensing is when a government issues a license to itself or companies for purposes of local production or importation of patented products or processes without the consent of the patent owner.”²⁶⁴ In other words a compulsory license is an unrestrained license between a disposed buyer and an indisposed seller. The use of compulsory licenses is also subject to the entitlement of the patent right holder to receive remuneration, or what is termed as a royalty fee.²⁶⁵ Thus the two main ways of issuing compulsory licenses are through:

- (i) A court or administrative tribunal may issue a licence in response to an application made by an interested party, such as a generic manufacturer that imports medicines or the state may issue a licence to itself or to companies that import and or;

promote access to pharmaceutical products.” See also M. Palmedo UN Report Recommends Greater Use of TRIPS Flexibilities for Access to Medicines March 17, (2011) <http://infojustice.org/archives/1822>. Accessed on 24/01/2012.

²⁶⁴ TRIPS And Health: Frequently Asked Questions : Compulsory licensing of pharmaceuticals and TRIPS. Available online at: http://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm Accessed on 07/01/2013. See also Article 31(f) Note 241above. See also Health and Democracy (2010). Available online at: <http://www.section27.org.za/wp-content/uploads/2010/04/Chapter14.pdf>. Accessed on 30/03/2012. Hereinafter referred to as, Health & Democracy: Access to Medicines (2010). “Generally, compulsory licenses are non-voluntary licenses that allow the generic use of a patented invention through importation or local production of the end product or the process of producing a product by either the state or private companies”.

²⁶⁵ TRIPS Agreement Article 31 (h) states that: “the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization...”

(ii) The manufacture generic medicines also called "government-use licences".²⁶⁶

Although the Doha declaration has emphasized that governments across the globe are unregimented to determine the grounds upon which they can grant compulsory licenses,²⁶⁷ the jurisprudence on the TRIPS Agreement has mentioned a number of probable policy spaces upon which compulsory licenses may be granted these are; refusal to deal,²⁶⁸ dependent patents, failure to exploit or insufficient working of a patent, public interest and anti-competition.²⁶⁹ Thus as discussed later in this section, taking note of Zambia's issue of a compulsory license in 2004 for the local production of ARV drugs for a period of five years, it is crucial that the government explores supplementary grounds to issue compulsory licenses on. These grounds are discussed as follows:

3.4.1.1. Refusal of a license or refusal to deal

This ground permits a Member (government) or third party to issue a compulsory license after prior negotiations²⁷⁰ with regard to obtaining a voluntary license on reasonable commercial terms from the patent right holder have failed. Nevertheless, the requirement of prior negotiations can be waived in the case of public non-commercial or government use or in emergency situations. The latter waivers are discussed in turn under the two succeeding headings:

3.4.1.1.1. Public non-commercial use or government use

A compulsory license or government-use license permitting a particular government department or contractor to utilize a patented invention for 'public non-commercial' use and without the permission of the patent right holder is known as a government use order or authorization.²⁷¹ However the meaning of 'public non-commercial use' has not been defined in the TRIPS Agreement.²⁷² Therefore,

²⁶⁶ TRIPS Agreement Article 31 See Note 241 above. See also Health and Democracy: Access to Medicines (2010) Note 264 above.

²⁶⁷ Paragraph 5 (b) of the Doha Declaration Note 231 above.

²⁶⁸ Jaktar Note 209 above. "Refusal to deal, as a ground for granting a compulsory license, has been provided in many national laws, such as the patent laws of China, Argentina and Israel."

²⁶⁹ TRIPS Agreement Article 31(f) Note 241 above. See also WHO Mission on the use of TRIPS flexibilities Bangkok, 31 January to 6 February 2008 Note 229 above. See also Jaktar Note 209 above. See also Musungu & Oh Note 195 above. See also Avafia, Berger & Hartzenberg Note 200 above.

²⁷⁰ TRIPS Agreement Article 31 (b) 'Other Use without Authorization of the Right Holder' states that "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."

²⁷¹ TRIPS Agreement Article 31 (b) states that... "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".

²⁷² See TRIPS Agreement Note 55 above.

as indicated by Jaktar, governments remain subjected either to the “rules of interpretation²⁷³ or, in “the disposition of the transaction or the purpose of the use of the patent”. This means that, with regard to the transaction or license itself, the government must not yield any profit from such use, while, as far as the purpose of the use is concerned, the patented invention must not be commercially exploited.²⁷⁴

Government-use provisions in terms of the Zambian patent Act ²⁷⁵ are provided for under Section 40 which “authorises the government or any party acting on its behalf to use a patented invention without the patent owner’s permission excluding the payment of royalties in certain instances.”²⁷⁶ The use of this provision by WTO governments is advantageous in that it is a fast-track process as it negates usual conditions of obtaining a compulsory license such as prior negotiations for a voluntary license with patent right holder, obtaining permission from or informing the patent right holder of the use of such a license by a particular government.

On the other hand it is crucial to note that governments are required under TRIPS’ Article 31(h) to pay adequate remuneration or a royalty fee to the patent right holder and to ensure that the production of medicines under such a license is for public non-commercial purposes in terms of Article 31 of TRIPS. Due to the less onerous conditions required in the process of obtaining a government use license for the manufacture of medicines the Zambian government issued such a license in 2004. However the process of granting this license seemed flawed despite Zambia’s legal preparedness with regard to existing provisions in its Patent Act and the regulatory frameworks being available. A review of Zambia’s issue of a government use compulsory license will be discussed in section 3.4.1.1.2 below.

²⁷³ Jaktar Note 209 above. See also the Vienna Convention on the Law of Treaties which instructs nations as a general rule of interpretation, to interpret a treaty, “in good faith in accordance with the ordinary meaning given to the terms” Article 31 of the Vienna Convention. Available online at: http://untreaty.un.org/ilc/texts/instruments/english/conventions/1_1_1969.pdf. Accessed on 04/01/2012.

²⁷⁴ Ibid.

²⁷⁵ The Zambian Patent Act Note 33 above “regulates the granting of protection for inventions in Zambia and does not except any area of technology.”

²⁷⁶ Section 40(1) provides that: “Notwithstanding anything in this Act, any Government department or any person ‘authorised in writing by the Minister may make, use or exercise any invention disclosed in any specification lodged at the Patent Office for the service of the State in accordance with the provisions of this section.”

3.4.1.1.2. Cases of extreme urgency or national emergencies

This waiver involves situations where a Member government, prior to issuing a compulsory license, declares a particular situation (for instance HIV/AIDS) as a national disaster. Other situations might be the outbreak of war, natural disasters or catastrophes.²⁷⁷ However, neither the TRIPS Agreement nor the Doha declaration requires Members to first declare a national disaster prior to the granting of a compulsory license.²⁷⁸ Thus provisions under national law encompassing the grant of a compulsory license during cases of extreme urgency and a notification of the grant of a compulsory license to the patent right holder as soon as it practicably can be sent are sufficient for Members to grant compulsory licenses.²⁷⁹ However, most African countries including Zambia, have issued government-use compulsory licenses by declaring a national disaster beforehand.²⁸⁰ Zambia's first issue and only of a compulsory license for the local production of ARV drugs dates back to September 2004. Accordingly government use provisions are provided for under Section 41 of the Zambian Patent Act. Section 41 authorises the:

Minister of State to declare a period of emergency under which the Zambian government or any authorised party is permitted to exploit and vend the patented invention for purposes of maintaining or securing of supplies and services essential to the life and well-being of the community.²⁸¹

This provision, like Paragraph 5(b) and (c) of the Doha declaration, legally empowers the Zambian government with full discretion to determine which situations amount to such emergencies. Furthermore its wording has inbuilt broad policy spaces designed to allow the Zambian government to apply whatever steps it considers expedient when dealing with public health emergencies in this instance access to ARV drugs. These policy spaces allowed Zambia to issue a compulsory license in 2004 after the late former President Levy Mwanawasa made a declaration that the HIV/AIDS

²⁷⁷ Avafia, Berger & Hartzberg Note 200 above.

²⁷⁸ Ibid.

²⁷⁹ Ibid

²⁸⁰ Ibid. See also Section 37 of the Zambian Patent Act provides for compulsory licences under the following grounds:

- a) no satisfactory reason for the non-working of a patent;
- b) inadequate working of the patent on a commercial scale by the patentee;
- c) not meeting the demand for the patented article on reasonable terms or in adequate amounts;
- d) anti-competitive behaviour by the patentee; and
- e) the unreasonable refusal by the patentee to license the patent to a third party on reasonable grounds.

²⁸¹ Sectio Note 33 above.

situation in Zambia was a national emergency.²⁸² This declaration of HIV/AIDS as a national disaster²⁸³ constituted a valid ground upon which the Minister of Commerce, Trade and Industry relied in granting a compulsory license²⁸⁴ for the local production of a Triple-dose of ARV drugs for a period of 5 years.²⁸⁵ Nevertheless Avafia, Berger and Hartzenberg have argued that, there was no need for Zambia to declare a national emergency prior to the issue of the compulsory license.²⁸⁶ Furthermore Zambia allocated a royalty fee of 2.5% to the patent right holding drug firms when the drugs in question were not under patent protection in Zambia and when it need not have awarded royalties.²⁸⁷

It thus emerges that even though Zambia may well have some legal preparedness in its domestic frameworks to permit access to ARV drugs, the procedure to be followed in executing such provisions has not been appropriate. Neglecting the legal procedures to be followed in the granting of compulsory licenses could cause unnecessary delays in the local production and later on importation of ARV drugs thereby restricting access to medicines.

Moreover Zambia's awarding of a 2.5% royalty fee for local production of unpatented drugs illustrates that the functions of the legal and regulatory frameworks are not working in concurrence. In this instance the two bodies which should have worked in coalition are the Patents and Companies Registration Office (PACRO), the regulatory body for registration of patents in Zambia²⁸⁸ and the

²⁸² See ZAMBIA: 'Third-Line ARVs Available Soon'. (PlusNews/IRIN) AfricaFiles 7th MARCH 2011 Note 82 above. NHSP 2006-2010 Note 23 above. See also UNGASS (2010) Note 69 above. See also GRZ &USG (2011-2015) Note 77 above. "High HIV/AIDS infections and most recently erratic access to ARV drugs previously underscored in chapter one, are the major challenges to the Zambian health system."

²⁸³ In terms of statutory instrument No.83 of 2004.

²⁸⁴ Compulsory License No. CL 01/2004. Available online at: <http://www.cptech.org/ip/health/cl/recent-examples.html>. Accessed on 22/01/2012.

²⁸⁵ Med links-Health News; 'Zambia grants 5-year compulsory license for generic ARV production': Thursday, September 23rd, 2004. Available online at: <http://medilinkz.org/news/news2.asp?NewsID=7922>. Accessed on 19/04/2010. "The Ministry of Commerce, Trade and Industry had granted the first compulsory licence under Statutory Instrument 83 of 2004 to Pharco Limited an Italian pharmaceutical manufacturing company incorporated in Zambia, to locally produce a triple-drug AIDS treatment containing Lamivudine, Stavudine and Nevirapine. The license gives a Zambian company permission to produce the triple-drug - without permission from international companies that own the patents. The Zambian company will pay royalties not to exceed 2.5 percent." Zambia Issues Compulsory License for AIDS Drug. Available online at: http://sippi.aas.org/ipissues/updates/?res_id=432. Accessed on 08/01/2013.

²⁸⁶ Avafia, Berger & Hartzenberg Note 200 above.

²⁸⁷ O' Carroll Note 204 above.

²⁸⁸ PACRO was an independent Agency of the Ministry of commerce and Trade Industry and it is responsible for the efficient and effective registration and protection systems for commercial and intellectual property rights in order to promote innovation and orderly trade for the benefit of the nation. Additionally, PACRO received its mandate in 2007 to ensure that it formulate policy to promote objectives that are in line with the world wide accepted ethical norms and values. Though the policy is still awaiting the governments' approval, it contains interesting features such as elaborate institutional, legal and monitoring and evaluation frameworks as well as the scope of protection for patents. Furthermore PACRO has taken up a multi-sectoral approach in its mandate to ensure proper protection of IP laws in Zambia by

Ministry of Commerce, Trade and Industry. These two bodies need to maintain track of which drugs are or are not under patent protection. This could be achieved by, inter alia, drawing up of an essential drugs list of patented and unpatented ARV drugs, to avoid costly mistakes that could restrict access to medicine in future.

3.4.1.2. Dependent Patents

A dependant patent has been described as, “a patent which cannot be exploited without infringing another”.²⁸⁹ This means that a compulsory licence “may only be granted on the earlier patent if the invention in the later patent involves an important technical advance or use of a dominant invention. In such a case, the owner of the earlier patent has a right to obtain a cross-licence for the later patent”²⁹⁰.

The latter could be interpreted to mean that, for instance, if a generic pharmaceutical drug manufacturing company develops and patents a highly effective medical drug for HIV/AIDS patients, which can only be stimulated by means of an earlier drug protected by an earlier patent, that generic pharmaceutical drug manufacturing company could seek the grant of a compulsory license, but normally only after attempting to negotiate a voluntary license on reasonable commercial terms with the originator pharmaceutical drug company (the patent right holder).

Thus in Zambia’s context, the ground of dependant patents could be used to issue compulsory licenses, in circumstances where the local generic manufacturing companies develop a combination

initiating an *ad hoc* committee, (comprising government Ministries, the University of Zambia and private sector organizations) to discuss the development of a national IP policy. PACRO’s ample success is owed to the overwhelming assistance it has received from the World Intellectual Property Organization (WIPO) since its inception. WIPO has assisted PACRO in its mission to conduct comprehensive assessments of compliance with legislation, the setting up of information-technology(IT) infrastructure to facilitate in the electronic registration of patents and in the training of IP office personnel including other officials crucial to the protection of patents, these officials include customs, police and judges of the courts. This Information available online on the PACRO website at: <http://www.pacro.org.zm/> accessed on 29/09/2010.

Today PACRO is known as the Patents and Companies Registration Agency (PACRA) http://www.pacra.org.zm/index.php?option=com_content&view=category&layout=blog&id=25&Itemid=85. Accessed on 28/02/2013.

²⁸⁹ Compulsory licensing and Data Protection. Available online at: http://trade.ec.europa.eu/doclib/docs/2006/may/tradoc_122031.pdf. Accessed on 07/01/2013.

²⁹⁰ The WTO TRIPS Agreement – A Practical Overview for Climate Change Policymakers. Available online at: http://www.wto.org/english/tratop_e/trips_e/ta_docs_e/8_3_overviewclimatechange_e.pdf. Accessed on 07/01/2013.

See also TRIPS Agreement Article 31 (l) states that: ... “the following additional conditions shall apply: (i) the invention claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent; (ii) the owner of the first patent shall be entitled to a cross-licence on reasonable terms to use the invention claimed in the second patent; and (iii) the use authorized in respect of the first patent shall be non-assignable except with the assignment of the second patent.”

of ARV drugs that are only effective when used with another advanced combination of ARVs which are unavailable in Zambia due to high prices. This could assist accelerating access to advanced regimens of ARV drugs discussed in chapter one.

3.4.1.4. Public interest

With regard to the ground of public interest, Musungu and Oh²⁹¹ have argued that although most Members have incorporated it into their patent laws as ground for issuing compulsory licenses, none of the Members have been able to strictly define what is in 'the public interest'. Nevertheless, Article 8.1 of the TRIPS Agreement could somewhat be regarded as a general delineate of what the ground of public interest entails as it provides that:

Members in formulating or amending their laws and regulations, adopt measures necessary to protect to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their economic and technological development provided that such measures are consistent with the provisions of this Agreement.²⁹²

Moreover the United Nations conference on Trade and Development had identified examples of sectors and situations that could be regarded as in the public interest, these include, "health, environment, economic development/defence or development of vital sector an economy, national security".²⁹³ This means that for purposes of this dissertation, a Member may use health reasons including restricted access to advanced ARV drugs as a ground for issuing compulsory licenses as it is in the interest of the public that governments protect public health by making essential drugs available and accessible. This is furthermore supported by the principle from the Indian case cited as *Roche vs. Cipla* in which the court held that when:

²⁹¹ Musungu & Oh Note 195 above. See also E. J Broster Access to Antiretroviral Drugs are there any Solutions? (Thesis 2010) Faculty of Law Howard College Campus University of Kwazulu-Natal (UKZN), available in the GMJ Sweeney Law Library Howard College Durban.

²⁹² See note 193 above.

²⁹³ TRIPS Post-Grant Flexibilities: Compulsory Licenses & Government Use Workshop on Flexibilities in International Intellectual Property Rules and Local Production of Pharmaceuticals for the Southern, Central and West African Region 7 – 9 December 2009, Cape Town Ermias Tekeste Biadgleng, Legal Expert, UNCTAD. Available online at: http://unctad.org/sections/dite_totip/docs/tot_ip_0021_en.pdf Accessed on 8/01/2013.

Public interest is weighed against the private interests of the right holder or [patent holding company] to fully exhaust its privileged rights, access to the patented product is considered more important than the private interests.²⁹⁴

Thus the ground of public interest could be used by the Zambian government to access medicines, including advanced regimens of ARV drugs, as it could be broadly interpreted within the provisions under section 41 previously discussed in this chapter. As well the current situation of a lack of advanced regimens of ARV drugs could serve as a ground for issuing another compulsory license for the importation or even the manufacture of advanced regimens of ARV drugs.

3.4.1.5. Anti-competitive compulsory/ voluntary licenses.

Competition law as a ground for issuing compulsory licenses by Member governments is probably the most convoluted ground to be relied upon in the area of access to medicines. This is because it is a non-patent related flexibility.²⁹⁵ It is considerably an interdisciplinary flexibility between economics (competition law) and IPRs (intellectual property law).²⁹⁶ Thus it raises the issue as to “whether an interface between competition law and the granting of compulsory licenses on the basis of rectifying anticompetitive practices and or refusal to deal purely or morally exists.”²⁹⁷

It has been argued by Jaktar²⁹⁸ that there are legitimate instances under which non-intellectual property rights compulsory licenses could be granted by WTO Members by means of rectifying anti-competitive practices that conflict with broader socio-economic rights issues particularly access to essential drugs. Such instances include the provisions in Article 40.2 of TRIPS, of which could be regarded as ‘guidelines’ that Members could employ in order to resolve the above interdisciplinary conflict between intellectual rights and competition law or policies.

²⁹⁴ *Roche Ltd & another Vs Cipla Ltd*, FAO (O.S.) No. 188/2008. Available online at: <http://www.internationallawoffice.com/newsletters/detail.aspx?g=09718e13-08f6-41d0-9499-2b3f8481cbe1>. Accessed on 22/02/2012 in which: “Roche [A Swiss patented drug manufacturing company] dragged vs. Cipla (an Indian generic drug manufacturing company) to the Delhi High court, alleging that *Cipla* infringed their patent rights over Tarceva, an anti-cancer drug sold as ‘Tarceva’. The judge, Justice Ravindra Bhat, refused to grant an interim injunction on the ground that since *Cipla* was selling the drug at one-third of the price of Roche, an injunction would have meant lack of affordable access for a large number of cancer patients in India. Therefore, “public interest” demanded that no injunction [restraining order] be granted. *Roche* then appealed to the Division Bench 27, whose order proved much more detrimental for Roche. Not only did the appellate bench uphold the key findings of the trial judge, it went on to impose costs on Roche for suppression of material patent information. It also went on to find that Roche had not established a prima facie case of infringement, since the patent in question did not seem to be implicated by *Cipla*’s generic product”. See also Jaktar Note 209 above on the discussion of the *Roche* case.

²⁹⁵ WHO Mission on the use of TRIPS flexibilities Bangkok, 31 January to 6 February 2008. Note 229 above.

²⁹⁶ Jaktar Note 209 above.

²⁹⁷ *Ibid.*

²⁹⁸ *Ibid.*

Article 40.2 states as follows:

Nothing in this Agreement shall prevent Members from specifying in their legislation licensing practices or conditions that may in particular cases constitute an abuse of intellectual property rights having an adverse effect on competition in the relevant market. As provided above, a Member may adopt, consistently with the other provisions of this Agreement, appropriate measures to prevent or control such practices, which may include *for example exclusive grant-back conditions, conditions preventing challenges to validity and coercive package licensing.*²⁹⁹

Thus Article 40.2 deals with abusive practices related to contractual licenses and allows Members to grant compulsory licenses based on three abusive scenarios, “*exclusive grant-back conditions; conditions preventing challenges to validity and coercive package licensing.*”³⁰⁰ Additionally the use of the wording ‘*for example*’ in Article 40.2 could be considered to mean that the nations are authorized to detect any other abusive practices that are regarded as anticompetitive within their national competition Acts.³⁰¹ This broadens the policy space for the granting of compulsory or voluntary licenses established in the Doha declaration³⁰² and has been corroborated by foreign international courts such those in the USA and European Union (EU).³⁰³

Furthermore Article 8.2 of the TRIPS Agreement has provided Members with the opportunity of addressing the control of anti-competitive practices in the area of pharmaceutical patents for public health reasons.³⁰⁴ Additionally Article 31 (k) provides that:

²⁹⁹ The emphasis in italics is the authors own.

³⁰⁰ The emphasis in italics is the authors own.

³⁰¹ Jaktar’s Note 209 above.

³⁰² Paragraph 5 (b) & (c) of the Doha declaration Note 231 above.

³⁰³ ‘tHoen Note 213 above discussed the -US Federal Trade Commission (FTC) vs. Ciba – Geigy HO, Ciba – Geigy Corp., Chiron Corp., Sandoz Corp. and Novartis AG. Docket No. C-3725 FTC File No. 961 005. Available online on the USA Federal Trade Commission Webpage: <http://www.ftc.gov/os/caselist/9610055.shtm>. Accessed on 23/02/2012. “USA’s position on compulsory licensing is that compulsory licenses for the benefit of private competitors are not favoured by the tradition of America statute law, except as sanctions for actual violation of the antitrust laws.”

See also ECJ ruling on the Joined cases C-501/06P, C-513/06P, C-515/06P and C-519/06P. GlaxoSmithKline services Unlimited formerly Glaxo Wellcome plc v Commission of the European Communities. Available online at: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:62006J0501:EN:HTML>. Accessed on 05/01/2013. This decision is the most recent example on the position in Europe – “the decision by the ECJ on October 06, 2009, overturned the decision of the European Commission, which found parallel trade and price differentiation practice of GSK in Spain as –an export ban and hence anti-competitive. The ECJ ruled that this parallel trade practice was not a restriction of competition, and goes on to distinguish the pharmaceutical sector on the ground that competition by innovation is fierce in this sector and that competition on price exists after patent expiry and the arrival of generic medicines.”

³⁰⁴ TRIPS Agreement Article 8 (2) states that: “Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.”

Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases.

Accordingly Jaktar argues that Article 31 (k) of TRIPS provides Members with remedial provisions against patent holding companies found guilty of anti-competitive practices, such as; “imposition of fines; regulation of prices; granting of voluntary and compulsory licenses; reduction or exclusion of payment of royalties to the drug manufacturing companies if grave anti-competitive practices are established.”³⁰⁵

Hence, the provisions in Articles 40.2, 8.2 and 31(k) of the TRIPS Agreement confirm that there is a link between IPRs and competition law. Despite the fact that most Competition Acts (including that of Zambia) excludes the application of competition law contracts to intellectual property rights,³⁰⁶ Members can integrate such wording in to their intellectual property legislation to precipitate the use of competition law as a non-intellectual property rights mechanism of accessing ARV drugs.³⁰⁷

However, Avafia, Berger and Hartzenberg have cautioned that; “these provisions should be interpreted in a manner that the dominant authority associated with intellectual property rights is not disproportionately compounded or regulated and overextended to the detriment of competition.”³⁰⁸ Therefore Members have to realize that, “the exercise of rights in a patent does not automatically give rise to what the law recognises as ‘anti-competitive’ a patent holder would have to abuse their patent rights before competition law has a role to play.”³⁰⁹

³⁰⁵ Jaktar Note 209 above. Further argues that, “Article 31(k) can be interpreted by Members to mean that they can bypass both the voluntary licensing requirements, and the requirement that production be primarily for the domestic market where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive.”

³⁰⁶ Ibid.

³⁰⁷ Zambian Competition and Consumer Protection (CCP) Act No. 24 of 2010. Available online at: http://www.parliament.gov.zm/index.php?option=com_docman&task=doc_view&gid=714. Accessed on 23/02/2012. Hereinafter referred to as the CCP Act of 2010.

Section 3(3)(a) of the Zambian Competition and Consumer Protection Act No. 24 of 2010 states that: “ the Act shall not apply to—an agreement or conduct insofar as it relates to intellectual property rights including the protection, licensing or assignment of rights under, or existing by virtue of, a law relating to copyright, design rights, patents or trademarks...”

See also O’ Caroll Note 204 above argues that; “in the very rare circumstance that a country issues a compulsory licence to combat anti-competitive conduct, Zambia could import unlimited quantities of the pharmaceutical in question (to the extent that it was available) from India under this provision.”

³⁰⁸Avafia, Berger & Hartzenberg Note 200 above.

³⁰⁹ Health and Democracy: Access to Essential Medicines (2010) Note 264 above.

3.4.1.5.1. The South African Competition Act and its bearing on access to cost-effective generic ARV drugs

The following case study serves as a good example to LDCs specifically Zambia as to how the policy space under competition law can be legitimately utilised to escalate access to patented ARV drugs. It is discussed here in order to determine whether competition policy can indeed offer concrete solutions to the issue of restricted access to ARV drugs in LDCs and specifically Zambia. The case study concerns South Africa's utilisation of its Competition Act to correct anti-competitive practices used by originator drug companies locally incorporated in South Africa to increase local production of generic ARV drugs.

The South African Competition Act provides three main regulatory mechanisms;³¹⁰ the Competition Commission, Competition Tribunal and the Competition Appeal Court. These regulatory frameworks and two mechanisms namely 'abuse of dominance' and 'restrictive practices' control the exploitation of rights in patents under the South African Competition Act. These regulatory frameworks and mechanisms under the South African Competition Act are discussed below to ascertain how they facilitated the South African governments' negotiations to obtain voluntary licenses and reduce the price of ARV drugs, escalating access to the drugs in question.³¹¹

Firstly the South African Competition Act prohibits the abuse of dominance³¹² - "this provision recognizes that there is not a problem with a drug manufacturing holding a dominant position in the market. However, it becomes a problem once drug companies abuse their dominant position, such as setting excessive prices."³¹³

For example prior and up to 2005 the ARV drug AmB in South Africa was locally marketed as fungizone in both the public and private at a higher price than what was being offered in other

³¹⁰ The South African Competition Act No. 89 of 1998. Available online at: http://www.saflii.org/za/legis/num_act/ca1998149.pdf. Accessed on 23/02/2012. The ACT states: "To provide for the establishment of a Competition Commission responsible for the investigation, control and evaluation of restrictive practices, abuse of dominant position, and mergers; and for the establishment of a Competition Tribunal responsible to adjudicate such matters; and for the establishment of a Competition Appeal Court; and for related matters".

³¹¹ Health and Democracy: Access to Essential Medicines (2010) Note 264 above.

³¹² Ibid. Chapter 2 Restrictive Practices: (PART B) ABUSE OF A DOMINANT POSITION Dominant firms: Section 7. A firm - is dominant in a market if - (a) it has at least 45% of that market; (b) it has at least 35%, but less than 45%, of that market, unless it can show that it does not have market power: or (c) It has less than 35% of that market, but has market power-.

³¹³ Ibid.

developing countries.³¹⁴ Using provisions on the prohibition of abuse of dominant position under the South African Competition Act the Treatment Action Campaign (TAC)³¹⁵ represented by the South African AIDS Law Project (ALP) in 2005, put pharmaceutical drug company Bristol-Myers Squibb (BMS) on conditions “to reduce its excessive prices for the generic version of ARV drug AmB, which at the time of the ALP started correspondences with BMS, was being offered at very low prices in comparable countries such as Brazil.”³¹⁶ Although this matter was not taken further such as to the Competition Commission later on the Competition tribunal the ALPs’ threats to pursue the matter legally through the competition legal frameworks compelled BMS to reduce the price of fungizone in South Africa by 80% in the public sector and 85% in the private sector.³¹⁷

Still on the issue of excessive pricing of medicines, the next case cited as *Hazel Tau and Others v GlaxoSmithKline and Boehringer Ingelheim*,³¹⁸ was successfully brought before the (Competition Commission) by a group of PLWHA and non-governmental organizations who collectively filed a complaint in terms of section 49B (2) (b) of the South African Competition Amendment Act³¹⁹ against pharmaceutical drug companies GlaxoSmithKline (GSK) & Boehringer Ingelheim (BI) in (2002).³²⁰ *Hazel Tau and others* (the complainants) alleged that the respondent engaged in anti-competitive practices of setting high prices for certain ARV drugs. These allegations were formulated around three main broad issues, “the prohibition of excessive pricing of medicine in terms of the Competition

³¹⁴ Guidelines for the Prevention, Diagnosis and Management of Cryptococcal Meningitis and Disseminated Cryptococcosis in HIV-infected patients. Available online at: <http://www.kznhealth.gov.za/medicine/cryptoguidelines.pdf> Accessed on 23/02/2012.

³¹⁵ The Treatment Action Campaign (TAC), South Africa’s largest and most effective organization advocating for the rights of people living with HIV/AIDS (PLWHAs), who are open about their status. For more information. Available online at: <http://www.tac.org.za/community/about> . Accessed on 23/02/2012.

³¹⁶ The correspondence between the ALP and BMS. Available online: <http://www.tac.org.za/Documents/AmphotericinB/bms.htm>. Accessed on 23/02/2012.

³¹⁷ Avafia, Berger & Hartzberg Note. 200 above. “Prior to being challenged by the TAC and ALP BMS’ retention of *de facto* exclusive rights on the generic version of AmB (Fungizone) caused it to offer a higher price for the drug under South Africa’s public sector, even though AmB was already off patent.”

³¹⁸ Competition Commission Case No. 2002 Sep 226. Available at www.info.gov.za/otherdocs/2003/aidsplan.pdf. Accessed on 22/08/2011.

³¹⁹ Section 49B. Initiating a complaint (1) The Commissioner may initiate a complaint against an alleged prohibited practice.

(2) Any person may –

(a) submit information concerning an alleged prohibited practice to the Competition Commission, in any manner or form; or

(b) submit a complaint against an alleged prohibited practice to the Competition Commission in the prescribed form.

(3) Upon initiating or receiving a complaint in terms of this section, the Commissioner must direct an inspector to investigate the complaint as quickly as practicable.

(4) At any time during an investigation, the Commissioner may designate one or more persons to assist the inspector. The South African Competition Amendment Act No. 1 of 2009. Available online at <http://www.compcom.co.za/assets/Files/Competition-Amendment-Act.pdf>. Accessed on 18/04/2012.

³²⁰ Hereinafter referred to as GSK & BI.

Act,³²¹ the public health emergency of HIV/AIDS in South Africa³²² and the constitutional principles of access to health services.”³²³ Thus Avafia, Berger and Hartzenberg explain that:

The structure of the complainants’ argument narrowed the alternative courses of action that they could have adopted in terms of the competition Act and some of issues that the respondents GSK& BI were likely to argue purely on competition policy, such as market definition and the determination of a dominant position by GSK & BI.³²⁴

Nevertheless, it took the Competition Commission a year to arrive at its findings that GSK & BI were abusing their exclusive rights by setting excessive prices for ARV drugs whilst preventing market entry of generic drug manufacturers.³²⁵ At the onset of December 2003 and within two months of the Commission's announcement of its referral of the matter to the Competition tribunal GSK & BI had entered into separate settlement agreements with the complainants.³²⁶ These voluntary licenses opened up the local generic market for competitors to commercially manufacture generic versions of patented medicines owned by GSK& BI for the first time in South Africa.³²⁷

The second ground for anticompetitive behaviour under the South African Competition Act is in terms of Section 4 ‘restrictive business practices’ and According Health and Democracy: Access to Essential Medicines (2010), ‘restrictive practices’ entail:

Conduct between companies who would normally be competitors that is intended to exclude other competitors and is not in the public interest because it usually leads to high prices. There are two types of restrictive practices that are prohibited under the Act, these are: Between companies or people in a *horizontal relationship* – a relationship between competitors and between parties in a *vertical relationship* – a relationship between a company and its suppliers, or between a company and customers.

³²¹ See Statement of Complaint at paragraph 107. Available online at: www.tac.org.za/Documents/DrugCompaniesCC/HazelTauAndOthersVGlaxoSmithKlineAndOthersStatementOfComplaint.doc. Accessed on 23/02/2012 .

³²² Avafia, Berger & Hartzenberg Note 200 above –The *Operational Plan for Comprehensive HIV and AIDS Care, Management and Treatment for South Africa* was adopted on 19 November 2003, some 20 days before the complainants entered into settlement agreements with both GSK and BI.

³²³ In terms of section 39(2) of the Constitution; “every court, tribunal or forum’, when interpreting any legislation ... must promote the spirit, purport and objects of the Bill of Rights.” The Constitution of the Republic of South Africa No. 108 of 1996. Available online at: <http://www.info.gov.za/documents/constitution/1996/a108-96.pdf>. Accessed on 08/03/2012. Hereinafter referred to as the South African Constitution. See also Avafia, Berger and Hartzenberg. Note 200 above.

³²⁴ Avafia, Berger & Hartzenberg Note 200 above.

³²⁵ See Statement of Complaint at paragraph 107. Note 321 above.

³²⁶ The settlement agreements with the complainants. Available online: <http://www.alp.org.za/modules.php?op=modload&name=News&file=article&sid=225>. Accessed on 23/02/2012.

³²⁷ Avafia, Berger & Hartzenberg Note 200 above.

With the above provision in place it means that competition cannot be prevented or restricted by drug manufacturing companies that have a dominant position in the pharmaceutical sector in South Africa. Therefore any practices by drug companies that advance restrictive practices whether vertically or horizontally would be in contravention of the Competition Act and thus would be subject to the regulatory frameworks under the South African Competition Act commencing with the Competition Commission which deals with complaints and refers such complaints in form of cases to the Competition Tribunal if it finds that the law has been contravened.

Therefore in light of the above regulatory frameworks and mechanism provided for under the South African Competition Act adjacent to the success of *Hazel Tau* and others and the TAC/ALP matter, the issue that emerges is whether the interface between intellectual property rights and competition law is a prospective mechanism to advance access to ARV drugs in Zambia and other least developed WTO African Members?

3.4.1.5.2. The application of competition law in African countries

According to Avafia, Berger and Hartzenberg not every African country can utilise the policy space in competition law to access ARV drugs.³²⁸ This is in view of the fact that in most cases where competition law has been used to override patent rights of originator drug companies, voluntary licenses end up being negotiated and granted. Voluntary licenses, unlike compulsory licenses, are private arrangements between a patent holder and a third party (the licensee) strategically arranged for market penetration by competing companies.³²⁹ So due to the private nature of these contracts, their potential to reduce prices for medicines, is subject to the negotiation capabilities of the licensee.³³⁰

For example, in certain instances the patent holder may grant exclusive rights to the generic drug producer, which then acts as an agent of the patent holder. In this case, terms which allow considerable price cutbacks may be included.³³¹ However, in other instances the patent holder may grant non-exclusive rights to the generic drug producer, affecting their right to produce market or

³²⁸ Ibid

³²⁹ WHO Mission on the use of TRIPS flexibilities Bangkok, 31 January to 6 February 2008 Note 264 above. "With respect to the terms of the license the prohibition on the sale or transfer of the license or price ranges that maintain prices at or near the same level as those offered by the patent holder as well as the terms on the amount to be paid as royalties."

³³⁰ Ibid.

³³¹ Ibid.

distribute pharmaceutical products under the patent.³³² On the other hand voluntary licenses are generally effective in countries that have comparatively advanced manufacturing industries³³³ to produce pharmaceutical drugs including advanced lines of ARV drugs.

Therefore in Zambia's context, the sufficient exploitation of the policy space in competition law for purposes of accessing advanced ARV drugs is contingent on the CCP Act's legal provisions that prohibit anticompetitive practices or restrictive business practices such as "discriminatory prices or restrictions on the supply of goods, bundling or tying, market division and collusion."³³⁴ These would have to be implemented within the CCP Act's regulatory frameworks.³³⁵

The Zambian government on the other hand, as part of the non-patent related mechanisms of reducing prices for medicines highlighted above must also ensure that it funds its local pharmaceutical industry sufficiently to develop its local generic drug manufacturing plants. This will assist to sustain the supply of ARV drugs as is the case in Brazil and Indonesia where government-owned drug manufacturing companies have been sufficiently funded to bolster the production of ARV drugs for the state.³³⁶ Such a development will also help the Zambian government to institute price control mechanisms as the local generic manufacturing industry will be mainly government owned with minimal competition from private companies.

³³² Ibid.

³³³ Avafia, Berger & Hartezenberg Note 200 above. "Aside from brand pharmaceutical companies, the only country in southern Africa with a well- established and entrenched generic manufacturing industry is South Africa. Hence no other country in the SADC region possesses the requisite capacity or expertise needed to establish a multi-company generic drug industry. The research based pharmaceutical industry in southern Africa is well represented with GSK, Boehringer Ingelheim, Abbott, Bristol Meyers Squibb (BMS) and Merck, Sharp and Dohme (MSD), a few of the several multi-national pharmaceutical companies with local offices in South Africa".

³³⁴ Part II Sections 5, 6, 7, 8,9,10 and 11.

³³⁵ Part II Section 4 (1) – "established the Zambian Competition Commission established under the repealed Act shall continue to exist as if established under this Act and is for purposes of this Act hereby re-named the Competition and Consumer Protection Commission." Section 4(2) – " the Commission shall be a body corporate with perpetual succession and a common seal, capable of suing and being sued in its corporate name and with power, subject to the provisions of this Act, to do all such acts and things as a body corporate may, by law, do or perform." Section 4(3) – "the provisions of the First Schedule apply to the Commission. The Competition and Consumer Protection Commission (CCPC) has assumed all the functions of adjudicating amongst other things issues involving prohibited practices or anti-competitive practices."

³³⁶ TRIPS, intellectual property rights and access to medicines. Briefing note. WHO SEARO/WPRO, 2006. Available online at: http://www.searo.who.int/LinkFiles/IPT_Briefing_note1_IPR_&_Access.pdf. Accessed on 27/01/2012. "Brazil produces most of the ARVs required for the local market, at prices significantly lower than those charged by brand-name companies. In addition, the existence of a significant local capacity to manufacture medicines, among other factors, increased Brazil's negotiating power in discussions with brand-name companies over price discounts."

See also Government of Indonesia (2007). Decree of the President Republic of Indonesia number 6 year 2007, amending Decree number 83 year 2004 regarding exploitation of patent on antiretroviral drugs by the Government. Available online at: http://www.bkpm.go.id/file_uploaded/PPres-36-2010.pdf. Accessed on 27/01/2012. "During the 1998 Asian financial crisis, the Indonesian Government was able to supply hospitals, health centres and other health facilities with essential medicines thanks to the existence of state-owned local pharmaceutical manufacturers. Privately-owned local and foreign companies practically halted production for several weeks as the collapse of the local currency and uncertainty in foreign exchange rates prevented them from importing necessary raw materials."

Nevertheless, for now the most viable option for Zambia in respect of competition law and access to medicine in Zambia is through the importation of essential drugs manufactured under competition law/policy voluntary licensing in developing African countries such as South Africa and Kenya. On condition that countries (including Zambia) have common membership to certain regional trade agreements and national competition laws are harmonized with that of exporting Members in this instance South Africa or Kenya.

Thus Avafia, Berger and Hartzenberg³³⁷ elaborate that Zambia's membership to the Common Market for Eastern and Southern Africa (COMESA)³³⁸ and the Southern African Development Community (SADC)³³⁹ and South Africa's membership to the Southern African Customs Union (SACU)³⁴⁰ and SADC could facilitate the opportunity for Zambia SADC as a Member of SADC to conclude a regional competition policy trade agreement with South Africa to be synchronized with both these Members' national competition laws or policies to advance regional parallel importation and exportation of ARV drugs as well as the compulsory export licensing of drugs under the waiver in the decision of the General Council of the 30th August 2003 decision.³⁴¹

Similar arrangements would have to be made if Zambia pursues importation of drugs from Kenya. For instance, a trade agreement between the East African Community (EAC),³⁴² COMESA and SACU would have to be concluded. This would permit Zambia under the new CCP Act, to utilize the policy space in competition law to pursue access to ARV drugs through a regional competition policy. However for 'uncomplicated' importation of ARV drugs Zambia would have to incorporate the flexibility of parallel importation into its national law, discussed at a later stage in this chapter.

³³⁷ Avafia, Berger & Hartezenberg Note 200 above.

³³⁸ Common Market for Eastern and Southern Africa (COMESA) - COMESA-webpage. Available at: <http://about.comesa.int/lang-en/overview>. Accessed on 30/08/2010. Hereinafter referred to as COMESA.

³³⁹ Southern African Development Community (SADC) web-page: <http://www.sadc.int/>. Accessed on 27/01/2012.

³⁴⁰ SACU Member Information online at: <http://www.sacu.int/>. Accessed on 27/01/2012.

³⁴¹ Avafia, Berger & Hartezenberg Note 200 above.

³⁴² Zambia- European community country strategy paper and national indicative programme for the period of (2008=2013): Available online at: http://ec.europa.eu/development/icenter/repository/scanned_zm_csp10_en.pdf. Accessed on 20/014/2012. According to the Zambia-EC Report: "In 2000, Zambia also signed the SADC Trade Protocol for duty-free access to the regional market for specified products. Implementation of the SADC Trade Protocol commenced in September 2000 with the introduction of tariff preferences leading to an Article XXIV compatible FTA by 2008... In addition, Zambia is negotiating bilateral trade agreements with Botswana, the Democratic Republic of the Congo, Mozambique, Namibia, Tanzania and Zimbabwe. Unless both SADC and COMESA share identical common external tariffs, it will not be possible for Zambia to belong to both customs unions. Zambia has decided to discuss the future EPA with the EU in the Eastern and Southern Africa (ESA) grouping in coordination with COMESA."

3.4.1.6. Failure to exploit or insufficient working of a patent

This ground may be used by Members to issue compulsory licenses-; if a patent is not being worked on reasonable commercial terms in a country of its registration.³⁴³ This was the issue in the *United States of America (USA) V Brazil* case of February 2000, in which the United States instituted a suit against Brazil with the WTO dispute settlement body, challenging Brazil's threats to issue a compulsory license on the grounds of "non-working or insufficient use of patent" in terms of Brazil's Industrial Property Law.³⁴⁴ The United States eventually withdrew its complaint against Brazil in the WTO dispute settlement body after entering into an agreement with the Brazilian government under which Brazil pledged that it would first consult the United States if it planned to put to use its local working provision.³⁴⁵

Another similar example to that of Brazil is the Thai government's issue of compulsory licenses in 2007 after years of prior negotiations with patent-holding companies for the local production of ARV drug Kaletra, a fixed-dose combination (FDC) manufactured by Abbot, Merck and Sanofi-Aventis and administered to 20 per cent of Thailand's HIV/ AIDS patients through the public health care system.³⁴⁶ The issue of these licenses by the Thai government resulted into Abbot, Merck and Sanofi-Aventis' refusal to register drugs for sale including the ARV drug Kaletra in Thailand, this refusal invoked the lodging of a complaint by Thai treatment activists with the Thai Competition Commission. The complaint alleged that Abbot, Merck and Sanofi-Aventis' withholding of products from the Thai markets is prohibited under the Thai Competition Act and thus Abbot, Merck and Sanofi-Aventis' were in violation of Thailand's Competition Act.

On the other hand, Thailand was placed under intense pressure from the United States government demanding that it withdraws issue of the licenses. However, upon Thailand's reluctance to withdraw

³⁴³ Article 5A(2) of the Paris Convention provides that: 'Union Members shall have the right to take legislative measures providing for the grant of compulsory licenses to prevent abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work'. Paris Convention 1883 as amended by the Stockholm Act of 1967. Available online at: http://www.wipo.int/treaties/en/ip/paris/trtdocs_wo020.html. Accessed on 23/02/2012.

³⁴⁴ USA v Brazil Note 237 above. See also The Intellectual Property Law of Brazil, effective as of May 15, 1997, at art. 68. Available at: <http://www.ararape.com.br/law9279eng.htm>. Accessed on 27/01/02/2012. See also discussion by Sekalala Note 242 above of the *USA V Brazil* "where the United States brought a complaint before the WTO Dispute Settlement Body in February 2001, alleging that the law violated TRIPS Articles 28 and 27 of the TRIPS agreement because it discriminated between patents as to the place of their invention and use. Brazil quickly retaliated by filing its own complaint before the WTO challenging portions of the US code requiring that products made with certain government supported funding be manufactured in the United States."

³⁴⁵ Sekalala Note 242 above.

³⁴⁶ Compulsory licensing Controversy in Thailand. Available online at: https://www.abbot.com/global/url/pressRelease/en_US/60.5.5/Press_Release_0442.htm. Accessed on 04/11/2010.

the licenses, the United States government trade representatives placed Thailand on its 301 priority watch list, subsequently leading to Thailand's loss of trade privileges.³⁴⁷ Nonetheless, Thailand was vindicated in May 2007 when the World Health Organization Assembly (WHA) buttressed its use of compulsory licenses.³⁴⁸

In Zambia's context, Section 37 of the Zambian Patent Act provides that, "an interested third party may apply for the grant of a compulsory license based on insufficient working of a patent." Sub-section 13 states that, "an interested third party who has been granted a compulsory licence under section 37 may not grant a sub-license; however, further compulsory licenses may well be granted to other interested third parties."

These provisions appear to be legally reasonable to authorize the Zambia government to grant compulsory licenses for further local production of other lines of ARV drugs. However, the US sessions initiated against Brazil and Thailand illustrate the gravity of the threats posed to developing and least developed countries wanting to effectively utilise compulsory licensing to ameliorate the grave impact of HIV/AIDS on their mostly poor populations.

However, in the African context, given the coming to a standstill of the USA-SACU negotiations³⁴⁹ access to medicines is more likely to be less problematic for LDCs like Zambia that are in the same

³⁴⁷ The Office of the US Trade representative releases an annual 'Special 301' report on the adequacy of effectiveness of intellectual Property Rights protection by their trading partners. USTR Special 301 Report 2007(April 30 2007). Available at: http://www.ustr.gov/Document_Library/Press_Releases/2007/April/SPECIAL_301_Report.html. Accessed on 08/11/2010. Hereinafter referred to as USA v Thailand. Some of the reasons that were given by the US government in its trade representatives special 301 annual report, for placing Thailand on its' watch list were as stated as follows: "In addition to the longstanding concerns with deficient IPR protection in Thailand, in late 2006 and early 2007, there were further indications of a weakening of respect for patents as the Thai government announced decisions to issue compulsory licenses for several patented pharmaceutical products. While the US acknowledges country's ability to issue such licenses in accordance with WTO rules, the lack of transparency and due process exhibited in Thailand represents a serious concern. These actions have compounded previously expressed concerns such as delay in the granting of patents and weak protection against unfair commercial use for data generated to obtain marketing approval."

³⁴⁸ The USA later withdrew these threats. For more on the Thai case see Human Rights Watch, 'WTO Summit; Don't undercut AIDS drug access,' (2001). Available online at: <http://hrw.org/english/docs/2001/11/07/global3340.html>. Accessed on 20 /09/ 2011.

³⁴⁹ November 4, 2002. Robert Zoellick. [Letter to the Speaker of the House of Representatives](#) which formally notifies Congress of the USTR's intention to negotiate the Free Trade Agreement(SACU-US). Available online at: <http://www.cptech.org/ip/health/trade/sacu/>. Accessed on 03/01/2012. In which the former US Trade Representative Mr Robert Zoellick set out reasons for entering into such negotiations, as well as the USTR's specific objectives for negotiations with the SACU countries by stating the following: "We plan to use our negotiations with the SACU countries to address barriers in these countries to U.S. exports including; high tariffs on certain goods, overly restrictive licensing measures, inadequate protection of intellectual property rights, and restrictions the SACU governments impose that make it difficult for our services firms to do business in these markets. We also see the negotiations as an opportunity to advance U.S. objectives for the multilateral negotiations currently underway in the World Trade Organization (WTO)."

economic region as South Africa and want to parallel import ARV drugs produced under compulsory licensing. Parallel importation is discussed below.

3.4.2. Parallel importation: The significance of the doctrines of exhaustion of rights to regional access to ARV drugs in African LDCs.

According to the World Intellectual Property Organisation (WIPO 2011)³⁵⁰:

Parallel importation relates to the situation in which the patent holder in this instance the research based Drug Company or its licensee suffers loss of control to distribute or commercially exploit its protected product by virtue of placing it on the commercial market.

Thus, in the context of pharmaceutical patents rights, the mechanism of parallel imports or grey goods raises the issue of whether a patent holding company can prevent a third party from importing its pharmaceutical product at a cheaper cost from elsewhere without requisite authorisation.³⁵¹ The issue that rises is that of differential pricing which is the rationale behind parallel importation and in a way defeats the purpose of price regulations, as pharmaceutical drugs under the protection of patents or even trademarks are put into circulation by the patent right holder or a local licensed dealer in higher markets (markets with less price regulation) by means of parallel importation provisions under TRIPS and domestic legislation. These drugs in higher markets imported into a lower market (market with higher price regulations) without the right holder or licensed dealer's authorization. The natural consequence of parallel importation is that the right holder of patented products may lose out on potential profits from international sales as the rationale behind parallel imported products is differential pricing which occurs when international prices surpass the cost of transporting and importing goods across the borders.³⁵²

³⁵⁰ (WIPO) CDIP/6/10: Patent-Related Flexibilities In The Multilateral Legal Framework and their Legislative Implementation at the National and Regional Levels - PART II Document prepared by the Secretariat March 18, 2011 Committee on Development and Intellectual Property (CDIP) Seventh Session Geneva, May 2 to 6, 2011. Available online at: http://www.wipo.int/meetings/en/doc_details.jsp?doc_id=164302. Accessed on 27/02/2012.

³⁵¹ Musungu & Oh Note 195 above. See also Jackline Irene Muthoni Nyaga: Implementing Parallel Importation Mechanisms to Increase Access to Medicines in Kenya (2009). A Thesis Submitted to the Stanford Program in International legal studies at Stanford University in partial fulfilment of the requirements for the degree of Master of the Science Law. Available online at: <http://www.law.stanford.edu/sites/default/files/biblio/108/138899/doc/slspublic/JacklineNyaga-tft2009.pdf> Accessed on: 05/02/2013. Hereinafter referred to as Nyaga(2009) "Parallel imported goods are goods which are genuinely protected by patent, copyright or trademarks and are legally placed in one market and are imported into another market without the intellectual property rights holder's or local licensed owner's authorization."

³⁵² Keith. E. Maskus Parallel Imports, 23 'The World Economy', 1269, 1271(2000). See Paragraph 5(c) of the Doha Declaration.

Thus Markus argues that despite differential pricing being an advantage of parallel importation in that it encourages competition facing the originator drug companies and benefits consumers by lowering prices it also has the negative effective of firstly wasting resources due to cross hauling of goods between borders and secondly consumer deception and trade in counterfeit and pirated goods.³⁵³

However Paragraph 5(c) of the Doha declaration, with due regard to the doctrine of state sovereignty, resolves this issue by permitting Members through the use of wide discretionary powers, to adopt any regimes under their domestic legal frameworks that could advance access to medicines. This means that Members have the discretion to incorporate the flexibility of parallel importation of products based on the principle of exhaustion of rights.³⁵⁴ Accordingly the TRIPS Agreement provides three levels on which Members can parallel import ARV drugs namely; national, regional or international levels.³⁵⁵ Parallel importation on any one of these levels is on condition that the patent holding company or its licensee had legitimately sold or discharged the product into the commercial markets locally or abroad.³⁵⁶

Article 6 of the TRIPS Agreement provides the principle of 'exhaustion of patent rights' by stating the following: "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."

Thus it is imperative that Members adopt a regime of 'exhaustion of rights' that facilitates the importation of patented pharmaceutical drugs by restricting the patent holder to reaping profits only from the first sale of their product.³⁵⁷ This is in view of Article 6's regulatory function in relation to the issue of differential pricing of medicines such as ARV drugs; thereby permitting the importation of bargain priced pharmaceutical products for general consumers and for the government in developing and least developed African nations.³⁵⁸

³⁵³ Sekalala Note 242 above.

³⁵⁴ See Paragraph 5 (c) and (d) of the Doha declaration Note 231 above.

³⁵⁵ Musungu & Oh Note 195 above explain that: "Exhaustion can be approached from: a national standpoint 'where resell within the same country is permitted as in the case of the United States', regionally 'where imports are permitted within a regional market as in the case of the European Union or OAPI countries' or international 'where the rights are exhausted with the placing of the product anywhere in the world market'."

³⁵⁶ Ibid.

³⁵⁷ Ibid.

³⁵⁸ Avafia, Berger & Hartzenberg . Note 200 above.

It is nevertheless important to caution that the above provisions under Article 6 are also subject to TRIPS obligations under Article 4 MFN and Article 3 NT.³⁵⁹ However, Musungu and Oh have argued that Article 6 also gives deference to state sovereignty and intellectual property rights as these are more or less domestic issues.³⁶⁰ This means that the regime of exhaustion of patent rights a Member indicates to implement under national patent laws is not subject to challenge by other Members.³⁶¹

Therefore, developing and least developed African countries alike can maximise or minimise the advantages that ensue from this flexibility, depending upon the category of 'exhaustion of rights regime' a country decides to implement.³⁶² These regimes are discussed below to determine their capacity to increase or diminish access to ARV drugs in least developed WTO Members, specifically Zambia.

(a) National exhaustion of patent rights regime:

Under this regime of exhaustion of patent rights, a member's capacity to use of patented medicines is confined to the exhaustion of patent rights to the domestic commercial market. First sales of patented products abroad will not have an effect on the domestic patent (thereby inhibiting parallel imports).³⁶³

(b) International exhaustion of patent rights regime:

Here the distribution of patent rights nationally are exhausted by a first sale out of the country in the same way as if that first sale happened domestically (thereby facilitating parallel imports).³⁶⁴

(c) Regional exhaustion of patent rights regime:

Lastly, regional exhaustion regime of patents rights in WTO Members' national laws would allow importation into their national territory of a patented product originating from any other Member state of a regional trade agreement, strengthening financial capacity and industry development of generic industries, in this instance in South Africa and or Kenya.³⁶⁵

³⁵⁹ Article 3 MFN and Article 4 NT obligations under TRIPS Agreement Note 55 above. See also Fink 2007 Note 190 above.

³⁶⁰ Sekalala Note 242 above.

³⁶¹ Paragraph 5(d) Note 231 above.

³⁶² Musungu & Oh Note 195 above.

³⁶³ Ibid.

³⁶⁴ Ibid.

³⁶⁵ Avafia, Berger & Hartzberg 200 above.

It is clear that the international and regional exhaustion of rights regimes offer a much more viable option for Zambia and other least developed nations as they would facilitate the parallel importation of ARV drugs from other WTO Members with competitive generic manufacturing industries. In the sub-Saharan region the potential Member states would be South Africa³⁶⁶ and in the East African region Kenya.³⁶⁷

3.4.2.1. Case study one: South Africa as a potential regional exporter of ARV drugs to Sub-Saharan LDCs

South Africa has been used in this study due to its geographical proximity to Zambia; its economic standing of a developing African WTO Member that has retained developed local generic drug manufacturing industries³⁶⁸; and its domestic legal preparedness pertinent to this research, namely, the Medicines and Related Substances Control Act Amendment 90 of 1997³⁶⁹ that could facilitate parallel exports of generic ARV drugs to Zambia.

The South African Medicines Act of 1997 authorises the Minister of health to parallel import pharmaceutical patented drugs in to South Africa under Section 15 (C), “Measures to ensure supply of more affordable medicines”. Paragraphs (a) (b) and (c)³⁷⁰ award broad powers to the Minister of health to bypass or override the exclusive nature of patent rights set by TRIPS’ IPRs provisions on patent protection. These provisions are regulated by regulation 7 of the general regulations of April

³⁶⁶ The South African Medicines Act of 1997 Note 236 above.

³⁶⁷ “It is important to note that this flexibility of parallel importation does not automatically decode into the different Members’ national legal frameworks . It like every other flexibility requires requisite explicit legal provisions to be present in national or regional laws in order for it to be effected.” Commission on Intellectual Property Rights, Innovation and Public Health, Public Health, Innovation and Intellectual Property Rights (WHO, Geneva, 2006). Available online at: <http://www.who.int/intellectualproperty/documents/thereport/CIPIH23032006.pdf>. Accessed on 04/01/2012. Hereinafter referred to as CIPIH (2006).

³⁶⁸ See geographical details about Zambia and its neighbouring countries in the CIA World Fact Book (2011) Note 1 above. See also Avafia, Berger & Hartzenberg Note 200 on the point of South Africa’s generic industry development.

³⁶⁹ Medicines Act of 1997 Note 236 above.

³⁷⁰ Ibid. Section 15(C) states that: The Minister may prescribe conditions for the supply of more affordable medicines in certain circumstances so as to protect the health of the public and, in particular may: (a)Notwithstanding anything to the contrary contained in the Patent Act 57 of 1978, determine that the rights with regards to any medicine under a patent granted in the Republic shall not extend to acts in respect of such medicine which has been put onto the market by the owner of the medicine or with his or her consent;(b) Prescribe the conditions on which any medicine which is identical in composition, meets the same quality standard and intended to have the same proprietary name as that of another medicine already registered in the Republic. But which is imported by a person other than the person who is the holder of the registration certificate of the medicine already registered and which originates from any site of manufacture of the original manufacturer as approved by the council in the prescribed manner, may be imported;(c) Prescribe the registration procedure for as well as the use of the medicine referred to in Paragraph (b).

10th 2003,³⁷¹ which envisage the procedure to be used when making parallel imports and requires that:

- (a) Only medicines under patent in South Africa are allowed to be imported under section 15C (b).³⁷²
- (b) The details to be included in the application for a license to parallel import medicines.
- (c) The powers of the Minister around the approval of licenses. The process is complex, dealing with issues of safety, quality and efficacy, as well as affordability. By late 2006, no medicines have been imported into South Africa under Regulation 7, probably as a result – in large part – of the difficult processes that must be followed.³⁷³

In this regard the Minister of Health has the power to approve the use of parallel importation where the applicant complies with the formal requirements detailed in Regulation 7 (2).³⁷⁴ The Minister also has the power to cancel his/her permission regarding the parallel importation of medicine. In brief the Act provides for the following:

- (i) Measures to ensure the supply of cheaper medicines, including introducing competition through parallel importation.
- (ii) Section 22G: Requires the setting up of a transparent medicine pricing system, openness and accountability in the setting of drug prices through the establishment of a pricing committee.
- (iii) Section 22F: Deals with Generic substitution of off patent medicines and medicines imported and produced under compulsory licenses.
- (iv) Section 22G (2) and 22C (III): Introduced a fee-for-service system at various levels in the medicine supply chain, with government setting the upper level of the “appropriate” fees.

³⁷¹ The General Regulations 510 of 10 April 2003. Government Gazette No. 24727. Are Available online at: <http://www.info.gov.za/view/DownloadFileAction?id=123196>. Accessed on 27/01/2012. Regulation 7(1) – (9).

³⁷² Ibid. Regulation 7(1) (e) (i).

³⁷³ Health and Democracy: Access to Essential Medicines(2010) Note 264 above.

³⁷⁴The General regulations 510 of 10 April 2003 Note 371 above.

(v) 152(b) requires; fast-track procedures for the registration of essential medicines.³⁷⁵

The above provisions under the South African Medicines Act of 1997 guarantee legal preparedness on the part of the government of South Africa to not only implement non-patent related mechanism of transparent price information which has facilitated reduced prices for medicines but would also warrant the legitimate import and export of economical pharmaceutical drugs to poor countries within the sub-Saharan region.³⁷⁶

However, in May 2000 the measure of parallel importation under Section 15C of the South African Medicines Act of 1997 incited forty 40 Pharmaceutical Companies under the South African Pharmaceutical Manufacturers Association (PMA) to sue the South African government in a case cited as the *Pharmaceutical Manufacturers Association of South Africa and Another: In re Ex Parte President of the Republic of South Africa and Others*.³⁷⁷ In this matter the pharmaceutical companies with the US government's³⁷⁸ full support alleged, inter alia, that Section 15(C) as amended violated the TRIPS Agreement and conflicted with the provisions of the South African patent law.³⁷⁹ Nonetheless, in April 2001, the PMA unconditionally withdrew the case due to its unconvincing legal preparation and mounting massive world-wide public antagonism.³⁸⁰

Incoherently, South Africa has not made any practical use of its Section 15(C) parallel importation provisions, even though it has been producing generic ARV drugs under voluntary licensing.³⁸¹ For this reason, Avafia, Berger and Hartzenberg contend that South Africa needs to urgently consider the issuance of compulsory licenses under the decision of the General Council of 30th of August 2003 to facilitate parallel exportation of ARV drugs to LDCs in the southern and eastern African regions.

³⁷⁵ Health and Democracy: Access to Essential Medicines(2010) Note 264 above.

³⁷⁶ Avafia, Berger & Hartzenberg. Note 200 above highlighted that: "South Africa has attempted to export ARV drugs to Tanzania and well as Uganda, but encountered problems in the process due to poor and inefficient pharmaceutical management and procurement systems."

³⁷⁷ Pharmaceutical Manufacturers Association of South Africa and Another: In re Ex Parte President of the Republic of South Africa and Others (CCT31/99) [2000] ZACC 1; 2000 (2) SA 674; 2000 (3) BCLR 241 (25 February 2000) available online at: <http://www.saflii.org/za/cases/ZACC/2000/1.html> last accessed on 19/04/2012. Hereinafter referred to as the PMA'S case.

³⁷⁸ USTR Special 301 Report Office of the United States Trade Representative(1999) Executive Office of the President Washington, D.C. 20508 99 – 41 For Immediate Release April 30, 1999 USTR ANNOUNCES RESULTS OF SPECIAL 301 ANNUAL REVIEW Submitted by James Love on 16. September 2009 - 13:48. Available online at: <http://keionline.org/ustr/1999special301>. Accessed on 27/02/2012. "The US government placed South Africa on its USTR 301 Priority Watch list".

³⁷⁹Avafia, Berger & Hartzenberg Note 200 above.

³⁸⁰ Ibid.

³⁸¹ Avafia, Berger & Hartzenberg Note 200 above. See also Health and Democracy: Access to Essential Medicines (2010) Note 264 above.

3.4.2.2. Case study two: Kenya as a potential regional exporter of ARV drugs to East African LDCs

Kenya has been used in this dissertation because of its role as both an importer and a potential exporter³⁸² of generic drugs to its least developed neighbouring East African countries, Tanzania, Uganda, Rwanda and Burundi.³⁸³ It is important to note that under the WTO, Kenya is self-designated as a developing country. Thus it would countenance a much more challenging³⁸⁴ process when wanting to increase access to ARV drugs through importation from or exportation to Members under the customs union agreement of the East African Community (EAC).³⁸⁵ However, Kenya's legal preparedness in terms of its parallel importation provisos under the Kenyan Industrial Property Act³⁸⁶ could facilitate its parallel exportation of ARV drugs to its neighbouring LDC's.

Section 58(1) of the KIP Act deals with parallel importation and it states that; "the rights under the patent shall not extend to acts in respect of articles which have been put on the market in Kenya or in any other country or imported into Kenya".

The provision under Section 58(1), is unambiguous, sanctioning Kenya's adoption of the mechanism of parallel importation as a legally enforceable flexibility in Kenya based on international exhaustion of patent rights regime.³⁸⁷ This means that the Kenyan government or any authorized party is permitted to parallel import both patented and generic pharmaceutical products, including ARV drugs that have been legitimately placed on the commercial market by the patent holder or his licensee.³⁸⁸

The use of this flexibility may assist Kenya to export ARV drugs to Uganda and Tanzania as they are Members of the EAC, including Zambia as it is Member of COMESA³⁸⁹. However, in the Sub-

³⁸² Avafia, Berger & Hartzberg Note 200 above.

³⁸³ Refer to WTO LDC Members at Note 188 above.

³⁸⁴ O'Carroll. Note 204 above.

³⁸⁵ Tanzania, Kenya and Uganda (EAC) countries signed a protocol in 2004 to establish a customs union by 1 January 2005. Available online at: <http://www.eac.int/about-eac.html>. Accessed on 27/01/2012. See also COMESA Note 338 above. See also Nyaga(2009) Note 351 above " Kenya is currently the largest producer of pharmaceutical drugs in the COMESA region, supplying about 50% of the region's market. Out of the COMESA region's 50 most recognized pharmaceutical manufacturers, more than two thirds of them are based in Kenya. These include local manufacturing companies, multinational corporations, subsidiaries, joint ventures as well as Indian generic manufacturers."

³⁸⁶ Kenyan Industrial Property Act 27/07(2001) No.3 .Available on the World Intellectual Property organization Web-page at: http://www.wipo.int/wipolex/en/redir.jsp?ref=/clea/docs_new/en/ke/ke001en.html. Accessed on 25/10/2010. Hereinafter referred to as the KIP Act.

³⁸⁷ Refer to discussion on Exhaustion patent rights from page 70-71 of this chapter.

³⁸⁸ Avafia, Berger & Hartzberg Note 200 above.

³⁸⁹ S. F. Musungu Access to ART and Other Essential Medicines in Sub-Saharan Africa: Intellectual Property and Relevant Legislations (UNDP September (2007). Available online at:

Saharan and Eastern regions of Africa only a few countries have explicitly implemented parallel importation of pharmaceutical drugs into their domestic laws,³⁹⁰ whilst the position with the most African countries including Zambia remains uncertain.³⁹¹ Consequently, although parallel importation might be a legitimately viable substitute mechanism for Zambia³⁹² and other LDCs to increase access to ARV drugs, it is unlikely to be practically useful, due to inconsistencies in regional intellectual property laws.³⁹³

This means that most LDCs Zambia included which are currently in the process of formulating policies on intellectual property rights, must adopt parallel importation provisions with the international or regional exhaustion of patent rights regime in order to facilitate the importation of patented pharmaceuticals from other countries such as South Africa and Kenya or from markets tendering lower prices than the prices they would be sold for in domestic markets.³⁹⁴

3.4.3. Pre-grant TRIPS flexibilities as mechanisms to safeguard access to medicines

In contrast to the previously discussed post-grant TRIPS flexibilities,³⁹⁵ Pre-grant TRIPS flexibilities are policy alternatives incorporated into national laws, prior to patent registration or issuance, so as to restrict the exploitation of exclusive patent rights granted to patent right holders under Article 28 of TRIPS. Thus in terms of the pre-grant flexibilities, these are envisaged under Articles 27 and 29 of the TRIPS Agreement.³⁹⁶ However, for purposes of this study a discussion of Article 27 will be conducted to ascertain how its provisions have been utilised by developing countries inter alia South

<http://apps.who.int/medicinedocs/documents/s18248en/s18248en.pdf>. Accessed 26/03/2012. Hereinafter referred to as Musungu (2007).

³⁹⁰ Ibid. Kenya, Mauritius, Namibia, South Africa and Zimbabwe.

³⁹¹ Ibid.

³⁹² EQUITY WATCH: Assessing Progress towards Equity in Health in Zambia, (EQUINET 2011). Note above 32 above.

³⁹³ Avafia, Berger & Hartzberg Note 200 above have argued that: "To date, the factors that have prevented South African producers from exporting larger volumes to other African countries are the lack of licences and an adequate domestic legal framework in most sub-Saharan countries, and the incompatibility of the regulations of specific domestic systems for example Aspen Pharmacare of South Africa experienced difficulties when attempting to export ARVs to Ethiopia, Nigeria, Tanzania and Uganda in June 2005. Much like South Africa, Kenya's role as an exporter is hampered by the differing regulations on the manufacture, import, export and distribution of pharmaceutical products in each of the EAC countries differences of pharmaceutical regulations in the three countries. The medicines regulations of the three countries that comprise the customs union will have to be addressed to facilitate intra-regional trade, one example is the essential drugs produced by a Kenyan manufacturer which will have to be included in the WHO's Essential Drug List."

³⁹⁴ Ibid.

³⁹⁵ "Post-grant flexibilities are policy options that, if incorporated into national law, are generally employed to address particular cases in the exercise of exclusive patent rights." See the use of TRIPS flexibilities Report of a WHO Mission Bangkok, 31 January to 6 February 2008 Note above 229 above.

³⁹⁶ Ibid .

Africa and India to prevent early patenting or re-patenting of medicines in order to accelerate access to medicines. Accordingly Article 27.1 states that:

Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.

The provision in Article 27.1 above does not define what 'subject matter is patentable'. So Members are generally left with the policy space of defining what subject matter is tantamount to a patentable invention,³⁹⁷ permitting further government restriction on patent rights protection by suspending registration of pharmaceutical patents until at least the 2016 deadline for WTO LDCs.³⁹⁸

Accordingly in the area of pharmaceutical patents, the meaning of an 'invention' becomes imperative when a patent right holder such as an originator pharmaceutical drug company, discovers a new medical use or second indications for an existing medical product or first indications and patenting officers in Member nations could possibly deny to patent a product on grounds of lack of novelty or an 'inventive step'.³⁹⁹ A claim involving a patent holder wanting to obtain a second patent on an existing patented product is known as the Swiss type claim which originated from the European patent courts⁴⁰⁰ and accepted the position that;

A patent holder may very well enforce a new use or secondary use patent on a pharmaceutical product already under patent, if they can show a 'novel' second medical use and not just a mere discovery about the existing old use.⁴⁰¹

Hence, the process of establishing that a legitimate new use has been discovered on an existing patented product makes it very difficult for patent holders to engage in anti-competitive practices such as ever-greening.⁴⁰² This is particularly the case in Member countries that have strict national

³⁹⁷ Ibid.

³⁹⁸ In terms of Article 28 'Rights Conferred' "Members can restrict patents rights." See Note 207 above.

³⁹⁹ Ibid.

⁴⁰⁰ TD Burrell's *'Burrell's South African Patent and Design Law'* 3rd ed. (1999) 240.

⁴⁰¹ Ibid.

⁴⁰² Correa explains that: "Ever -Greening of patents occurs when in the absence of any apparent additional therapeutic benefits, patent-holders use various strategies to extend the length of their exclusivity beyond the 20-year patent term."

patent law requirements for registering pre-grant TRIPS flexibilities on dependent patents. For example, South Africa's case law⁴⁰³ has emphasized the need for any manufacturer wanting to patent a combination of drugs that will amount to a Fixed-Dose combination (FDC)⁴⁰⁴ such as in the case of ARV drugs to demonstrate the existence of an 'inventive step'.⁴⁰⁵ This means that the combination must rather be "where old integers are placed together they have some inter-relation producing new or improved results."⁴⁰⁶ Thus such provisions that prevent ever-greening of patents when adapted in to national patent legislation are considered to enforce high patentability standards. The enforcement of high patentability standards is in tandem with Article 27.3 (a) of the TRIPS Agreement which permits Members to exclude from patentability; "diagnostic, therapeutic and surgical methods for the treatment of humans or animals".⁴⁰⁷

C. M Correa Report On Public health, innovation and intellectual property rights to the Commission on Intellectual Property Rights , Innovation and Public Health. Available online at: <http://www.who.int/intellectualproperty/documents/thereport/ENPublicHealthReport.pdf> last Accessed on 12/03/2012 .See also CIPIH (2006) Note 367 above.

⁴⁰³ *Ensign-Bickford (SA) Ltd And Others v AECI Explosives and Chemicals Ltd* 1998 1998(1) SA 70 (SCA). Available online at: <http://www.saflii.org/za/cases/ZASCA/1998/73.html>. Accessed on 09/03/2012. Plewman JA explained the inquiry to be used when establishing whether a product has an inventive step by referring to a combination of South African and English cases such as *Roma Roller CC v Speedmark Holdings (Pty) Ltd* 1996 (1) SA 405(A) at 413, in which the court held that the "in order to apply to these provisions (inventive step) to a particular case it is necessary to determine what the art or science to which the patent relates is, who the skilled person in the art and what the state of art at the relevant date was. But the inquiry in my view must then proceed further. After those factors have been determined, a more structured inquiry must be undertaken. For it is appropriate to adopt tests formulated in certain English authorities. The tests proposed do not differ from some of the inquiries suggested in the earlier case of *Molnlycke AB and Another v Procter & Gamble Ltd and other* (No.5) [1995] RPC 49 (CA) at 115. Available online at: <http://www.ipo.gov.uk/p-manual-hearing-content/table-of-cases.htm> accessed on 01/03/2012 and in the English of *Pfizer Ltd's Patent* [2001] F.S.R, 16,226. Available online at: <http://www.saflii.org/za/cases/ZACC/toc-P.html>. Accessed on 27/01/2012. In which Laddie J explained the test for obviousness by stating the following:

"The question of obviousness has to be addressed through the eyes of the skilled non-inventive man in the art. This is not a real person. He is a legal creation. He is supposed to offer an objective test of whether a particular development can be protected by a patent. He is deemed to have looked at and read publicly available documents and to know of public uses in the prior art. He understands all languages and dialects. He never misses the obvious nor stumbles on the inventive... Patents are not granted for the discovery and wider dissemination of public material and what is obvious over it, but only for making new inventions. A worker who finds or is given or stumbles upon any piece of public prior art must realize that that art and anything obvious over it cannot be monopolised by him and he is assured that it cannot be monopolised by anyone else."

⁴⁰⁴ 'Fixed dose Combination ARV'. Available at: <http://www.essentialdrugs.org/edrug/archive/200707/msg00032.php>. Accessed on 22/08/2011. "A fixed Dose Combination (FDC) is a single medicine that is made up of a number of other medicines that ordinarily would be taken in conjunction with each other. FDC's of RVs are particularly beneficial because they reduce the number of tablets and, often, the frequency of the dosage. This leads to better patient adherence."

⁴⁰⁵ Correa argues that, "unless the combination generates a new synergy appropriately described and proven in the patent specifications, for instance, on the basis of biological tests between the components, or a new and distinct effect, the combination should be deemed anticipated by prior art, and not patentable. There is and should be the manifestation of an inventive step." CM. Correa 'Pharmaceutical Inventions: When is the granting of a patent justified?' (2006) Vol. 1 *Int .J. Intellectual Property Management* 7-8.

⁴⁰⁶ Lord Tomlin in *British Celanese Ltd v Courtaulds* (1935) 52 RPC 171,193. Available online at: <http://www.jurisdiction.com/britcel.htm>. Accessed on 24/02/2012.

⁴⁰⁷ TRIPS Agreement Note 55 above.

As a result certain countries have taken a step further to exclude a whole list of secondary discoveries that may not qualify as patentable matter under Article 27.3 in that they do not meet the “inventive step” requirement under Article 27.1. A good example of such a provision is that of section 3(d) of the Indian Patent (Amendment) Act of 2005 which excludes from patentability:

The mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.

Section 3(d) of the Indian Patent (Amendment) Act of 2005 is supplemented with the following justification:

For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy.⁴⁰⁸

Therefore under Indian Patent law a drug which merely contains in it a new form or discovery of a known substance that does not enhance its original efficacy would not qualify as an invention as described under Article 27.1. This has caused Section 3(d) to be the subject of legal contention in the past few years. For instance, the case that caused world-wide attention was the *Norvatis AG v Union of India & others case*⁴⁰⁹ in which:

Several generic drug manufacturers in India opposed a patent application filed by Swiss originator drug company Norvatis for the beta crystalline form of imatinib mesylate, the active ingredient of the anti-cancer drug Gleevec. The generic manufacturers (in this case the opponents) argued that the beta crystalline form of imatinib mesylate was not patentable

⁴⁰⁸ Indian Patent Amendment Act No.15 of 2005. Available online at: http://www.wipo.int/wipolex/en/text.jsp?file_id=128116 .Accessed on 05/01/2013. Hereinafter referred to as the Indian Patent Act 2005.

⁴⁰⁹ What future for India's Patent Act?:Update on Novartis vs. Union of India, Cancer Patients Aid Association & others in relation to the interpretation of Section 3(d) of the Indian Patent Act(MSF February 2012). Available online at: <http://www.msfacecess.org/content/what-future-india%E2%80%99s-patent-act-novartis-vs-union-india>. Accessed on 22/04/2012.

under the provision of 3(d) of the Indian Patent (Amendment) Act⁴¹⁰ in that it states that a new form of a known substance which does not result in the enhancement of the known efficacy is not patentable.

Accordingly the patent office in India rejected Novartis's patent application on the basis that the beta crystalline form of imatinib mesylate section is considered a polymorph of the cancer drug Gleevec and it was the same substance as it did not differ significantly in proprieties with regard to efficacy.

Novartis challenged the patent office's rejection of their application in Madras high court. Furthermore in a separate court case it challenged the relevant section of the Patents Act under both the Indian Constitution and the TRIPS Agreement. The Chennai High Court found the concerned article did not run counter to the Indian Constitution, and dismissed the second challenge, on the ground that it has no jurisdiction to decide compliance with TRIPS.⁴¹¹

The Novartis case remains unresolved as the company's appeal application is still pending with the Indian Supreme Court.⁴¹² Nevertheless, it illustrates how WTO LDCs, specifically Zambia, could restrict patent protection through pre-grant flexibilities as they form the subject of TRIPS-plus provisions discussed in the last section of this chapter. For example, the US government, in the name of offering technical assistance in the process of re-writing laws in less developed nations, requires that such nations offer stringent patent protection.⁴¹³ This further restricts access to medicines.⁴¹⁴

Thus the question that arises is whether the Zambian Patent Act legally enforces high or low patentability standards?

⁴¹⁰ Indian Patent Act of 2005 Note 408 above.

⁴¹¹ The use of TRIPS flexibilities Report of a WHO Mission Bangkok, 31 January to 6 February 2008 Note 229 above.

⁴¹² What future for India's Patent Act? Novartis vs. Union of India: Update on Novartis vs. Union of India, Cancer Patients Aid Association & others in relation to the interpretation of Section 3(d) of the Indian Patent Act (MSF February 2012) Note 409 above.

⁴¹³ Sekalala Note 242 above. Cited as an example "the US Agency for International Development (USAID) has been funding the Commerce department of Nigeria in providing it with technical assistance to re-write its patent laws. The draft legislation demands far more stringent measures than are required by TRIPS Agreement. These even go as far as criminalisation of patent infringements all of which send a strong message discouraging Nigerians from trying to access affordable generic drugs. There has been increasing pressure on countries wanting to join the WTO to adopt measures that contravene the spirit of the Doha Declaration."

⁴¹⁴ B. Baker 'US Trade negotiations with the South African Customs Union Undermine Access to medicine and Violate US Law Health Gap. Available at: <http://www.cptech.org/ip/health/trade/sacu/hgap07072003.html>. Accessed on 22/08/2011.

The Zambian Patent Act has maintained patent provisions enacted during the British colonial government.⁴¹⁵ This implies that the Zambian patent system could be enforcing low patentability standards which form background preparation for restricted access to ARV drugs. However, two relevant sections of the Act are briefly examined to determine whether Zambia has low patentability standards.

Firstly Section 2(1)⁴¹⁶ under the definition section of the Zambian Patent Act sets out very much standard and apparently unproblematic requirements for 'novelty' requisite to the registration of subject matter being alleged to be new by an applicant. However, the phrasing of the requirement for an 'inventive step' calls for close scrutiny, as it is most likely to restrict access to essential medicine in Zambia. Thus, Section 31(6) of the Zambian patent Act states:

The grant of a patent of addition shall be conclusive evidence that the invention is a proper subject for such a patent, and shall not be refused, nor shall any such patent be liable to be revoked or invalidated, on the ground only that the invention claimed in the complete specification does not involve any inventive step having regard to the main invention, so, however, that the provisions of this subsection shall not apply to an independent patent referred to in the proviso to subsection (5).⁴¹⁷

The above phrasing in section 31(6) stating that "an additional patent may not refuse re-patenting merely on the basis that it does not show an inventive step" is ambiguous and could generally be regarded to include patentability of any living substances, new methods of known substances, mere admixtures or combination drugs, or methods of treatment. This implies that the Zambian Patent Act's requirements for registering dependent patents have low patentability standards.⁴¹⁸

Hence, Zambia should consider revisiting this pre-grant patent provision under section 36(1) before the expiration of its transition periods on 1st January 2013 and 2016 in order to allow PACRO to

⁴¹⁵ WTO Trade Policy Review (2009) on Zambia Note 169 above. Refer also to the discussion under item 1.3.1 in chapter one of this dissertation.

⁴¹⁶ Section 2(1) provides that: " 'invention' means any new and useful art (whether producing a physical effect or not), process, machine, manufacture or composition of matter which is not obvious, or any new and useful improvement thereof which is not obvious, capable of being used or applied in trade or industry and includes an alleged invention."

⁴¹⁷ Section 5 of the Zambian Patent Act of 1958. See Note 33 above.

⁴¹⁸ The use of TRIPS flexibilities Report of a WHO Mission Bangkok, 31 January to 6 February (2008) Note 229 above. "The Indian patent law is a good example of a piece of legislations that envisages high and elaborative patentability standards these include; specific restrictions to the patentability of salts, polymorphs, isomers and pro-drugs. Patent offices and other governmental agencies should consider integrating some exclusive wording in the national patent legislation in order to facilitate the work of the patent examiner."...

exclude certain advanced lines from being patented. Currently the provisions under 36(1) could be regarded as national TRIPS plus provisions. As is the case in Cambodia:

Which had been hailed for its proactive legislation that excluded pharmaceutical patents till 2016, it totally changed tack as a result of closed door negotiations for its ascension to the WTO. Under pressure from the USA, Cambodia has evidently agreed to implement TRIPS earlier in 2007, while immediately linking drug registration approval with patent status and granting 5 years of data exclusivity measures that could delay generic availability and cause a massive reduction in access to essential medicines.⁴¹⁹

For that reason inter alia, Zambia needs to consider revising its pre-grant provisions under section 36(1) of the Zambian patents Act to resemble those in Section 3(d) of the Indian Patent Act. In order to avoid finding itself in Cambodia's position taking in to account its membership to AGOA which seems to encompass TRIPS-plus provisions discussed below.

3.5. TRIPS-PLUS FREE TRADE AGREEMENTS AND THEIR INFLUENCE ON THE FUTURE OF ACCESS TO ARV DRUGS IN WTO AFRICAN STATES

TRIPS-Plus agreements could be argued to have stemmed from the refusal by the US government at the end of the Uruguay negotiations to adhere to TRIPS' standards and level of protection of IPRs.⁴²⁰ The US government alleged that TRIPS' provisions do not provide sufficient protection of IPRS and decided that it would continue to pursue higher standards of protection for IPRs through its bilateral, regional and multilateral free trade agreements (FTAs).⁴²¹ These FTAs are mainly instituted under its intellectual property trade policy in terms of its Trade Act of 2002⁴²² typified in its 301 United States trade reports (USTR) list.⁴²³ The provisions in the US FTAs are generally known to carry measures that undermine the force of the Doha declaration on the use of TRIPS flexibilities mainly compulsory licensing.⁴²⁴ Some of the measures advanced by the US in its FTAs include:

⁴¹⁹ Sekalala Note 242 above.

⁴²⁰ WHO& WTO (2002) Note 114 above.

⁴²¹ Musungu & Oh Note 195 above.

⁴²² The Trade and Development Act of 2002. Available online at: http://www.state.gov/www/regions/africa/fs_whitehouse_agoa.html. Accessed on 08/01/2013.

⁴²³ Office off the United States Trade Representative Executive Office of the President (Reports and Publications) Available online at:<http://www.ustr.gov/about-us/press-office/reports-and-publications>. Accessed on 08/01/2013.

⁴²⁴ Ibid.

Restrictions on the circumstances under which compulsory licenses for production of pharmaceuticals may be issued; the patent term of 20 years as required by TRIPS is extended disallowing generic entry; exportation of drugs produced under compulsory license is banned.⁴²⁵

The above provisions have caused serious concerns about the future of global access to patented essential medicines especially in developing nations.⁴²⁶ Thus, in 2000 the US President at the time issued an Executive Order⁴²⁷ stating the following:

In administering sections 301-310 of the Trade Act of 1974, the United States shall not seek, through negotiation or otherwise, the revocation or revision of any intellectual property law or policy of a beneficiary sub-Saharan African country, as determined by the President, that regulates HIV/AIDS pharmaceuticals or medical technologies if the law or policy of the country: (1) promotes access to HIV/AIDS pharmaceuticals or medical technologies for affected populations in that country; and (2) provides adequate and effective intellectual property protection consistent with the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) referred to in section 101(d)(15) of the Uruguay Round Agreements Act (19 U.S.C. 3511(d)(15)).

Despite the above Executive Order by the US President in the African context, the most threatening provisions to the future of public health and access to medicine are envisaged in the African Growth and Opportunities Act of 2000 (AGOA) previously cited as the Trade and Development Act of 2000.⁴²⁸ AGOA is an independent expansion of freer market access initiated by the United States of America (US) into 41 selected eligible Eastern and sub-Saharan African countries, to the exclusion of Zimbabwe.⁴²⁹

In terms of section 104 of AGOA eligible African countries are required to assume particular stances under the patronage of the US' multilateral trading level including inter alia, the guarantee to eradicate trade and investment barriers against the US by protecting intellectual property rights.⁴³⁰

⁴²⁵ Ibid.

⁴²⁶ Ibid.

⁴²⁷ US White House Executive Order 13155, May 20, 2000 - Access To HIV/AIDS pharmaceuticals and medical technologies. Available online at: <http://www.archives.gov/federal-register/executive-orders/2000.html>. Accessed on 08/01/2013.

⁴²⁸ African Growth and Opportunities Act (AGOA) of 2000. Available online at: http://www.agoa.gov/agoa_legislation/agoa_legislation.html. Accessed on 02/02/2012.

⁴²⁹ General country eligibility provisions. Available online at: http://www.agoa.gov/eligibility/country_eligibility.html. Accessed on 02/02/2012.

⁴³⁰ AGOA Act Section 104 'Eligibility Requirements' under states that: (a) in general.—the president is authorized to designate a sub-Saharan African country as an eligible sub-Saharan African country if the president determines that the

This provision is tied in with the condition in terms of section 10(A)⁴³¹ which requires that: “African governments must refrain from interfering in their national economies through measures such as price controls, state subsidies and ownership of fiscal assets.”

Despite AGOA having conceded that HIV/AIDS is a public health emergency in sub-Saharan Africa, it has remained silent on the pandemic’s affiliation to relaxation of IPRs under TRIPS for public health reasons.⁴³² Similar arrangements were proposed in the abandoned negotiations of an FTA between the Southern African Customs Union (SACU)⁴³³ and the US.⁴³⁴ According to Robert Zoellick (the former US trade representative to congress) the arrangements on intellectual property rights had specific objectives⁴³⁵ that sought to:

Advance and establish standards that reflect a standard of protection similar to that found in US law and that build on the foundations established in the WTO Agreement on Trade-Related Aspects of Intellectual Property (TRIPS Agreement) and other international intellectual property agreements, such as the World Intellectual Property Organization

country—...(c) the elimination of barriers to united states trade and investment, including by—...(ii) the protection of intellectual property.

⁴³¹ Ibid. Section. 104. ... (1) Has established, or is making continual progress toward establishing— (A) A market-based economy that protects private property rights, incorporates an open rules-based trading system, and minimizes government interference in the economy through measures such as price controls, subsidies, and government ownership of economic assets...;

⁴³² E. Munyuki & R. Machemedze. “Implementation of the TRIPS flexibilities by east and southern African countries: Status of patent law reforms by 2010”- Southern and Eastern African Trade, Information and Negotiations Institute (SEATINI) in the Regional Network for Equity in health in East and Southern Africa (EQUINET) EQUINET Discussion paper 80 January 2010 With support from SIDA (Sweden). Available online at: <http://equinetafrica.org/bibl/docs/Diss80TRIPSupdate2010.pdf>. Accessed on 25/10/2010. Hereinafter referred to as Munyuki & Machemedze

⁴³³ Information about SACU. Available online at: <http://www.sacu.int/>. Accessed on 02/02/2012.

⁴³⁴ [Ip-health] Inside US Trade: US Drops FTA with SACU. Available online at: <http://www.cptech.org/ip/health/trade/sacu/> also on the SACU web-page <http://www.sacu.int/main.php?id=252>. Accessed on 02/01/2012.

See also *Trade Negotiations: SACU Bilateral Trade*. Available on :<http://www.sacu.int/traden.php?id=414>. Accessed on 03/02/2012. “The US began negotiating a free trade agreement with the Southern African Customs Union—in June 2003. The talks first got stalled in mid-2004, largely because of the US’ extreme and inflexible demands regarding intellectual property rights and a demand for a negative list in services. By April 2006, the process was suspended. While the talks were stalled, the US administration reportedly began looking into the possibility of negotiating bilaterals FTAs with individual sub-Saharan African countries. Washington also proposed that the US and SACU adopt a Trade and Investment Cooperation agreement—more than a TIFA, but less than an FTA—as step towards a full-fledged FTA. On 16 July 2008, the US Trade Representative and the SACU Trade Ministers signed a Trade and Investment Development Cooperation Agreement. The TIDCA is meant to be a stepping stone to a full FTA, so the process is still in motion.”

⁴³⁵ [Ip-health] TAC/ALP Submission re SACU-US FTAA: available online at: <http://lists.essential.org/pipermail/ip-health/2004-February/005904.html>. Accessed on 03/02/2012. Hereinafter referred to as TAC/ALP Submission re SACU-US FTAA.

Copyright Treaty and Performances and Phonograms Treaty, and the Patent Cooperation Treaty.⁴³⁶

Likewise AGOA's principles on eligibility can categorically function as a peripheral or bilateral force on African governments' implementation of policy initiatives with regard to TRIPS flexibilities aimed at increasing access to medicines.⁴³⁷ It follows that the provisions in AGOA have the potential to borderline the execution of constitutional obligations, in this instance the right of access to health care services by African governments,⁴³⁸ consequently denying PLWHA their right to health and life as discussed in chapter four. This is because AGOA does not only depict a strong opposition to the behests of the Doha declaration envisaged under paragraphs 4 and 5 from developed nations, chiefly the US government. It also has the potential to censor the use of flexibilities specifically calculated to protect public health, despite the Doha declaration's prohibition of Members from taking any action that hinders other Members' rights to protect public health. ⁴³⁹ Accordingly Munyuki and Machemedze⁴⁴⁰ have rightly argued that:

African WTO Members especially LDCs who still have the opportunity to develop (IP) laws must ensure that they incorporate TRIPS flexibilities and demand that the (IPRs) under the WTO's multilateral trading system should govern both the AGOA's IPR eligibility criteria and US-SACU FTA if finalised.

Hence, WTO LDCs must use their discretion in broadening their use of TRIPS flexibilities, as a broader range of flexibilities in national laws, could serve as counter threats that are legally enforceable against patent holding pharmaceutical drug companies for public health purposes at any relevant time, irrespective of the pressure from developing countries.⁴⁴¹

⁴³⁶ November 4, 2002. Robert Zoellick. [Letter to the Speaker of the House of Representatives](#) which formally notifies Congress of the USTR's intention to negotiate the Free Trade Agreement(SACU-US). Available online at:<http://www.cptech.org/ip/health/trade/sacu/>. Accessed on 03/01/2012 .

⁴³⁷ Munyuki & Machemedze Note 432 above.

⁴³⁸ TAC/ALP Submission re SACU-US FTAA Note 433 above.

⁴³⁹ See Paragraph 4 Note 231 above and Paragraph 5 Note 231 above of the Doha declaration Refer also to country experiences such as USA v Brazil Note 237 above. See also USA v Thailand Note 347 and the PMA'S case.Note 377 above.

⁴⁴⁰ Munyuki & Machemedze Note 435 above.

⁴⁴¹ Sekalala Note 242 above cited P. McCalman, '*The Doha Agenda and Intellectual Property Rights*,' A study on Regional Integration and Trade: Emerging Policy Issues for Selected Developing Member Countries. October 2002 pp 2-4.

3.6. CONCLUSION

The global cry for access to medicine continues to date as the HIV/AIDS infection reaches desperate proportions in WTO countries positioned in the poorer regions of the world, predominantly sub-Saharan and East Africa.⁴⁴² In this regard it is submitted that Zambia is among the low income WTO African countries adversely affected by HIV/AIDS and battling to sustain the national provision of ARV drugs,⁴⁴³ due to a combination of non-patent and patent related factors.⁴⁴⁴ This combination of challenges, require Zambia to, inter alia, implement legal frameworks encompassing a broad range of TRIPS flexibilities in its domestic patent legislation⁴⁴⁵ in order to legally relax IPRs standards on pharmaceutical patents advanced by TRIPS on both national and international levels. The legal relaxation of IPRs on patented medicines through the use of existing national policies on HIV/AIDS and TRIPS flexibilities such as government-use provisions as was the case in 2004 could help Zambia to manufacture and provide medicines on a non-commercial basis, meaning subsidized or free ARV drugs to patients in desperate need of advanced regimens of ARV drugs in this way increasing access to ARV drugs as a human right to health and life.

⁴⁴² Global Report on HIV/AIDS Regions(UNAIDS) Note 222 above.

⁴⁴³ ZAMBIA: 'Third-Line ARVs Available Soon'. Africa Files 7th of March 2011 Note 82 above. See also ZAMBIA: 'Corruption Scandal Rocks ARV Programme' (PlusNews) JOHANNESBURG, 14 March 2011 Note 81 above. See also Uganda: *Misuse of funds as global fund inquiry quizzes ministers,* IRIN (24 March 2006). Available at <http://www.aegis.com/news/irin.2006/IR060372.html>. last Accessed 16/11/ 2011.

⁴⁴⁴ For non-patent related challenges and for patent related challenges refer to discussion in chapter of this dissertation.

⁴⁴⁵ Mabika A. H SADC and HIV/AIDS-Countries should use TRIPS flexibilities (SEATINI2006).Available online at: <http://www.seatini.org/bulletins/2006/9.04.php>. Accessed on 13/04 2010.

CHAPTER FOUR: THE HUMAN RIGHT TO HEALTH/LIFE AND ACCESS TO MEDICINE AS A CORE OBLIGATION FOR ZAMBIA IN THE WAKE OF WTO TRADE AGREEMENTS

4.1. INTRODUCTION: THE INTERNATIONAL RECOGNITION OF THE RIGHT TO HEALTH

The right to health is a fundamental human right⁴⁴⁶ that forms part of our conception of a life with dignity.⁴⁴⁷ Its international recognition has been influenced by several factors ranging from the atrocities of the first and second world wars to global health threats, such as communicable diseases. This study is focusing on HIV/AIDS and the right to health and or life in relation to globalization of health services and IPRs as discussed previously in chapter two and three respectively.⁴⁴⁸

The right to health was first verbalised in the preamble to the 1946 Constitution of the World Health Organization (WHO)⁴⁴⁹ in which health was defined as: “[a] state of complete physical, mental and social well-being and not merely the absence of disease or infirmity”.⁴⁵⁰

Today, various human rights treaties,⁴⁵¹ national constitutions,⁴⁵² organizations⁴⁵³ and declarations⁴⁵⁴ recognize the right to health and its components as indispensable to the realization of other human

⁴⁴⁶ United Nations GENERAL COMMENT No. 14 E/C.12/2000/4 11 August (2000). Available online at: [http://www.unhcr.ch/tbs/doc.nsf\(symbol\)/E.C.12.2000.4.En](http://www.unhcr.ch/tbs/doc.nsf(symbol)/E.C.12.2000.4.En). Accessed on 3/03/2012. Hereinafter referred to as, UN General Comment No. 14. See also: The Right to Health: ‘An Assessment of Kenya’s commitment to health as a fundamental human right’ Health Rights Advocacy Forum (HERAF) Savelberg Retreat Centre, Nairobi-Kenya 2007. Available online at: www.heraf.or.ke/heraf_2007.../96-heraf-annual-report-2007.html. Accessed on 13/09/2010.

⁴⁴⁷ Correa (2008) Note 187 above. See also World Health Report (WHO 2010) Note 225 above.

⁴⁴⁸ Ibid.

⁴⁴⁹ The Constitution of the World Health Organization (WHO) was adopted by the International Health Conference held in New York from 19 June to 22 July 1946, signed on 22 July 1946 by the representatives of 61 States (*Off. Rec. Wld Hlth Org.*, 2,100), and entered into force on 7 April 1948.. Available online at: http://www.who.int/hhr/activities/Right_to_Health_factsheet31.pdf. Accessed on 03/03/2012.

⁴⁵⁰ Ibid.

⁴⁵¹ The 1965 International Convention on the Elimination of All Forms of Racial Discrimination: Article 5 (e) (IV); the 1966 International Covenant on Economic, Social and Cultural Rights, Article. 12; the 1979 Convention on the Elimination of All Forms of Discrimination against Women: Articles. 11 (1) (f), 12 and 14 (2) (b); the 1989 Convention on the Rights of the Child: Article. 24. See also The Right to Health Fact Sheet No. 31 World Health Organization Office of the United Nations High Commissioner for Human Rights. Available online at <http://www.ohchr.org/Documents/Publications/Factsheet31.pdf>. Accessed on 03/03/2012. Hereinafter referred to as, The Right to health Fact Sheet No.31.

⁴⁵² Ibid. The right to health or the right to health care is recognized in at least 115 constitutions.

⁴⁵³ D. Ovettt Making Trade Policies More Accountable and Human Rights-Consistent: A NGO Perspective of Using Human Rights Instruments in the Case of Access to Medicines (2001). Available online at: http://www.3dthree.org/pdf_3D/DOvetttHRandAccessMedChapter.pdf accessed on 07/03/2012. Hereinafter referred to as Ovettt (2001). Chiefly the United Nations: “That established Special Rapporteur on right of everyone to the enjoyment of the highest attainable standard of physical and mental health in 2002 through the Human Rights Council .The Special Rapporteur has worked closely with many stakeholders, including the relevant departments of WHO. This work has laid the foundation for including progress by State Parties in ensuring access to essential medicines in the standard reporting format required by the monitoring bodies”.

⁴⁵⁴ Declaration of Alma-Ata, International Conference on Primary Health Care, Alma-Ata, USSR, September 1978. Available online at: http://www.who.int/hpr/NPH/docs/declaration_almaata.pdf. Accessed on 03/03/2012. “The

rights such as the right to life to be discussed later in this chapter. For example, Article 25 of the 1948 Universal Declaration of Human Rights (UDHR) declares that “health [is] part of the right to an adequate standard of living.”⁴⁵⁵

Moreover, the right to health was again recognized as a human right in the more legally binding 1966 International Covenant on Economic Social and Cultural Rights (ICESCR) which provides the most precise stipulation in international human rights law.⁴⁵⁶ Article 12.1 of the ICESCR states that; “State parties must recognize that everyone enjoys the highest standard of the right to physical and mental health.” This means that every State that has ratified at least one human rights treaty recognizing the right to health or even merely encompassing its components, such as medical care or, most pertinent to this research, access to essential drugs, has to pursue national interests that protect the right to health as a holistic right through domestic legislation and policies.

In view of these obligations, access to essential medicines, principally ARV drugs, may be seen as a key component of the right to health for specific vulnerable groups,⁴⁵⁷ in this instance people living with HIV/AIDS (PLWHA) globally and specifically in Zambia.

Declaration affirms the crucial role of primary health care, which addresses the main health problems in the community, providing promotive, preventive, curative and rehabilitative services (Articles VII & V).”

See also: The United Nations Millennium Declaration and Millennium Development Goals. Available online at: <http://www.un.org/millennium/declaration/ares552e.pdf>. Accessed on 03/03/2012.

See also The Declaration of Commitment on HIV/AIDS, General Assembly resolution S-26/2 of 27 July 2000. Available online at: <http://www.un.org/ga/aids/docs/aress262.pdf>. Accessed on 03/03/2012.

See also *Political declaration on HIV/AIDS Draft resolution submitted by the President of the General Assembly: Intensifying our Efforts to Eliminate HIV/AIDS (2011)*. Available online at: http://www.un.org/ga/search/view_doc.asp?symbol=A/65/L.77. Accessed on 16/03/2012.

See also Resolution adopted by the General Assembly 60/262. Political Declaration on HIV/AIDS the General Assembly Adopts the Political Declaration on HIV/AIDS annexed to the present resolution. 87th plenary meeting 2 June 2006. Available online at: http://www.un.org/ga/search/view_doc.asp?symbol=A/65/L.77. Accessed on 16/03/2012. Hereinafter referred to as Political declaration on HIV/AIDS Draft resolution submitted by the President of the General Assembly: Intensifying our Efforts to Eliminate HIV/AIDS (2011).

⁴⁵⁵ The Universal Declaration of Human Rights. Adopted by the General Assembly of the United Nations on 10 December 1948. Available online at: <http://www.un.org/en/documents/udhr/>. Accessed on 07/03/2012. Hereinafter referred to as, the UDHR.

⁴⁵⁶ International Covenant on Economic, Social and Cultural Rights Adopted and opened for signature, ratification and accession by General Assembly resolution 2200A (XXI) of 16 December 1966 entry into force 3 January 1976, in accordance with Article 27. Available online at: <http://www2.ohchr.org/english/law/cescr.htm>. Accessed on 03/03/2012. Hereinafter referred to as, the ICESCR.

⁴⁵⁷ Political declaration on HIV/AIDS Draft resolution submitted by the President of the General Assembly: Intensifying our Efforts to Eliminate HIV/AIDS (2011) Note 454 above. “Some groups or individuals, such as children, women, persons with disabilities or persons living with HIV/AIDS, face specific hurdles in relation to the right to health. These can result from biological or socio-economic factors, discrimination and stigma, or, generally, a combination of these. Considering health as a human right requires specific attention to different individuals and groups of individuals in society, in particular those living in vulnerable situations.”

This chapter will elaborate on the issue which pivots upon the obligations of Members globally and on Zambia specifically to respect, protect and fulfil the entitlement of access to medicines as part of the human right to health in the wake of WTO trade agreements, namely TRIPS and GATS.

Reference will be made in the discussion to South Africa's constitutional recognition of the right to health to support the argument for the legal adoption of a justiciable right to health in Zambia's current Constitution Bill.

Finally this chapter will explore possible options for PLWHA in Zambia to legally enforce their right of access to medicines as part of the broader right to health despite the Zambian Constitution's non recognition of the right to health.

4.2. THE RIGHT TO HEALTH: UNDERLYING SOCIAL DETERMINANTS, FREEDOMS AND ENTITLEMENTS AS NATIONAL RESPONSIBILITIES FOR STATES TO SUSTAIN THE HUMAN RIGHT TO LIFE

The Committee on Economic, Social and Cultural Rights (CESCR), the body in charge of monitoring the ICESCR, requires that Members implement programmes that address the social determinants of the right to health, such as access to safe drinking water and adequate sanitation, safe food, adequate nutrition and housing, healthy working and environmental conditions, health-related education and information and gender equality.⁴⁵⁸

Additionally the right to health encompasses certain freedoms. These include the right to be free from non-consensual medical treatment, such as "medical experiments and research or forced sterilization, and to be free from torture and other cruel, inhumane or degrading treatment or punishment."⁴⁵⁹ These freedoms are coupled with certain entitlements⁴⁶⁰ which include for purposes of this research the following two:

⁴⁵⁸ CESCR GENERAL No.14 Note 446 above. See also The Right to Health: 'An Assessment of Kenya's commitment to health as a fundamental human right' Health Rights Advocacy Forum (HERAF) 2007 Note 446 above.

⁴⁵⁹ ICESCR GENERAL No.14 Note 446.

⁴⁶⁰ Ibid. (iii) the right to a system of health protection providing equality of opportunity for everyone to enjoy the highest attainable level of health; (iv) maternal, child and reproductive health; equal and timely access to basic health services; (v) the provision of health-related education and information; (vi) and participation of the population in health-related decision-making at the national and community levels.

(i) access to essential medicines and;

(ii) the right to prevention, treatment and control of diseases.

Therefore Members to the ICESCR are obligated, through implementation of national health policies, to achieve the abovementioned social determinants and the interconnected freedoms and entitlements pertinently of the right of access to medicines and prevention, treatment and control of disease such as HIV/AIDS. Furthermore, and in order to achieve this, state parties have to ensure that; “health services, goods and facilities are provided to all without discrimination or marginalization of specific population groups.”⁴⁶¹ In this instance a specific population group is that of PLWHA who require constant access to ARV drugs and treatment.⁴⁶²

Governments, therefore, have to ensure that health-care facilities, goods and services are available and accessible. Accessibility means both physical accessibility and financial affordability. Financial affordability requires that both private and public provision of health facilities, goods and services including “appropriate treatment for prevalent diseases, illnesses, injuries and disabilities and the provision of essential drugs such as ARV drugs should be affordable⁴⁶³ and that poorer households should not be disproportionately burdened with health expenses as compared to more affluent households”.⁴⁶⁴

Safeguarding the aforesaid underlying determinants, freedoms and pertinently the entitlement of access to essential medicines as components of the right to health facilitates the enjoyment of other

⁴⁶¹ The Right to Health Fact Sheet No. 31 Note 451 above. “Non-discrimination and equality are fundamental human rights principles and critical components of the right to health”. According to the CESCR, ‘other status’ may include health status (e.g., HIV/AIDS) or sexual orientation. States have an obligation to prohibit and eliminate discrimination on all grounds and ensure equality to all in relation to access to health care and the underlying determinants of health.) Along the same lines, the CESCR has made it clear that “there is no justification for the lack of protection of vulnerable members of society from health-related discrimination, be it in law or in fact. So even if times are hard, vulnerable members of society must be protected, for instance through the adoption of relatively low-cost targeted programmes.”

⁴⁶² Ibid.

⁴⁶³ CESCR GENERAL No.14 Note 446 above.

See also P. Hunt Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health A/61/338(2006). Available online at: <http://www.un.org/ga/61/third/item67summary.shtml>. Accessed on 09/04/2012. Hereinafter referred to as P. Hunt UN General Assembly A/61/338:2006) Emphasis in italics is the authors own.

⁴⁶⁴ P. Hunt (2003) Economic, Social and Cultural Rights the right of everyone to the enjoyment of the highest attainable standard of physical and mental health Report of the Special Rapporteur, Paul Hunt, submitted in accordance with Commission resolution 2002/3. Available online at: <http://www.un.org/womenwatch/ods/E-CN.4-2003-58-E.pdf>. Accessed on 09/04/2012. Hereinafter referred to as P. Hunt E/CN.4/2003/58 2003.

human rights, such as the right to life.⁴⁶⁵ Accordingly the right to life as articulated by the United Nations Human Rights Committee (UNHRC)⁴⁶⁶ cannot be understood in a “restrictive manner⁴⁶⁷ and requires that Members adopt positive health policies which include all possible measures that reduce malnutrition, epidemics [in this instance HIV/AIDS] and infant mortality and increase life expectancy.”⁴⁶⁸

It thus transpires that access to medicine is an intrinsic component and a sequel to the right to life for PLWHA. This is the inherent interdependent and indivisible nature of human rights. ⁴⁶⁹ Thus Members to ICESCR have a duty to legislate measures that legally protect the right of access to medicines as a minimum core component of the right to health.⁴⁷⁰

The CESCR in its General comment No. 3 has accentuated the satisfaction of certain minimum essential goals of each of the rights envisaged under the ICESCR. Despite most of these essential goals being contingent on the availability of state resources,⁴⁷¹ states nevertheless have a minimum core obligation to prioritise them in order to safeguard and satisfy each of the rights under the Covenant. In respect of the right to health, the Committee has emphasised that states must ensure, inter alia:

- (i) The provision of essential drugs as from time to time defined under the WHO Action Programme on Essential Drugs; and:
- (ii) Equitable distribution of all health facilities, goods and services.⁴⁷²

⁴⁶⁵ Human Rights Committee General Comment No. 6: The right to life (Article 6), Compilation of General Comments and General Recommendations Adopted by Human Rights Treaty Bodies, UN Doc. HRI/GEN/1/Rev.6 (2003) at 127. Available online at: <http://www1.umn.edu/humanrts/gencomm/hrcom6.htm>. Accessed on 07/03/2012.

⁴⁶⁶ Ibid. “The body responsible for monitoring the implementation of International Covenant on Civil and Political Rights (ICCPR)”.

⁴⁶⁷ Ibid.

⁴⁶⁸ Oveit (2006) Note 453 above.

⁴⁶⁹ Mabika & London Note 24 above argue that: “The recognition and application of the principle of health as a human right are significant in many respects: (a) It signifies awareness of the relationship and interdependence of health with the other human rights such as civil and political, economic, cultural and social rights. (b) The link between health and human rights indicates the centrality of the right to health in the attainment of the development. To promote human life and dignity, the right to health must be held in highest regard by society. Since realizing human dignity is the ultimate goal of development, health should be an essential component of any development program - GATS and TRIPS included.”

⁴⁷⁰ HRC, Uganda, Concluding Observations, UN Doc. CCPR/CO/80/UGA (2004). Available online at: [http://www.unhcr.ch/tbs/doc.nsf/\(Symbol\)/CCPR.CO.80.UGA.En?Opendocument](http://www.unhcr.ch/tbs/doc.nsf/(Symbol)/CCPR.CO.80.UGA.En?Opendocument). Accessed on 05/03/2012.

⁴⁷¹ ICESCR GENERAL COMMENT No 3. The nature of States parties obligations (Art. 2, para. 1 of the Covenant: 12/14/1990) (Fifth session, 1990). Available online at: [http://www.unhcr.ch/tbs/doc.nsf/\(Symbol\)/94bdbaf59b43a424c12563ed0052b664?Opendocument](http://www.unhcr.ch/tbs/doc.nsf/(Symbol)/94bdbaf59b43a424c12563ed0052b664?Opendocument). Accessed on 07/03/2012. Hereinafter referred to as ICESCR General Comment No.3.

⁴⁷² CESCR GENERAL No.14 Note 446 above.

See also Commission on Human Rights (CHR), *The right of everyone to the enjoyment of the highest attainable standard of physical and mental health*, Report of the Special Rapporteur of the Commission on Human Rights on the right of

According to the CESCR, the above provisions mean that every nation that has ratified the ICESCR has specific legal obligations to respect, protect and fulfil the above goals of provision of essential drugs and equitable distribution of health facilities, goods and services as part of their overall realisation of the right to health.⁴⁷³ Therefore the three legal obligations to respect, protect and fulfil are now examined to determine their scope and function counting state parties to the ICESCR's obligations under the WTO trade agreements on TRIPS and GATS.

4.2.1. The obligation to respect

This obligation requires states to refrain from interfering directly or indirectly with the right to health. Accordingly Members States that adopt "[a]ctions, policies or laws that contravene the standards set out in Article 12 of the ICESCR and that are likely to result in bodily harm, unnecessary morbidity and preventable mortality are in violation of the duty to respect."⁴⁷⁴ This means that Members should refrain from denying or limiting access to health-care services, for example through the implementation of neo-trade economic policies. These would include, as previously discussed in chapter three bilateral free trade agreements that contain TRIPS-plus provisions that have the effect of limiting access to advanced ARV drugs.⁴⁷⁵

4.2.2. The obligation to protect

This obligation requires states to prevent third parties from interfering with the right to health. In the context of access to ARV drugs this means the following:

- (a) legally implementing policies or even laws aimed at the regulation of marketing of medical equipment and medicines by private actors;⁴⁷⁶
- (b) ensuring that privatization does not constitute a threat to the availability, accessibility, acceptability and quality of health-care facilities, goods and services.

Each of the above obligations is discussed in more detail below.

everyone to the enjoyment of the highest attainable standard of physical and mental health: Paul Hunt, UN Doc. E/CN.4/2004/49/Add.1 (1 March 2004), at 37 (c). Available online at: <http://daccess-dds-ny.un.org/doc/UNDOC/GEN/G05/108/93/PDF/G0510893.pdf?OpenElement>. Accessed on 07/03/2012.

⁴⁷³ CESCR General Comment No.14 at Paragraph 33. See also Ovet (2006) Note 453 above.

⁴⁷⁴ CESCR General Comment No.14 at Paragraph 34.

⁴⁷⁵ Ovet (2006) Note 453 above.

⁴⁷⁶ CESCR General Comment No. 14 Paragraph 35 Note 443 above.

An example of ;- (a) implementation of laws aimed at the, regulation of marketing of medical equipment and medicines by private actors may be found in *Minister of Health v New Clicks South Africa (Pty) Ltd and others*⁴⁷⁷ in which a unanimous judgment by the South African Constitutional Court held that:

The South African government has a legal duty to take all reasonable steps to ensure that essential medicines are accessible. Some of the reasonable steps include the implementation of regulatory measures such as direct price controls if these measures are the only reasonable way it may carry out its duty. Where it is possible, less invasive means can be used, such as the regulation of pricing practices rather than direct price controls.⁴⁷⁸

The judgment in *New Clicks* is in line with the United Nations international guidelines on HIV/AIDS,⁴⁷⁹ which state that: "State parties have a duty to prevent unreasonably high costs for access to essential medicines."⁴⁸⁰ Furthermore, it is in line with the CESCR's affirmation that: "State parties must ensure that private actors conform to human rights standards when providing health care or other services."⁴⁸¹

Likewise the UN Special Rapporteur on the Right to Health released in September 2007, the draft Human Rights Guidelines for Pharmaceutical Companies in Relation to Access to Medicines, which, inter alia, stipulate that the company's corporate mission statement should:

Expressly recognize the importance of human rights generally, and the right to the highest attainable standard of health in particular, in relation to the strategies, policies, programs, projects and activities of the company and that the company should integrate human rights, including the right to the highest attainable standard of health, into the strategies, policies, programs, projects and activities of the company⁴⁸².

⁴⁷⁷ *Minister of Health v New Clicks South Africa (Pty) Ltd and others* CCT (59/2004) [2005] ZACC 14; 2006 (8) BCLR 872 (CC); 2006 (2) SA 311 (CC) (30 September 2005). Available online at: <http://www.saflii.org/za/cases/ZACC/2005/14.html> Accessed on (04/04/2012). Hereinafter referred to as New clicks case. See also summary of the New Clicks judgment in Health and Democracy: Access to Essential Medicines (2010) Note 264 above.

⁴⁷⁸ Ibid.

⁴⁷⁹ International Guidelines on HIV/AIDS and Human Rights (2006) Consolidated Version. Available online at: [Shttp://data.unaids.org/Publications/IRC-pub07/jc1252-internguidelines_en.pdf](http://data.unaids.org/Publications/IRC-pub07/jc1252-internguidelines_en.pdf). Accessed on 21/10/2011.

⁴⁸⁰ Ibid.

⁴⁸¹ CESCR General Comment No. 14 Note 446 above.

⁴⁸² Draft for Consultation Comments by 15 May 2008 to rkhosl@essex.ac.uk Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicines Prepared by the United Nations Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health (19 September 2007 Available online at: http://www.essex.ac.uk/human_rights_centre/research/rth/projects.aspx. Accessed on 09/04/2012. See also CIPIH (2006) Note 367 above. See also Correa 2008 Note 187 above.

An example where ;- (b) availability, accessibility, acceptability and quality of health-care facilities, goods and services is compromised by privatization may be found in the Zambian privatization policies discussed in chapter one, which consequently, curtailed government subsidies to various State Ministries including health and has rendered health services unaffordable, reducing and in certain instances disconnecting access to primary health services to Zambia's general populaces and denying basic human rights including access to ARV drugs.⁴⁸³

Therefore, Zambia's legal adoption of provisions on liberalisation of trade in health services under GATS and its imminent adoption of TRIPS provisions on pharmaceutical patent rights protection and test data require government's adoption of legal regulatory frameworks to assist in the protection of the right of access to medicine. This may be achieved through the national constitution which can be used to give content to the right and define the Zambian government's obligations to devise the necessary policy and legal frameworks to help cushion vulnerable groups such as PLWHA from any adverse impact that GATS and TRIPS may have on access to ARV drugs as a public health service.

4.2.3. The obligation to fulfil

The obligation to fulfil requires States to adopt appropriate legislative, administrative, budgetary, judicial, promotional and other measures to fully realize the right to health.⁴⁸⁴ Therefore governments must adopt legal frameworks that individual members of society should be able to rely on to realise their rights through their own action. Thus the duty to fulfill denotes "government's function as a regulator, as opposed to as a provider."⁴⁸⁵ This means that even when governments provide "certain essential medicines free of charge in the public health sector they are still under a constitutional obligation or bound by international human rights law where applicable to take steps aimed at decreasing the prices of the same drugs in the private sector and safeguarding a sustainable supply thereof."⁴⁸⁶

For instance, in the Zambian context, there is a need for government adoption of national legal regulatory frameworks to regulate liberalised health services in terms of GATS for the benefit of the general public as previously discussed in chapter two. Moreover, in respect of TRIPS, governments must take all reasonable steps to adopt and make use of viable legal frameworks such as those

⁴⁸³ EQUITY WATCH: Assessing Progress towards Equity in Health in Zambia, (EQUINET 2011) Note 32 above. See also Mabika & London Note 24 above. See also AFRODAD (2007) Note 6 above.

⁴⁸⁴ CESCR General Comment No. 14 Note 446 above.

⁴⁸⁵ Health and Democracy: Access to essential medicines 2010). Note 264 above.

⁴⁸⁶ Ibid.

discussed in chapter three in order to expedite improved access to essential medicines. Thus the duty to fulfil the right to health includes the obligation to progressively realise it. Article 16 (2) of the African Charter on Human and People's rights⁴⁸⁷ states that: ... "State parties to the present Charter shall take the necessary measures to protect the health of their people and to ensure that they receive medical attention when they are sick."

Therefore States are required to "take reasonable steps", within available resources, to realize the right to health. In this regard African states party to ICESCR specifically Zambia when seeking the interpretation of the phrase "reasonable steps" could refer to the South African Constitutional Court judgement in *Government of the Republic of South Africa (RSA) v Grootboom & Others*⁴⁸⁸ which established that to be "reasonable, measures cannot leave out of account the degree and extent of denial of the right they endeavour to realize." The court went on to clarify that this means that:

Those whose needs are the most urgent and those whose ability to enjoy all rights therefore is most in peril, must not be ignored by the measures aimed at achieving realization of the right...If the measures, though statistically successful, fail to respond to the needs of the most desperate, they may not pass the test.

Hence with regard to the *Grootboom* case, when faced with immediate obligations, including minimum core ones such as access to essential drugs and equitable distribution of all health facilities, goods and services, a country's constrained financial situation does not absolve it from duties of taking the necessary and reasonable steps to expeditiously realize the right to health.⁴⁸⁹ Furthermore the CESCR General Comment 14 explains that:

If resource constraints render it impossible for a State to comply fully with its Covenant obligations, it has the burden of justifying that every effort has nevertheless been made to use all available resources at its disposal in order to satisfy, as a matter of priority, its obligations.⁴⁹⁰

⁴⁸⁷ OAU Doc. CAB/LEG/67/3 rev. 5, 21 I.L.M. 58 Adopted 27 June 1981, (1982), entered into force 21 October 1986 Available online at: http://www.africa-union.org/official_documents/treaties_%20conventions_%20protocols/banjul%20charter.pdf. Accessed on 18/02/2012.

⁴⁸⁸ *Government of the RSA v Grootboom & Others* 2000 (11) BCLR 1169 [at paras 44 and 45]. Available online at: <http://www.saflii.org/za/cases/ZACC/2000/19.html>. Accessed on 09/03/2012. Hereinafter referred to as *Grootboom case*.

⁴⁸⁹ World Health Report (2010) Note 225 above. Highlighted that: "It is often argued that States that cannot afford it are not obliged to take steps to realize this right or may delay their obligations."

⁴⁹⁰ CESCR General Comment No. 14 Note 446 above.

The above provision means that resource challenged states like Zambia, when raising the issue of funding as the main impediment to sustained access to ARV drugs and HIV/AIDS related services, ought to prove that other measures, such as the use of a broad range of TRIPS flexibilities discussed in chapter three, including the regulation of private health services discussed in chapter two, have been employed to realize the right of access to medicines including ARV drugs. However, Zambia does not have a broad range of TRIPS flexibilities and has not devised any legal regulatory in respect of GATS to make private health services serve a complementary role to the provision of public health services.

Moreover and as will be discussed later in this chapter, Zambia like most African countries does not recognize the socio-economic right to health as justiciable in its national constitution.⁴⁹¹ Thus it can be argued that in as much as Zambia is a poor country as highlighted throughout this study, when the government fails to fulfil the right of access to medicines case in point the ARV drug stock-outs and erratic drug supply in 2009 discussed in chapter one. The argument of lack of finances will not always be sufficient due to its minimal recognition of the right to health in its domestic legislation.

In order to establish how such socio-economic rights can be upheld, the section below will briefly analyse South Africa's implementation of HIV/AIDS policies subject to its incorporation of socio-economic rights, principally the right to health, into its national constitution. This analysis is an illustration to the Zambia government, which is currently in the process of developing IP laws and drafting its National Constitution Bill to allow it to appreciate the significance of incorporating the right to health in its Bill of Rights as a justiciable human right and a mitigating mechanism against any adverse corollaries that may arise from the implementation of TRIPS provisions on pharmaceutical patents and test data and GATS' provision on liberalised trade in services.

4.3. INCORPORATION OF THE RIGHT TO HEALTH IN THE SOUTH AFRICAN CONSTITUTION: REASONS FOR ZAMBIA'S CONSTITUTIONAL ADOPTION OF THE RIGHT TO HEALTH

The Constitution of South Africa has incorporated the socio-economic right to health under its Bill of rights (BORs)⁴⁹² as a legally enforceable right in a court of law.⁴⁹³ This has been evidenced in

⁴⁹¹ D.M Chirwa "An Overview of the impact of the International Covenant on Economic, Social and Cultural Rights in Africa" (2001) LLM research assignment (unpublished). Available online at http://www.Communitylawcentric.org.2a/ser/rights_in_africa_doc . Accessed 13/03/2012. Hereinafter referred to as, Chirwa (2001). "Some countries have completely excluded the Bill of rights in their national constitutions"

⁴⁹² In terms of the South African Constitution Note 323 above ESCR) are found under Chapter 2: of the South African constitution which is the Bill of Rights and its provisions purport the 'Progressive realization of ESCRs'. For example,

different South African Constitutional Court Judgments,⁴⁹⁴ in which the court has dealt with issues of enforcing socio-economic rights, including access to medicine, as a facet of the broader right to health. Pertinent to this research is the case of *Minister of Health and Others v Treatment Action Campaign (TAC) and others*.⁴⁹⁵ This case generally dealt with a complaint lodged by the TAC against the Minister of health before the Pretoria High Court in 2001, in which the TAC alleged that:

The national health policy which by confining the roll out of Nevirapine (AZT) an ARV drug used in treatment and prevention of mother to child transmission (MTCT) of HIV/AIDS to two research or pilot sites per province, resulted into restricted availability of the drug ...Thus, the conduct of the government was irrational, in breach of the Bill of Rights, and contrary to the values and principles prescribed for public administration in section 195 of the Constitution. Furthermore, government conduct was in breach of its international obligations as contained in a number of conventions that it has both signed and ratified.

The relief sought by the TAC included, inter alia, that the South African government distributes Nevirapine [ARV drugs] to pregnant women in all public hospitals. The Pretoria High Court ruled in favour of the TAC and held that the South African government's restrictions on the distribution of Nevirapine were unreasonable. The matter was taken on appeal by the Minister of Health, and in July 2002, the Constitutional Court upheld the High Court ruling that the government's policy on the roll out of Nevirapine "had not met its constitutional obligations to provide people with access to healthcare services in a manner that is reasonable and takes account of pressing social needs."⁴⁹⁶

Section 27(1) of the Bill of rights makes the right to health a progressively realizable right by the state. It states that: "Everyone has the right to have access to (a) Health care services, including reproductive health care.

(b) Sufficient food and water; and;

(c) Social security, including if they are unable to help themselves and their dependants, appropriate social assistance."

Section 27(2) states that: "The state must take reasonable and other legislative measures, within its available resources, to achieve the progressive realization of each of these rights".

Section 27(3) states that: "No one may be refused the right to emergency medical treatment".

⁴⁹³ Mark Heywood, "Current developments: Preventing mother-to-child HIV transmission in South Africa: Background, strategies and outcomes of the Treatment Action Campaign's case against the Minister of Health", *South African Journal of Human Rights*, vol. 19, part 2 (2003).

⁴⁹⁴ South African Constitutional court judgments. Available at: <http://www.joasa.org.za/aricles/caselist.pdf>. Accessed on 23/02/2012. For example *Soobramoney v Minister of Health (KwaZulu-Natal)* CCT32/97 ZACC 17; 1998(1) SA 765(CC); 1997 12 BCLR1696 (27 November 1997). *Republic of South Africa v. Grootboom* 2001 Note 462 above; Recent examples include *Minister of Home Affairs v. Fourie*; *Lesbian and Gay Equality Project v Minister of Home Affairs*, 2006 (1) SALR 524 (CC) (holding the common-law definition of marriage and sec. 3(1) of the Marriage Act, No. 25 of 1961 unconstitutional to the extent that they discriminated against homosexual couples).

⁴⁹⁵ *Minister of Health and Others v Treatment Action Campaign and Others* 2002 (5) SA 721/ (No 2) (CCT8/02). [at paras 11,19, 22.14]. Hereinafter referred to as, the TAC case.

⁴⁹⁶ *Ibid.*

The Constitutional court further confirmed that the “policy discriminated against poor people who could not afford to pay for services” and ordered the government to make Nevirapine “immediately available to pregnant women infected with the HIV virus who give birth in the public health sector, when this is medically indicated.”⁴⁹⁷ Additionally the Constitutional Court made a declaration that; “the State has a duty to devise and implement in a reasonable manner an effective national programme to reduce MTCT of the HIV virus, by administering Nevirapine or other appropriate medicine, as well as providing voluntary counselling and testing, and formula milk for the babies.”⁴⁹⁸

The TAC case above suggests some valuable reasons as to why Zambia should consider constitutional protection of the right to health, including access to essential drugs and services. Firstly, the TAC case epitomized the imperative role that courts can play in ensuring that government departments discharge their social- economic human right duty of making ARV drugs and treatment services readily accessible and available through the implementation of comprehensive health policies. This was affirmed on appeal by the South African Constitutional Court in the TAC case when it stated that; “socio-economic rights were justiciable and that judges must exercise their powers to effect policy or legislation where it was appropriate to do so”⁴⁹⁹

Secondly, the TAC case illustrates how constitutional protection of the right to health can reverse injudicious or ‘bad’ government policy and programmes including the adoption of international trade agreement policies that may cause prohibitive prices for patented ARV drugs for PLWHA. As affected vulnerable groups could upon infringement of their right to health seek relief thereof through the court system.⁵⁰⁰ In this regard, Zambia’s legal adoption of human rights conventions and the protection of

⁴⁹⁷ Orders of the Constitutional Court in the *TAC* case are on Paragraph [135 at page 73 subparas 1, 2, 3, 4, 5, 6]. See also “Facts about Nevirapine are Simple - But Unnecessary Confusion Endangers Lives - *TAC* Newsletter Treatment Action Campaign (TAC) News”. Available online at: http://www.tac.org.za/newsletter/2004/ns15_07_2004.htm. Accessed on 03/11 2009.

⁴⁹⁸ *Ibid*.

⁴⁹⁹ J. M Woods, ‘Emerging paradigms of protection for “second-generation” human rights’, (2005) 6 *Loy J Pub Int L* 103.

⁵⁰⁰ Section 38: Enforcement of rights states the following: Anyone listed in this section has the right to approach a competent court, alleging that a right in the Bill of Rights has been infringed or threatened, and the court may grant appropriate relief, including a declaration of rights. The persons who may approach a court are –

(a) anyone acting in their own interest;

(b) anyone acting on behalf of another person who cannot act in their own name;

(c) anyone acting as a member of, or in the interest of, a group or class of persons;

(d) anyone acting in the public interest; and (e) an association acting in the interest of its members.

See also S. Mwale JCTR Policy *Brief Promotion of Social Justice and the Concern for the Poor* Third and Fourth Quarter 2004 ZAMBIA’S ECONOMIC, SOCIAL AND CULTURAL RIGHTS: WHY SHOULD THEY BE IN THE NEW CONSTITUTION? Available online at: <http://www.jctr.org.zm/downloads/HIPCbrief-34q04.pdf>. Accessed on 08/03/2012. Hereinafter referred to as Mwale (2004).

the right to health specifically access to medicines for PLWHA amidst WTO trade agreements on TRIPS and GATS is discussed below.

4.4. ZAMBIA'S ADOPTION OF INTERNATIONAL HUMAN RIGHTS AND WTO TRADE TREATIES: AND JUDICIAL PROTECTION OF THE RIGHT TO HEALTH FOR PEOPLE LIVING WITH HIV/AIDS(PLWHA)

Internationally Zambia has ratified not less than 10 conventions and declarations on human rights alone. This means that the Zambian government has a specific legal duty to respect, protect and fulfil the human rights of its population including the socio-economic right to health principally access to medicines as a health service in its domestic laws.⁵⁰¹ Furthermore Zambia adheres to the Bangalore principles which provide that national courts should interpret human rights in a manner that does not detract from international human rights treaties. However, in Zambia "human rights in international conventions are not necessarily automatically protected by the law, even though the government has to ensure that they are protected. The responsibilities of the government under international human rights conventions can only be locally effective if they are incorporated in the Laws of Zambia"⁵⁰².

⁵⁰¹ CESCR General comment No. 14 Note 446 above.

Zambia has agreed to the following international human rights treaties: (A) ICESCR Adopted 16 December 1966. Entered into force 3 January 1976, acceded to by Zambia 10 April 1984.

(B) Convention against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment (Convention against Torture) Adopted 10 December 1984. Entered into force 26 June 1987, acceded to by Zambia 7 October 1998.

(C) Convention on the Elimination of all forms of Discrimination against Women (CEDAW) Adopted 18 December 1979. Entered into force 3 September 1981, acceded to by Zambia 21 June 1985.

(D) Convention on the Rights of the Child Adopted 20 November 1989. Entered into force 2 September 1990, acceded to by Zambia 6 December 1991.

(E) International Convention on the Elimination of All Forms of Racial Discrimination Adopted 21 December 1965. Entered into force 5 January 1969, ratified by Zambia 4 February 1972.

(F) African Charter on Human and Peoples' Rights Adopted 27 June 1981. Entered into force 21 October 1986, ratified by Zambia 10 January 1984.

(G) Protocol to the African Charter on Human and Peoples' Rights on the Rights of Women in Africa Adopted by the 2nd Ordinary Session of the Assembly of the African Union, Maputo on 13 September 2000. Entered into force 25 November 2005. All these treaties have been cited in EQUITY WATCH: Assessing Progress towards Equity in Health in Zambia, (EQUINET 2011) Note above 32 above.

See also Professor Alfred W Chanda, 'Zambia' in Christof Heyns (ed), Vol. 2 *Human rights in Africa*, Martinus Nijhoff Publishers, Leiden/Boston 2004 at p 1685.

⁵⁰² L. Kasonde The Need For Justiciable Socioeconomic Rights in the Bill Of Rights in the Zambian Constitution. Faculty of Law University of Cape town (UCT 2007). Available online at http://www.publiclaw.uct.ac.za/usr/public_law/LLMPapers/kasonde.pdf last Accessed on 08/03/2012. Hereinafter referred to as Kasonde (2007). See also HUMAN RIGHTS COMMISSION STATE OF HUMAN RIGHTS IN ZAMBIA 2007: Human Rights in the Fifth National Development Plan with special reference to Education and Skills Development Health Water and Sanitation Public Safety and Order Governance Gender and Development and Youth and Child Development March 2008 a Human Rights Commission project funded by UNDP. Available online at: http://www.hrc.org.zm/media/annual_state_of_human_rigths_report.pdf or <http://www.hrc.org.zm> Accessed on 05/02/2013 . Hereinafter referred to as HRC State of Human Rights in Zambia (2007).

Accordingly socio-economic rights in this instance the right to health in Zambia have only been incorporated in the Zambian constitution as policy directives.⁵⁰³ This is stated in Part IX on the Directive Principles of State Policy and the Duties of a Citizen provided for under Article 111 which states the following:

The economic, social and cultural principles of state policy set out in this Part shall not be justiciable and shall not thereby, by themselves, despite being referred to as rights in certain instances, be legally enforceable in any court, tribunal or administrative institution or entity.

The above provision in the Zambian constitution entails that even though socio-economic rights are referred to as rights they are nonetheless not justiciable. Thus the Zambian population countenancing human rights violations cannot approach a court of law and sue the government on the grounds that for instance their right to health has been violated.⁵⁰⁴ Correspondingly PLWHA in Zambia currently in need of third line ARV drugs cannot demand that government fulfils their right of access to medicines as Article 111 of the Zambian Constitution does not give them legal grounds to enforce this right or even seek relief in form of compensation as ESCRs are not justiciable in the Zambian Judicial system.⁵⁰⁵

On the other hand the Zambian Constitution has established the Human Rights Commission (HRC)⁵⁰⁶ whose powers are envisaged in the Human Rights Commission Act.⁵⁰⁷ Although the HRC provides a broader standing than the courts by dealing with representatives and interest groups as

⁵⁰³ Article 1(3) of the Constitution of Zambia (1996). The Constitution of Zambia Chapter 1, Volume 1 of the Laws of Zambia Act of 1991 Adopted on: 24 Aug 1991 subsequently Amended in 1996. Available online at: http://www.parliament.gov.zm/index.php?option=com_content&task=view&id=21&Itemid=49. Accessed on 31 /08/2011. Hereinafter the Zambian Constitution.

⁵⁰⁴ "The 1996 Constitution of Zambia does not include a provision on the right to health, although Article 12 provides for the right to life and Article 24 provides for young people to be protected from exploitation, including protection from employment that would prejudice their health." See Mabika & London Note 24 above.

See also M. Mulumba, D. Kabanda & V. Nassuna "Constitutional provisions for the right to health in East and Southern Africa Centre for Health, Human Rights and Development" (CEHURD) in the Regional Network for Equity in Health in East and Southern Africa (EQUINET) EQUINET DISCUSSION PAPER 81 April 2010 with support from SIDA Sweden. Available online at: <http://equinetafrica.org/bibl/docs/Diss81%20ESAconstitution.pdf>. Accessed on 07/03/2012. Hereinafter referred to as Mulumba, Kabanda & Nassuna (2010).

See also The Consideration of Reports Submitted by States Parties Under Articles 16 And 17 of the Covenant Concluding observations of the Committee on Economic, Social and Cultural Rights ZAMBIA E/C.12/1/Add.106 23 June 2005. Available online at: <http://www.chr.up.ac.za/undp/global/docs/observations5.pdf>. Accessed on 09/03/2012. Hereinafter referred to as observations of the Committee on Economic, Social and Cultural Rights ZAMBIA E/C.12/1/Add.106 23 June 2005.

⁵⁰⁵ *Nkumbula v The Attorney General* (1972) ZR 204 (C.A.) set the principle stating that "for an individual to have *locus standi* "there must be an actual or threatened action in relation to him."

⁵⁰⁶ Articles 125-126 of the Zambian Constitution Note 504 above.

⁵⁰⁷ Human Rights Commission Act No 39 of 1996. Available online at: <http://www.hrc.org.zm/mandate.php>. Accessed on 05/02/2013.

well as aggrieved individuals in the area of human rights abuse, its mandate does not encompass the protection of socio-economic rights.⁵⁰⁸ This means that human rights such as access to ARV drugs as part of the right to health and violations thereof cannot be enforced and prosecuted by the HRC.

Consequently the unenforceability of socio-economic rights in the Zambian judicial system and the limited mandate of the HRC when dealing with the violation socio-economic rights elicit that the implementation of these rights can only be done by the executive arm of the government. This dissertation argues that the corollary of implementing socio-economic rights in this manner is two-fold:

Firstly the executive's policies have to be drafted in a manner that they in actual fact give effect to socio-economic rights including the right to health. However the intricacy with relying on the executive to implement socio-economic rights is that it is under no immediate obligation to devise policies that take these rights into account as there is no legislation mandating it to make such policies and to hold it legally responsible for defective policies.⁵⁰⁹

This is evident from Zambia's previous adoption of economic policies such as SAPs recommended by international financial institutions (IFIs) namely the IMF and World Bank which called for, "large scale privatisation of industries and liberalisation of the economy which led to massive job losses, neglect of basic infrastructure, fees for basic needs such as health, an increase in the cost of living, and the problem of street children."⁵¹⁰ Accordingly, government implementation of trade policies under the GATS and TRIPS Agreements cannot be challenged by the affected Zambian population despite their potential to further fuel the current poor delivery of health services and restricted access to advanced regimens of ARV drugs.⁵¹¹

Secondly, the inadequacy of the executive to implement policies that foster the realisation of socio-economic rights in Zambia has a restrictive and crippling effect of the content of legislation the legislative arm of government can enact.⁵¹² This is because legislation is incidental to policy and if

⁵⁰⁸ See Kasonde (2007) Note 502 above. See also UNGASS (2010) Note 69 above. "With regard to human rights violation cases: "The Human Rights Commission has a standard form for recording cases for follow-up in addressing general human rights grievances .The courts of law also handle such cases under the labour law. Other avenues that document and address issues of human rights abuses include the Zambia Police and the Zambia AIDS Law Research and Advocacy Network which offers a free legal clinic for victims of HIV related discrimination."

⁵⁰⁹ Kasonde (2007) Note 502 above.

⁵¹⁰ Ibid. Refer also to discussion under item 1.1 and 1.2 in chapter one of this dissertation.

⁵¹¹ Mabika & London Note 24 above; Mwale (2004) Note 500 above.

⁵¹² Kasonde (2007) Note 502 above.

the executive's policies in place disregard socio-economic rights there is no constitutional mandate obliging the legislature to pass laws that espouse socio-economic rights and as such they will remain directive principles which are merely aspirations of the state.

Although the Zambian legislature has passed a number of pieces of legislation in the area of labour law, that endorse socioeconomic rights to achieve equality and avoid discrimination and could be interpreted to give effect to certain ESCRs such as the right to work and the right to a pension.⁵¹³ Most of these Acts' are short of specific provisions on ESCRs. Accordingly Kasonde⁵¹⁴ argues that currently:

There is no specific legislation on the right to food, health, or education. Zambia cannot be described as a welfare state – far from it, the people have to fend for themselves. The provisions that do relate to socio-economic rights are not measured against a standard provided by a constitutional right. If the law is inadequate one has no further recourse.

Therefore pending the passing of the Constitutional Amendment Bill discussed briefly below, the question that arises from the above discussion is; what is the way forward for the Zambian population in respect of access to basic socio-economic rights principally the right to health? As currently the protection of the right to health and access to ARV drugs and HIV/AIDS related services linger in the various policies Zambia adopted between 2006 and 2011⁵¹⁵ and in government supported institutional frameworks for PLWHA who have suffered human rights violations in different areas,⁵¹⁶ which also have restricted powers when it comes to legal protection of ESCRs.

⁵¹³ (A) Section 108 of the Industrial and Labour Relations Act Chapter 269 of the Laws of Zambia. (B) Sections 15A and 15B of the Employment Act Chapter 268 of the Laws of Zambia. (C) The Marriage Act, Chapter 50 of the Laws of Zambia. (D) the Maintenance Orders Act Chapter 55 of the Laws of Zambia. (E) Sections 4, 24, 12(c) and 25 of the Education Act Chapter 134 of the Laws of Zambia. (F) The Industrial and Labour Relations Act Chapter 269 of the Laws of Zambia. (G) The Employment Act Chapter 268 of the Laws of Zambia. (H) The Apprenticeship Act Chapter 275 of the Laws of Zambia. (I) National Pension Scheme Act, No. 40 of 1996; "requires employers to deduct a certain percentage of their employees' salaries and put it in the national pension fund for their retirement". (J) The Intestate Succession Act Chapter 59 of the Laws of Zambia. Kasonde (2007) Note 502 above. See also HRC State of Human Rights in Zambia (2007) Note 502 above.

⁵¹⁴ Kasonde (2007) Note 502 above.

⁵¹⁵ The National HIV and AIDS/STI/TB Policy and the National HIV and AIDS Strategic Framework (2006-2010 and 2011-2015) "these policy frame works have established a correlation between HIV/AIDS and human rights and hence advocate for government fulfilment of its specific political declarations and commitments to provide universal access to prevention and treatment of HIV and AIDS." See Note 76 above.

See also EQUITY WATCH: Assessing Progress towards Equity in Health in Zambia, (EQUINET 2011) Note 32 above.

⁵¹⁶ UNGASS (2010) Note 69 above. Refer also to Note 508 above.

4.5 THE FUTURE OF SOCIO-ECONOMIC RIGHTS UNDER ZAMBIA'S CONSTITUTIONAL BILL AND THE CURRENT LEGAL OPTIONS OF ENFORCING THE RIGHT TO HEALTH.

Between 2006 and 2010, the Zambian parliament conducted a constitution review process which has led to the inclusion of the right to health as part of the ESCRs in the new Constitutional Bill.⁵¹⁷ Under the Zambian Constitutional Bill, the right to health is provided for in terms of section 67(1) and (2) as follows:

- (1) Every person has the right to health, which includes the right to health care services and reproductive health care.
- (2) A person shall not be refused emergency medical treatment.

Section 67(1) has been further coupled with clause 63 which provides that: "Parliament shall enact legislation which provides measures which are reasonable in order to achieve the progressive realization of the economic, social and cultural rights referred to in Articles 65, 66, 67 68, 69, 70 and 71."

The progress in the above draft constitutional provisions has been endorsed by the recommendations advanced by the Mung'omba Commission,⁵¹⁸ that ESCRs such as health should be included in the Bill of Rights.⁵¹⁹ However Zambia still maintains a very restrictive approach to the protection of the right to health as the enforcement of this right is still at the behests of the policies devised by the executive of which can be argued to be susceptible to abuse taking into account the 2009 ARV drug stock-outs.⁵²⁰ Furthermore the Zambian government's policies on HIV/AIDS neglect other crucial issues affecting PLWHA such as discrimination due to the stigma that remains attached

⁵¹⁷ The Constitutional Bill. Available on the Zambian National Assembly Official Website at: http://www.parliament.gov.zm/index.php?option=com_content&task=view&id=21&Itemid=49. Accessed on 08/03/2012.

⁵¹⁸ "Since Independence in 1964, Zambia has had four major constitutional changes. The 1964 Constitution emerged as a document of the Independence struggle; the 1972 Chona Commission enabled the introduction of a 'One Party Participatory Democracy in 1973'; the 1991 Mvunga Commission re-introduced multiparty democracy; and finally the 1996 Mwanakatwe Commission, which was meant to effectively draft a Constitution that will stand the test of time. But the final elements of these Constitutions have not been embraced by all Zambians, for they were all considered to be the products of the ruling government. The current Mung'omba Commission [is the national constitutional review commission in charge of monitoring the current constitution drafting process] may face the same problem of legitimacy if government insists to own the whole process of constitutional review and denies the popular demand for a Constituent Assembly. Moreover the previous constitutional review commissions argued against the incorporation of these rights in the Bill of Rights." Kasonde (2007) Note 502 above. See also Mwale (2004) Note 500 above.

⁵¹⁹ EQUITY WATCH: Assessing Progress towards Equity in Health in Zambia, (EQUINET 2011) Note 32 above.

⁵²⁰ Ibid.

to the disease.⁵²¹ According to the ICESCR the latter amounts to an absolute violation of the duty to fulfil the right to health by the Zambian government.⁵²² Thus in the interim the right of access to medicines by PLWHA in Zambia can be enforced through the broad interpretation of directive principles of state policies as justiciable rights, as illustrated in the following brief study of case law developed under Nigerian and Indian jurisprudence.

Firstly in Nigeria, the court for the first time referred to directive principles of state policy as 'rights' in the case of *Uzuokwu v. Ezeonu*⁵²³ by stating that "...there are rights which may pertain to a person which are neither fundamental nor justiciable in the court. These may include rights given by the Constitution as under the Fundamental Objectives and Directive Principles of State Policy under Chapter II of the Constitution."⁵²⁴

This principle in the case of *Uzuokwu V Ezeonu* was subsequently confirmed in the Nigerian Supreme Court case of *Attorney General of Ondo State v The Attorney General of the Federation of Nigeria*⁵²⁵ in Justice Uwaifo's concurring judgment on the issue of justiciability of directive principles in which he stated that:

As to the non-justiciability of the Fundamental Objectives and Directive Principles of State Policy in Chapter II of our Constitution, section (6(c) says so.⁵²⁶ While they remain mere declarations, they cannot be enforced by legal process but would be seen as a failure of duty and responsibility of State organs if they acted in clear disregard of them, the nature of the consequences of which having to depend on the aspect of the infringement and in some

⁵²¹ UNGASS (2010) Note 69 above: "Barriers on access to free prevention, treatment and care and support services exist. PLWHA are reluctant to approach the hospitals and clinics for voluntary counselling and testing and treatment for fear of discrimination. Whilst for pregnant women, the non-involvement of men in PMTCT services is a documented barrier as some women fail to disclose their positive status and fail to access treatment freely for fear of reprimand from their husbands".

⁵²² Paragraph 52 of the CESCR's General Comment No. 14 Note 446 above, states that: "Violations of the obligation to fulfil occur through the failure of States parties to take all necessary steps to ensure the realization of the right to health. Examples include the failure to adopt or implement a national health policy designed to ensure the right to health for everyone; insufficient expenditure or misallocation of public resources which results in the non-enjoyment of the right to health by individuals or groups, particularly the vulnerable or marginalized;..."

⁵²³ *Uzuokwu v Ezeonu II* (1991) 6 NWLR (Pt. 200) 708. See also Kasonde (2007) 502 above.

⁵²⁴ *Ibid* *Uzuokwu v Ezeonu II* (1991) 6 NWLR (Pt. 200) at 761-762.

⁵²⁵ *Attorney General of Ondo State v The Attorney General of the Federation of Nigeria* [2002] 9 NWLR (Pt 772) 222.

⁵²⁶ The Federal Constitution of Nigeria 1979 was repealed in 1983 and a new constitution was promulgated in 1999. Available online at: <http://www.constitutionnet.org/vi/item/constitution-federal-republic-nigeria-1979>. Accessed on 15/03/2012. "The judicial powers vested in accordance with the foregoing provisions of this section-(c) shall not, except as otherwise provided in this Constitution, extend to any issue or question as to whether any act or omission by any authority or person or as to whether any law or judicial decision is in conformity with the Fundamental Objectives and Directive Principles of State Policy set out in Chapter II of this constitution."

cases the political will of those in power to redress the situation. But the Directive Principles (or some of them) can be made justiciable by legislation.⁵²⁷

Moreover and much more relatable to this research is the Indian Supreme Court's enforcement of socio-economic rights, including access to health care treatment, through the broad interpretation of the civil and political rights right to life and equal treatment before.⁵²⁸ This is instanced in the case of *Paschim Banga Khet Mazdoor Samity and Others v State of West Bengal and another*,⁵²⁹ in which the applicant's effort to obtain medical attention for head injuries from several public hospitals proved futile⁵³⁰ compelling him to seek treatment from a private hospital.⁵³¹ In an application to the Supreme Court of India the applicant sought relief for the State's human rights violation of his right to life. The Court found that in fact the applicant should have received treatment from any one of the hospitals that had refused to treat him.⁵³² It further revealed that the persons responsible for making the decision not to treat him were guilty of misconduct.⁵³³ In its ruling the Court held as follows:

The Constitution envisages the establishment of a welfare state at the federal level as well as the State level. In a welfare State the primary duty of the Government is to secure the welfare of the people. Providing adequate medical facilities for the people is an essential part of the obligations undertaken by the Government in a welfare State. Failure on the part

⁵²⁷ *Attorney General of Ondo State v The Attorney General of the Federation of Nigeria* at 382 para B. 492 above. See also discussion by: L. I Uzoukwu Constitutionalism, Human Rights And The Judiciary In NIGERIA Submitted in accordance with the requirements of the degree of Doctor of Laws at the University Of South Africa (UNISA) June 2010. Available online at: http://uir.unisa.ac.za/bitstream/handle/10500/3561/thesis_ozoukwu_.pdf?sequence=1 Accessed on 10/03/20120.

⁵²⁸ In the case of *Olga Tellis v. Bombay Municipal Corporation*, Supreme Court of India, 1985 AIR 1986 Supreme Court 18. Available online at: <http://indiankanoon.org/doc/709776/>. Accessed on 10/03/2012: "A group of pavement and slum dwellers petitioned the Court against the arbitrary eviction from the pavement and slum dwellings by the Bombay Municipal Council. The petitioners claimed that in being evicted they were being deprived of their livelihood, under Article 39 of the directive principles of state policy, and subsequently their right to life under the Bill of Rights. The Supreme Court of India interpreted Article 21, the right to life, very widely to so as to engulf the directive principles of State policy. Upon which it upheld the claim."

See also *People's Union for Democratic Rights v. Union of India in which the Supreme court of India* Available online at: <http://indiankanoon.org/doc/496663/>. Accessed on 10/03/2012. In this case the Supreme Court of India found that; "payment of less than the minimum wage to a group of construction workers who were the claimants in this case, amounted to a violation of Article 23 of the Indian Constitution which prohibits human trafficking and forced labour. Therefore the Court held that the; "government of India had failed in its duty under the Constitution to protect the workers and ensure that the minimum wage was enforced."

⁵²⁹ *Paschim Banga Khet Mazdoor Samity and Others v State of West Bengal and Another* Cited as: (1996) AIR SC 2426/ (1996) 4 SCC 37. Available online at: http://www.escri-net.org/caselaw/caselaw_show.htm?doc_id=401236. Accessed on 10/03/20121996). See also citation in *Soobramoney v Minister of Health (Kwa-Zulu-Natal)* at para 18 Note 494 above. SOL Case No. 169, 4 S.C.C. 37, 3 SCJ 25, 2 CHRLD 109 (Supreme Court of India). Available online at: http://www.escri-net.org/caselaw/caselaw_show.htm?doc_id=401236. Accessed on 10/03/2012.

⁵³⁰ At para 2.

⁵³¹ Ibid.

⁵³² At para 7(i)-(vii).

⁵³³ At para 18.

of a Government hospital to provide timely medical treatment to a person in need of such treatment results in violation of his right to life guaranteed under Article 21.⁵³⁴

The Nigerian and Indian cases discussed above illustrate how the directive principles of state policy although deficient of legal force can nevertheless be enforced through the Court's interpretation of the right to life. Thus, pending the adoption of the right to health in Zambia's Constitutional Bill, PLWHA could have recourse to any violation of their right to access to medicines through enforcement of their civil and political right to life as established in Article 12 of the Zambian Constitution.

However, it may be argued that such legal enforcement would prove to be more possible in theory than in reality as the court's broad interpretation of civil and political rights to realize the right to health under international jurisprudence demonstrates that they cannot adequately protect the right to health. Additionally the court's broad interpretation of civil and political rights to realize the right to health could be dismissed as intrusive on the independent exercise of executive powers. Therefore it ultimately depends on the level of independence awarded to the Judiciary in Zambia and its will to creatively defend the right of health for PLWHA. The issue of judicial activism falls well outside the scope of this research topic question and will not be pursued any further.

Hence the definitive resolve for the Zambian population in general lies in the incorporation of provisions on the right to health in the Zambian constitution. This will empower the judiciary to defend the public health interests of vulnerable groups such as PLWHA, especially in the wake of WTO trade agreements.⁵³⁵ As it will have the necessary tools domestically and in terms of international human rights law to assist it in enforcing the right to health in Zambia by reviewing the executive's implementation of policies that disregard socio-economic rights as mere aspirations for the vulnerable sections of society, who urgently require effective health service delivery as a human right to life.

⁵³⁴ At para 9.

⁵³⁵ See Attorney General of Zambia for and on behalf of the Republic of Zambia (Claimant) - and - Meer Care & Desai (a firm) & Ors [2007] EWHC 952. Available online at: http://www.assetrecovery.org/kc/node/4ec2e572-cd77-11dc-b471-db7db47931e5.0;jsessionid=60421A5212AD7164C0F3B8FDC9973636#toc0_3_2. Accessed on 15/03/2012. This case signified "the noble role an Attorney-General should play in defending the Constitution of a country and the public interest of the people."

See also *Kesavananda Bharati v State of Kerala*, (1973) 4 SCC 225 at 879. In which the court held "that in building up a just social order, it is sometimes imperative that the fundamental rights should be subordinated to the directive principles." Cited by L. I Uzoukwu Constitutionalism, Human Rights and the Judiciary in Nigeria Note 527 above.

4.6. CONCLUSION

The discussion in this chapter on the definition and function of the human right to health, with its focus on non-discrimination, takes as a given the constitutional democratic principles of many governments across the world.⁵³⁶ Nevertheless, the day-to-day government processes of implementing international economic policies on trade in services and patent protection of pharmaceutical drugs go counter to their international human rights obligations to, respect, protect and fulfil the right of access to health services and ARV drugs.⁵³⁷

Accordingly Zambia is no exception as for the past forty-eight years socio-economic rights, including the right to health, have not been given protection in the three Constitutions adopted in Zambia,⁵³⁸ despite its previous adoption of economic trade policies having altered its national health systems' delivery of health services and generally denied the human right to health and or life for the poor especially PLWHA.⁵³⁹

Therefore, due to the advent of neo-international economic trade policies under GATS and TRIPS, it is imperative that Zambia includes the right to health in its Constitutional Bills' Bill of Rights legal text to be adopted in Zambia's new Constitution. This would empower the Judiciary to monitor government implementation of health policies. Furthermore it would also compel health and trade policy-makers to ensure that they work together to better plan health and trade economic programmes to avoid trading off any benefits of increasing access to affordable quality health services, including medicine, through the adoption of trade policies.

⁵³⁶ Hogerzeil & Mirza (2011) Note 226 above.

⁵³⁷ Ibid.

⁵³⁸ See Mwale 2004 Note 500 above; Kasonde (2007) Note 502 above.

⁵³⁹ AFRODAD (2007) Note 6 above.

CHAPTER FIVE: SUMMARY OF FINDINGS: RECOMMENDATIONS AND OVERALL CONCLUSION

5.1. SUMMARY

The advent of macro-economic trade policies commencing with the privatization or liberalisation of goods and services under the IMF and World Bank in the 1980s, although aimed at reducing poverty by increasing efficiency in previously state controlled sectors, in this instance health services, have also led to deterioration in delivery of health services in developing nations.⁵⁴⁰ This deterioration of public health services has been linked to the disease burden arising from HIV/AIDS which has been further linked to socio-economic factors including high poverty levels resulting from the premature legal adoption of economic trade policies,⁵⁴¹ negatively impacting on health care, including the restricted accessibility and affordability of ARV drugs.

Sequentially, although unrelated, today neo-economic globalisation of trade in health services under GATS and intellectual property rights under TRIPS aim to resolve the foregoing contradictions⁵⁴² by emphasising the urgent need for African LDCs to make changes in their national laws that will accommodate GATS and TRIPS provisions in exchange for public health benefits such as adequate professional health care workers, up-to-standard health facilities, and most crucially in terms of this study, access to good quality essential medicines, namely ARV drugs.⁵⁴³

However, it is also crucial to note that not all WTO Member economies have the ability to regulate these economic trends for the benefit of the majority population that are poverty and disease stricken.⁵⁴⁴ Hence, as discussed in chapters one and two, in the absence of regulatory frameworks for least developed states like Zambia.⁵⁴⁵ Liberalised trade in health services under GATS poses risks such as the exacerbation of weak and imbalanced access to and delivery of public health services, the rise in the "brain-drain" of health professionals, loss of state subsidies by public health institutions, and the neglect of poor patients. This is because health services provided from foreign

⁵⁴⁰ Baker (2004) Note 216 above. See also Goldsbrough Note 18 above. See also CIPHI Note 367 above. See also 'Pharmaceutical Patents and Access to Essential Medicines in Sub-Saharan Africa' (2011) Note 225 above.

⁵⁴¹ Ibid.

⁵⁴² Ndulo (2001) Note 26 above.

⁵⁴³ Chanda (2008) Note 92 above.

⁵⁴⁴ Ibid.

⁵⁴⁵ Ibid. See also Ndulo (2001) Note 26 above.

investment are inclined to target more profitable markets and sections of society to cover their investor costs.⁵⁴⁶

Similarly, as discussed in chapter three, with regard to the TRIPS Agreement the global standardization of IPRs and legal enforcement of pharmaceutical patent rights that supposedly foster research into and continued development of new and improved drugs limit competition and cause major price escalations of essential medicines such as advanced regimens of ARV drugs, rendering them unaffordable for resource challenged countries like Zambia.⁵⁴⁷ This is despite the availability of various WTO policy mechanisms aimed at helping resource challenged African nations access ARV drugs by 'circumventing' patents rights. Thus according to this research the risks posed by GATS and TRIPS mentioned above are the external restrictive factors inhibiting global access to ARV drugs and quality health services.

In Zambia's context, access to ARV drugs has been influenced by mainly national legal issues such as the previous adoption of privatization policies under the IMF and World Bank, which altered the structure of the national health system and weakened the delivery of public health services, due to, inter alia, under staffing, compromised health funds and an increase in HIV/AIDS infections.

Today Zambia's neo-adoption of GATS and the pending adoption of TRIPS provisions on pharmaceutical patents and test data in 2016, stand to further restructure its already ailing health system. Thus comprehensive legal and policy regulatory frameworks for private health practitioners⁵⁴⁸ and protection of pharmaceutical patents must be implemented in time to ensure the protection of public access to ARV drugs as a health service and a human right. It is problematic enough that currently the Zambian national health system is overstrained and inefficient. If this dire situation is coupled with poor ARV drug procurement legal mechanisms, it will result in the total collapse of the national health system and the denial of the right to health and life for PLWHA as discussed in chapter four.

Consequently, driven by the findings of this study, the following recommendations are made in order to address the current inequity in access to quality health services and ARV drugs in Zambia:

⁵⁴⁶ WHA(2003) Note. 62 above.

⁵⁴⁷ Correa (2008)Note 187 above; t'hoen Note Note 213 above; Drahos Note 212 above.

⁵⁴⁸ Fidler, Correa & Oginam. Note 99 above : "The GATS agreement has been described to have had a direct legal impact on the formulation of national health policies, including on; "public health activities designed to protect community health; the provision and regulation of health care services to individuals; the financing of health services, and efforts to improve social determinants of health which umbrella access to medicines."

5.2. RECOMMENDATIONS

5.2.1. The Constitutional amendments must incorporate the right to health as a justiciable Socio-economic right in Zambia

In Zambia's current Constitution making process, the right to health must be incorporated in the national Constitution's Bill of Rights as a justiciable right. This is for the following three main reasons as suggested by Mwale:

Firstly, the right to health would for the first time be, enforceable in a court of law in Zambia and the Zambian population would be able to require that the government fulfil its constitutional obligations. Especially when the right to health for PLWHA has been denied or infringed, constitutional provisions for the right to health would grant them *locus standi* to take matters to court and serve as points of reference and advocacy tools for interest groups operating in Zambia.⁵⁴⁹

Secondly, the Zambian government could then be held accountable for lack of transparency and commitment in funding and carrying out policies on HIV/AIDS, as apportioned funds would in effect be constitutionally "ring-fenced" and would not be easily diverted or mismanaged as was the case in 2009.⁵⁵⁰

5.2.1.1. The establishment of institutional frameworks to deal with human rights violations of the right to health

Thirdly bearing in mind that the Zambian government has currently in place institutional frameworks such as the Human Rights Commission to deal with general human rights violations, it could still be argued that these institutions are not necessarily adequate to protect the rights of PLWHA considering Zambia's pending inclusion of socio-economic rights inter alia the right to health in the Zambian constitution amidst the escalating increase in HIV/AIDS cases, unrelenting delays and restricted supply of ARV drugs.

Thus in the wake of globalised health services and IPRs and their potential to weaken the delivery of health services in legally unprepared WTO Members, this dissertation concurs with the recommendations by the Mung'omba Commission to the Zambian government to establish a

⁵⁴⁹ Mwale (2004) Note 500. See also The Treatment, Advocacy & Literacy Campaign (TALC) Note 85 above.

⁵⁵⁰ ICESCR's General Comment No. 14 "obligation to fulfil" Note 446 above.

constitutional court mandated to deal with constitutional issues especially ESCRs such health. Constitutional protection of the right to health through the court system could be achieved through increased capacity of legal aid and broader *locus standi* to allow interest groups to bring human rights violation matters in the area of access to health services and ARV drugs on behalf of PLWHA before the courts. Such an approach as applied in the South African legal system could compel government to deal with issues arising from violation of the right to health and life in a much more rigorous and expeditious manner as the court could use its discretion to make orders it deems fit including 'the adoption or revision of policy or legislation' of which the executive have to respect due to the doctrine of separation of powers.

Furthermore, such court orders would set precedents for future challenges to the delivery of health services in Zambia, as has been done in South Africa and could bring about a serious awareness within core Ministries such as Health and Finance, which deal with funding and co-ordinating of HIV/AIDS programmes that, public health issues must be appreciated as fundamental human rights and not mere policy directives⁵⁵¹ and that penalties will be imposed by the court to protect the lives of the vulnerable and chronically ill Zambian population.

5.2.2 The establishment of legal frameworks to deal with trade in health services as an aspect of the right to health

Although the overall effect of the GATS Agreement has not been fully experienced in Zambia due to the lack of foreign investment in the private health sector discussed in chapter two of this dissertation. This does not, nevertheless, detract from the issue that Zambia's full liberalisation of its health services under GATS, in the absence of pre-scheduled restrictions on mainly national treatment of foreign health service investors could have adverse effects on access to health services.

Furthermore taking note that most foreign health providers, supply services that were not previously provided domestically, minimal regulation of foreign health services through policies and legislation in both the Health and Commerce, Trade and Industry sectors, could compound the current situation of unequal delivery of health services in Zambia, with quality health services being restricted to those who can afford them mainly urban dwellers.

⁵⁵¹ Ibid.

Thus the Zambian government should consider devising new legislation or revising existing legislation such as the Pharmaceutical Act and Medical Aid Societies and Nursing Homes Dissolution and Prohibition Amendment Act to include more conditions for private health investors wanting to supply health services in Zambia.

Accordingly this dissertation concurs with the joint study by WHO/WTO (2002)⁵⁵² on some of the suggested conditions that Members could utilise to facilitate public health service delivery under GATS' provisions of liberalised trade in health services. These include;

- a) levying taxes on foreign facilities and transferring revenue to public health institutions, and;
- b) require private health service providers to offer free services in rural areas where the issue of scarcity of health workers due to the local and external 'brain-drain' has created an imbalance in the delivery of health services especially access to ARV drugs.

It is crucial to highlight that Zambia's scheduling of the latter conditions amongst others would be in line with the preamble of the GATS Agreement which allows Members to adopt regulations, on the supply of services within their national territories that support their policy objectives irrespective of their impact on trade but as long such conditions remain within the boundaries of the MFN principle.

5.2.3 Re-enactment of the Zambian Patent Act of 1958 or amendment of defective sections.

As highlighted by the WTO in its 2009 trade policy review on Zambia, there is a need to urgently re-enact the Zambian Patents Act (CAP 400) of 1958 due to its retention of provisions inherited from the colonial government. However, in the interim, this dissertation concurs with the recommendation by author O'Carroll that the following sections found under Part V Grant, Effect and Term of Patent of the Zambia patent Act must be amended to facilitate access to ARV drugs:

- (i) Section 29(a) which awards patent protection of products for a period of sixteen years must be immediately suspended from operation in Zambia until 2016 when Zambia will be required to offer pharmaceutical protection in terms of TRIPS. Such an amendment would

⁵⁵² See Note 114 above.

permit Zambia to import generic drugs from South Africa or Kenya under the 30th of August decision.

- (ii) Section 31(6) here a patent holder could patent an additional invention on an existing patented product. This provision should be amended to include guidelines that set out an elaborative list of certain discoveries on an existing patent that will not be deemed to involve an inventive step. This will exclude a lot of pharmaceutical patents that are mere derivations of discoveries on the existing patent from being re-patented and will allow the production or even the importation of generic ARV drugs as well as the shorter effective duration of patents.

5.2.4 The inclusion of parallel importation provisions in the Zambian Patent Act of 1958

For future purposes of having alternative mechanisms of increasing access to ARV drugs, Zambia should include parallel importation with either international or regional exhaustion of rights regime in the Patents Act of 1958. According to the WHO Mission on the use of TRIPS flexibilities in Bangkok, 31 January to 6 February 2008, the adoption of parallel importation provisions in domestic legal frameworks would have to be coupled with an updated essential drugs list which should be included in Member's national medicines procurement programmes.

Accordingly Zambia's adoption of parallel importation provisions in its domestic legal frameworks coupled with an updated essential drugs list which should be included in its medicines procurement programmes, will help the government to maintain track of patented medicines in terms of Zambian Patent law and ARIPO provisions and to determine the correct procedure in terms of TRIPS provisions prior to the importation of medicines, effectively reducing any possibilities of delay once the process of importation has commenced.

5.2.5 The use of other grounds for granting compulsory licenses and pre-grant TRIPS flexibilities to improve and sustain access to advanced regimens of ARV drugs

Whereas the Zambian government undertook a commendable initiative in 2004 to issue a compulsory license for the local production of ARVs, it is regrettable that this license was only for a period of five years. Hence since it has been more than five years from the time when the first

compulsory license was granted for the production of ARV drugs, Zambia should consider employing more grounds into its national Patent Act for purposes of issuing more compulsory licenses to different pharmaceutical drug manufacturing companies so as to increase competition and possibly drive down the prices of advanced ARV drugs.

Therefore this dissertation recommends the following grounds but non-exhaustive list, as the most viable ones for Zambia to issue compulsory licenses on considering its level of economic development;

- a) 'public interest' this ground has a broad meaning regarding what circumstances could be in the public interest and health is one of them.⁵⁵³ Thus the current crisis of restricted access to third-line ARV drugs in Zambia could potentially suffice as a public health interest for those in need of these drugs and be used by the government as a ground for issuing a compulsory license;
- b) pre-grant TRIPS flexibilities such as 'observation procedures' these allow any interested third party to file for an observation with the patent office on a pending patent application. These procedures would facilitate the revocation of the registration of a patent on medical drugs where there is evidence that insufficient data was provided to warrant such registration.⁵⁵⁴ This could delay the process of early patenting of medicines especially ARV drugs and sanction the local production of such drugs.

5.3. CONCLUSION

The recommendations proposed above would ensure that Zambia's injudicious legal adoption of macro-economic trade policies do not negatively affect the future of public health service delivery, chiefly access to ARV drugs. This is in view of the fact that, the current economic trade policies on liberalised health services (GATS) and standardisation of patent protection on pharmaceutical medicines including ARV drugs (TRIPS), have given enough policy flexibility to least developed countries to accommodate these policies according to the level of development of economic and legal frameworks.

⁵⁵³ See item 3.4.1.4 in chapter three of this dissertation.

⁵⁵⁴ See TRIPS Agreement Article 29.1 Note 230 above. The use of TRIPS flexibilities Report of a WHO Mission Bangkok, 31 January to 6 February 2008 Note 229 above.

Thus there is a need for the Zambian government in the process of adopting legal regulatory frameworks for TRIPS in the near future to involve all stake holders including; academics, relevant government Ministries such as Commerce, Trade and Industry; Health and Finance and National Planning and civil society especially PLWHA, to assist in developing policy and legal regulatory frameworks to regulate TRIPS provisions for the benefit of public health which is also a human right of the majority, principally the poor who are currently infected and affected by HIV/AIDS.

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