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Expanding access to essential medicines through the right to health: A case study of South Africa

By

Shelton Tapiwa Mota Makore

(Student No: 201013362)

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Supervisor: Prof Nasila Selasini Rembe

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ABSTRACT

Lack of access to essential medicines has proven to be a persisting problem which is in conflict with the goal of realising the right to health envisaged by the South African constitution and international human rights instruments. With more than twenty years of democracy, South Africa is still plagued with a multiplicity of pandemics such as HIV and AIDS, cancer, malaria, tuberculosis, among others, leading to premature death and untold suffering of the people. According to a 2015 United Nations AIDS (UNAIDS) Gap report, South Africa is still regarded as the epicentre of HIV and other infectious diseases. The 2015 UNAIDS Gap report states that South Africa has more women than men living with HIV and AIDS. The report further indicates that the impact of this pandemic is worsened by the inaccessibility of essential medicines that are vital for life saving.

This dissertation posits that the epidemiological health crisis described above can be largely eradicated through the utilisation of the right to health. The right to health, according to this dissertation, contains a legal and transformative power which can be utilised to limit the negative impact of patent laws on access to essential medicines in South Africa. This dissertation validates the long held view that World Trade Organisation (WTO) intellectual property laws have contributed to the inaccessibility of essential medicines through causing patent ever greening, patent linkages and pharmaceutical company's monopolies. Consequently, many marginalised groups in South Africa lack access to essential medicines owing to the higher prices charged for such medicines thus violating the right to health, life and other fundamental human rights.

The right to health which is the immediate right infringed when there is lack of access to essential medicines form the core theme of this dissertation. This dissertation argues that access to essential medicine is a fundamental part of the right to health protected under international and national human rights instruments. This dissertation further argue that the right to health imposes obligations which requires South African government to take reasonable legislative and other measures, within its available resources, to provide access to essential medicines. The dissertation's key contribution is its proposed solutions on how to ensure that patents rules in South Africa are tamed with obligations consistent with the right to health. If properly implemented, these solutions have the potential to give greater specification to the

normative commitments imposed by the right to health in the patent claims scenarios.

DECLARATION

I, **SHELTON TAPIWA MOTAMAKORE** declare that this dissertation which is hereby submitted for the award of *Legum Magister* (LL.M) in Human rights, Faculty of Law, at the University of Fort Hare, is my own work and that all the sources that I have used or quoted have been indicated and acknowledged by means of complete references. I further declare that it has not been previously submitted for the award of a degree at this or any other tertiary institution and that this dissertation represents the state of the law as at 30 November 2015.

Signed.....

Date.....

DEDICATION

This dissertation is dedicated to the memory of my parents, Thomas Motamakore (father) and Tukisai Munava (mother), for leading me into the corridors of education where I now understand that law, depending in whose hands it is, can be a tool of liberation or repression. This dissertation, to a larger extent, is the fruit of your efforts and labour in my life. Above all, it is also dedicated to the inhabitants of a democratic South Africa, who have been denied the opportunity to enjoy their right to health because of inaccessibility of essential medicines.

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Embarking on a project of penning a dissertation is like travelling through a ragged, rocky and unpredictable road. It demands personal security and divine benevolence emanating from the very throne of God himself-the Lord of the universe. As such I see it befitting to give thanks to the only wise God, the everlasting Father, and invisible God for upholding my life, in the palm of his hands, throughout the whole journey. My Lord and my God, you are the fairest of ten thousand to my soul!! This whole work and my life I owe it to you. My gratitude also goes to my spiritual brothers and sisters, particularly Bishop Alois Rutivi whom God has planted in my life, on whose prayers my life is anchored upon, your supplications have sustained me and brought me this far.

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LIST OF ABBREVIATIONS

ACHPR	African Commission on Human and Peoples Rights
ACPHR	African Charter on Human and Peoples Rights
ANC	African National Congress
ARV	Antiretroviral Drugs
AU	African Union
BI	Boehringer Ingelheim
CCSA	Constitutional Court of South Africa
CEDAW	Convention on the Elimination of All Forms of Discrimination against Women
CESCR	Medicines and Related Substances Control Amendment Act
CIPRO	Companies and Intellectual Property Registry Office
CPRAMW	Convention on the Protection of the Rights of all Migrant Workers and Members of their Family
CRPD	Convention on the Rights of Persons with Disabilities
CTPA	Choice on Termination of Pregnancy Act
DFID	The Department for International Development
DSB	Dispute Settlement Body
ESCRC	Economic, Social and Cultural Rights Committee
FDI	Foreign Direct Investments decisions
GDP	Gross Domestic Product
GSK	GlaxoSmithKline
HIV and AIDS	Human Immunodeficiency Virus and Acquired Immune Deficiency Syndrome
HRC	Human Rights Council
ICCPR	International Covenant on Civil and Political Rights
ICEAFRD	International Convention on the Elimination of all Forms of Racial Discrimination
ICESCR	International Covenant on Economic, Social and Cultural Rights
ILO	International Labour Organisation
IP	Intellectual Property

MDGs	Millennium Development Goals
MRSCAA	Medicines and Related Substances Control Amendment Act
MSA	Medical Schemes Act
MSF	Medecins Sans Frontiers
NCDs	Non-communicable diseases
NCP	National Strategic Plan
NDH	National Health Department
NHA	National Health Act
NHI	National Health Insurance
NTDs	Non-Tropical Diseases
NTP	National Telemedicine Policy Pharmaceuticals
PAMA	Manufacturers Association
PMTCT	Prevention of Mother- to- Child Transmission
RIA	Regulatory Impact Assessment
SADC	Southern African Development Community
SAMMDRA	South African Medicines and Medical Devices Regulated Act
SSA	Social Security Act
STIs	Sexually Transmitted Infections
TAC	Treatment Action Campaign
TB	Tuberculosis
TK	Traditional Knowledge
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights
UDHR	Universal Declaration of Human Rights
UK	United Kingdom
UN	United Nations
UNICEF	The United Nations Children's Fund
USA	United States of America
USD	United States Dollars
WB	World Bank
WHO	World Health Organisation
WPH	White Paper on Health

WTO

World Trade Organisation

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CHAPTER ONE: An Overview of the Study

1.1 Introduction

*Healing is a matter of time, but it is also a matter of opportunity*¹

Access to essential medicines is vital for sustaining human life and indispensable for combating infectious diseases.² The United Nations (UN) has recognised the importance of access to essential medicines by making it a Millennium Development Goal target.³ Despite this recognition by the UN, lack of access to essential medicines remains ubiquitous in many parts of the world.⁴ A significant portion of South African population does not have sufficient access to essential medicines that are necessary to treat, prevent or cure diseases.⁵ The World Health Organisation (WHO) estimates that about one-third of the world's population lacks access to essential medicines.⁶ Globally, a 2015 UNAIDS Gap Report indicates that nearly two billion people lack access to medicines.⁷ Lacking access to essential medicines

¹This is a part of the Hippocratic precepts derived from the philosophy advanced by Hippocrates in his Greek medical texts. Originally, the precept constitutes a part of the Hippocratic Oath which obliges a new physician to swear, by a number of healing gods, to adhere to specific ethical standards. They are still regarded as having historic and traditional value, and are still recited by medical practitioners who have just begun their careers of medicines in some countries. Hippocrates is considered to be the father of medicines in the western context. See Hulkowe "The history of the Hippocratic Oath: out dated, inauthentic, and yet still relevant" https://www.einstein.yu.edu/uploadedFiles/EJBM/page41_page44.pdf (accessed 28/05/2014). See also Hestermeyer "Access to medicines as a human right" http://www.mpil.de/files/pdf2/mpunyb_hestermeyer_8.pdf (accessed 28/04/2014).

²Hogerzeila "Essential medicines and human rights: what can they learn from each other?" <http://www.who.int/bulletin/volumes/84/5/371.pdf?ua=1> (accessed 29/05/2014).

³United Nations Millennium Development Goal 8e requires States to provide access to essential medicines in developing countries. See WHO "Access to affordable essential medicines" <http://www.who.int/medicines/mdg/MDG08ChapterEMedsEn.pdf> (accessed 26/05/2014).

⁴World Health Organisation "The world medicines situation: access to essential meds as part of the right to health" <http://apps.who.int/medicinedocs/documents/s18772en/s18772en.pdf> (accessed 27/08/2014).

⁵Strauss and Horsten "Human rights-based approach to poverty reduction: the role of the right of access to medicine as an element of the right of access to health care" <http://www.scielo.org.za/pdf/pej/v16n3/12.pdf> (accessed 20/09/2014). See also the *Affordable Medicines Trust and Others v Minister of Health and Another* 2006 (3) SA 247 (CC), where the Constitutional Court of South Africa emphasised that the exercise of public power must be properly regulated to ensure that the "public interest" of ensuring access to essential medicines is respected.

⁶The World Health Organisation (hereafter WHO) is an arm of the United Nations established on 7 April 1948. http://www.who.int/about/brochure_en.pdf (accessed 19/06/2014).

⁷UNAIDS Gap Report "Global Aids response progress reporting 2015" http://www.unaids.org/sites/default/files/media_asset/JC2702_GARPR2015guidelines_en.pdf (accessed 15/05/2015).

compounds the effects of untreated infectious diseases, resulting in preventable deaths. According to the WHO, this may directly infringe fundamental human rights.⁸

Access to essential medicines is a *sine qua non* for the enjoyment of various human rights.⁹ The full enjoyment of the right to health and the right to life hinges upon achieving access to essential medicines.¹⁰ For instance, when a South African or any other pharmaceutical company, invents life-saving medicines it will have performed a vitally important public health or right to health function.¹¹ By saving lives, reducing suffering and improving public health, it would not have only enhanced the quality of life of individuals, but also contributed to the realisation of the right to health and the right to life.¹² Likewise, lack of access to essential medicines violates the right to health, and the right to life.¹³ It also stands as an obstacle to social, economic and political development.¹⁴

There are many factors which determine the accessibility of essential medicines in South Africa. Access to essential medicines depends on the following key factors (a) maintaining a strong health system (b) a good health infrastructure (c) fighting corruption (d) reducing the disease burden (e) improving the quality of essential medicines (f) political will to secure medicines (g) the trade rules and intellectual

⁸World Health Organisation "Measuring and correcting biased child mortality statistics in countries with generalised epidemics of HIV infection" <http://www.who.int/bulletin/volumes/88/10/09-071779/en/>(accessed 18/06/2014).

⁹Vawda and Baker "Achieving social justice in the human rights/intellectual property debate: realising the goal of access to medicines"2001 *Africa Human Rights Journal* 55 81.

¹⁰The World Health Organisation "The right to health" <http://www.ohchr.org/11f07178-9054-48a8-bafceeb281e098e8/finaldownload/downloadidab1b72c19ae1ec4fc3fde038d2708c34/11feeb281e098e8/documents/publications/factsheet31.pdf>(accessed 11/01/2014).

¹¹World Health Organisation "Background document potential Ebola therapies and vaccines" 2014 <http://www.who.int/csr/disease/ebola/ebola-new-interventions-02-sep-2014.pdf>(accessed 11/01/2014)

¹²Wen and Matsanena "Patents, pharmaceuticals and competition: benefiting from an effective patent examination system" <http://www.compcom.co.za/wp-content/uploads/2014/09/Patents-PharmaceuticalsandCompetitionYuFangWenandThapiMatsanengAnnualCompetitionConference20.df> (accessed 12/03/2014).

¹³*ibid* 5 para 5.

¹⁴The World Bank "The economic impact of the 2014 Ebola epidemic: short and medium term estimates for Guinea, Liberia, and Sierra Leone." The Ebola disease has costed US\$93 million 4.7 percent of Gross Domestic Product (GDP) for Liberia, US\$79 million, 1.8 percent of GDP for Sierra Leone,US\$120 million which is 1.2 percent of GDP for Guinea. This has slowed down the projected economic growth for those countries. This really vindicates the fact that were there is rampant spread of diseases without treatment then the economy will be affected negatively <https://openknowledge.worldbank.org/bitstream/handle/10986/20218/907480wp0econo00201400901700public0.pdf?sequence=1> (accessed 29/09/2014).

property protection.¹⁵ Lastly, prices of patented medicines. All of these factors inherently determine access to essential medicines.¹⁶ However, within the context of this study, exorbitant prices of patented medicines will be considered as the greatest barrier limiting access to essential medicines.¹⁷

The concept of essential medicines was first propounded by WHO.¹⁸ According to WHO, essential medicines are “those that satisfy the priority health care needs of the population and selected with due regard to public health relevance, evidence on efficacy and safety, and comparative cost-effectiveness and intended to be available within the context of functioning health systems at all times.”¹⁹ WHO has created a list of essential medicines called Model Essential Medicines List containing a number of medicines vital for life-saving and combating diseases such as HIV and AIDS, respiratory infections, Tuberculosis and Malaria. WHO calls for States to prioritise the procurement of these essential medicines.²⁰ WHO further defines accessibility of essential medicines as meaning, affordability, acceptability and availability of essential medicines for all who wish to have them.²¹

There is a strong linkage between lack of access to essential medicines and poverty. People living in extreme poverty have limited access to essential medicine.²² Millions of people live in sickness, illness and diseases simply because they cannot afford to

¹⁵WTO “Regional issues brief: Intellectual property rights and access to medicines” http://www.google.co.za/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&ved=0cbwqfjaa&url=http%3a%2f%2fwww.hivlawcommission.org%2findex.php%2fregionaldialoguesmain%2fasiapacific%2fregionallissuesbriefintellectualpropertyrightsandaccesstomedicines%2fdownload&ei=wzayvigvd8aaucypgggg&usq=afqjcngblfsq-roxq4b34mq4mmttielx3a&sig2=ptqu6a4y2vgfdes_ikjqxq (accessed 11/01/2015).

¹⁶Horn “The basics of generic medications, bioequivalence, and the push for good manufacturing practices” 2014 *Tagline Journal* 4 1.

¹⁷South African courts have long since acknowledged that high prices of patented essential medicines are the chief factor which limits access to treatment. In *Pharmaceutical Society of South Africa v Minister of Health* 2006 (8) BCLR 872 (CC) the gist of litigation was that South African government had made an attempt to improve access to essential medicines by putting measures aimed at slashing the prices of medicines. However, pharmaceutical companies challenged these measures on the basis that they would interfere with their right to trade freely and intellectual property rights.

¹⁸World Health Organisation “Model list of essential medicines” http://www.who.int/medicines/publications/essentialmedicines/18th_EML_Final_web_8Jul13.pdf. (accessed 11/01/2015)

¹⁹World Health Organisation “Access to essential medicines” http://www.who.int/healthinfo/systems/WHO_MBHSS_2010_section4_web.pdf (accessed 29/09/2014).

²⁰*Ibid* 3 para 2.

²¹Ferrera “Access to affordable HIV/AIDS drugs: the human rights obligations of multinational pharmaceutical corporations” 2002 *Fordham Law Review* 71 1133.

²²World Bank “Dying for change poor people’s experience of health and ill-health” <http://siteresources.worldbank.org/intpah/resources/publications/dying-forchange/dyifull2.pdf> (accessed 29/09/2014).

buy the required medicines.²³ Resolutions adopted by the UN Human Rights Council (HRC) and the African Commission on Human and Peoples' Rights (ACHPR) have recognised the fact that poverty inhibits access to affordable essential medicines.²⁴ These resolutions indicate that access to medicines remains a pipe dream for many people living in poverty especially the inhabitants of developing countries.²⁵ Therefore, the link between poverty and lack of access to essential medicines has been acknowledged in the resolutions adopted by the UN and other organisations.

In South Africa, the concept of access to essential medicines developed as a consequence of several major events which transpired some decades ago.²⁶ Some of these events have left an indelible mark on South Africa. Firstly, the outbreak of the HIV and AIDS pandemic necessitated an intensive discussion on access to essential medicines.²⁷ Secondly, the difficulties South Africa is experiencing in securing new essential medicine has raised concerns about the effects of the 1994 World Trade Organization (WTO)'s Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).²⁸ South Africa became a member of the WTO in 1994 and signed the TRIPS Agreement.²⁹

²³World Health Organisation "Diseases of poverty and the 10/90 Gap" <http://www.who.int/intellectualproperty/submissions/InternationalPolicyNetwork.pdf>(accessed 29/09/2014).

²⁴The UN Human Rights Council is the principal UN intergovernmental body responsible for strengthening promoting and protecting human rights around the globe, and making recommendations to address violations of human rights, including gross and systematic violations. See UN Human Rights Council: *a practical guide for NGO participants* (2013) 1.

²⁵The African Commission adopted this resolution at its 44th ordinary session held in Abuja, Federal Republic of Nigeria, from the 10th to 24th November 2008. The ACHPR/Res.141 (XXXVIII) 08 resolution recognized that poverty is a barrier to accessing medicines in Africa. See "African Commission on Human and Peoples Rights" available on http://www.chr.up.ac.za/images/files/research/ahrru/news/ahhru_news_15_resolution_access_health_needed_medicines_africa.pdf (accessed 29/09/2014). See also the resolution passed by European parliament on the WTO TRIPS and Access to Medicines on 12 July 2007 http://www.un.org/en/development/desa/policy/mdg_gap/index.shtml (accessed 22/09/2014). See also the Southern African Development Community (SADC) Protocol on Health which emphasis on the importance of access to essential medicines for the SADC region <http://www.sadc.int/index/browse/page/152> (accessed on 29/09/2014).

²⁶Sibanda "Comparative analysis of access to patented HIV/AIDS pharmaceutical medicines through the Canadian and EU TRIPS flexibilities measures: are they efficacious or overly burdensome and ineffective?" <http://www.saflii.org/za/journals/PER/2012/31.pdf> (accessed 23/09/2014).

²⁷Gumedze "HIV/AIDS and human rights: the role of the African Commission on human and People's Rights" 2004 *African Human Rights law Journal* 4 181.

²⁸The TRIPS Agreement is annex 1C of the Marrakesh Agreement establishing the World Trade Organisation, signed in Marrakesh, Morocco on 15 April 1994. The Agreement sets out the minimum standards of protection to be provided by each member. Each of the main elements of protection is defined, namely the subject-matter to be protected, the rights to be conferred and permissible exceptions to those rights, and the minimum duration of protection. The Agreement sets these standards by requiring, first, that the substantive obligations of the main conventions of the World

The TRIPS Agreement is an international agreement which prescribes minimum standards that relate to the protection and enforcement of intellectual property rights such as patents, trademarks, copyright, and industrial designs.³⁰ These minimum standards are legally binding on all WTO members.³¹ Patents are a form of intellectual property.³² They are an incentive mechanism granted to investors in order to stimulate innovation by the creation of a monopoly.³³ Prior to the coming into force of TRIPS, South Africa retained the right to shape its intellectual property laws to meet national needs. This right has been severely constrained under TRIPS.³⁴

Further, patents have the potential to create market exclusivity by ensuring that there is only a single supplier of new medicine. This may result in the creation of monopoly rights over a new medicine.³⁵ As a result of the monopoly created, the market could be starved of competition and in the absence of strict price regulation prices go up, problem which could impede the realisation of the right to health, in particular access to essential medicines.³⁶ This study, therefore, seeks to explore how the right to health can be used as an instrument for enhancing access to essential medicines in light of the intellectual property regime.

1.2 Research Problem

A very large part of South Africa's population has inadequate or no access to essential and life-saving medicines which are the most significant means used to

Intellectual Property Organisation (WIPO), the Paris Convention for the Protection of Industrial Property (Paris Convention) and the Berne Convention for the Protection of Literary and Artistic Works (Berne Convention) in their most recent versions be complied with. With the exception of the provisions of the Berne Convention on moral rights, all the main substantive provisions of these conventions are incorporated by reference and thus become obligations under the TRIPS Agreement. http://www.wto.org/english/tratop_e/trips_e/t_agm0_e.htm (accessed 29/09/2014).

²⁹ Avafia "The potential impact of TRIPS Plus IP enforcement provisions on access to medicines in Africa" https://www.thedti.gov.za/business_regulation/presentations/counterfeiting.pdf (accessed 01/10/2014).

³⁰ Drahos "Developing countries and International intellectual property standard-setting" 2002 *Journal of Intellectual Property* 5 765.

³¹ *Ibid* Article 27.

³² Pfumrodze "WTO TRIPS Agreement and access to medicines in South Africa" 2011 *University of Botswana Law* 13 87.

³³ Brand "Intellectual property and abuse of dominant position in South African competition Law" 2005 *South African Law Journal* 4 910.

³⁴ *Ibid* 916 para 7.

³⁵ Scherer and Wata "Competition policy and intellectual property: insights from developed country experience" [file:///C:/Users/Downloads/RWP14-013_Scherer%20\(1\).pdf](file:///C:/Users/Downloads/RWP14-013_Scherer%20(1).pdf) (accessed 06/10/2014).

³⁶ Muswaka "The impact of patent protection and lack of generic competition on the right of access to medicines in South Africa: explicating corporate responsibility for human rights" 2014 *Mediterranean Journal of Social Science* 2 229.

prevent, alleviate, and cure diseases.³⁷ Most illnesses, especially infectious diseases, are either preventable or to some extent, treatable. Combined with purposeful public health interventions, appropriately prescribed essential medicines and vaccines could, in principle, massively reduce the impact of disease on communities.³⁸ The lack of access to life-saving and health-supporting medicines for the poor people stands as a direct contradiction to the fundamental principle of health as a human right.³⁹

Lack of access to essential medicines has been worsened by the loopholes existing in the South Africa Patent Act.⁴⁰ The Act meanwhile does not incorporate fully the flexibilities contained in the TRIPS Agreement after the Doha decisions.⁴¹ These flexibilities allow developing countries like South Africa to be amenable to issues relating to public health and access to essential medicines. The problem of access to essential medicines took a centre stage in the case of *Minister of Health v Treatment Action Campaign and Others*.⁴² In this case, the Court affirmed a lower court decision holding that the government could not reasonably limit the provision of Nevirapine to eighteen pilot sites in the public health system when such medication has been demonstrated to reduce mother-child transmission of HIV.⁴³

In the case of *CiplaMedpro v Aventis Pharma (139/12) Aventis Pharma SA v Cipla Life Science*⁴⁴ the acknowledged that patents creates monopoly that cause the problem of access to essential medicines.⁴⁵ Non-governmental organisations such as Treatment Action Campaign (TAC) and *Médecins Sans Frontiers* (MSF) have launched the “Fix the patent laws” which shows the negative effect of patents on

³⁷Ndlovu “The WTO TRIPS Agreement and access to medicines in South Africa twenty years into democracy” <http://www.speculumjuris.co.za/files/pdf/SJ2314FPLonias.pdf> (accessed 28/09/2014).

³⁸Hogerzeila and Miiza “The world medicines situation 2011, access to essential medicines as part of the right to health” <http://apps.who.int/medicinedocs/documents/s18772en/s18772en.pdf> (accessed 29/09/2014).

³⁹Tomlinson and Rutter “The economic and social case for patent law reform in South Africa” <http://www.health-e.org.za/wp-content/uploads/2014/02/The-Economic-and-Social-Case-for-Patent-Law-Reform-in-South-Africa.pdf> (accessed 29/09/2014).

⁴⁰*Ibid* 1 para 1.

⁴¹Director General, Department of Trade and Industry “Draft National Policy on Intellectual Property, Invitation to the Public to make Comment on National Policy on Intellectual Property” <http://ip-unit.org/wp-content/uploads/2013/09/DRAFT-IP-POLICY.pdf> (accessed 06/10/2014).

⁴²(2002) 5 SA 721 (CC).

⁴³*Ibid* 2 para 1.

⁴⁴(2012) ZASCA 108.

⁴⁵*Ibid* 63 para 2.

access to essential medicines.⁴⁶ The 2013 Draft National Policy on Intellectual Property of South Africa published by the Department of Trade and Industry admitted that the weak patent system has intensified the problem of access to essential medicines.⁴⁷

Further, the problem of access to essential medicines has become the subject of discussion on many international platforms such as the WTO. For instance, on the agenda of the 134th session of the WHO meeting which was held on 20 January 2014 was the problem of access to essential medicines.⁴⁸ The scope of the discussion encompassed the recent effort by some pharmaceutical companies to undermine efforts of the South African government to amend its Intellectual property laws. This was revealed through a leaked document titled, “Campaign to Prevent Damage to Innovation from the Proposed Draft National IP Policy in South Africa.”⁴⁹ Therefore, the principal idea of this study is to explore how the right to health as protected under international and South African Constitution can be used as a device for enhancing access to essential medicines in light of the intellectual property regime.

1.3 Research aims and objectives

It is the objective of this study to explore how the right to health as protected under international and South African Constitution can be used as a device for enhancing access to essential medicines in light of the intellectual property regime. This objective will be achieved by a way of looking at the problems that have ensued as a result of implementing the TRIPS and patent laws and how such problems have affected South Africa’s obligations to respect, promote and fulfil the human right to health. This dissertation aims to ensure that patent laws in South Africa may not

⁴⁶Treatment Action Campaign “Fix the patent laws”http://www.fixthepatentlaws.org/wpcontent/uploads/2013/10/TAC_MythBuster_Patent_Reform.pdf (accessed 06/10/2014).

⁴⁷Director General, Department of Trade and Industry “Draft National Policy on Intellectual Property, Invitation on the Public to make Comment on National Policy on Intellectual Property”<http://ip-unit.org/wp-content/uploads/2013/09/draft-ip-policy.pdf> (accessed 06/10/2014).

⁴⁸Daniels “Intellectual property watch, concerns erupt over leaked Pharma lobbying plan against IP policy in South Africa”<http://www.ip-watch.org/2014/01/22/concerns-erupt-over-leaked-pharma-lobbying-plan-against-ip-policy-in-south-africa/>(accessed 15/12/2014).

⁴⁹See A proposal for Pharma and IPASA “Campaign to prevent damage to innovation from Proposed Draft National IP Policy in South Africa”http://keionline.org/9b1df08644c5475eb69a61549c836c4b/finaldownload/downloadid8725fea7867d0a9b3726a0f9d9c35a22/9b1df086-44c5-475e-b69a61549c836c4b/sites/default/files/pae-proposal_rsa-patent-reform.pdf (accessed 15/12/2014).

have an adverse impact on the right to health and that non-state actors are appropriately regulated so as to guarantee access to essential medicines as a part of the right to health.

1.4 Hypothesis

This research is predicated on the following hypothesis:

The intellectual property rights of pharmaceutical manufactures stands in contradistinction with the need to provide sufficient access to essential medicines to the poor in South Africa. Currently, South African's patent laws inhibit access to essential medicines and therefore, *prima facie* violate the right to health. Therefore, the research proceeds from the assumption that South Africa should give due regard to the human right to health so that essential medicines are accessible.

1.5 Significance of the Study

The study endeavours to gain an insight into the utility of the right to health within the context of patent scenarios. The study seeks to look at the possible impact of South African patent protection laws on access to essential medicines. The knowledge which is generated from the study can help to mitigate the effects of infectious diseases by achieving access to essential medicines. Securing access to essential medicines is an indispensable tool for combating many pandemics in South Africa.

Further, the full realisation of the right to health via access to essential medicines brings to end the social disparities characterising health provision.⁵⁰ Currently, in South Africa, only well to do people can afford to buy expensive patented medicines.⁵¹ The majority of the population who live under the poverty datum line cannot afford to buy these essential medicines.⁵² The study endeavours to close this social disparity gap by putting forward recommendations on how to increase access to essential medicines.

Therefore, the policy relevance of this study is to investigate if South African patent laws restrict access to essential medicines. In other words, should South Africa continue with the implementation of the current patent laws? The study will assist policy makers and practitioners in ensuring the full realisation of the right to health for

⁵⁰Hogerzeila "Essential medicines and human rights: what can they learn from each other?"<http://www.who.int/bulletin/volumes/84/5/371.pdf?ua=1> (accessed 29/09/2014).

⁵¹*Ibid* 372 para 1.

⁵²Statistics South Africa "Millennium Development Goals, Country Report 2013" 71 http://www.statssa.gov.za/MDG/MDGR_2013.pdf (accessed 17/06/2014).

the marginalised groups. The study also encourages the protection of other human rights such as the right to human dignity, equality and life within the context of access to essential medicines.⁵³ The enjoyment of these rights depends on the achievement of access to essential medicines.⁵⁴

1.6 Research Questions

This research is predicated on the following legal questions:

What is the nature, scope and content of the right to health under international law?

Whether access to essential medicines is a part of the right to health?

What is the impact of South African patent laws on the right to health in particular access to essential medicines?

Can the right to health be used to solve the problem of access to essential medicines in South Africa?

1.7 Literature Review

1.7.1 The right to health under International human rights instruments

A plethora of literature has been written on the protection of the right to health under international human rights framework. This body of literature exist in the form of international declarations and conventions and other scholarly publications.⁵⁵ The right to health is principally enshrined in the following binding human rights instruments: the International Covenant on Economic, Social and Cultural Rights (ICESCR),⁵⁶ the Convention on the Rights of the Child,⁵⁷ the Convention on the Elimination of Discrimination against Women and the African Charter on Human and People's rights.⁵⁸ Within the context of South Africa, the right to health is guaranteed

⁵³Ferrera "Access to affordable HIV/AIDS drugs: the human rights obligations of multinational pharmaceutical corporations"2002 *Fordham Law Review* 71 1133.

⁵⁴*Ibid* 1143 para 5.

⁵⁵Mok "International assistance and cooperation for medicines" <http://scholarship.law.georgetown.edu/11f07178905448a8bafceeb281e098e8/finaldgi/view/content.cgi?article=1606&context=facpub> (accessed 24/11/2014).

⁵⁶International Covenant on Economic, Social and Cultural Rights, United Nations General Assembly resolution 2200A (XXI) of 16 December 1966, which came into force 3 January 1976.

⁵⁷The Convention on the Rights of the Child (CRC) was adopted and opened for signature, ratification and accession by General Assembly resolution 44/25 of 20 November 1989. It was entered into force on 2 September 1990, in accordance with Article 49.

⁵⁸The (CRC) enshrines the right of the child to the enjoyment of the highest attainable standard of health and to facilities for the treatment of illness and rehabilitation of health.⁵⁸ Under Article 24 of the CRC, member States are to ensure that no child is deprived of his or her right of access to health care services.⁵⁸

⁵⁸Marks "Health: a human rights perspective: access to essential medicines as a component of the right to

under the Constitution or in terms of ordinary legislation, and in non-binding form through policies and programmes.⁵⁹

The right to health was first articulated in the Preamble to the constitution of WHO,⁶⁰ though, as a preamble, it is not in itself considered to be legally binding on the states members of the organisation.⁶¹ The WHO constitution describes health as “a state of complete physical, mental and social well-being, and not merely the absence of disease or infirmity.”⁶² The WHO meaning of health goes further than the lack of disease or physical and mental maladies.⁶³ The non-binding Declaration of Alma-Ata on Primary Health Care⁶⁴ (Alma-Ata Declaration) expands the definition of health to include primary health care services such as a functioning health system.⁶⁵ This definition is very broad and creates the impression that health means synonymous with human well-being.⁶⁶ This is an impossible goal. Nature itself imposes a series of limitations that make such a state of well-being physically impossible to attain.⁶⁷

health”http://www.hsph.harvard.edu/wpcontent/uploads/sites/580/2012/10/marks_access_to_essential_medicines-2009.pdf (accessed 08/10/2014).

⁵⁹Wen and Matsaneng “Patents, pharmaceuticals and competition: benefiting from an effective patent examination system”
<http://www.compcom.co.za/wpcontent/uploads/2014/09/patentspharmaceuticals-and-competition-yu-fang-wen-and-thapi-matsaneng-annual-competition-conference-2013.pdf> (accessed 06/09/2014)

⁶⁰Art 12.

⁶¹Anderson “Unnecessary deaths and unnecessary costs: getting patented drugs to patients most in need” <http://scholarship.law.cornell.edu/cgi/viewcontent.cgi?article=1021&context=facpub> (accessed 07/10/2014).

⁶²Cliff “The role of the World Health Organisation in international affairs”http://www.chathamhouse.org/sitetamhouse/public/Research/Global%20Health/0213_who.df (accessed 07/10/2014).

⁶³Chapman: *Core obligations related to the right to health* (2002) 187.

⁶⁴Declaration of Alma-Ata International Conference on Primary Health Care strongly reaffirms that health is a fundamental human right and that the attainment of the highest possible level of health is one of the most important world-wide social goal whose realisation requires the action of many other social and economic sectors in addition to the health sector. See Alma-Ata, USSR, 6-12 September 1978http://www.who.int/publications/almaata_declaration_en.pdf (accessed 07/10/2014).

⁶⁵The basic premise underlying the idea of Primary Health Care is the commitment to provide health care services to everyone. This entails bringing to an end the social disparities characterising health care provision. See World Health Organisation “Primary Health Care now more than ever”
http://www.who.int/whr/2008/08_overview_en.pdf (accessed 05/05/2014).

⁶⁶Bryant et al “Alma-Ata and Primary Health Care: an evolving story”
http://parthealth.3cdn.net/ea9818ff461c9fbd2c_89m6bh39v.pdf (accessed 12/10/2014).

⁶⁷Labonté et al “Is the Alma Ata vision of comprehensive primary health care viable? findings from an International project” 2014 *Global Health Action* 7 6.

The right to health is further included in the Universal Declaration on Human Rights (UDHR) adopted in 1948.⁶⁸ The UDHR gave greater content to this right by proclaiming in Article 25.1 that “everyone has the right to a standard of living adequate for the health of himself and of his family, including food, clothing, housing and medical care.”⁶⁹ The term “medical care” as used by the UDHR is understood to include essential medicines or vaccines.⁷⁰ A declaration adopted by the United Nations is not considered legally binding on states unless or until it becomes part of customary international law.⁷¹ While most human rights in the Declaration are now widely considered to be part of customary international law, there remain controversies in that respect, particularly with regard to the economic, social and cultural rights included in the Declaration.⁷²

The International Covenant on Economic, Social and Cultural Rights (ICESCR), unlike the UDHR, provides a detailed pronouncement of the right to health.⁷³ The ICESCR was adopted by the UN in 1966 and holds the status of an international treaty that is legally binding upon member states of the UN.⁷⁴ According to Article 12.1 of the ICESCR, states must “recognise the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.”⁷⁵ The ICESCR clearly outlines steps to be taken by member states in order to achieve full realisation of the right to health. It states that member states shall (a) provide for the reduction of the stillbirth-rate and of infant mortality and for the healthy development of the child; (b) improve all aspects of environmental and industrial hygiene; (c) prevent, treat and control epidemic, endemic, occupational and other diseases; (d) create conditions

⁶⁸Universal Declaration of Human Rights, G.A. Res. 217 (III) A, U.N. Doc. A/RES/217(III) (Dec. 10, 1948) (hereinafter UDHR) <https://www1.umn.edu/humanrts/instree/b1udhr.htm> (accessed 12/10/2014).

⁶⁹Art 25.

⁷⁰Strauss and Horsten “A human right based approach to poverty reduction: the role of the right of access to medicines as an element of the right of access to health care” <http://www.corteidh.or.cr/tablas/r31680.pdf> (accessed 13/10/2014).

⁷¹Hunnum “The status of the Universal Declaration of Human Rights in national and International law” http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1957798 (accessed 07/10/2014).

⁷²*Ibid* 145 para 2.

⁷³The International Covenant on Economic Social and Cultural Rights, GA Resolution 2200A (XXI) 16 December 1966, entered into force 3 January 1976 (hereinafter “the ICESCR”).

⁷⁴Coolmads “Application of the International Covenant on Economic, Social and Cultural Rights” http://www.mpil.de/files/pdf1/mpunyb_14_coomans_11.pdf (accessed 16/09/2014).

⁷⁵Limburg Principles on the Implementation of the Covenant on Economic, Social and Cultural Rights, 1987 *Human Rights Quarterly* 9 124.

which would assure to all medical service and medical attention in the event of sickness.⁷⁶

The CESCRC contains a lot of vagueness by subjecting the right to health and other rights to progressive realisation, based on the availability of resources.⁷⁷ It remains uncertain on how slowly the steps can be undertaken without constituting a violation of these rights.⁷⁸ The phrase can be used as a scapegoat by member states thereby escaping the liability imposed under the Covenant.⁷⁹ De chutter⁸⁰ opines that, the term create more problems than solutions, because it leaves a lot of discretion on member states to determine what resources are in fact there for use.⁸¹ It can be submitted that this discretion is an inherent loophole which could be used to postpone the realisation of the right to health.

At regional level in Africa, several binding obligations and declaratory commitments concerning the right to health have been adopted.⁸² For instance, Article 16 of the African Charter on Human and Peoples' Rights contains the right to the highest possible level of health "to which end necessary measures shall be taken, including guarantees for medical services in case of illness".⁸³ The African Charter on the Rights and Welfare of the Child requires states parties to recognise the right to

⁷⁶Article 12 1.

⁷⁷Chenwi "Unpacking "progressive realisation", its relation to resources, minimum core and reasonableness, and some methodological considerations for assessing compliance" (2013) *De Jure* 74 1.

⁷⁸There was a lot of doubt expressed pertaining to the efficacy of the concept of progressive realisation in advancing socio-economic rights. During the *travaux* diplomats from many countries submitted that the word "progressively realisation" would render the Commission's work meaningless if it was to be inserted within the ICESCR. The Russian diplomats in particular, argued that states would use this phrase as a tool to escape liability under the covenant. Other diplomats from the western hemisphere had a contrary opinion. They asserted that the phrase "progressively realisation" had replaced the former proposal "progressive implementation" as a way of strengthening rather than weaken the objective of the covenant. See Weinstein "On the meaning of the term progressive realisation: a philosophical investigation"<http://web.wmitchell.edu/law-review/wp-content/uploads/Volume33/documents/1.Weinstein.pdf> (accessed 16/09/2014).

⁷⁹Mbazira: *Litigating socio-economic rights in South Africa: a choice between corrective and distributive justice* (2009).

⁸⁰De Schutter "Economic, social and cultural rights as human rights: an introduction." <http://crikho.uclouvain.be/11f07178905448a8bafceeb281e098e8/finaldownload/downloadid644a2236f1eab687bf0fd7193c6bc897/11f07178905448a8bafceeb281e098e8/documents/workng.papers/crikho-wp2013-2-odeschutterescrights.pdf> (accessed 18/09/2014).

⁸¹*Ibid* 7 para 3.

⁸²Mosissa "Ensuring the realisation of the right to health through the African Union (AU) system: a review of its normative, policy and institutional frameworks" <file:///C:/Users/sheltonmotamakore/Downloads/9789462650138-c2.pdf> (accessed 06/10/2015).

⁸³*Ibid* 73.

health of the child and to take a set of measures closely patterned on the global Convention on the Rights of the Child.⁸⁴

South Africa has ratified all of the above mentioned instruments and incorporated them into its domestic law.⁸⁵ However, as this research will show later, the mere fact of ratification does not guarantee effective implementation of the right to health within the domestic law. Sections 27 (1) of the Constitution states that “everyone has the right to have access to health care services” and that “the state must take reasonable legislative and other measures within available resources to achieve the progressive realisation of each of these rights.”⁸⁶ Dugard⁸⁷ points out that the Constitution of South Africa is modelled after the CESCRR and fully protects the right to health.⁸⁸

The courts have added to the normative content of the right to health by bringing clarity on the concepts of available resources and reasonable measures. In the *Soobramoney v Minister of Health, Kwa-Zulu Natal*⁸⁹ case, the Constitutional Court opined that the scarcity of resources available to the state were constraints to the enjoyment of the right by the appellants, given the socio-historical context of South Africa.⁹⁰ The foregoing case, according to Forman,⁹¹ highlights the enormous challenges facing the legal operation of the right to health in particular the realisation of access to essential medicines.⁹²

⁸⁴African Charter on the Rights and Welfare of Children OAU Doc. CAB/LEG/24.9/49 (1990), entered into force November 29, 1999. http://www.au.int/en/sites/default/files/Charter_En_African_Charter_on_the_Rights_and_Welfare_of_the_Child_AddisAbaba_July1990.pdf (accessed 06/10/2014)

⁸⁵In 2014, South Africa ratified the ICESCR and it entered into force on 12 April, 2015. The ratification of this Covenant represents an important step forward, giving the ICESCR greater legal force. See more on the importance of an act of ratification Mashingaidze “The ICESCR – “South Africa engaged but not married? – a test of our commitments to International Covenants” <http://www.blacksash.org.za/files/icescropsinion.pdf> (accessed 23/09/2014).

⁸⁶The Constitution of the Republic of South Africa, section 27 (1).

⁸⁷Dugard “The influence of international human rights law on the South African Constitution” 1996 *Current Legal Problem* 49 305-324.

⁸⁸*Ibid* 306 para 2.

⁸⁹1997 (12) BCLR 1696 (CC).

⁹⁰*Ibid* 1 para 1.

⁹¹Forman and Kohler: *Access to essential medicines as a human right: implications for pharmaceutical Industry Responsibility* (2012) 37.

⁹²Roth “Defending Economic, social and cultural Rights” http://www.law.yale.edu/documents/pdf/Defending_Economic_Social_and_Cultural_Rights.pdf (Accessed on 06/10/2014).

1.7.2 Access to essential medicines as an aspect of the right to health

Vawda and Baker's⁹³ have analysed the legal source for the right to have access to essential medicines and posited that it is a core aspect of the right to health.⁹⁴ In turn, the right to health as demonstrated above is protected by international human rights. Article 12 (2) (d) of the ICESCR in particular, clearly identifies the provision of essential medicines as one of the obligations imposed by the treaty. The UN Committee on Economic, Social and Cultural Rights (CESCR), a body of 18 independent experts that monitors implementation of the ICESCR, has elucidated more on the right to health and access to essential medicines through its General Comment 14.⁹⁵

The General Comment 14 states that medicines must be available in sufficient quantity, without discrimination, overcoming physical and economical constrictions, respecting medical ethics, being scientifically and medically appropriate.⁹⁶ The Committee maintained that the provision of essential medicines should be in adequate amounts all the times, in the appropriate dosage forms, with assured quality and information, and at a price that the individual and community can afford. The Committee assert that access to essential medicines is a key component of the right to health.⁹⁷

1.7.3 Intellectual Property Protection in South Africa.

The major legal instrument responsible for the introduction of patent protection in developing countries is the WTO's Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement, which came into force in 1995.⁹⁸ TRIPS prescribe minimum standards that relate to the protection and enforcement of intellectual

⁹³Vawda and Baker "Achieving social justice in the human rights/intellectual property debate: realising the goal of access to medicines" 2013 *African Human Rights Law Journal* 13 10.

⁹⁴*Ibid* 11 para 2.

⁹⁵The Committee consist of a body of independent experts established under ECOSOC Resolution 17 in 1985 and mandated to monitor the implementation of the ICESCR Covenant. The comments made by the Committee are cited in domestic and international tribunals. The comments are not binding *per se*, however, they are considered as authoritative interpretation of the Covenant. See General Comment No 14 8 November 2011 (UN Doc. E/C.12/2000/4) paragraph 12, <http://www.unhcr.ch/tbs/doc.nsf/%28symbol%29/E.C.12.2000.4.En> (accessed 13/10/2014).

⁹⁶UN Committee on Economic, Cultural and Social Rights (CESCR), General Comment No.14: The Right to the Highest Attainable Standard of Health (Article 12) at Article 12 (a), and paragraphs 42 & 43 (2000) (E/C.12/2000/4) <http://www.refworld.org/docid/4538838d0> (accessed 14/10/2014).

⁹⁷*Ibid* 1 para 1.

⁹⁸The TRIPS Agreement is annex 1C of the Marrakesh Agreement establishing the World Trade Organization, signed in Marrakesh, Morocco on 15 April 1994 http://www.wto.org/english/tratop_e/trips_e/t_agm0_e.htm (accessed 16/12/2014).

property rights, including patents, trademarks, copyright, and industrial designs. These minimum standards are legally binding on all WTO members.⁹⁹ Members are supposed to domesticate these standards within time frames stipulated in the TRIPS Agreement. Failure to domesticate and implement these provisions may attract trade sanctions. In addition, complaints against a recalcitrant member can also be taken to the WTO Dispute Settlement body.¹⁰⁰

In 1994, upon becoming a member of the WTO, South Africa started re-aligning all of its patent laws so that they become compatible with TRIPS rules.¹⁰¹ Before TRIPS came into force, South Africa's patent laws were modelled along the Paris Convention for the Protection of Industrial Property (1883).¹⁰² Unlike the TRIPS Agreement, the Paris Convention excludes patenting of pharmaceutical products. Indeed, this was good news for South Africa because the country retained the right to define its patent legal frame work so as to meet its public health demands.¹⁰³ South Africa had a flexible compulsory licensing procedure for granting patents which catalysed the manufacturing of generic medicines. Generic medicines are a version of the patented medicines manufactured and sold at a much lower price than their patented counterparts.¹⁰⁴

In 1997, South Africa passed the Medicines and Related Substances Control Amendment Act.¹⁰⁵ The purpose of the Act was to improve access to essential medicines in the wake of the deadly HIV pandemic that had hit the country.¹⁰⁶ The provisions included generic substitution of off-patent medicines, transparent pricing

⁹⁹Bors *et al* "Improving access to medicines in low-income countries: a review of mechanisms" 2015 *The Journal of World Intellectual Property* 18 1.

¹⁰⁰Article XX111 and XX11 of TRIPS Agreement. See also Bond "Globalisation, pharmaceutical pricing and South African health policy: managing confrontation with us firms and politicians" (1999) 29 *International Journal of Health Service* 767.

¹⁰¹Tomlinson and Rutter "The economic and social case for patent law reform in South Africa" <http://www.tac.org.za/sites/default/files/The%20Economic%20and%20Social%20Case%20for%20Patent%20Law%20Reform%20in%20South%20Africa.pdf> (accessed 17/12/2014).

¹⁰²The Paris Convention for the Protection of Industrial Property, signed in Paris, France, on 20 March 1883, was one of the first intellectual property treaties. The Convention is still in force as of 2015 and binding on contracting parties. http://www.wipo.int/treaties/en/text.jsp?file_id=288514 (accessed 17/12/2014).

¹⁰³Agitha "Global health for facilitating access to medicines: role of World Health Organisation" 2013 *Journal of Intellectual Property* 18 589-595.

¹⁰⁴Krishnamurthy and Pogge "How not to exclude the poor from advanced medicines: a plea for the Health Impact Fund" 2010 *For Rights and Development Bulletin* 2 240.

¹⁰⁵Act 90, 1997 was inserted as an amendment of the Act 1, 1965.

¹⁰⁶Lee: *A human rights framework for intellectual property, innovation and access to medicines* (2015) 49.

for all medicines, and the parallel importation of patented medicines.¹⁰⁷ In *Pharmaceutical Manufacturer's Association of South Africa v President of the Republic of South Africa*,¹⁰⁸ about 41 pharmaceutical companies reacted against the enactment of the Act by filing a lawsuit against the government.¹⁰⁹ The pharmaceutical companies claimed that the Act unjustifiably restricted the right to freedom of trade which is guaranteed by the supreme law-the Constitution.¹¹⁰ Pharmaceutical companies argued that the Act empowered the government to deprive owners of their intellectual property and expropriate such property without any form of compensation.¹¹¹

At the start of the litigation, the pharmaceutical companies could rely on the support of their home governments.¹¹² The United States (US) resorted to putting pressure on South Africa by withholding trade benefits and threatening further trade sanctions, aiming to force the South African government to repeal the Act.¹¹³ In 1998, the European Commission joined the US in pressuring South Africa to repeal the legislation. However, these threats attracted a lot of criticism from protesters and other AIDS advocacy groups who lamented the harm that was caused by preferring intellectual property rights over the right to health. Due to public pressure, pharmaceutical companies withdrew the lawsuit.¹¹⁴

Klug¹¹⁵ notes that the evocation of the right to health care to contest TRIPS and patent protection in South Africa had a number of important effects on the international intellectual property regime. First, it promoted the acceptance of a

¹⁰⁷ *Ibid* 52 para 4.

¹⁰⁸ 1998, SA 4183/9

¹⁰⁹ *Ibid* 1 para 1.

¹¹⁰ *Ibid* 1 para 1.

¹¹¹ *Ibid* 2 para 2.

¹¹² Hoen: *The global politics of pharmaceutical monopoly power: drug patents, access, innovation and the application of the WTO Doha Declaration on TRIPS and Public Health* (2009) 6.

¹¹³ The World Intellectual Property Report "Patent protection and access to HIV/AIDS pharmaceuticals in Sub-Saharan Africa" http://www.wipo.int/11f07178-9054-48a8-bafc-eeb281e098e8/finaldownload/downloadid-efccbd046a1edf67064d43c824b93e10/11f07178-9054-48a8-bafc-eeb281e098e8/export/sites/www/about-ip/en/studies/pdf/iipi_hiv.pdf (accessed 24/108/2014).

¹¹⁴ Fisher and Rigamonti "The South Africa AIDS controversy: a case study in patent law and policy" [file:///C:/Users/sheltonmotamakore/Desktop/vongai%20thesis/South%20Africa%20\(5\).pdf](file:///C:/Users/sheltonmotamakore/Desktop/vongai%20thesis/South%20Africa%20(5).pdf) (accessed 12/24/2014).

¹¹⁵ Kluge "Access to medicines and the transformation of the South African state: exploring the interactions of legal and policy changes in health, intellectual property, trade, and competition law in the context of South Africa's HIV/AIDS pandemic" 2012 *Law and Social Inquiry* 297.

human rights perspective that the right to health should gain pre-eminence over any particular claim of intellectual property.¹¹⁶ Second, it established awareness of health and human rights considerations as essential correctives to potential injustices that arise from enhanced Intellectual property laws.¹¹⁷

On the other hand, proponents of patent protection base their claim on the theory of innovation.¹¹⁸ According to this theory, patents encourage research and development, leading to new products that improve medical care.¹¹⁹ The financial return afforded by patent protection, they claim, is an inducement toward innovation and reinvestment into further research and development.¹²⁰ But this view has been challenged in recent years.¹²¹ Cullet¹²² concluded that current patent laws do not encourage research in diseases which cause the most morbidity and mortality in developing countries. This is because such diseases principally offer little in terms of profit incentives. This has led to the access gap being created for the so called neglected diseases.¹²³

Vawda and Baker¹²⁴ appeal for the reinforcing of public health provisions of TRIPS by putting greater prominence on public health for developing nations.¹²⁵ They state that TRIPS Agreement seems to have safeguards to ensure access to essential medicines is not impeded in poorer countries.¹²⁶ However, ambiguity exists in applying the exceptions to patent protection. Thus, it appears that the current trade agreements under the WTO are frustratingly vague in their approach to the task of

¹¹⁶ *Ibid* 298 para 1.

¹¹⁷ *Ibid* 298 para 1.

¹¹⁸ Outterson "Pharmaceutical arbitrage: balancing access and innovation in international prescription drug markets" 2013 *Yale Journal of Health Policy, Law, and Ethics* 5 4.

¹¹⁹ Klug "Comment: access to essential medicines – promoting human rights over free trade and intellectual property" https://media.law.wisc.edu/m/qyn2g/commentreichmanaccess_to_medicines.pdf Claims (accessed 12/24/2014).

¹²⁰ *Ibid* 22 para 2.

¹²¹ Velásquez and Boulet "Globalisation and access to drugs: implication of the WTO/TRIPS Agreement" <http://www.who.int/medicines/areas/policy/who-dap-98-9rev.pdf> (accessed 12/24/2014).

¹²² Cullet "The relationship between TRIPS and the human right to medicines" <http://ielrc.org/content/a0301.pdf> (accessed 15/24/2014).

¹²³ The term "neglected diseases" refers to a cluster of tropical diseases such as helminthiasis, among others, commonly found in poor environment. These diseases flourish and thrive in poverty. They have disappeared in developed countries because of economic empowerment. In South Africa, neglected diseases are still rife due to unprecedented levels of poverty and depravity. See Scielo "The neglected triple disease burden and interaction of helminths, HIV and tuberculosis: an opportunity for integrated action in South Africa" 2014 *South African Medical Journal* 104 258.

¹²⁴ Vawda and Baker "Achieving social justice in the human rights/intellectual property debate: realising the goal of access to medicines" 2013 *African Human Rights Law Journal* 13 14.

¹²⁵ *Ibid* 14 para 3.

¹²⁶ *Ibid* 14 para 3.

balancing protection for health against other trade-related concerns and this may affect the development of policies and programmes connected to promoting health as a human right.¹²⁷

Hestermeyer¹²⁸ observes that access to essential medicines has developed to such an extent that it can be framed as a purely human right issue.¹²⁹ Herstermeyer work is highly significant for the purpose of this study because it constructs access to medicines as a supreme norm. This supreme norm could be used as a contingency to overrule ordinary law and government policies that create the problem of access to essential medicines.¹³⁰

In light of the foregoing literature review, it is apparent that the theory of innovation with its pro-patent approach may have failed to increase access to essential medicines in areas of neglected diseases. Further, a lot of literatures seem to be increasingly focusing on the impact of patents on access to essential medicines rather than proposing ways to mitigate these effects. This is the gap that this research intends to fill. The research seeks to explore whether the right to health can be utilised to ameliorate the problem of access to essential medicines. The right to health has the potential to provide a means of achieving a more amicable formulation, implementation, and interpretation of trade rules by South African courts, and the WTO alike, and perhaps even a mechanism to assist efforts to amend the TRIPS Agreement itself.¹³¹

1.8 Research Methodology

The research methodology employed in this study is mainly based on desk top. The research utilises both primary and secondary sources of data. The primary sources included basic documents such as Statutes and Declarations, treaties, cases and communiqués, official circulars and publications by relevant government departments and speeches and declarations. For example, UNDHR, ICESCR, TRIPS agreement, African Charter. The research extracts data from municipal laws

¹²⁷ *Ibid* 14 para 3.

¹²⁸ Hestermeyer, "Access to medication as a human right" http://www.mpil.de/files/pdf2/mpunyb_hestermeyer_8.pdf (accessed 20/08/2014).

¹²⁹ *Ibid* 127 para 1.

¹³⁰ *Ibid* 127 para 1.

¹³¹ Forman "Rights" and wrongs: what utility for the right to health in reforming trade rules on medicines?" 2013 *Health and human rights Journal* 10 41.

such as the Constitution of the Republic of South Africa, statutes and policies that have a bearing on access to essential medicines in South Africa. For instance, the South African Patent Act and The Draft National Policy on Intellectual Property of South Africa. The bulk of the research is based on research conducted from secondary sources. This included archival library research and the use of books, monographs, the internet, journal articles, magazines, conference and seminar proceedings and reports.

1.9 Delimitations of the Research

The major limitation of this study is that it does not deal with all human rights which are affected by lack of access to essential medicines. Although there is recognition that human rights are indispensable, interrelated and interdependent, the study rather looks at the immediate right which is impacted, namely the right to health. The study does not also deal with the impact of bilateral and regional Intellectual property agreements on the right to health, in particular access to essential medicines. Rather, it looks at the TRIPS Agreement which is multilateral in nature. The study is based on a limited number of cases that have made an impact upon the right to health and access to essential medicines in South Africa. Lastly, the research is geographically restricted to the case study of South Africa.

1.10 Ethical Considerations

The research is based on reviewing of already published material. Therefore, the reviewer needs no ethical permission to conduct this study. Given the extensive use of the literature, a potential ethical problem that may arise will be copyright issues. To prevent this, the researcher will acknowledge all sources used in accordance with the University of Fort Hare research policy.

1.11 Outline of Chapters

This research is divided into five chapters.

Chapter One is an introductory chapter which provides the background to the study; the research problem that has prompted the researcher to undertake this study; the aims and objectives; the assumptions underlying the research as well as the delimitation of the research. The chapter also provides a description of the methodology to be employed in the research as well as a review of the relevant literature, exploring the works of other authors in the area of the right to health and intellectual property.

Chapter Two discusses the right to health. The chapter provides a detailed discussion on the nature, scope and content of the right to health under the international and regional human rights frame work. The aim of this chapter is to demonstrate that access to essential medicines constitute an essential component of the right to health.

In Chapter Three, the study looks at the protection of the right to health under South African Constitution and relevant legislation. In that regard, this chapter provides a discussion on how courts in South Africa have adjudicated and interpreted the right to health through a number of cases law.

Chapter Four looks at the problem of access to essential medicine in South Africa. It provides a discussion on TRIPS Agreement and South African patent laws in order to show how they affect access to essential medicines in South Africa. The major aim of this Chapter is to demonstrate that patents have a far reaching impact on access to essential medicines in South Africa.

Chapter Five provides the conclusions and the findings of this research. The chapter will also suggest areas for further research.

CHAPTER TWO

The historical origin, scope and content of the right to health within the corpus of international human rights instruments

2.1 Introduction

The concept of health as a human right is a controversial one.¹³² While this controversy is not unique to the right to health only, the fact that health itself is a relative concept introduces further ambiguity and imprecision.¹³³ For many legal scholars, the right to health cannot be simply justified.¹³⁴ It is said that it lacks a convincing theoretical account of its conceptual foundations.¹³⁵ These scholars dismiss the right to health as a “vacuous” concept that should be demoted from the list of human rights recognised under international human rights framework.¹³⁶ Indeed, this position questions the legitimacy of the right to health. However, there is a need to explore whether a legal defence of the right to health exists.¹³⁷ Such a defence has the potential to defeat sceptic notions and to provide a strong theoretical foundation upon which to erect the normative content of the right to health, in light of access to essential medicines.¹³⁸

This chapter will attempt to clear this ambiguity by providing a comprehensive discussion on the origin, scope and content of the right to health. The first section of this chapter will provide a detailed overview of the developments that led to the recognition of the right to health in international law. The second section of this chapter examines in considerable detail the meaning of the right to health enshrined under various international instruments, and General Comments, in light of the need to provide access to essential medicines.¹³⁹ The major object of this chapter is to

¹³²Ruger “Toward a theory of a right to health: capability and incompletely theorised agreements” 2014 *Yale Journal Law* 18 294.

¹³³Harrington and Stuttford: *Routledge research in human rights law, global health and human rights legal and philosophical perspectives* (2010) 165.

¹³⁴Mutua “The complexity of universalism in human right” <http://cscs.res.in/dataarchive/textfiles/textfile.2009-08-21.0544949818/file> (accessed 16/01/2015).

¹³⁵*Ibid* 52 para 1.

¹³⁶Tarantola “A perspective on the history of health and human rights: from the Cold War to the gold war” 2008 *Journal of Public Health Policy* 29 49.

¹³⁷File “The liberal grounding of the right to health care: an egalitarian critique” (2014) *The Modern Law Review* 77 336.

¹³⁸*Ibid* 337 para 2.

¹³⁹General Comments are recommendations adopted by any of the bodies established under the auspices of the UN treaties for the promotion and protection of human rights. See Ando “General

demonstrate that international law recognises access to essential medicine as a fundamental part of the right to health. Therefore, it is the responsibility of South Africa to give effect to the international obligations of access to essential medicines in the domestic sphere.

2.2 Terminological Problems

As a preliminary issue, it is worthy to note that the modern conceptualisation of a right to health is associated with much terminological complexity.¹⁴⁰ There is no clarity as to the proper terminology to be utilised. Numerous writers make use of different terminology and phraseology.¹⁴¹ Some writers prefer to use the term right to health whilst others use the right to health care or right to health protection.¹⁴² All three terminologies carry similarities and differences in terms of their scope and meanings. The right to health protection is strongly linked to various human rights such as the right to dignity, food, shelter, and a healthy environment. It denotes that a State has to take measures to prevent violations of the right to health by non-state actors and to offer accessible redress to the people in the event of any such violation.¹⁴³

The right to health care can be distinguished from the right to health protection and the right to health. According to Daniels,¹⁴⁴ the right to health care is much more definite and can be interpreted as the right to provide medical services. The parameters of the right to health care are that it only protects the means for the achievement of health such as, services or suppliers related to the health of a person.¹⁴⁵ On the other hand, the right to health has been criticised for creating an assumption that people have a right to perfect health which is something that cannot

comments/recommendations, Max Planck Institute for Comparative Public Law and International Law, Heidelberg and Oxford University Press” http://ilmc.univie.ac.at/uploads/media/general_comments_recommendations_empil.pdf (accessed 25/06/2015).

¹⁴⁰Ngwenya “Four rights concerning health” http://www.chr.up.ac.za/chr_old/centre_publications/socio/book/Chapter%204-Health.pdf (accessed on 26/01/2015).

¹⁴¹*Ibid* 58 para 2.

¹⁴²Chirwa “The right to health in international law: Its implications for the obligations of state and non-state actors in ensuring access to essential medicine” 2003 *South African Journal of Human Rights* 19 541 (accessed 27/02/2015).

¹⁴³*Ibid* 542 para 1.

¹⁴⁴Maruthappu *et al* “Is health care a right? health reforms in the USA and their impact upon the concept of care” [http://www.annalsjournal.com/article/S2049-0801\(13\)70021-9/pdf](http://www.annalsjournal.com/article/S2049-0801(13)70021-9/pdf) (accessed on 27/02/2015).

¹⁴⁵Congressional Research “Health care: constitutional rights and legislative powers” <https://www.fas.org/sqp/crs/misc/R40846.pdf> (accessed 28/02/2015).

be guaranteed by the State.¹⁴⁶ A clear demarcation must be made between health as a state or condition, physical, psychological or social and health care services designed to maintain and recuperating health. Therefore, the right to health does not mean the right to be healthy.¹⁴⁷

The term right to health is considered to be broader than other competing terms, mentioned above which are said to be included in the right to health.¹⁴⁸ It also corresponds most closely with the term “right to the highest attainable standard of health” which is delineated in various human rights instruments and documents.¹⁴⁹ The right to health is also regarded as a shorthand expression to the more detailed language contained in human right treaties.¹⁵⁰ For these reasons, this dissertation adopts the term right to health as a way of referring to various formulations of health rights in international human rights instruments and domestic law.

2.3 Historical evolution of the right to Health

Historically, the concept of health as a public good did not so much originate from a human rights organ. Rather, it can be traced back to at least 2600 BC when a scientist in 3rd dynasty Egypt wrote texts describing the diagnosis and treatment of at least 200 diseases.¹⁵¹ Since then, humanity has been attempting to tackle the problem of diseases and to neutralise its impact.¹⁵² However, throughout many centuries diseases and their cures were understood through religious and cultural beliefs.¹⁵³ The early societies believed that diseases were caused by divine judgements which came from the gods to punish the immoral mankind.¹⁵⁴ It was believed that diseases could be cured by appeasing to the gods through offering

¹⁴⁶Taylor “Making the World Health Organization work: a legal framework for universal access to the conditions for health” 1992 *American Journal of Law and Medicine* 4 301.

¹⁴⁷World Health Organization “The right to health fact sheet No. 31” <http://www.ohchr.org/1F16B239-159849FC9247A0085D123D68/FinalDownload/DownloadId8B7E068B0CA9C861BF6085719C047235/1F16B239-1598-49FC-9247-A0085D123D68/Documents/Publications/Factsheet31.pdf> (accessed 23/01/2015).

¹⁴⁸Himong “The right to health in an African cultural context: the role of Ubuntu in the realisation of the right to health with special reference to South Africa” (2013) *Journal of African Law* 17 165.

¹⁴⁹*Ibid* 166 para 1.

¹⁵⁰Toebe : *The right to health as a human right in international law* (1999) 4.

¹⁵¹Health and Democracy “A background to health law and human rights in South Africa”. <http://www.section27.org.za/wp-content/uploads/2010/04/Chapter1.pdf> (accessed 24/01/2015).

¹⁵²Schoenbach “An evolving historical perspective” <http://www.epidemiolog.net/evolving/HistoricalPerspective.pdf> (accessed 12/12/2015).

¹⁵³Hessim *et at. Health and democracy: a guide to human rights, health law and policy in post-Apartheid South Africa* (2007) 3.

¹⁵⁴*Ibid* 3 para 2.

sacrifices.¹⁵⁵ Caring for the sick was considered to be the responsibility of private actors such as families, churches and charities. The only public method designed to curb the spread of epidemic diseases was quarantine of the ill.¹⁵⁶

However, the greater impetus for the recognition of the right to health and other fundamental human rights emanated from the need to promote global peace.¹⁵⁷ The architects of the international Bill of Rights who consisted mainly of the Allied Powers believed that contempt for human rights had contributed to the outbreak of Second World War.¹⁵⁸ Indeed, the horrors of Second World War provided a profound push for the beginning of the greater recognition of the right to health.¹⁵⁹ All these historical events, culminated in the creation of the basic premise that states should take measures to protect the right to health of their people.¹⁶⁰

2.4 The genesis of the right to health within international human rights instruments

Although the previous discussion suggests that the right to health has deep historical roots tracing back to the ancient world,¹⁶¹ what is known today as the right to health began to take a more concrete shape after the Second World War with the establishment of the United Nations (UN).¹⁶² The UN officially came into existence on 24 October 1945, when the UN Charter was ratified by China, France, the Soviet Union, the United Kingdom, and United States and by a majority of other signatories.¹⁶³ From this period onwards, the UN has pushed for unprecedented

¹⁵⁵Sama and Nguyen : *Governing health systems in Africa* (2008) 3.

¹⁵⁶*Ibid* 3 para 2.

¹⁵⁷Baker and Taylor “The right to health: a right on the rise?” 2013 *The Journal Jurisprudence Volume Nineteen* 5 147.

¹⁵⁸Cassese: *Human rights in a changing world* (1990) 17.

¹⁵⁹Hayden “The human right to health and the struggle for recognition” (2011) *Cambridge Journals* 28 569.

¹⁶⁰Tobin : *The right to health in international law* (2011) 13.

¹⁶¹Mazower “The strange triumph of human rights” 2004 *The Historical Journal* 2. 47.

¹⁶²In 1945, representatives of 50 countries met in San Francisco at the United Nations Conference on International Organisation to draw up the United Nations Charter. Those delegates deliberated on the basis of proposals worked out by the representatives of China, the Soviet Union, the United Kingdom and the United States at Dumbarton Oaks, United States in August-October 1944. The Charter was signed on 26 June 1945 by the representatives of the 50 countries. Poland, which was not represented at the Conference, signed it later and became one of the original 51 Member States. The United Nations officially came into existence on 24 October 1945, when the Charter had been ratified by China, France, the Soviet Union, the United Kingdom, the United States and by a majority of other signatories. <http://www.un.org/en/aboutun/history/> (accessed on 12/02/2015).

¹⁶³United Nations “Human rights education” <http://www.humanrightseducation.info/hr-materials/the-united-nations-charter.html> (accessed 13/02/2015).

world-wide legal recognition of the right to health.¹⁶⁴ Globally, at least about 115 Constitutions around the world now recognise the right to health either as a justiciable claim, aspirational guarantees, or a combination of the two.¹⁶⁵ Apart from treaty instruments, the right to health has been elucidated in international debates.¹⁶⁶ Some of these international debates culminated in the adoption of declarations and statements of action regarded as authoritative. For instance, the Programme of Action of the international Conference on Population and Development (the Cairo Programme) which was followed by Cairo's Programme (Cairo Plus), the Five Beijing Declaration¹⁶⁷ and Platform of the fourth World Conference on Women (Beijing Platform) which was followed by Beijing Plus.¹⁶⁸ These international debates produced documented authoritative statements on the meaning and scope of the right to health as it applies to different context and groups of people especially women.¹⁶⁹

2.4.1 The right to health in the UN system

The UN articulates the right to health in the collection of three basic human rights documents known as the International Bill of Human Rights.¹⁷⁰ In Articles 55 and 56 of the UN Charter, member States pledge to take action to achieve solutions to “international economic, social, health, and related problems”.¹⁷¹ While the UN Charter does not itself establish a right to health, this statement in the founding document of the UN signals the degree to which health is viewed as an essential human right.¹⁷² The UN Charter laid the foundation for the international framework which recognises the right to health.¹⁷³ South Africa, being a UN member is bound by the UN Charter.

¹⁶⁴Toebe et al. *The right to health a multi-country study of law, policy and practice* (2014) 6.

¹⁶⁵Yound and Lemaitre “The comparative fortunes of the right to health: two tales of justifiability in Columbia and South Africa” 2013 *Harvard Human Rights Journal* 26 182.

¹⁶⁶Cook et al : *Reproductive health and human rights : Integrating medicines, ethics and law* (2003) 160-164.

¹⁶⁷*Ibid* 225 para 1.

¹⁶⁸Benatar and Brock: *Global Health and Global Health Ethics* (2011) 16.

¹⁶⁹Wolf: *The human right to health* (2012) 206.

¹⁷⁰Keener and Vasquez “Life worth living: enforcement of the right to health through the right to life in the Inter-American court of human rights” 2009 *Columbia Human Rights Law Review* 40 595. (accessed on 27/02/2015).

¹⁷¹Article 55, and 56.

¹⁷²Doyle “A Global Constitution?The struggle over the UN Charter” <http://www.iilj.org/courses/documents/HC2010Sept22.Doyle.pdf> (accessed 23/02/2014).

¹⁷³*Ibid* 3 para 6.

2.4.2 The right to health in WHO Constitution

The first legal pronouncement on the right to health at the global level can be found in the Constitution of the World Health Organization (WHO) of 1946.¹⁷⁴ The WHO was founded in 1948, in the immediate aftermath of the Second World War, under the auspices of the UN system.¹⁷⁵ One of the apparent objectives of WHO is to promote the attainment of the “highest possible level of health.”¹⁷⁶ This ambition is widely spelt out in its Constitution and other policy documents. Health is defined in the Preamble to the WHO Constitution as “a state of complete physical, mental and social well-being, and not merely the absence of disease or infirmity.”¹⁷⁷

The Preamble further asserts that “the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, or economic or social condition.”¹⁷⁸ Young and Lemaitre¹⁷⁹ have note that, this definition of health presupposes, *inter alia*, the protection of the social determinants of health, the provision of essential medicines, and equitable access to health care.¹⁸⁰ In sum, the definition encompasses a meaning of health which goes further than the mere lack of disease or physical and mental maladies.¹⁸¹

The definition of health was expanded by the Declaration of Alma-Ata on Primary Health care.¹⁸² The Declaration of Almata , strongly stated that the right to health is a “fundamental human right” and “ the attainment of the highest possible level of health is a most important world-wide social goal whose realisation requires the action of

¹⁷⁴World Health Organization “Preamble to the Constitution, in: The first ten years of the world Health Organisation” http://www.who.int/governance/eb/who_constitution_en.pdf (accessed 23/02/2014).

¹⁷⁵Clift “What’s the World Health Organisation for?”http://www.chathamhouse.org/sites/files/chathamhouse/field/field_document/20140521WHOHealthGovernanceClift.pdf (accessed on 23/01/2015).

¹⁷⁶Paul “Our right to the highest attainable standard of health”[http://www.ifhhro.org/images/stories/ifhhro/Right to Health/3 2 2 factsheet our rth 2007.pdf](http://www.ifhhro.org/images/stories/ifhhro/Right%20to%20Health/3_2_2_factsheet_our_rth_2007.pdf) (accessed on 15/02/2015).

¹⁷⁷World Health Organisation “Constitution of the World Health Organisation”http://www.who.int/governance/eb/who_constitution_en.pdf (accessed on 14/01/2015).

¹⁷⁸World Health Organisation “1946 Preamble to the Constitution of the World Health Organisation”http://www.who.int/governance/eb/who_constitution_en.pdf(accessed 15/01/2015).

¹⁷⁹Tobin: *The right to health in International Law* (2012) 56.

¹⁸⁰*Ibid* 56 para 2.

¹⁸¹*Ibid* 56 para 2.

¹⁸²World Health Organisation “Declaration of Alma-Ata International Conference on Primary Health Care, Alma-Ata “ http://www.who.int/publications/almaata_declaration_en.pdf (accessed 15/01/2015).

many other social and economic sectors in addition to the health sector.”¹⁸³ The Declaration of Alma-Ata pledged to progressively develop a comprehensive health care system for universal health care.¹⁸⁴ Meier¹⁸⁵ laments that, despite loft pledges and language, WHO intentionally neglected human rights discourse during its crucial years in the development of the right to health to the detriment of public health.¹⁸⁶

The WHO definition has been criticised by scholars as being very broad and creating the impression that the right to health means that individuals have the right to be healthy.¹⁸⁷ This is misleading because States Parties cannot guarantee protection against every possible cause of human ill health. Bok¹⁸⁸, in rethinking the WHO definition, concludes that it is a “mystifying definition” and posit that the terms such as “complete” and “social” and even “well-being” contributes to the further ambiguity of the right to health.¹⁸⁹ The nebulous character of the right to health become more vivid when one consider that health hinges on many factors isolated to direct health interventions.¹⁹⁰ Factors such as a person’s genetic history, social milieu, and actions play a significant part in determining the state of health. This makes it impossible for States to guarantee health but rather health care services.¹⁹¹

In spite of the massive queries raised against the WHO definition of health, the recognition of health as a right was a breakthrough in the field of international health

¹⁸³Marks “The emergence and scope of the human right to health” http://www.who.int/publications/almaata_declaration_en.pdf (accessed 16/01/2015).

¹⁸⁴Kinney and Clark “Provisions for health and health care in the constitutions of the countries of the world” 2014 *Cornell International Law Journal* 37 290.

¹⁸⁵Meier “Global health governance and the contentious politics of human rights: mainstreaming the right to health for public health advancement” 2010 *Stanford Journal of International law* 46 4.

¹⁸⁶*Ibid* 65 para 1.

¹⁸⁷It is apparent that the wording of the WHO’s definition of health was borrowed from Henry Sigerist. The verbatim expression and lexicon of the definition reflects identical properties of Henry Sigerist definition, found in his book: *Medicine and Human Welfare* (1941) and *Civilisation and Diseases* (1943). Henry Sigerist was a companion of, Yugoslav delegate named Andrija Stampar, who played a significant role in drafting WHO definition and was influenced by the works of his friend. See Thomas and Flood “*Putting Health to Rights: A Canadian View on Global Trends in Litigating Health Care Rights*” 2015 53 <http://www.cjcl.ca/wp-content/uploads/2015/01/9.-Thomas--Flood-Putting-Health-to-Rights.pdf> (accessed 11/6/2015).

¹⁸⁸Bok: *Rethinking the definition of health: The international Encyclopaedia of Public health* (2013) 6.

¹⁸⁹ *Ibid* 593 para 2.

¹⁹⁰Cliff “The role of the World Health Organization in the international system” https://www.chathamhouse.org/sites/files/chathamhouse/public/Research/Global%20Health/0213_who.pdf (accessed 27/02/2015).

¹⁹¹*Ibid* 11 para 2.

and human rights law.¹⁹² It created an important point of departure for the further elaboration of a right to health in other human rights documents. Further, the WHO recognition of the right to health became a point of inspiration and a cornerstone for the right to health provisions that were drafted at a later stage.¹⁹³

2.4.3 The right to health in the UDHR

The second pronouncement of the right to health at the global level is found in the Universal Declaration of Human Rights (UDHR) of 1948.¹⁹⁴ The UDHR was adopted as a resolution by United Nations General Assembly on 10 December 1948.¹⁹⁵ The UDHR contains a catalogue of fundamental human rights and lays them down as a common standard of achievement for all peoples.¹⁹⁶ The UDHR mentioned access to essential medicines as a part of the right to an adequate standard of living. Article 25(1) provides that;

Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control¹⁹⁷

Although the UDHR is not binding *per se*, it has become a yardstick by which to measure the degree of respect for, and compliance with, international human rights standards.¹⁹⁸ Joseph and Adam¹⁹⁹ argue that the UDHR has evolved into a binding legal document through customary international law.²⁰⁰ There is an important reason for ascertaining whether the UDHR has evolved into customary international

¹⁹²Toebes *et al.* *The right to health, and the other health-related rights, health and human rights in Europe* (2012) 8.

¹⁹³*Ibid* 8 para 1.

¹⁹⁴The Universal Declaration of Human Rights, adopted 10 Dec, G.A., Res.217A (UN) GAOR 3d Sess, art. 25. Doc A/ RES/3/ 217 (1948).

¹⁹⁵*Ibid* para 1.

¹⁹⁶Kinney "realizing the international human right to health: the challenge of for-profit health care" 2011 *West Virginia Law Review Volume* 113 4.

¹⁹⁷Article 25:1

¹⁹⁸Kabasakal and Zehraf "Forging a global culture of human rights: Origins and proponents of the international bill of rights" 2006 *Human rights Quarterly* 28 416-432.

¹⁹⁹Joseph and Adam: *Research handbook on international human rights* 2010 489.

²⁰⁰In *Hostages case US v. Iran*, 1981 General list No 54, the International Court of Justice referred directly to the UDHR and found in its "principles" proof of the existence of universal human rights. The references to the UDHR continued to support the claims that at least some rights had attained the quality of customary rules in other forms. The UDHR was even quoted as containing rules of *jus cogens*. See Dimitrijevic "Customary law as an instrument for the protection of human rights" ISPI working Paper http://www.ispionline.it/it/documents/wp_7_2006.pdf (accessed 12/10/2014).

law.²⁰¹ The reason is that the UDHR provisions would be legally binding upon states regardless of the fact that it is a declaration. This is so because norms of customary international law are of binding nature even in the absence of ratification.²⁰²

However, determining the existence of an international customary law rule is not an easy task. There must be evidence for the existence of state practice (*usus*) and a belief by states that their practice is legally required by the norm (*opinio juris*) for a customary norm to come into existence.²⁰³ Mendelson²⁰⁴ argues that the difficulty of ascertaining the existence of such a norm is further compounded by a lack of clarity of what constitute state practice and *opinio juris*.²⁰⁵ In spite of the controversy surrounding its legal authority, the UDHR remains the most important and far-reaching of all UN declarations, and a fundamental source of inspiration for national and international efforts to promote and protect the right to health.²⁰⁶

2.4.4 The right to health in the ICESCR

The third pronouncement of the right to health at the global level is found in the International Covenant on Economic, Social and Cultural Rights (ICESCR).²⁰⁷ The ICESCR constitutes one branch of the “hard law” version of the Universal Declaration of Human Rights (UDHR) incorporating what are traditionally called economic, social and cultural rights.²⁰⁸ The ICESCR stands in tandem with the International Covenant on Civil and Political Rights (ICCPR), as a part of the International Bill of Rights, a project promoted by United Nations.²⁰⁹ Since the

²⁰¹Dimitrijevic “Customary International law as an instrument for the protection of human rights” http://www.ispionline.it/it/documents/wp_7_2006.pdf (accessed 18/03/2015).

²⁰²*Ibid* 7 para 3.

²⁰³Lepard “The necessity of *opinio juris* in the formation of customary international law” http://law.duke.edu/cicl/pdf/opiniojuris/panel_2lepardthe_necessity_of_opinio_juris_in_the_formation_of_customary_international_law.pdf (accessed 18/03/2015).

²⁰⁴Mendelson: *The subjective element in customary international law* (1995) 206.

²⁰⁵*Ibid* 206 para 5.

²⁰⁶Claude “Health, Medicine and Science in The Universal Declaration of Human Rights” <http://www.aaas.org/sites/default/files/migrate/uploads/4065304.pdf> (accessed 23/03/2014).

²⁰⁷International Covenant on Economic, Social and Cultural Rights, United Nations General Assembly resolution 2200A (XXI) of 16 December 1966, which came into force 3 January 1976 <http://www1.umn.edu/humanrts/instree/ainstls1.htm> (accessed 19/04/2014).

²⁰⁸Toebe: *Right to Health, A Multi-Country Study of Law, Policy and Practice* 2012 5.

²⁰⁹Ajigboye “Realisation of health right in Nigeria: A case for judicial activism” (2014) *Global Journal of Human-social Science: Political Science* 43 4.

adoption of ICESCR in 1966, it has become a reference point for defining economic, social and cultural rights.²¹⁰

Many international and regional human rights instruments and domestic constitutions have been modelled on this instrument as far as economic, social and cultural rights are concerned.²¹¹ As of March 2015, the ICESCR has been ratified by 162 countries.²¹² Article 2(1) of the ICESCR obliges each state party “to take steps to the maximum of its available resources”,²¹³ in order to progressively achieve the full realisation of the economic, social and cultural rights in the Covenant “by all appropriate means, including particularly the adoption of legislative measures”.²¹⁴ Article 12(1) of ICESCR declares that:

“The States Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.

2. The steps to be taken by the States Parties to the present Covenant to achieve the full realization of this right shall include those necessary for:

(a) The provision for the reduction of the stillbirth-rate and of infant mortality and for the healthy development of the child;

(b) The improvement of all aspects of environmental and industrial hygiene;

(c) The prevention, treatment and control of epidemic, endemic, occupational and other diseases;

(d) The creation of conditions which would assure to all medical service and medical attention in the event of sickness.”²¹⁵

Article 1 of the ICESCR provides a detailed list of the steps that are necessary to achieve the full realisation of the right.²¹⁶ States are required to provide facilities,

²¹⁰Chirwa “An overview of the impact of the International Covenant on Economic, Social and Cultural Rights in Africa”<http://aihrresourcescenter.org/administrator/upload/documents/Socio> (accessed 23/10/2014).

²¹¹Heyns and Steffens: *Human rights, peace and justice in Africa* (2006) 76.

²¹²Liebenberg and Oppenheimer *The potential of the international covenant on economic, social and cultural rights as a tool for poverty-reduction in South Africa* (2013) 4.

²¹³Chapman “The foundations of a human right to health: human rights and bioethics in dialogue” 2015 *Health and Human Rights Journal* 12 9.

²¹⁴*Ibid* 13 para 1.

²¹⁵ Art 12 (1).

goods and services, including relevant programmes to ensure the realisation of the right to health.²¹⁷ The ICESCR recognises the infinity of resources and subjects the realisation of the right to health to progressive realisation and resource availability.²¹⁸

The term “progressive realisation” might lead to an inference that the right to health is incapable of immediate claim.²¹⁹ However, the Committee on Economic, Social and Cultural rights (CESCR)²²⁰ has warned against such a unwarranted interpretation.²²¹ The CESCR has maintained that the terms ‘progressive realisation’ and ‘to the maximum of the available resources’ are necessary flexibility devices given the practical difficulties surrounding the full realisation of economic, social and cultural rights.²²² The CESCR Committee has also submitted that the Covenant establishes ‘clear obligations’ for states parties to move as expeditiously and effectively as possible towards the full realisation of these rights.²²³ Therefore, the ICESCR embeds the recognition that resource constraints are legitimate limitations on the realisation of the right to health.

Although the CESCR has commented extensively on the phrase “progressive realisation” scholars still doubt its efficacy.²²⁴ For instance, Forman²²⁵ has opined that

²¹⁶Paul “Neglected diseases, social justice and human rights: some preliminary observation, special topics in social, economic and behavioural research report series” http://www.who.int/hhr/working_paper4_neglected%20diseases.pdf (accessed 19/02/2015).

²¹⁷*Ibid* 10 para 2.

²¹⁸In the common legal parlance, the term progressive realisation simply implies that the rights cannot be realised immediately. It means that progressive steps must be employed to achieve the rights by meeting the basic needs of all in the society. The phrase is always underpinned by the notion of minimum core. The case of *Government of South Africa v Grootboom, Constitutional Court of South Africa* 2000 (11) SA BCLR 1169 (CC), elucidates more on the concept of progressive realisation.

²¹⁹Ssenyonjo “Reflections on state obligations with respect to economic, social and cultural rights in international human rights law” (2011) *The International Journal of Human Rights* 15 6.

²²⁰The Committee on Economic, Social and Cultural Rights (CESCR) is the body of 18 independent experts that monitors implementation of the CESCR by its States parties. The Committee was established under ECOSOC Resolution 1985/17 of 28 May 1985 to carry out the monitoring functions assigned to the United Nations Economic and Social Council (ECOSOC) in Part IV of the Covenant <http://www.ohchr.org/Documents/ProfessionalInterest/cescr.pdf> (accessed 10/03/2015).

²²¹United Nations Economic and Social Council, *The right to the highest attainable standard of health*, E/C.12/2000/4 General Comments no 14, (article 12 of the International Covenant on Economic, Social and Cultural Rights), 11 August 2000, paragraph 1-3 <http://www.un.org/documents/ecosoc/docs/2001/e2001-22.pdf> (accessed 11/03/2014).

²²²Chenwi “Unpacking “progressive realisation”, its relation to resources, minimum core and reasonableness, and some methodological considerations for assessing compliance” 2013 *De Jure Law Journal* 39 747.

²²³*Ibid* 749 para 2.

²²⁴Forman *et al* “Human rights and global health funding: what contribution can the right to health make to sustaining and extending international assistance for health” 2012 *Global Health governance* 6 3.

²²⁵*Ibid* 6 para 3.

the contribution of the right to health towards global health policy and equity is limited by the principle of progressive realisation, which on its face, conditions the provision of essential and basic health needs on the availability of adequate resources. This limitation creates a loophole large enough in practical terms to nullify the ICESCR guarantees. The loophole exists in form of a possibility that governments will illegitimately claim lack of resources as the reason they have not met their obligations.²²⁶

Liebenberg,²²⁷ observes that this is further worsened by the fact that ICESCR does not provide clarity about the specific requirements of international duties of assistance and cooperation for wealthier countries to realise the right to health in other countries.²²⁸ The scholars argue that this can be regarded as a key deficiency given the dependence of many lower income countries on international funding to realise universal health coverage. In this light, progressive realisation may serve to permit almost any kind of health deprivations in the short term, an idea ostensibly at odds with the basic human rights imperative of protecting human life and dignity.²²⁹ The CESCR has developed the concept of ‘minimum core obligations’ in order to ensure that the right to health and other rights are not relegated as mere ideas incapable of attainment.²³⁰

2.4.5 Deconstructing the concept of “minimum core” in light of the right to health

The concept of “minimum core” demarcates basic essential health services levels obligated for states to provide.²³¹ It provides a minimum baseline to be protected as a matter of right against governmental claims of scarcity.²³² In clarifying the extent to which progressive realisation within resources could limit the right to health, in 2000 the CESCR issued a General Comment 14 that extensively interprets the right to

²²⁶ *Ibid* 6 para 3.

²²⁷ Liebenberg: *Socio-economic rights adjudication under a transformative constitution* (2010) 189.

²²⁸ *Ibid* 189 para 1.

²²⁹ *Ibid* 189 para 1.

²³⁰ Strauss and Horsten “Human rights-based approach to poverty reduction: the role of the right of access to medicine as an element of the right of access to health care” 2013 *Potchefstroom Electronic Law Journal* 16 3.

²³¹ Forman, *et al* “What could a strengthened right to health bring to the post-2015 health development agenda?: interrogating the role of the minimum core concept in advancing essential global health needs” 2013 *International Health and Human Rights* 1 6.

²³² Flood and Gross “Litigating the right to health: what can we learn from a comparative law and health care systems approach? 2014 *Health and Human Rights Journal* 16 2.

health.²³³ The General Comments made by the CESCR are “soft law” instruments and not legally binding.²³⁴ However, the Comments are very influential and it is expected that they are to be respected.²³⁵ The CESCR endorsed its earlier suggestion that states hold “minimum core obligations” to ensure satisfaction of minimum essential levels for all.²³⁶

The CESCR indicated that these minimum core obligations would include essential primary health care, essential foodstuffs, basic shelter and housing, and the most basic forms of education.²³⁷ However, the essential primary health care was not defined, and in General Comment 14 for the first time, the Committee clarified the content of “core obligations” under the right to health.²³⁸ The Committee indicated that these core obligations include at least: (1) ensuring non-discriminatory access to health facilities, goods and services, especially for vulnerable or marginalized people, (2) ensuring access to food, basic shelter, housing, sanitation and water, (3) providing essential drugs as defined by WHO, (4) ensuring equitable distribution of all health facilities, goods and services and (5) adopting a national public health strategy and plan of action addressing the concerns of all. Therefore, the minimum core concept bestows upon states minimum obligations to provide access to essential medicines.²³⁹

2.5 Normative content of the right to health

The General Comment 14 mentions a set of principles that are widely used for the definition of the general framework of the right to health.²⁴⁰ These four standards are

²³³Masanque “Comment progressive realisation without the ICESCR: the viability of South Africa’s Socio-economic rights framework, and its success in the right to access health care” 2013 *California Western International Law Journal* 43 9.

²³⁴Burris *et al* “Making the case for laws that improve health: a framework for public health law research” 2010 *The Milbank Quarterly* 88 169.

²³⁵General Comments may go through metamorphosis over time from being “soft” law into binding into a binding “hard” law. Meanwhile, the Comments are not binding, but rather are persuasive and instrumental in the interpretation of the Covenant. See Posner “Soft Law in Domestic and International Settings”<http://www.j.utokyo.ac.jp/coelaw/download/0603Soft%20Law%20in%20Domestic%20and%20International%20Settings.pdf> (accessed 14/04/2014).

²³⁶Young “The minimum core of economic and social rights: a concept in search of content” 2008 *The Yale Journal of International Law* 33 2.

²³⁷Gable and Meier “Human rights to develop and implement the Framework Convention on Global Health” 2013 *Health and Human rights* 15 34.

²³⁸Yamin “The future in the mirror: incorporating strategies for the defence and promotion of economic, social, and cultural rights into the mainstream human rights agenda” (2005) *HRQ*, 1202 1214.

²³⁹*Ibid* 1202 para 2.

²⁴⁰General Comment No. 14: The right to the highest attainable standard of health. <http://www.refworld.org/pdfid/4538838d0.pdf> (accessed 27/01/2015).

utilised as analytical tools to measure how far a particular State's policy has complied with the obligations of the right to health. The four standards are availability, accessibility, acceptability and quality of public health and health care facilities.²⁴¹

2.5.1 Availability

The principle of availability within the context of the right to health means that public health and health-care facilities, goods and services, as well as programmes, have to be available in sufficient quantity within the State party.²⁴² The precise nature of the facilities, goods and services will vary depending on numerous factors, including the State party's developmental level.²⁴³ They will include, however, the underlying determinants of health, such as safe and potable drinking water and adequate sanitation facilities, hospitals, clinics and other health-related buildings, trained medical and professional personnel receiving domestically competitive salaries, and essential drugs.²⁴⁴

2.5.2 Accessibility

The principle of accessibility implies that health facilities, goods and services have to be accessible to everyone without discrimination.²⁴⁵ The concept of accessibility by extension encapsulates four other sub-concepts namely (a) physical accessibility (b) economic affordability, (c) information accessibility and non-discrimination which imply health facilities, goods and services must be accessible to all, especially the most vulnerable or marginalised sections of the society.²⁴⁶ The UN Report of the UN Special Rapporteur on the right to the highest attainable standard of health emphasis that to health facilities, goods and services must be within safe physical reach for all sections of the population, especially vulnerable or marginalised groups, such as

²⁴¹Toebe, "Taking a human rights approach to health care commercialisation"<http://cop.health-rights.org/files/b/3/b3b8d72ab4d6a537d2e483c883210597.pdf> (accessed 28/01/2015).

²⁴²*Ibid* 442 para 2.

²⁴³Potts "Accountability and the right to the highest attainable standard of health, university of essex human rights centre"http://www.essex.ac.uk/human_rights_centre/research/rth/projects.aspx (accessed on 27/01/2015).

²⁴⁴*Ibid* 4 para 1.

²⁴⁵ Sandhu "A legal right to health care: what can the United States learn from foreign models of health rights jurisprudence" 2007 *California Law Review* 95 1161.

²⁴⁶Leary "Implications of a right to health" 1994 *Health and Human Rights* 1 24.

ethnic minorities and indigenous populations, women, children, adolescents, older persons, persons with disabilities and persons with HIV and AIDS.²⁴⁷

The principle of accessibility also implies that medical services and underlying determinants of health, such as safe and potable water and adequate sanitation facilities, are within safe physical reach, including in rural areas.²⁴⁸ Accessibility further includes adequate access to buildings for persons with disabilities and economic accessibility and services which must be affordable for all.²⁴⁹ The notion advocates for payment of health-care services, as well as services related to the underlying determinants of health, based on the principle of equity, ensuring that these services, whether privately or publicly provided, are affordable for all, including socially disadvantaged groups.²⁵⁰ The equity aspect of the right to health requires that poorer people should have access to health care services.²⁵¹

2.5.3 Acceptability

Within the province of the right to health, acceptability implies that all health facilities, goods and services must be respectful of medical ethics and culturally appropriate.²⁵² For instance, being sensitive of the culture of individuals, minorities, peoples and communities, sensitive to gender and life-cycle requirements, as well as being designed to respect confidentiality and improve the health status of those concerned²⁵³.

2.5.4 Quality

Quality means that health facilities, goods and services must be scientifically and medically appropriate and of good quality. This requires, *inter alia*, skilled medical personnel, scientifically approved and unexpired medicines and hospital equipment, safe and potable water, and adequate sanitation.²⁵⁴

²⁴⁷United Nations General “Right of everyone to the enjoyment of the highest attainable standard of physical and mental health” http://www.wma.net/en/20activities/20humanrights/20distress/A_-Grover-Report-UN-GA-October-2013.pdf (accessed 23/04/2014).

²⁴⁸*Ibid* para 13.

²⁴⁹ Leary “The right to complain: the right to health” *Health and Human Rights* (1994) 1 25.

²⁵⁰*Ibid* para 28 para 1.

²⁵¹*Ibid* 28 para 1.

²⁵²*Ibid* 28 para 2.

²⁵³*Ibid* 28 para 3.

²⁵⁴Friedman *et al* “Realizing the right to health through a Framework Convention on Global Health?” 2013 *health and human rights special issue 1093* para 6.

2.6 The general obligations of States

The right to health imposes some tripartite obligations on states parties.²⁵⁵ The three types of obligations generated under the ICESCR are the obligation (a) to respect, (b) protect and (c) to fulfil the right to health.²⁵⁶ The ICESCR obliges states to cooperate to ensure that these obligations are complied with.²⁵⁷

2.6.1 Obligation to respect

This is a negative State obligation and requires States to refrain from interfering directly or indirectly with the enjoyment of the right to health.²⁵⁸ It bestows a duty upon states not to impair access to human rights. For example, denying or limiting equal access to health services; enforcing discriminatory practices as a State policy; unlawfully pollution of the air, water and soil, e.g. through industrial waste from State-owned facilities, or through using or testing nuclear, biological or chemical weapons if such testing results in the release of substances harmful to human health.²⁵⁹

According to Liebenberg,²⁶⁰ this obligation requires States not only to implement policies that lead to the infringement of the right to health for the marginalised groups, but rather encompasses the duty not to simply interfere with the existing right.²⁶¹ This simply means that States are required to respect the right-holders, their freedoms, autonomy, resources, and liberty of their action. Therefore, denying access to essential medicine or other medical products would constitute a violation of this duty.²⁶²

Further, the state is enjoined to refrain from marketing unsafe medicines. It is further enjoined to refrain from deliberately withholding or misrepresenting information vital to treatment or the use of the medicine.²⁶³ The states would be in breach of the

²⁵⁵The tripartite typology of human rights obligations were initially coined by the scholar Henry Shue and later adopted by UN Committee on Economic, Social and Cultural Rights, See Toebes *et al* : *The right to health a multi-country study of law, policy and practice* (2008) 43.

²⁵⁶*Ibid* 43 para 3.

²⁵⁷Article 2 (1) ICESCR requires states to work together in ensuring the obligations imposed by the covenant are complied with. This is also in line with the UN General Assembly Declaration on the Principles of International law concerning Friendly Relations and Cooperation among States in Accordance with the Charter of the United Nations A/RES/2625 (XX) of 24 October 1970.

²⁵⁸Hunt and Khosla "The human right to medicines" 2008 *International Journal on human rights* 8 104.

²⁵⁹*Ibid* 104 para 2.

²⁶⁰Liebenberg: *Social-economic rights adjudication under a transformative constitution* 2010 83.

²⁶¹*Ibid* 83 para 2.

²⁶²*Ibid* 83 para 2.

²⁶³Javaid: *International human rights law- a practical approach* (2003) 63.

obligation to respect if it adopts legislation and policies which curtail the enjoyment of the right to health. Ultimately, failure to take into account its legal obligations regarding this right when entering into bilateral or multilateral agreements with other states, international organisations and other entities such as multinational corporations would also amount to a violation of this duty.²⁶⁴

2.6.2 Obligation to protect

The duty to protect obligates States to take positive action to protect citizens from harmful conduct that may be committed by other actors including private actors.²⁶⁵ Accordingly, the state has the duty to ensure equal access to health care (including essential medicine) provided by third parties.²⁶⁶ It also has an obligation to ensure that third parties do not limit people's access to information relating to essential medicines. Where the service is privatised, the state must ensure that the privatisation 'does not constitute a threat to the availability, accessibility, acceptability and quality of health facilities'.²⁶⁷ The state is further enjoined, among other things: to control the marketing of medical equipment and medicines by third parties; and to ensure that medical practitioners and other health professionals meet appropriate standards of education, skill and ethical codes of conduct.²⁶⁸

The duty to protect also requires that vulnerable groups be given special protection.²⁶⁹ In relation to people with disabilities, for example, the CESCR has stated that, in a context in which arrangements for the provision of public services are increasingly being privatised and in which the free market is being relied upon to an ever greater extent, it is essential that private employers, private suppliers of goods and services, and other non-public entities be subject to both non-discrimination and equality norms in relation to persons with disabilities.²⁷⁰

²⁶⁴ *Ibid* 163 para 1.

²⁶⁵ World Health Organisation "The right to health" <http://www.ohchr.org/Documents/Publications/Factsheet31.pdf> (accessed 03/03/2015).

²⁶⁶ Meier "Bridging international law and rights-based litigation: Mapping health-related rights through the development of the Global Health and Human Rights Database" 2012 *Health and human rights* 14 3.

²⁶⁷ *Ibid* 14 para 3.

²⁶⁸ *Ibid* 14 para 3.

²⁶⁹ *Ibid* 14 para 3.

²⁷⁰ *Ibid* 14 para 3.

The state discharges the duty to protect through the creation and maintenance of an atmosphere or framework by an effective interplay of laws and regulations to enable individuals to freely realise their rights and freedoms.²⁷¹ It has to establish an effective regulatory system providing for independent monitoring, genuine public participation and imposition of penalties for non-compliance. Adoption of legislation is not exhaustive of the state's duty to protect citizens from violations by third parties.²⁷² Administrative, economic, social, political and other measures must compliment legislation. In accordance with the principle of economic accessibility, the CESCR has stated, that the state is enjoined to protect its citizens from unreasonable prices of essential medicine.²⁷³

2.6.3 Obligation to fulfil

The obligation to fulfil applies to positive measures that the government is required to take in order to promote the right to health.²⁷⁴ It requires that all crucial steps be taken to ensure that the benefits covered by the right to health are provided and that appropriate legislative, administrative, budgetary, judicial, promotional and other relevant measures are adopted to ensure its full realisation. It also requires that special measures be taken to prioritise the health needs of the poor and other vulnerable and disadvantaged groups in society. In other words, the duty to fulfil enjoins governments to facilitate the actual realisation of the right.²⁷⁵

The obligation to fulfil the right to health is commonly associated with the obligations to facilitate, provide and promote the right to health.²⁷⁶ This reflects the different types of responsibility that governments incur which obliges them to take positive measures to implement the right to health. The facilitation of the right to health requires states to take positive measures that enable and assist individuals and communities to enjoy the right to health. The provision of the right to health requires states to intervene when individuals or groups are unable, for reasons beyond their

²⁷¹George, "The human right to health and HIV/AIDS: South Africa and South-South cooperation to reframe global intellectual property principles and promote access to essential medicines" 2011 *Indiana Journal of Global Legal Studies* 18 169.

²⁷²*Ibid* 167 para 170.

²⁷³*Ibid* 167 para 170.

²⁷⁴Potts "Participation and the right to the highest attainable standard of health" http://www.essex.ac.uk/human_rights_centre/research/rth/projects.aspx (accessed 03/03/2015).

²⁷⁵*Ibid* 13 para 1.

²⁷⁶Alston and Gerard "The nature and scope of states parties obligations under the International Covenant on Economic, Social and Cultural Rights" 1987 *Human Rights Quarterly* 2 156.

control, to realise the right to health themselves through the means at their disposal. Whereas, promoting the right to health requires states to undertake actions that create, maintain and restore the health of the population.²⁷⁷

The state is obliged by the duty to fulfil to provide for a public, private or mixed health insurance system, which is affordable to all.²⁷⁸ This obligation also requires the state to adopt positive measures that enable and assist individuals and communities to enjoy the right in question. The Committee has included access to essential medicines as part of the core content of the right to health. The committee states that the right to health contains a series of interrelated and minimum elements such as availability, accessibility, acceptability and quality of health goods and programmes. In this frame-work, medicines must be available in sufficient quality, without discrimination, overcoming physical and economic constrictions and especially medical ethics, provided they are scientifically and medically appropriate.²⁷⁹

2.6.4 Obligation to cooperate

Article 2 (1) of the ICESCR imposes a duty of international assistance and cooperation on States parties.²⁸⁰ The obligation to cooperate finds its roots in Article 1 (3), 55 (b), (c) and 55 of the UN Charter. The duty requires States to cooperate in the realisation of the right to health. According to the CESCR, the duty requires states that are in a position to assist other states to do so.²⁸¹ Historically, in international law, this obligation finds its ancestral origin in the pragmatism of Grotius who envisaged transnational cooperation as a pre-requisite for achieving international peace and security.²⁸² Whatever is the logic behind this obligation, it has been proven that such an obligation is difficult to enforce in real life circumstances. Hestermeyer,²⁸³ points out that that the obligation seem to put cooperation into the

²⁷⁷ *Ibid* 157 para 1.

²⁷⁸ *Ibid* 157 para 1.

²⁷⁹ *Ibid* 157 para 2.

²⁸⁰ Article 2 (1) of ICESCR.

²⁸¹ Hestermeyer "Access to essential medicines as a human right" http://www.mpil.de/files/pdf2/mpunyb_hestermeyer_8.pdf (accessed 28/04/2014).

²⁸² Günter Brauch "The three worldviews of Hobbes, Grotius and Kant foundations of modern thinking on peace and security contextual change and reconceptualisation of security" http://www.afes-press.de/pdf/Hague/Brauch_Worldviews.pdf (accessed 23/07/2014).

²⁸³ Gostin "The duty of states to assist other states in need: ethics, human rights, and international law" https://www.google.co.za/?gfe_rd=cr&ei=ie5aVo_eJ4ep8weWsluAAw&gws_rd=ssl#q=citation+on+Convention+of+the+Rights+of+the+Child+adopted+20+November+1989 (accessed 23/07/2014).

realm of wishful thinking. Indeed, it is nearly impossible to force states to help each other in the fulfilment of the right to health.

Notwithstanding the above criticisms, the obligation to cooperate demands that States assist each other in working towards the realisation of the right to health.²⁸⁴ This entails provision of health services, products which includes access to essential medicines. States are obliged to work together bilaterally or institutionally to tackle any health related inequalities.²⁸⁵ This duty will lead to a very hard question of determining whether there is a duty imposed on developed countries to provide development aid to poor countries? Developed countries have refused the idea that they have such a duty insisting that aid is granted purely on voluntary grounds.²⁸⁶ Perhaps, the duty to provide aid may only arise in cases where there is an emergence. Such emergence situations would include the outbreak of HIV and AIDS or any other pandemic depending on the mortality rate of the disease.²⁸⁷

2.6.5 The principle of non-discrimination and the right to health.

Pursuant to the General Comment 14, states are prohibited from exercising any discrimination in providing access to essential medicines.²⁸⁸ Discrimination on the grounds of race, colour, sex, language, religion, political or other opinion, national or social origin, property, birth, physical or mental disability, health status, sexual orientation, civil, political, social or other status, which has the intention or effect of nullifying or impairing the equal enjoyment or exercise of the right to health is prohibited.²⁸⁹

The General Comment further states that “the obligation to ensure non-discrimination is closely linked to the principle of equity, which implies that states must pay attention to all sectors of the population.”²⁹⁰ The implication is that the principle of non-discrimination obligates States to ensure there is equality in

²⁸⁴ *Ibid* 527 para 2.

²⁸⁵ *Ibid* 527 para 3.

²⁸⁶ *Ibid* 538 para 4.

²⁸⁷ *Ibid* 538 para 4.

²⁸⁸ Masanque “Comment progressive realisation without the ICESCR: the viability of South Africa's socio-economic rights framework, and its success in the right to access health care” 2013 *California Western International Law Journal* 43 1.

²⁸⁹ *Ibid* 43 1.

²⁹⁰ Chirwa “The right to health in international law: Its implications for the obligations of state and non-state actors in ensuring access to essential medicine” 2003 *South African Journal on Human Rights* 541.

obtaining access to essential medicines. States have a responsibility of creating the conditions which enable marginalised individuals to have access to essential medicines.²⁹¹

2.7 The protection of the right to health in other human rights instruments

There are other International human rights instruments which recognise the right to health. Some of these instruments focus on equal access to essential medicines of a particular group of people. For example, the Convention of the Rights of the Child (CRC)²⁹², ratified by in South Africa, protects the right to health of children. Article 24 of the CRC obligates States to protect the right to health for children, on the basis of non-discrimination.²⁹³ This obligation was spelt out by the Committee on the Rights of the Child (CRC) which stated that states parties must ensure the incorporation of HIV and AIDS and child rights issues in programmes dealing with children victims of abuse.²⁹⁴ Article 24 CRC covers the broader right to health of children, in referring not only to health care facilities, but also to adequate food, drinking water, and prohibition of harmful traditional practices.²⁹⁵

The International Convention on the Elimination of All Forms of Racial Discrimination (ICERD)²⁹⁶ also recognises the right to health. Article 5(e) (iv) of the ICEPD provides in general terms that “States Parties are to prohibit and eliminate racial discrimination in the enjoyment of public health, medical care, social security and social services”²⁹⁷ The Committee on the Elimination of All Forms of Racial Discrimination (CERD) expressed its concerns with regard to the rapid spread of HIV and AIDS among marginalised groups, particularly women.²⁹⁸

²⁹¹ *Ibid* 541 para 1.

²⁹² The Convention on the Rights of the Child was adopted and opened for signature, ratification and accession by General Assembly resolution 44/25 of 20 November 1989 and came into force on 2 September 1990. See United Nations <http://www.ohchr.org/en/professionalinterest/pages/crc.aspx> (accessed 22/02/2014).

²⁹³ United Nations’ Convention on the rights of child, The General Comment 3 c (2003): HIV /AIDS and the right of the children”. http://www.unicef.org/southafrica/SAF_resources_crcgeneralcomments.pdf (accessed 13/01/2015).

²⁹⁴ *Ibid* 3 para 2.

²⁹⁵ Article 24.

²⁹⁶ The International Convention on the Elimination of All Forms of Racial Discrimination (CERD) was adopted and opened for signature and ratification by General Assembly resolution 2106 (XX) of 21 December 1965 and entered into force 4 January 1969. See United Nations Human rights <http://www.ohchr.org/EN/ProfessionalInterest/Pages/CERD.aspx> (accessed 12/01/2015).

²⁹⁷ *Ibid* Article 5 (d) (iv).

²⁹⁸ The Committee on the Elimination of Racial Discrimination (CERD) is the body of independent experts that monitors implementation of the Convention on the Elimination of All Forms of Racial

In addition, Article 12 of the Convention on the Elimination of all forms of Discrimination Against Women (CEDAW)²⁹⁹ primarily focuses on access to health care for women by providing that:

*“States Parties shall take all appropriate measures to eliminate discrimination against women in the field of health care in order to ensure, on a basis of equality of men and women, access to health care services, including those related to family planning”*³⁰⁰

In the same vein, the International Convention on the Rights of Persons with Disabilities (ICRPD)³⁰¹ protects the right to health of disabled persons.³⁰² The ICRPD is based on the principles proclaimed in the UN Charter which recognise the inherent dignity and worth and the equal and inalienable rights of all members of the human family as the foundation of freedom, justice and peace in the world.³⁰³ Article 25 of the ICRPD expresses;

*States Parties recognize that persons with disabilities have the right to the enjoyment of the highest attainable standard of health without discrimination on the basis of disability. States Parties shall take all appropriate measures to ensure access for persons with disabilities to health services that are gender-sensitive, including health-related rehabilitation. In particular, States Parties shall.*³⁰⁴

The ICRPD obliges States parties to take measures, either legislative or policies to ensure that people who are living with disabilities are attended to and their right to

Discrimination by its State parties. <http://www.ohchr.org/EN/ProfessionalInterest/Pages/CERD.aspx> (accessed 12/01/2015).

²⁹⁹On 18 December 1979, the Convention on the Elimination of All Forms of Discrimination against Women was adopted by the United Nations General Assembly. It was entered into force as an international treaty on 3 September 1981 after the twentieth country had ratified it. By the tenth anniversary of the Convention in 1989, almost one hundred nations have agreed to be bound by its provisions <http://www.un.org/womenwatch/daw/cedaw/text/econvention.htm> (accessed 12/01/2015).

³⁰⁰Article 12 (1)

³⁰¹The Convention on the Rights of Persons with Disabilities and its Optional Protocol was adopted on 13 December 2006 at the United Nations Headquarters in New York, and was opened for signature on 30 March 2007. There were 82 signatories to the Convention, 44 signatories to the Optional Protocol, and 1 ratification of the Convention. The Convention entered into force on 3 May 2008. The main purpose of the Convention is to protect the fundamental human rights of people living with disabilities. <http://www.un.org/disabilities/default.asp?id=150> (accessed 16/01/2015).

³⁰²Article 25.

³⁰³Preamble, UN Charter <https://treaties.un.org/doc/publication/ctc/uncharter.pdf>(accessed 17/01/2015).

³⁰⁴*Ibid* Article 25.

health is realised.³⁰⁵ Therefore, the ICRPD protect the right to health for people living with disability.³⁰⁶ It can be suggested that the ICRPD protects the right to have access to essential medicines as an important part of the right to health. Further, the Convention on the Protection of the Rights of All Migrant Workers and Members of their Families puts emphasis on equal access to medical care for migrant workers and members of their families (ICMW).³⁰⁷ In addition, the Conventions of the International Labour Organisation (ILO)³⁰⁸ contain numerous references to a specific area of health, namely occupational health.³⁰⁹ Article 25 of the ILO Convention explicitly recognises a right to health of indigenous and tribal peoples.³¹⁰

Finally, worth mentioning are Rules 22 to 26 of the Standard Minimum Rules for the Treatment of Prisoners, that establish a number of principles for the treatment of sick prisoners.³¹¹ These rules require States to provide access to medical services and other related medical suppliers for prisoners at the State's expense.³¹² It must be understood that prisoners have no alternative but to rely on the authorities to protect and promote their health.³¹³ To safeguard the right to health of prisoners, international law subordinates to the state a legally enforceable duty of care.³¹⁴ A state can be held liable for failure to prevent all forms of avoidable health impairment or damage to the well-being of its prisoners.³¹⁵ If the health of any prisoner is harmed, a government trying to escape from its legal accountability must prove that

³⁰⁵ *Ibid* Article 25.

³⁰⁶ Article 25 (a) provides require States to provide persons with disabilities with the same range, quality and standard of free or affordable health care and programs as provided to other persons, including in the area of sexual and reproductive health and population-based public health programs.

³⁰⁷ Article 43 (e).

³⁰⁸ International Labour Organisation "Health and life at work: a basic human right" http://www.ilo.org/public/portugue/region/eurpro/lisbon/pdf/28abril_09_en.pdf (accessed 18/01/2015).

³⁰⁹ *Ibid* 10 para 1.

³¹⁰ *Article 25.*

³¹¹ The Standard Minimum Rules for the Treatment of Prisoners, which were adopted by the First United Nations Congress on the Prevention of Crime and the Treatment of Offenders in 1955 and approved by the Economic and Social Council by its resolutions 663 C (XXIV) of 31 July 1957 and 2076 (LXII) of 13 May 1977, are broadly considered to be the universally acknowledged minimum standards for the treatment of prisoners. See United Nations Office of Drugs and Crime, Standard Minimum Rules for the Treatment of Prisoners <http://www.unodc.org/unodc/en/justice-and-prison-reform/expert-group-meetings-8.html> (accessed 16/01/2015).

³¹² Exworthy, "Asserting prisoners' right to health: progressing beyond equivalence" *Psychiatric Service* 63 271.

³¹³ *Ibid* 64 para 3.

³¹⁴ *Ibid* 64 para 4.

³¹⁵ WTO "Good governance for prison health in the 21st century" https://www.unodc.org/documents/hiv-aids/publications/Prisons_and_other_closed_settings/Good-governance-for-prison-health-in-the-21stcentury.pdf (accessed 17/01/2015).

state bodies did not cause the harm directly and (cumulatively) that it has taken all reasonable measures of safeguarding and prevention.³¹⁶

2.8 The right to health under the African human rights system

2.8.1 The right to health in the African Charter

At the African regional level, the right to health is guaranteed in the African Charter on Human and Peoples' Rights (African Charter).³¹⁷ The African Charter came into force in October 1986. It contains provisions which are significant for the protection of the right to health. Article 16 states that:

- (1) Every individual shall have the right to enjoy the best attainable state of physical and mental health;*
- (2) 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.*³¹⁸

The African Commission on Human and Peoples' Rights (African Commission) in *Purohit and Moore v The Gambia*³¹⁹ has explained that the provision of Article 16 of the African Charter imposes obligations on states to ensure that access to health-related goods and services (including access to essential medicines) is guaranteed to all without discrimination.³²⁰ The African Commission has also noted that realising access to life-saving medications is a human rights issue and thus urges states to take necessary steps to facilitate access to life-saving medications for their citizens.³²¹

2.8.2 Protocol to the African Charter on the Rights of Women in Africa

Article 14 of the Protocol to the African Charter on the Rights of Women in Africa contains detailed provisions recognising the right to health.³²² Under Article 14 states

³¹⁶*Ibid* 19 para 12.

³¹⁷The African Commission was established in 1997, under the African Charter and is now headquartered in Banjul, Gambia. The commission provides oversight and interpretation of the African Charter. See African Commission on human and People's rights <http://www.achpr.org/instruments/achpr/> (accessed 19/01/2015).

³¹⁸Article 16.

³¹⁹(2003) AHRLR 96.

³²⁰*Ibid* 7 para 76.

³²¹*Ibid* 7 para 76.

³²²The Protocol to the ACHPR on the Rights of Women in Africa was adopted in Maputo 2003. The Protocol was entered into on 25 November 2005. See

are required to “ensure that the right to health of women, including sexual and reproductive health of women, is respected and promoted.”³²³ The Protocol is the first human rights treaty that clearly recognises women’s reproductive health as a human right and contains specific provisions on women’s protection in the context of HIV and AIDS.³²⁴

2.8.3 The right to health in the African Charter on the Rights and Welfare of the Child

The African Charter on the Rights and Welfare of the Child (ACRWC)³²⁵ is the first regional and comprehensive binding instrument proclaiming the human rights of children.³²⁶ The ACRWC is regarded as an important instrument under the African human rights system which protects the right to health for children.³²⁷ Article 14 of the ACRWC declares that;

- 1. Every child shall have the right to enjoy the best attainable state of physical, mental and spiritual health.*
- 2. States Parties to the present Charter shall undertake to pursue the full implementation of this right and in particular shall take measures:*
 - (a) to reduce infant and child mortality rate;*
 - (b) to ensure the provision of necessary medical assistance and health care to all children with emphasis on the development of primary health care*³²⁸

It is also crucial to note that the indivisibility and interdependence of human rights implies that the right to health overlaps with other human rights such as right to life, food, shelter, housing and environment among others.³²⁹ The impact of such

Protocol to the African Charter on Human and Peoples' Rights on the Rights of Women in Africa http://www.achpr.org/files/instruments/women-protocol/achpr_instr_proto_women_eng.pdf (accessed on 20/02/2015).

³²³ Article 14.

³²⁴ Durojaye, “Realising equality in access to HIV treatment for vulnerable and marginalised groups in Africa” 202 *PER* 15 216.

³²⁵ Bueren: *The International Law on the rights of the child* (1998).

³²⁶ Pan-African Voices for Freedom and Justice “Regional protection of child rights in Africa” <http://www.pambazuka.org/en/category/comment/44416>

³²⁷ World Council of Churches “Access to medicines: Key to MDGs on child health” <http://apps.who.int/medicinedocs/documents/s21409en/s21409en.pdf> (accessed 21/02/2015).

³²⁸ Article 14.

³²⁹ The two concepts, indivisibility and interdependence, are characterised by two salient features. The first characteristic is that the realisation of the right to health hinges on enjoyment of all other human

interdependence is that the human rights instruments discussed earlier address the right to health in a direct fashion, while the right to health can be extracted indirectly from a host of other human rights instruments whose provisions impact on the right to health.³³⁰ A good example is the expansive interpretation of the right to life found in Article 6 of the ICCPR, adopted by the Human Rights Committee to include a duty to take positive action to reduce infant mortality, increase life expectancy and eliminate diseases.³³¹ The Human Rights Committee has also interpreted Article 7 of the ICCPR which contains the right to be free from inhuman and degrading treatment generously as bestowing a corresponding duty upon States to provide reasonable access to abortion services for women.³³²

2.9 Access to essential medicines as a component of the right to health

2.9.1 CESCR General Comment 14

Article 12(1) of the ICESCR, as discussed earlier on, provides for the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.³³³ The CESCR, in its General Comment 14, maintains that access to essential medicines is a fundamental component of the right to health.³³⁴ The CESCR stated that the right to health in Article 12.2 (d) of the ICESCR includes the provision of essential medicines “as defined by the WHO Action Programme on Essential Drugs”.³³⁵ According to WHO definition, essential medicines are: “those that satisfy the priority health care needs of the population. Essential medicines are selected with due regard to disease prevalence, evidence on efficacy and safety, and comparative cost-effectiveness.”³³⁶ The General Comments of CESCR are not

rights. The second one is that it depends also on the realisation of other human rights. See Centre for Health and Human Rights and Open Society Foundations “*Palliative Care and Human rights* (2013) 5.3.

³³⁰ *Ibid* 513 para 1.

³³¹ This Human Rights Committee is the principal organ established by UN and mandated with the responsibility of monitoring States compliance with the legal obligations imposed by the ICCPR. See UN “Monitoring Civil and Political Rights” <http://www.ohchr.org/EN/HRBodies/CCPR/Pages/CCPRIndex.aspx> (accessed on 23/02/2015).

³³² Hammel “Is the right to health a necessary precondition for gender equality?” 2011 *N. Y. U. Review of Law and Social Change* 35 136.

³³³ UN Committee on Economic, Social and Cultural Rights, “General Comment No. 14, 14” <http://www.ohchr.org/Documents/Issues/Women/WRGS/Health/GC14.pdf> (accessed 23/02/2015).

³³⁴ *Ibid* para 17.

³³⁵ *Ibid* para 17.

³³⁶ World Health Organisation “Access to essential medicines” [http://www.who.int/healthinfo/systems/WHO MBHSS 2010 section4](http://www.who.int/healthinfo/systems/WHO_MBHSS_2010_section4) (accessed 26/02/2015).

legally binding per se, however, they are authoritative and occupy a prominent place in elaborating the right to health.³³⁷

On the same note, in 1978 the Alma-Ata Declaration on Health for All which provides a far-reaching framework for health services declared that “the provision of essential medicines is vital for attaining highest possible level of health.”³³⁸ The CESCR, in General Comment 3, confirmed that States parties have a core obligation to ensure the satisfaction of minimum essential levels of each of the rights outlined in the ICESCR, including essential primary care as described in the Alma-Ata Declaration.³³⁹ Further, the WHO is making serious efforts to renew Primary Health Care (PHC) by promoting four components of PHC reform which are needed to refocus health systems towards health for all.³⁴⁰ The first component is universal access to health care which, as a matter of course, includes universal access to essential medicines.³⁴¹ Therefore, the ESCR General Comments together with the Alma-Ata Declaration on Health unequivocally posit that access to essential medicines is an indispensable facet of the right to health.

2.9.2 CRC General Comment Number 15

In the same vein, the CRC has taken the same interpretative stance of deriving access to essential medicines from the right to health.³⁴² The CRC stated that the obligation in Article 24 of the CRC to ensure that children have access to the highest attainable standard of health meant that States have a duty to ensure access to essential medicines.³⁴³ The CRC, in its General Comment Number 15, submitted that Children’s right to health contains two major things.³⁴⁴ Firstly, a set of freedoms that includes the right to control one’s health and body, including sexual and reproductive

³³⁷Schluetter “Aspects of human rights interpretation by the UN treaty bodies, in Keller and Ulfstein (eds), *UN Human Rights Treaty Bodies: Law and Legitimacy* 2012 292.

³³⁸Bansail and Purohit “Accessibility and use of essential medicines in health care: Current progress and challenges in India” 2013 *Journal of Pharmacology and Pharmacotherapeutics* 24 2

³³⁹ESCR General Comment No. 3: The nature of states parties’ obligations (Art. 2, Para. 1, of the Covenant) Adopted at the Fifth Session of the Committee on Economic, Social and Cultural Rights, on 14 December 1990 (Contained in Document E/1991/23) <http://www.refworld.org/pdfid/4538838e10.pdf> (accessed 27/02/2015).

³⁴⁰Sambala *et al* “The role of Primary Health Care in Ensuring Access to Medicines” 2010 *Croat Medical Journal* 51 184.

³⁴¹*Ibid* 184 para 1.

³⁴²The CRC pronounced the General Comment Number 15 in 2013. See General comment No. 15 (2013) on the right of the child to the enjoyment of the highest attainable standard of health” https://www.crin.org/docs/CRC-C-GC-15_en-1.pdf (accessed 27/04/2014).

³⁴³*Ibid* 8 para 27.

³⁴⁴*Ibid* 8 para 28.

freedom to make responsible choices. Secondly, a set of entitlements which include access to a range of facilities, goods, services and conditions that provide equality of opportunity for every child to enjoy the highest attainable standard of health.³⁴⁵ Indeed, under CRC, access to essential medicines is envisaged as important for the enjoyment of the right to health for children.

2.9.3 African Commission resolution and access to essential medicines

The African Commission has adopted a resolution which indicates that access to essential medicines is a part of the right to health.³⁴⁶ The resolution states that “access to needed medicines is a fundamental component of the human rights to health and that States Parties to the African Charter have an obligation to provide appropriate needed medicines, or facilitate access to them.”³⁴⁷ This Resolution on Access to Health and Needed Medicines in Africa adopted by the African Union, goes even further to state that the right to health in Article 16 of the AC includes the provision of essential drugs as defined by the WHO Action Programme on Essential Drugs.³⁴⁸ The resolution also requires States Parties to progressively realise the right to health and access to essential medicines which should be equally available to all citizens without discrimination.³⁴⁹

2.9.4 Reports from UN Special Rapporteur on the Right to Health

Further, in April 2002, the United Nations Human Rights Council established the mandate of the first Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.³⁵⁰ Special Rapporteurs

³⁴⁵ *Ibid* 8 para 29.

³⁴⁶ ACHPR/Res.141 (XXXVIII) 08: Resolution on Access to Health and needed Medicines in Africa. http://www.chr.up.ac.za/images/files/research/ahrru/news/ahrru_news_15_resolution_access_health_needed_medicines_africa.pdf (accessed 09/01/2014). See also African Union Pharmaceutical Manufacturing Plan for Africa (2012) http://www.au.int/en/sites/default/files/newsevents/workingdocuments/14462-wd-mpma_business_plan_2.pdf (accessed 26/04/2014)). See SADC Draft Strategy for Pooled Procurement of Essential Medicines and Health Commodities 2013 http://www.sadc.int/files/6614/1890/8516/sadc_sadc_pooled_procurement_of_essential_medicines_and_medical_suppli....pdf (accessed 28/02/2015). See SADC Pharmaceutical Business Plan 2007 – 2013, published by the SADC Secretariat on 27 June 2007. See SADC Protocol on Health (1999) <http://www.sadcstan.co.za/Secure/downloads/protocol.pdf> (accessed 29/02/2015).

³⁴⁷ Niada “The human right to medicines in relation to patents in Sub-Saharan Africa: some critical remarks” 2011 *The International Journal of human rights* 15 715.

³⁴⁸ *Ibid* para 716 para 1.

³⁴⁹ *Ibid* para 716 para 2.

³⁵⁰ United Nations, General Assembly “Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health” http://www.who.int/medicines/areas/human_rights/A63_263.pdf (accessed 25/06/2014)

are independent experts appointed by the UN to examine and report back on a country situation or a specific human rights issue.³⁵¹ In close collaboration with WHO the Special Rapporteur prepared several reports on access to essential medicines and the role of the pharmaceutical industry.³⁵² These reports have promoted international recognition of access to essential medicines as an aspect of the right to health.³⁵³

2.10 Summary

This chapter has demonstrated that the right to health originate from human society's quest to eradicate diseases.³⁵⁴ In other words, the deepest part of the origins of the right to health derives from basic instinct of the species and manifestation of empathy.³⁵⁵ The preceding discussion has revealed that the right to health is enshrined in international human rights treaties such as the ICESCR, CEDAW, CRC and regional human rights instruments such as the AC. These international human rights instruments impose the duties to respect, protect and fulfil the right to health. It has been shown that the content of the right to health is discernible. Access to essential medicines is part of the content of the right to health. Therefore, lack of access to essential medicines limits the enjoyment of the right to health. The right to health is one among a range of socio-economic rights for which South Africa accept an obligation at international law.

South Africa, as a State Party to both the ICESCR and the African Charter and other international human rights instruments is enjoined to provide access to essential medicines at the domestic level. South Africa is required to progressively implement the right to health and through international cooperation to the extent of its available resources. Therefore, with such a strong global recognition of access to essential medicines as a key component of the right to health, it becomes pertinent to assess how this recognition translates into action at the country level in South Africa.

³⁵¹ *Ibid* 1 para 1.

³⁵² Hogerzeil, "The World Medicines situation access to essential medicines as part of the right to health" <http://apps.who.int/medicinedocs/documents/s18772en/s18772en.pdf> (accessed 27/06/2015).

³⁵³ *Ibid* 4 para 3.

³⁵⁴ Marks "The emergence and scope of the right to health" <http://www.oxfordscholarship.com/view/10.1093/acprof:oso/9780199661619.001.0001/acprof-9780199661619-chapter-01> (accessed 26/06/2014).

³⁵⁵ *Ibid* 1093 para 2.

Therefore, the next chapter will attempt to show how the right to health has been incorporated in the national constitution and laws of South Africa?

CHAPTER THREE

The protection of the right to health in South Africa: unpacking the obligations to provide access to essential medicines

3.1 Introduction

The protection of the right to health in South Africa can only be understood within the historical prism of apartheid, colonialism, deprivation and discrimination.³⁵⁶ The apartheid regime infringed a full gamut of human rights, including the right to health recognised in the International human rights instruments.³⁵⁷ Health provision was skewed in terms of race, gender, socio-economic status, sexual orientation, disability and a number of other arbitrary grounds.³⁵⁸ This means that the right to health was selectively enjoyed along racial demarcations.³⁵⁹ Whites controlled all the health institutions and enjoyed wide-ranging access to health. While relative access to health rights was conferred on the Coloured and Indian racial groups, the bulky of the general population was the most deprived.³⁶⁰ Although, there have been significant accomplishments in protecting the right to health in South Africa so far, the reality of a dual health care system has persisted with a significant private-for-profit sector existing alongside the public health sector.³⁶¹

The dualism described above has compromised the protection of the right to health. The public health care sector being financed by the government is plagued by poor governance which negatively impedes the full enjoyment of the right to health.³⁶² Although, access to health care services from the private sector has been far much

³⁵⁶The struggle against apartheid was a struggle for access to essential health care too. The Freedom Charter (1955), adopted by African National Congress (ANC) and other liberation movements prioritised the enjoyment of the right to health by all and sundry. The Freedom Charter, like a South Africa Magna Carter, became the centre piece of the Bill of Rights for the post-Apartheid South Africa. See Mbazira: *Litigating socio-economic rights in South Africa: a choice between corrective and distributive justice* (2009) 2.

³⁵⁷Coovadia *et al* "The health and health system of South Africa: historical roots of current public health challenges" <http://depts.washington.edu/sphnet/wp-content/uploads/2013/01/Coovadia.pdf> (accessed on 15/05/2015).

³⁵⁸Liebenberg "human development and human rights South African country study" http://hdr.undp.org/sites/default/files/sandra_liebenberg.pdf (accessed 15/06/2015).

³⁵⁹Pieters: *Can rights cure: the impact of the human rights litigation on South African health system* (2014) 5.

³⁶⁰Bannister "Equal access to health care services for survivors of gender-based violence: a South African perspective" 2014 *The Equal Rights Review* 12 64.

³⁶¹Kale "South Africa's Health: Impressions of health in the new South Africa: a period of convalescence". <http://www.bmj.com/content/310/6987/1119>(accessed 15/05/2015).

³⁶²Seedat: *Crippling a nation: Health in apartheid South Africa* (1984) 64.

better, a greater constituency of the poor population is excluded from quality health care services offered by the private sector health.³⁶³ In *Soobramoney v Minister of Health, KwaZulu-Natal*,³⁶⁴ a case which revolve around the right to health Chaskalson, the former Chief Justice of South Africa (CJ), captured so well the pre- and post -democratic South African social milieu by declaring that:

*We live in a society in which there are great disparities in wealth. Millions of people are living in deplorable conditions and in great poverty. There is a high level of unemployment, inadequate social security, and many do not have access to clean water or to adequate health services. These conditions already existed when the Constitution was adopted...*³⁶⁵

In 1996, in an attempt to address this legacy of apartheid, South Africa adopted one of the most progressive human rights oriented constitutions in the world.³⁶⁶ The South African Constitution has been described as belonging to the category of transformative constitutionalism which seeks to create a new legal and political system which breaks away from the legacy of officially sanctioned racism.³⁶⁷ The architects of the Constitution plainly pictured a far-reaching role for it in the transformation of post-apartheid society. Among the key aims of the Constitution is to “improve the quality of life of all citizens and free the potential of each person”.³⁶⁸ This constitutional concern with the socio-economic well-being of the people is especially evident in the entrenchment of the right to health.³⁶⁹

³⁶³South African Human Rights Commission “Public enquiry: access to health care services” <http://www.sahrc.org.za/home/21/files/Health%20Report.pdf> (accessed on 14/05/2015).

³⁶⁴1998 (1) SA 765 (CC) para 8.

³⁶⁵*Ibid* para 2.

³⁶⁶For many decades prominent liberal scholars, either largely drawn from political science or law disciplines have been decrying on the State of Apartheid regime. However, with adoption of a new Constitution and the successful dismantlement of Apartheid laws, this euphoria has dissipated. They saw the adoption of the new constitution as a precursor of socio-economic and political transformation of South African Society. See Christiansen “Transformative constitutionalism in South Africa: creative uses of constitutional court authority to advance substantive justice” 2014 *The Journal of Gender, Race and Justice* 13 576.

³⁶⁷Young and Lemaitre “The comparative fortunes of the right to health: two tales of justiciability in Colombia and South Africa” <http://harvardhrj.com/wp-content/uploads/2013/05/V26-Young-Lemaitre.pdf> (accessed 16/05/2015).

³⁶⁸The Constitution of South Africa, 1996.

³⁶⁹Liebenberg “South Africa’s evolving jurisprudence on socio-economic rights: an effective tool.in challenging poverty?” <http://www.google.co.za/url?sa=t&rct=j&q=&esrc=s&source=web&cd=2&ved=0cceqfjab&url=http%3a%2f%2fcommunitylawcentre.org.za%2fprojects%2fsocioeconomicrights%2fresearch%2520and%2520publications%2fresearch%2fsocioeconomic%2520rights%2520and%2520transformation%2520in%5>

The South African Constitution recognises the need to expand access to essential medicines by entrenching the right to have access to health care services.³⁷⁰ The right to have access to health care services guarantees reproductive health care services as well.³⁷¹ This entrenchment of the right to have access to health care services, on its own, is a profound step towards achieving access to essential medicines.³⁷² This is so because the right to have access to health care services embody a transformative legal power which can be utilised by the marginalised groups to demand access to social goods such as essential medicines.³⁷³

This chapter looks at the domestic protection of the right to health as provided for under the South African Constitution, which is further elaborated in relevant legislation and other policy documents. The protection of the right to health is crucial when framing the obligations to provide access to essential medicines domestically. In fact, from a legal stand point, solving the problem of access to essential medicines in South Africa would require the protection of the right to health domestically. Therefore, this chapter provides the necessary legal discourse on the protection of the right to health in South Africa. The major objective of this chapter is to demonstrate that access to essential medicines is protected domestically as a human right under the auspices of the right to health.

3.2 The protection of the right to health under the 1996 constitution

In South Africa, section 27 of the Constitution protects the right to health as a part of social-economic rights. Section 27 provides that:

(1) *Everyone has the right to have access to –*

(a) *Health care services, including reproductive health care;*

(b) *Sufficient food and water; and*

[20sa%2f2002%2fsouth%2520africas%2520evolving%2520jurisprudence%2520on%2520socioeoi2g
hts%2520%2520an%2520effective%2520tool%2520in%2520challenging%2520povert.pdf%2fdownloa
d&ei=chr1vfstfuyz7gsw4dobq&usq=afqjcner0kbcdbi2ra5t2kf8ozwzcpxxg&bvm=bv.95039771,d.zgu](#)
(accessed 17/05/2015).

³⁷⁰ *Ibid* 8 para 1.

³⁷¹ Section 27 of the Constitution, 1996.

³⁷² Dugard "International law and the South African constitution" 1997 *European Journal of International Law* 8 78.

³⁷³ Forman "Right and wrongs: what utility for the right to health in reforming trade rules on medicines" 2013 *Health and Human Rights Journal* 10 38.

(c) Social security, including, if they are unable to support themselves and their dependents, appropriate social assistance.

(2) The states must take reasonable legislative and other measures, within its available resources, to achieve the progressive realisation of each of these rights.

*(3) No one may be refused emergency medical treatment.*³⁷⁴

Similarly, there are other extra provisions providing guarantees for the right to health for children and for inmates, and the right to an environment that is not harmful to health.³⁷⁵ These provisions place an obligation on the South African government to provide access to essential medicines. In *N and Others v Government of Republic of South Africa and Others*³⁷⁶ the Constitutional Court stated that:

*The first of these obligations is set out in section 27 of the Constitution, the relevant portions of which read as follows: (1) Everyone has the right to have access to -(a)health care services, including reproductive health care...*³⁷⁷

Further, section 27(3) embodies the right to emergency medical treatment, which places an obligation on the South African state to ensure access to essential medicines. It places a positive obligation on South African state to ensure there is access to essential medicines in an emergency situation. In *Soobramoney v Ministry of Health*³⁷⁸ the Constitutional Court elucidated on what constitutes an emergency medical treatment under section 27(3) of the Constitution. Mr Soobramoney was suffering from renal failure which required on-going dialysis treatment in order to keep him alive. He claimed that because the treatment was life-saving, it should be

³⁷⁴Section 27 (1) (2) (3).

³⁷⁵Section 28(1)(c), 35(2)(e), 24(a).

³⁷⁶2006 (6) SA 543.

³⁷⁷*Ibid* para 1. The case pertains to HIV positive prisoners who had been denied access to essential medicines in particular ARV medicines by the state whilst in custody. The prisoners sought a court order to force the state to remove the restrictions that prevented them from having access these essential medicines. The prisoners claimed that they were eligible to have access to essential medicines in terms of the National Department of Health's Operational Plan for comprehensive HIV and AIDS care, Management and Treatment for South Africa (Operational Plan). The court struck down the restrictions which prevented access to essential medicines on the basis that they were unreasonable and inflexible. They are also many cases which relates to the inmates right to health emphasising on the need to expand access to essential medicines to the vulnerable groups. For instance, in *Van Bilijon v Minister of Correctional Services* 1997 (4) SA 411 (CC) and *S v Vanqa* 2000 (2) SACR 371 (Tk).

³⁷⁸1998 (1) SA 765 (CC).

considered emergency medical treatment which cannot be refused.³⁷⁹ However, the Constitutional Court ruled that:

*Soobramoney's case was not an "emergency" in the sense of a sudden catastrophe, but rather an "ongoing state of affairs". Instead, the case falls under sections 27(1) and (2) of the Constitution which deal with the allocation of non-emergency medical treatment. Obligations imposed on the state regarding access to health care are dependent upon the resources available, as stated in sections 27(1) and (2).*³⁸⁰

What is apparent from the above ruling is that a broader construction of the meaning of section 27(1) is unpalatable.³⁸¹ An attempt to interpret the phrase emergency medical treatment to include an ongoing treatment of chronic illnesses for the purpose of prolonging life would open a flood gate of cases and put a strain on the state resources.³⁸² It can be suggested that such a broad interpretation is inimical to the ordinary meaning of the phrase envisaged by this provision and if this had been the purpose which section 27(3) was intended to serve, one would have expected that to have been expressed in positive and specific terms.³⁸³ A further deduction can be made that the obligation to provide emergency treatment should be fulfilled immediately.³⁸⁴

3.2.1 The egalitarianism of section 27

Section 27(1) explicitly recognises the equality element of having access to essential medicines by declaring that "everyone" has a right to have access to health care services.³⁸⁵ This means that section 27 presupposes that all persons must be treated equally without any unfair discrimination.³⁸⁶ In *Khosa v Minister of Social Development*,³⁸⁷ the Constitutional Court stated that social-economic rights provided

³⁷⁹ *Ibid* para 1.

³⁸⁰ *Ibid* para 14.

³⁸¹ Albertus "The right to health in respect of terminally ill persons in South Africa" <http://www.speculumjuris.co.za/files/pdf/SJ01814FPAlbertus.pdf> (accessed 23/07/2014).

³⁸² Foley *et al* "The public health strategy for palliative care" 2007 *Journal of Pain and Symptom Management* 33 487.

³⁸³ Albertus "Palliative care for terminally ill inmates: does the state have a legal obligation" 2012 *SACJ* 1 78.

³⁸⁴ *Ibid* 78 para 2.

³⁸⁵ Liebenberg: *Socio-economic rights-adjudicating under a transformative constitution*, (2010) 20.

³⁸⁶ *Ibid* 17 para 1.

³⁸⁷ 2004 (6) SA 505 (CC).

should be understood against the background of section 9. In other words, there is a relationship between the right to equality and the right to health. In *Khosa*, the Constitutional Court revealed that section 4 of the Social Security Act (SSA)³⁸⁸ which conferred citizens only the right to receive social security grants and excluding permanent residents infringe the right not to be subjected to unfair discrimination provided for under section 27(1). By way of inference, *Khosa* indicates that access to essential medicines, by the virtue of being a part of social-economic rights encapsulates the equality component.³⁸⁹

In the same light, the equality component of access to essential medicines can also derived from section 1 and section 9 of the Constitution. Section 1 provides a clear obligation for the South African government to ensure that the right to health is equally enjoyed by all. By proclaiming that;

The Republic of South Africa is one, sovereign, democratic state founded on the following values:

*(1) Human dignity, the achievement of equality and the advancement of human rights and freedom.....*³⁹⁰

The Constitution identifies equality as one of the founding provision and value underpinning South Africa's democracy.³⁹¹ Further, the Constitution guarantees "equal protection" and "benefit of the law" in terms of section 1. The guarantee of equal protection and benefit of the law means that the Constitution envisages equal access to essential medicines.³⁹² Equal access to essential medicines, as enshrined in section 9(1) resonate so well with the requirements in international treaties which deal with equality.³⁹³

While the architects of the Constitution did not make clear or state the meaning of the phrases "equality before the law " and "equal protection of the law" the presence

³⁸⁸ *Ibid* para 87.

³⁸⁹ *Ibid* para 89.

³⁹⁰ Section 1(1).

³⁹¹ Section 9(1).

³⁹² Liebenberg and Goldblatt "The interrelationship between equality and socio-economic rights under South Africa's transformative constitution" 2007 *SAJHR* 23 335.

³⁹³ Article 7 of the UDHR provides for the guarantee of equal protection and benefit of the law as well.

of a distinct provision reveals that the rights are separate and different.³⁹⁴ There are two deductions which can be drawn from the import of the terms. According to Manfred Nowak,³⁹⁵ “equality before the law” basically means that the law must be applied in a similar way to all. In his observation, this provision contains no assurance of substantive equality but is rather aimed exclusively at implementation.³⁹⁶ On the other hand, equal protection of the law, is directed at the national legislature and imposes both negative and positive obligations.³⁹⁷

There is no agreement on the exact meaning of equality to this day. Equality remains a nebulous concept. Broadly speaking, equality as a constitutional value which informs the interpretation of the right to health exists in two major forms.³⁹⁸ The first form is “substantive equality” as contrasted to “formal equality”.³⁹⁹ Substantive equality obligates the State to treat people differently due to their different needs. This form of equality elucidates that the disadvantage that attaches to different marginalised groups emanates from their distinctive history.⁴⁰⁰ Thus, substantive equality is underpinned by the notion of social justice which endeavours to protect the marginalised groups from living a deprived life.⁴⁰¹ The idea of formal equality encapsulate that all people who are in a similar state should be given the same treatment and that people should not be treated differently because of capricious features such as religion, race or gender.⁴⁰²

³⁹⁴According to Nowak the bipartite phrases, “equality before the law” originated from the French Revolution, and equal protection of the law from the Fourteenth Amendment to the US Constitution. See Naughton “Healthcare systems and equality rights”. http://www.equalrightstrust.org/ertdocumentbank/ERR06_special_Gillian.pdf (accessed 18/05/2015).

³⁹⁵Naughton “Untangling equality and non-discrimination to promote the right to health care for all” <http://www.hhrjournal.org/wp-content/uploads/sites/13/2013/07/5-MacNaughton.pdf>(accessed 19/05/2015).

³⁹⁶*Ibid* 49 para 6.

³⁹⁷*Ibid* 49 para 6.

³⁹⁸Yamin and Norheim “Taking equality seriously: applying human rights framework to priority setting in health” 2014 *Human Rights Quarterly* 297 <http://fxb.harvard.edu/wp-content/uploads/sites/5/2014/06/Yamin-Norheim-Taking-Equality-Seriously.pdf> (accessed 20/05/2015).

³⁹⁹Gutto: *Equality and non-discrimination in South Africa: the political economy of law and law making* (2001) 4.

⁴⁰⁰*Ibid* 12 para 3.

⁴⁰¹*Ibid* 12 para 3.

⁴⁰²Smith “Equality constitutional adjudication in South Africa” 2014 *African Human Rights Law Journal* 14 609.

Similarly, substantive and formal equality are lenses that can be used to interpret equal protection and benefit of the law under section 9(1) of the Constitution.⁴⁰³ These two forms of equality can be utilised as tool to flesh out section 9(1) of the Constitution, for example to demand the inclusion of applicants in programmes conferring health related benefits from which they have been arbitrarily excluded, or to attain access to essential medicines there are arbitrarily or irrationally being denied.⁴⁰⁴ Similarly, where denial, exclusion or inequitable provision of health-related benefit results from unfair discrimination on one or more of the grounds listed in section 9(3) of the Constitution, such denial exclusion or inequitable provision will be unconstitutional unless it is found to be justifiable under the Constitution's general limitation.⁴⁰⁵

In the same light, the right to equality in sections 1 and 9 1(a) is reinforced by section 39(1) (a) which obligates the courts in the interpretation of the Bill of Rights to promote the values that underlie an open and democratic society based on human dignity, equality and freedom.⁴⁰⁶ Indeed, this means that the courts must take into account the legal commitment to prohibit discrimination in all its manifestations including in the context of access to essential medicines. According to Pieterse,⁴⁰⁷ the transformative aspects of the right to equality implicitly recognised under section 27(1) is that it prohibits any unfair distinctions between groups of persons and outlaws unfair exclusion of persons or groups from being entitled to health services and associated benefits, as well as disallowing the inequitable provision of health care services.⁴⁰⁸

3.2.2 The scope and meaning of the right to health under section 27

Indeed, under section 27(1) South African is obligated to provide certain types of health care services. However, this section is mum about the exact nature of health care services it entails, except for specifying that such services embrace

⁴⁰³ *Ibid* 609 para 4.

⁴⁰⁴ *Ibid* 609 para 4.

⁴⁰⁵ Section 9(1).

⁴⁰⁶ Section 39(1) (a).

⁴⁰⁷ Pieter's, *Can rights cure: the impact of the human rights litigation on South African health system*, (2014) 125.

⁴⁰⁸ *Ibid* 125 para 1.

reproductive health care.⁴⁰⁹ Liebenberg⁴¹⁰ observes that the health care services contemplated under this section are all services, goods and facilities aimed at securing the greatest attainable standard of physical and mental well-being.⁴¹¹ In addition, Pieters⁴¹² provides that section 27(1)(a) may thus be understood as requiring the availability, accessibility, and acceptability of preventative, diagnostic and curative health care services of adequate quality on primary, secondary and tertiary levels. This means that section 27(1)(a) could be invoked in claims for access to essential medicine as a part of the right to health as previously discussed.⁴¹³

3.2.3 Positive and Negative Duties under section 27 (1)

Section 7(2) of the Constitution describes the state's positive and negative duties. This section requires the state to "respect, protect, promote and fulfil the rights in the Bill of Rights."⁴¹⁴ According to Liebenberg,⁴¹⁵ the positive duties imposed by the right to health means that the South African government must protect the right to health by developing and implementing a comprehensive legal framework which prohibits non-state actors from infringing the right to health.⁴¹⁶ The negative duty imposed by the right to health means the government must not unfairly or unreasonably get in the way of people accessing essential medicines as a part of the health care provision, either in the public or private health care sectors. This also entails that the government must not enact a law or policy which indirectly or directly limits the enjoyment of the right to health without justification.⁴¹⁷

In light of above background, the duty to promote or fulfil encapsulates a transformative agenda which require the South African government to provide

⁴⁰⁹Benatar "The challenges of health disparities in South Africa" 2013 *South African Medical Journal* 103 154.

⁴¹⁰Liebenberg "South Africa's evolving jurisprudence on socio-economic rights: An effective tool in challenging poverty" <http://www.saflii.org/za/journals/LDD/2002/2.pdf> (accessed 17/05/2015).

⁴¹¹*Ibid* 125 para 2.

⁴¹²*Ibid* 126 para 1.

⁴¹³*Ibid* 126 para 2.

⁴¹⁴Section 7 (2).

⁴¹⁵Supra 47 para 4.

⁴¹⁶Section 28.

⁴¹⁷Nolan, "The justiciability of social and economic rights: an updated appraisal" http://www.right-to-education.org/sites/righttoeducation.org/files/resourceattachments/Nolan_Porter_Langford_The_Justiciability_of_Social_and_Economic_Rights_2007_en.pdf (accessed 17/06/2015).

access to essential medicines in terms of Section 27 of the Constitution. As Baret⁴¹⁸ put it:

*Positive duties encompass a gamut of measures that States must take in order to end systematic inequalities in health care services. Such measures must be aimed at reconfiguring the society's distribution of health resources.*⁴¹⁹

Following this logic, it can be noted that section 27 (2) defines the parameters of positive duties by stating that the measures to be taken in promoting or fulfilling the right to health must be reasonable and are subject to the criteria of progressive realisation and budgetary constraints. On the other hand, negative duties can be regarded as non-transformative as they are designed to ensure that access to essential medicines or health care services existing are preserved.⁴²⁰ This feature emanates from the South Africa obligation to respect the existing enjoyment of the right under section 27(1) (a) read with section 7(2) of the Constitution.⁴²¹

3.2.4 The right to health for children

The Constitution recognised that children are the most vulnerable and their right to health need to be protected.⁴²² Section 28(1) of the Constitution declares that “every child has the right towhich includes the right to basic nutrition, shelter, basic health care services and social services.”⁴²³ Section 28 creates an obligation which requires the South African government to intervene in situations where children have been deprived of access to essential medicines. It is interesting to note that this section provides for entitlement to a more expansive range of goods and services than a child would be not otherwise entitled to in terms of section 28.⁴²⁴

In sum, it is pertinent to note that section 27 (1) of the Constitution is aimed at advancing the healthy needs of South Africans including the poor, in order to uplift their human dignity.⁴²⁵ The constitutional protection of the right to health is an

⁴¹⁸Baret “The twin sisters- negative and positive obligations: are they enough to transform health care delivery systems in Africa?” 2013 *Health and Human Rights* 16 135.

⁴¹⁹*Ibid* 135 para 2.

⁴²⁰*Ibid* 136 para 1

⁴²¹*Ibid* 136 para 2.

⁴²²Jarobinson “Children’s rights in the South-African constitution” <http://www.ajol.info/index.php/pelj/article/viewFile/43475/27010> (accessed 21/05/2015).

⁴²³Section 28 (1).

⁴²⁴Section 28.

⁴²⁵Mbazira: *Litigating socio-economic rights in South Africa a choice between* (2009) 2.

indication of the fact that the Constitution's transformative agenda looks beyond merely guaranteeing abstract equality.⁴²⁶ There is a commitment to transform society, amongst others, from a society based on the deprivation of health needs, which includes access to essential medicines to one based on equal health provision.⁴²⁷

3.2.5 Reasonable legislative and other measures

The right to health in terms of section under section 27(1) is qualified by section 27(2), which determines that the state must take reasonable legislative and other measures, within its available resources, to achieve the progressive realisation of each of these rights guaranteed in section 27(1).⁴²⁸ Apart from limiting the extent to which the benefits implied by section 27(1) (a) may successfully be claimed at any given moment in time, section 27(2) also imposes specific obligations on South African government.⁴²⁹ In particular, it determines that the South African government is obliged to adopt legal measures in order to achieve the progressive realisation of the right to health and that these measures must be reasonable.⁴³⁰

McLean⁴³¹ observes that in order for the legislative measures taken under section 27(2) to pass the constitutionality test, the wording of the section requires them to be reasonable.⁴³² In this sense, it requires both substantive reasonableness by the state in taking positive steps to realise the right, as well as scrutiny by the courts of these steps on a reasonableness standard of review.⁴³³ Therefore, under section 27(2), the South African government is not only enjoined to desist from violating the right to health, it must also take reasonable steps to develop a legal and administrative frameworks for the realisation of the right.⁴³⁴

In a similar vein, the obligations engendered by section 27 must further be understood in conjunction with section 7(2) of the Constitution, which provides that

⁴²⁶ *Ibid* 3 para 2.

⁴²⁷ *Ibid* 3 para 3.

⁴²⁸ Section 27 (1).

⁴²⁹ 27 (2).

⁴³⁰ McLean: *Constitutional deference, courts and socio-economic rights in South Africa* (2009)96.

⁴³¹ *Ibid* 96 para 2.

⁴³² *Ibid* 96 para 3.

⁴³³ *Ibid* 97 para 1.

⁴³⁴ *Ibid* 97 para 3.

‘the state must respect, protect, promote and fulfil the rights in the Bill of Rights.’⁴³⁵ The obligations to fulfil the right to health is subjected to the limiting effect of the progressive realisation standard and resource limitation in section 27(2) of the Constitution, while the obligation to respect the right, as well as most aspects of the obligation to protect it, are more immediately enforceable.⁴³⁶ Infringements of the obligation to respect the right would typically occur where law or conduct intentionally deprives existing access to essential medicines.⁴³⁷

Linked to the above, the obligation could further be infringed by health-harming conduct such as pollution or the marketing of unsafe medicines by the adoption of deliberately retrogressive measures or by non-compliance with the guarantee of equal access to essential medicines.⁴³⁸ The obligation to protect the right to health in turn requires that certain elements thereof should be enforceable against third parties who infringe them.⁴³⁹ For instance, claimants should generally be afforded appropriate remedies where they did not receive access to essential medicines.⁴⁴⁰

3.2.6 The meaning and scope of progressive realisation under section 27(2)

According to Chenwi,⁴⁴¹ the concept of progressive realisation recognises that the full realisation of socio-economic rights, in particular the right to health, would not generally be achieved overnight.⁴⁴² The obligation on South Africa therefore is “to move as expeditiously and effectively as possible” towards the full realisation of the right to health.⁴⁴³ This view is compatible to the one advanced by the CESCR that progressive realisation imposes a specific and continuing obligation on states to, as

⁴³⁵Pieterse “Possibilities and pitfalls in the domestic enforcement of socio-economic rights: contemplating the South African experience” 2004 *Human Rights Quarterly* 26 897.

⁴³⁶*Ibid* 897 para 1.

⁴³⁷*Ibid* 897 para 1.

⁴³⁸Nolan et al “The justiciability of social and economic rights: An updated appraisal” <http://socialrightscura.ca/documents/publications/justiciability-social-econ-rights-updated-appraisal.pdf> (accessed 23/05/2015).

⁴³⁹*Ibid* 24 para 1.

⁴⁴⁰*Ibid* 24 para 2.

⁴⁴¹Chenwi “Unpacking “progressive realisation”, its relation to resources, minimum core and reasonableness, and some methodological considerations for assessing compliance” (2013)*De jure* 39 742.

⁴⁴²*Ibid* 744 para 1.

⁴⁴³See “The Limburg principles on the implementation of the International Covenant on Economic, Social and Cultural Rights” 1987 *Human Rights Quarterly* 9 122–135.

much as possible, be expeditious and effective in working towards the full realisation of social-economic rights.⁴⁴⁴

Further, it can be elaborated that there are three main arguments in terms of understanding progressive realisation.⁴⁴⁵ First, there must be immediate and tangible progress towards the realisation of the right to health. The fact that progressive realisation introduces an element of flexibility to the enforcement of the right to health does not therefore imply that South Africa can drag its feet.⁴⁴⁶ Progressive realisation cannot be interpreted under any circumstance to imply for South Africa the right to defer indefinitely efforts to ensure the full realization of the right. South Africa is required to begin immediately to take steps to fulfil the right to health.⁴⁴⁷ Therefore, progressive realization entails some immediate obligations on South Africa.

The secondly argument prohibits South Africa from implementing deliberate retrogressive measures against the realisation of the right to health in the name of progressive realisation.⁴⁴⁸ Liebenberg⁴⁴⁹ points out that section 27(2) requires any retrogressive measures taken by States to be justified, for example, by showing that the retrogressive measures are necessary to achieve equity in the realisation of the right or a more sustainable basis for adequate realisation of the right.⁴⁵⁰ She warns that when retrogressive measures result in depriving marginalised groups of access to basic social services, they will not be justifiable.⁴⁵¹

The third argument is that progressive realisation requires that special measures for vulnerable and disadvantaged groups need to be put in place.⁴⁵² South Africa is

⁴⁴⁴ Backman et al: *The right to health* (2012) 19.

⁴⁴⁵ *Ibid* 747 para 3.

⁴⁴⁶ The steps to be taken to achieve the full realisation of the right to health include those necessary for the provision of the reduction of the still-birth rate and of infant mortality and for the healthy development of the child; the improvement of all aspects of environmental and industrial health; the prevention, treatment and control of epidemics: endemic, occupational and other diseases; and the creation of conditions which would assure to all, medical services and medical attention in the event of sickness. See Backman "Health systems and the right to the highest attainable standard of health" *Health and Human Rights*, 10 82.

⁴⁴⁷ *Supra* 411 para 2.

⁴⁴⁸ London "What is a human-rights based approach to health and does it matter?" 2008 *Health and Human Rights* 10 67.

⁴⁴⁹ Liebenberg "South Africa's evolving jurisprudence on socio-economic rights: an effective tool in challenging poverty" 2002 *Law democracy and development* 6 159.

⁴⁵⁰ *Ibid* 159 para 1.

⁴⁵¹ *Ibid* 159 para 1.

⁴⁵² *Ibid* 159 para 2.

required to do more than just refraining from taking measures that might have a negative bearing on the enjoyment of their rights.⁴⁵³ South Africa has a duty to take positive action to reduce structural inequality and to give appropriate preferential treatment to vulnerable and marginalised groups. Positive action includes specially tailored measures or additional resource allocation for these groups.⁴⁵⁴

Further, Liebenberg states that section 27(3), determines that no-one may be refused emergency medical treatment.⁴⁵⁵ By virtue of its textual separation from section 27(1)(a) and the strong negative language it employs, it may be argued that section 27(3) operates free from the constraints posed by section 27(2) and that it may thus be immediately enforced against all entities that are able and qualified to render emergency care.⁴⁵⁶ Non-provision of emergency medical treatment would thus be constitutionally justifiable only in narrowly defined circumstances, in accordance with the general limitation clause in section 36 of the Constitution.⁴⁵⁷ Although there is a difference between these two rights, they should be seen in the light of the Preamble to the Constitution, which envisions the adoption of the Constitution as the supreme law in order to, *inter alia*, improve the quality of life of all citizens and to free the potential of each person.⁴⁵⁸

The Limburg Principles on the Implementation of the ICESCR have elucidated more on the term “progressive realisation”.⁴⁵⁹ The principles oblige States not to defer indefinitely the realisation of the right to health, but rather to take necessary steps towards the full realisation of the right.⁴⁶⁰ States are obliged to move as expeditiously as possible towards the full realisation of the right to. This means that the government of South Africa must take immediate steps to provide minimum core

⁴⁵³ *Ibid* 159 para 2.

⁴⁵⁴ *Ibid* 160 para 1.

⁴⁵⁵ *Ibid* 160 para 2.

⁴⁵⁶ Kapczynski and Berger “The story of the *TAC* case: the potential and limits of socio-economic rights litigation in” <https://www.law.berkeley.edu/php-programs/faculty/facultyPubsPDF.php?facID=7238&pubID=2> (accessed 26/05/2015).

South Africa

⁴⁵⁷ *Ibid* 9 para 2.

⁴⁵⁸ Mubangiza “HIV/AIDS and the South African Bill of Rights, with specific reference to the approach and role of the courts” 2004 *African Journal of AIDS Research* 113.

⁴⁵⁹ “The Limburg Principles on the Implementation of the International Covenant on Economic, Social and Cultural Rights” (1987) *Human Rights Quarterly* 9 122.

⁴⁶⁰ *Ibid* 123 para 1.

entitlements.⁴⁶¹This can be achieved through adopting either legislation or policy to ensure that the right to health with its component of access to essential medicines is realised.

3.2.7 The right to health and the limitation clause, section 36 (1)

There are no absolute rights; all rights contained in the Bill of Rights are justifiably limited in a democratic state premised upon the recognition of fundamental human rights.⁴⁶² The right to health is not an exception, section 36(2) subject it to a general limitation. This means that the exercise of this, must comply with the demand of section 36(1) or with the dictates of any other internal limitation provided for under the Constitution.⁴⁶³ In terms of section 36(1), the right to health may be limited only in terms of law of general application to the extent that the limitation is reasonable and justifiable in an open and democratic society based on human dignity, equality and freedom, taking into account all relevant factors, including—(a) the nature of the right; (b) the importance of the purpose of the limitation;(c) the nature and extent of the limitation; (d) the relation between the limitation and its purpose; and (e) less restrictive means to achieve the purpose.⁴⁶⁴

Christiansen⁴⁶⁵ notes that the “general application” reflects a broad definition of law, including limitations sanctioned by statutory provisions and the common law. He further states that the requirement of reasonableness was held to mean that a law or action limiting a right must have a reasonable goal and also that the means for achieving that goal must be reasonable.⁴⁶⁶ In *S v Makwanyane*⁴⁶⁷, case which concern the constitutionality of death penalty, the Constitutional Court elucidated more on how the general limitation clause operates by saying that:

*The limitation of constitutional rights for a purpose that is reasonable and necessary in a democratic society involves the weighing up of competing values, and ultimately an assessment based on proportionality. ...*⁴⁶⁸

⁴⁶¹ *Ibid* 123 para 1.

⁴⁶² Section 36 (1).

⁴⁶³ Section 36 (1).

⁴⁶⁴ Section 36.

⁴⁶⁵ Christiansen “Adjudicating non-justiciable rights: socio-economic rights and the South African Constitutional Court, Columbia.” 2014 *Human Rights Law Review* 38 332.

⁴⁶⁶ *Ibid* 332 para 2.

⁴⁶⁷ 1996 (2) SA 391 (CC).

⁴⁶⁸ *Ibid* para 69 para 1.

It is apparent that section 36 imposes a general limitation on the right to health that is justifiable in an open and democratic society based on human dignity, equality and freedom.⁴⁶⁹

The above legal discourse has indicated that the Constitution places an obligation upon the South African government to take programmatic measures so as to eradicate the prevailing inequalities in the enjoyment of the right to health, including its component of access to essential medicines.⁴⁷⁰ It does not really matter whether many of these inequalities are caused by the operation of the law itself, or interaction with the remnants of the structural racial oppression of apartheid, which continue to define access to health care facilities, goods and services. Further, the right to health, with its equality component, requires that the amelioration of these discrepancies receives urgent attention in a cluster of legislative and policy implementation mechanisms.

3.3 The right to health in health related legislative framework

3.3.1 Introduction

This section of the dissertation provides a discussion on the protection of the right to health through health related legislation in South Africa. The first part will focus on the provisions of the Choice on Termination of Pregnancy Act (CTPA), Mental Health Care Act (MHCA) and the National Health Act (NHA). This part will evaluate the degree to which people are enabled to have access to essential medicines in terms of these legislations. It will further provide a discussion on the protection of the right to health under the Medical Schemes Act 131 (MSA) and the Medicines and Related Substances Control Amendment Act (MRSCAA). This section reveals that a number of legislation in South Africa subscribes to a two-tier health system which has a bearing on access to essential medicines. Finally, it then briefly explore on the shortcomings of the proposed National Health Insurance Scheme.

3.3.2 The Choice on Termination of Pregnancy Act

One of the controversial pieces of health related legislative framework ever to be passed in a new South African democratic dispensation is the Choice on Termination

⁴⁶⁹ Supra 459.

⁴⁷⁰ Singh "South Africa a decade after apartheid: realising health through human rights" 2005 *Georgetown Journal on Poverty Law and Policy* 5 355.

of Pregnancy Act (CTPA).⁴⁷¹ For several years, South African health care did not have any legislation which legalised abortion on demand, except in exceptional circumstances.⁴⁷² However, the enactment of the CTPA anchored on the constitutionally protected right to reproductive freedom, enshrined in section 12(2)(a) of the Constitution decriminalised abortion, creating an avenue for many women to have access to essential medicines in the context of abortion.⁴⁷³ The CTPA has been hailed as a ground breaking piece of legislation which sought to end the criminalisation of abortion which was in conflict with the dictates of the norms, and values enshrined in the international human rights instruments.⁴⁷⁴ Criminalisation of abortion impacted negatively on the welfare of women, especially poor women who wanted to get rid of unwanted pregnancy due to economically -related compelling reason.⁴⁷⁵

According to section 12 (2)(a) of the Constitution, women have the right to bodily and psychological integrity which includes the right “to make decisions concerning reproduction.”⁴⁷⁶ Likewise, section 27(1) (a) of the Constitution provides that the right to health entails “...reproductive health care.”⁴⁷⁷ Pieterse⁴⁷⁸ notes that the foregoing two sections envisage a gender related substantive equality in the context of reproductive health.⁴⁷⁹ This is in line with the international obligations imposed on South Africa by the CEDAW. This means that the CTPA empowers women to freely request to have their pregnancy terminated within a specific period.⁴⁸⁰ It also determines the period in which institutions can provide pregnancy terminations services.⁴⁸¹

⁴⁷¹Act 92 of 1996.

⁴⁷²Ngwena “Accessing abortion services under the Choice on Termination of Pregnancy Act: realising substantive equality” 2000 *Journal for Juridical Science* 19 20.

⁴⁷³McQuoid-Mason “Are the restrictive provisions of sections 2(1)(c) and 5(5)(b) of the Choice on Termination of Pregnancy Act 92 of 1996 unconstitutional?” 2006 *Journal for Juridical Science* 31 121.

⁴⁷⁴De Roubaix “Ten years hence – has the South African Choice on Termination of Pregnancy Act, Act 92 of 1996, realised its aims? A moral-critical evaluation” 2007 *Medicine and Law* 26 145.

⁴⁷⁵*Ibid* 145 para 2.

⁴⁷⁶Section 12 (2) (a).

⁴⁷⁷Supra 465 para 2.

⁴⁷⁸Pieterse “Indirect horizontal application of the right to have access to health care services” 2007 *South African Journal on Human Rights* 23 158.

⁴⁷⁹*Ibid* 159 para 2.

⁴⁸⁰*Ibid* 160 para 1.

⁴⁸¹Section 3 of the CTPA provides minimum standards designed to guarantee the safety of abortion services.

In spite of the liberalism brought by the CTPA, the legislation has been the subject of controversy and criticism.⁴⁸² Such criticism comes from the objections raised by religious organisations and different groups in South Africa who question the morality side of abortion.⁴⁸³ Religious groups such as Christian organisations have challenged the entirety CTPA on the basis of the argument that it violates the fundamental right to life of an unborn child guaranteed under the South African Constitution. In *Christian Lawyers' Association of SA v Minister of Health*,⁴⁸⁴ the court thwarted this argument, on the basis that it had no merits because the protection of the right to life in the Bill of Rights does not suggest that the architects of the Constitution intended to alter the common-law legal rule which denies unborn children the capacity to be bearers of rights and duties.⁴⁸⁵ It can be suggested that the decision by the Court not to accord the right to life to an unborn child creates an untenable situation where the prevention of a child's birth by abortion reign sovereign over the need to protect the life of a child.

3.3.3 National Health Act

The right to health has been significantly embedded into legislation by the enactment of the National Health Act.⁴⁸⁶ The National Health Act is designed to protect, respect, promote and fulfil the right to health. This means that the Act was enacted in pursuance of section 27 (1) of the Constitution.⁴⁸⁷ The Act advances the right to health through the regulation of the national, public and private health care services in South Africa.⁴⁸⁸ The Act also provides a legislative framework which seeks to ensure that health care services are accessible by the marginalized groups in South Africa.⁴⁸⁹

The National Health Act brought to an end the fragmentation which had become the trade mark of the South African health care system.⁴⁹⁰ The Act provided a

⁴⁸²Pickles "Termination-of-pregnancy rights and foetal interests in continued existence in South Africa: the Choice on Termination of Pregnancy Act 92 of 1996" 2012 *P.E.R* 5 404.

⁴⁸³*Ibid* 404 para 2.

⁴⁸⁴1998 (4) SA 1113 (T).

⁴⁸⁵Supra 471 para 3.

⁴⁸⁶Act 61, 2003.

⁴⁸⁷*Ibid* Preamble.

⁴⁸⁸Section 27 (2) of the Constitution demands that legislation be enacted in order to give effect to the rights contained under this section.

⁴⁸⁹ Preamble of the Act.

⁴⁹⁰The White Paper for the Transformation of the Health System of South Africa published by the Department of Health in 1997 was one of the major policy documents which provided a foundation for

comprehensive and integrative approach to the fragmented National Health Service.⁴⁹¹ It promotes the accessibility and availability of health care services as well as ensures that access to medicines is improved.⁴⁹² The Act also spearheads the involvement of the community in health care service delivery through granting them primary health care and addressing human resource related issues.⁴⁹³ It brought structural transformation to the South African health care system which consisted of a bulk of isolated pieces of legislation entrenching health care services inequalities and stratification.⁴⁹⁴ This reconfiguration culminated in the alignment of the greater portion of health related legislation with the need to provide access to essential health care service.⁴⁹⁵ Section 3(1)(e) of the Act empowers the Minister of Health, based on available resources, to ensure that critical health care services are available on the basis of universality.⁴⁹⁶

In the same vein, section 5 of the Act provides that no one may be refused emergency medical treatment by public or private health care providers, workers or establishments.⁴⁹⁷ Significantly, the Act contains a spectrum of provisions pertaining to the manner in which health care must be delivered and the patients' rights to autonomy.⁴⁹⁸ Additionally, section 6 protects the right of patients to be informed and the available treatment options.⁴⁹⁹ In a word, the National Health Act can be said to be one of the profound statutes which the legislature and executive managed to enact and protect the constitutional right to health.

the National Health Act. One of the major purposes of this policy document was to unify the fragmented health services. See Department of Health "White Paper for The Transformation of The Health System in South Africa" http://www.gov.za/sites/www.gov.za/files/17910_gen667_0.pdf (accessed 28/05/2015).

⁴⁹¹Supra 97.

⁴⁹²Pieters: *Can rights cure: the impact of the human rights litigation on South African health system*, (2014) 42.

⁴⁹³*Ibid* 42 para 2.

⁴⁹⁴*Ibid* 43 para 2.

⁴⁹⁵*Ibid* 43 para 3.

⁴⁹⁶Pillay "Tracking South Africa's progress on health care rights: Are we any closer to achieving the goal"

<http://communitylawcentre.org.za/projects/socioeconomicrights/Research%20and%20Publications/research/SocioEconomic%20Rights%20and%20Transformation%20in%20SA/2003/Tracking%20South%20Africas%20progress%20on%20health%20care%20rights%20Are%20we%20any%20closer%20to%20achieving%20the%20goal.pdf/view> (accessed 26/05/2015).

⁴⁹⁷Section 5.

⁴⁹⁸AIDS Law Project: *The National Health Act 61 of 2003 A Guide* (2008) 21.

⁴⁹⁹Section 6.

3.3.4 The Mental Health Care Act

The objective of the Mental Health Care Act⁵⁰⁰ is to regulate, integrate and co-ordinate access to mental health care, treatment and rehabilitation services on a non-discriminatory basis.⁵⁰¹ The Act integrates mental health into primary health care. Other areas of focus are the development of community, district and regional mental health services; de-institutionalization from psychiatric hospitals through the development of community support services (group homes; day programmes; rehabilitation groups and home based care).⁵⁰² The Act entitles mental health care users to legal representation and to be informed of their rights. It further provides, that a prisoner, who after an investigation by prison authorities, is considered mentally unfit may be transferred to a mental health institution on recommendation of a health practitioner. He or she may be released after the expiry of the term of imprisonment.⁵⁰³

3.3.5 Medical Schemes Act

Apart from the National Health Act, the obligation to promote, protect and fulfil the right to health has been translated into legislation through the Medical Schemes Act.⁵⁰⁴ The Medical Schemes Act contains legal rules which govern medical schemes. Medical schemes are the primary financing mechanisms for private health care services in South Africa.⁵⁰⁵ The Act facilitates access to affordable health care services by providing a wider definition of the notion of health services which are offered in South African.⁵⁰⁶ The Act requires all persons who are able to secure membership of medical schemes to be recognised as members and protects them against discrimination based on their race, gender, marital status, ethnic or social origin, sexual orientation, pregnancy, disability or state of health.⁵⁰⁷

⁵⁰⁰ Act No.17 of 2002.

⁵⁰¹ Section 8.

⁵⁰² Simpson and Chipps "Mental health legislation: does it protect the rights of people with mental health problems?" <http://repository.uwc.ac.za/xmlui/bitstream/handle/10566/1346/ChippsMentalHealthLegislation2012.pdf?sequence=3> (accessed 17/05/2015).

⁵⁰³ *Ibid* 50 para 1.

⁵⁰⁴ Section 27 (2).

⁵⁰⁵ Section 29(1)(n) and Sec 29(1)(n). See Ramjee and Vieyra "Neither here nor there: the South African medical scheme industry in limbo" <http://actuariesocietyconvention.org.za/convention2014/assets/pdf/papers/2014%20ASSA%20Ramjee%20Vieyra.pdf> (accessed 20/05/2015).

⁵⁰⁶ Section 1 of the Act provides a comprehensive definition which captures all the facets of health care services.

⁵⁰⁷ Section 24(2)(e).

The Act precludes contributions to be determined on the basis of past or present state of health or the regularity of using health care services.⁵⁰⁸ In other words, the Act requires that contributions to medical schemes be made only on the basis of income or number of dependants, or both income and dependants.⁵⁰⁹ The prohibition of making contributions on the basis of health status makes access to essential medicines more affordable to those who need them. Further, the Act expands access to essential medicines by granting post-retirement membership and also enabling their dependents to remain beneficiaries of schemes after the demise of the member.⁵¹⁰ The Medical Schemes Act enables members to insist that their schemes fully cover the costs of diagnosis and treatment of a comprehensive and continuously updated list of conditions, designated in a schedule to the regulations as constituting prescribed minimum benefits of medical scheme membership, which must be made available to all members of medical schemes and to their dependants.⁵¹¹

The Medical Schemes Act creates various mechanisms in order to ensure that medical schemes comply with the requirements of the Act.⁵¹² The Act envisaged the creation of the Council for Medical Schemes whose duty is to monitor medical schemes compliance with the Act. The Act provides a complaints mechanism which empowers members to register their complaints to the Council after having exhausted all the internal dispute resolution procedures. The Act authorises the Council to terminate or suspend the operations of any medical scheme which violates the provisions of the Act or its regulations.⁵¹³

Indeed, the Medical Schemes Act and its regulations have been credited for significantly broadening access to essential medicines through private sector medical care for members of medical schemes.⁵¹⁴ However, its efficacy has been ominously affected by the fact that other features of private health care delivery in South Africa, such as the private hospitals and pharmaceutical industries, remain

⁵⁰⁸Gray and Jack "Health legislation and policy" 2008 *South Africa Health Review* 13 33.

⁵⁰⁹*Ibid* 33 para 1.

⁵¹⁰*Ibid* 33 para 2.

⁵¹¹*Ibid* 34 para 1.

⁵¹²Pearmain "Health Policy and Legislation" 2007 *South African Health Review* 13 19.

⁵¹³*Ibid* 19 para 1.

⁵¹⁴Pearmain "Impact of changes to the Medical Schemes Act" http://www.healthlink.org.za/uploads/files/chapter8_00.pdf (accessed 02/04/2015).

virtually unregulated.⁵¹⁵ This has resulted in significant increases in the costs of private health care services in recent years with the effect that, private medical treatment has become unaffordable to the marginalised people.⁵¹⁶ The escalation of treatment in the private health sector has further led to a decrease in the number of medical schemes in South Africa, as well as a reduction in benefits offered by these schemes.⁵¹⁷

3.3.6 Medicines and Related Substances Control Amendment Act

The enactment of the Medicines and Related Substances Control Amendment Act is a milestone achievement for increasing access to essential medicines in South Africa.⁵¹⁸ The purpose of the Act is to reduce the costs of essential medicines, thereby making access medicines affordable and available.⁵¹⁹ Section 15(c) permits the Minister of Health to take measures to ensure the supply of more affordable medicines by prescribing conditions so as to protect the health of the public.⁵²⁰ The availability of affordable medicines goes a long way in providing treatment for many infectious diseases and pandemics.

3.4 The right to health through policy

3.4.1 White Paper on Health (WPH)

Besides legislation, the organs of state have adopted policies and programmes aimed at respecting, protecting, promoting and fulfilling the right to health.⁵²¹ For instance, the principle of affordability underpins the vision of the White Paper on Health. The policy measure provides for free health care to pregnant women and

⁵¹⁵ *Ibid* 183 para 2.

⁵¹⁶ *Ibid* 183 para 3.

⁵¹⁷ *Ibid* 184 para 1.

⁵¹⁸ Act 102 of 1997.

⁵¹⁹ Section 15C

⁵²⁰ Mubangizi “The right to health care in the specific context of access to HIV/AIDS medicines: what can South Africa and Uganda learn from each other? <http://www.ahrlj.up.ac.za/mubangizi-j-c-twinomugisha-b-k> (accessed 20/05/2015).

⁵²¹ The National Health Department (NHD) is responsible for formulating national legislation, policy, guidelines and setting norms and standards. The implementation and delivery of public health care services are the responsibility of the nine provinces and local authorities. However, the NDH failure to report the HIV/AIDS Strategic Plan, the Human Genetics Policy and the Health had a negative impact on public health. See http://www.196.36.153/Department_of_Health/norms/contents.html (accessed 27/05/2015).

children under the age of six which is a further measure to ensure the accessibility of essential medicines.⁵²²

3.4.2 The National Telemedicine Policy

The policy was instituted by the National Department of Health (NDH)⁵²³ to expand access to essential medicines and tele-education at a distance to health care workers in rural areas by connecting them to health centres which can provide these services.⁵²⁴ An amalgamation of medical schools provides a cost-effective service which includes training and education of health care providers in remote areas. The system facilitates recruitment and retention of health care providers in rural communities.⁵²⁵ Images can be sent from the referring site to the provincial receiving site or the centre of excellence, which provides medical consultations. The consultations can be interactive and provide immediate advice to rural centres.⁵²⁶

3.4.3 National Health Insurance Plan

The National Health Insurance Plan (NHI) is a broad health policy initiative designed to close the division between the private and public health sectors.⁵²⁷ The policy document was coined by the Task Team on National Health Insurance, mandated to propose an appropriate health system for South Africa. NHI seeks to ensure that there is equality in access to health care services.⁵²⁸ This entails improving access to essential medicines as a party of the right to health. The NHI aim to eradicating various problems prevalent in South African health system such as inequity of access between private and public health sectors, inadequate funding of health care in the public sector and insufficient access to medicines and health care practitioners in the public sector.⁵²⁹ In spite of the loft objectives sought to be achieved by the NHI,

⁵²² *Ibid* 201 para 2.

⁵²³ The NDH also instituted the National Telemedicine Policy, the HIV/AIDS Strategic Plan for South Africa 2000-2005 and the National Policy on Quality of Care during 2000/2001. http://www.sahrc.org.za/home/21/files/Reports/4th_esr_chap_4.pdf (accessed 21/05/2015).

⁵²⁴ Mars "Telemedicine and advances in urban and rural healthcare delivery in Africa" http://www.millennia2015.org/files/files/M25_WeTelemed/telemedicine_and_advances_in_urban_and_rural_healthcare_delivery_in_africa.pdf (accessed 26/05/2015).

⁵²⁵ *Ibid* 238 para 2.

⁵²⁶ *Ibid* 238 para 2.

⁵²⁷ Department of Health "National Health Insurance in South Africa Policy Document" <http://www.bowman.co.za/FileBrowser/ContentDocuments/NHI.pdf> (accessed on 28/05/2015).

⁵²⁸ Econex "Integration of the public and private sectors under a National Health Insurance (NHI) system in SA" http://econex.co.za/wp-content/uploads/2015/04/econex_health-reform-note_4.pdf (accessed 28/05/2015).

⁵²⁹ Fraser "A step towards realisation of the twenty seventh right: a preliminary analysis of the proposed National Health Insurance for South Africa"

scholars have maintained that the egalitarian nature of this policy might create a conflict between public health interests and those of private sector beneficiaries.⁵³⁰

3.5 The right to health as interpreted through case law

3.5.1 Introduction

The objective of this section of the dissertation is to identify, analyse and summarise court cases in South Africa which individuals or groups have initiated against the government or a governmental institution, claiming access to essential medicines, as a part of the right to health. The ultimate goal is to look at how the courts have litigated the right to health in light of the need to provide access to essential medicines.

3.5.2 Justiciability of the right to health

South Africa has accepted the justiciability of the right to health as a necessity for advancing the right to health, including access to essential medicines.⁵³¹ Generally, justiciability of the right to health under the South African Constitution means that courts have a say in the manner in which the right to health is understood and implemented.⁵³² Although the linchpin of transforming the right to health embodied in the Constitution into reality is the duty of the legislature and executive, courts have been constitutionally empowered to oversee the state's compliance with the right to health.⁵³³ According to section 38 of the Constitution, anyone may approach a court for appropriate relief, either in their own interest, the interests of another or the public interest when a right in the Bill of Rights has been infringed or threatened.⁵³⁴

Section 38(1) makes the right to health justiciable so that a judge can consider this right in a concrete set of circumstances.⁵³⁵ However, there are manifold arguments

http://digitalcollections.sit.edu/cgi/viewcontent.cgi?article=1895&context=isp_collection (accessed 02/06/2015).

⁵³⁰Govadia "The health and health system of South Africa: historical roots of current public health challenges" <http://depts.washington.edu/sphnet/wp-content/uploads/2013/01/Coovadia.pdf> (accessed 02/06/2015).

⁵³¹Pieterse "Legislative and executive translation of the right to have access to health care services" 2010 *Law Democracy and Development* 10 232.

⁵³²*Ibid* 232 para 2.

⁵³³Mbazira: *Ligating socio - economic rights in South Africa, a choice between corrective and distributive justice* (2009) 17.

⁵³⁴*Ibid* 17 para 1.

⁵³⁵*Ibid* 17 para 2.

surrounding the debate on judicial enforcement of social-economic rights.⁵³⁶ One of the arguments is that unelected courts should not overturn, or otherwise interfere with the policy decisions of the democratic branches of government.⁵³⁷ This is said to strain the separation of powers doctrine, and to detract from principles of direct and representative democracy.⁵³⁸ Courts are further believed to be ineffectual in solving policy-centric matters, and in that they don't have the technical as well as the financial expertise necessary to decide complex matters of social policy.⁵³⁹

In spite of the massive critique raised above, in South Africa, the Constitutional Court has proclaimed that the right to health is judicially enforceable.⁵⁴⁰ A justiciable right to health is an important step in rectifying the problem of access to essential medicines in South Africa.⁵⁴¹ The adoption of a positive legal entitlement to health for all citizens means that the courts are empowered to enforce the right to health during adjudication.⁵⁴² For victims of a violation of the right to health it is important that a judicial or quasi-judicial human rights body can adjudicate their complaints in this regard.⁵⁴³ The justiciability contributes to the protection and realisation of the right to health and further determines the meaning of this right.⁵⁴⁴

3.5.3 *Soobramoney v Ministry of Health*

The right to health was litigated in South Africa in *Soobramoney v Ministry of Health*.⁵⁴⁵ At the hub of the litigation was a claimant, Thiagraj Soobramoney, who

⁵³⁶Sunstein "Social and economic rights? Lessons From South Africa" http://www.law.uchicago.edu/files/files/124.CRS_.pdf#page=1&zoom=auto,-17,430 (accessed 23/05/2015).

⁵³⁷Desierto "Justiciability of socio-economic rights: comparative powers, roles, and practices in the Philippines and South Africa" http://blog.hawaii.edu/aplpj/files/2011/11/APLPJ_11.1_desierto.pdf (accessed on 25/05/2015).

⁵³⁸*Ibid* 142 para 1.

⁵³⁹*Ibid* 142 para 2.

⁵⁴⁰Hunt describes the particular benefits of a justiciable right to health approach to health as including its ability to give special attention to disadvantaged individuals and communities. Its potential for achieving active and informed participation of individuals and communities in policy decisions that affect them, and its requiring "effective, transparent and accessible monitoring and accountability mechanisms." Hunt Report on health systems and human rights based approach to health indicators (submitted to the Commission on Human Rights on 3 March 2006, E/CN.4/2006/48)<http://stannesmcr.org.uk/oldsite/documents/staar/issue4/13.%20A%20Justiciable%20Right%20to%20Health.pdf> (accessed 30/05/2015).

⁵⁴¹Hasselgard-Rowe and Mpinga "Justiciability of the right to health in South Africa and Switzerland through the lens of its normative components" 2014 *Human rights and humanitarian law* 3 18.

⁵⁴²*Ibid* 18 para 1.

⁵⁴³*Ibid* 18 para 2.

⁵⁴⁴*Ibid* 18 para 3.

⁵⁴⁵1998 (1) SA 765 (CC),

suffered from chronic renal failure among other diseases.⁵⁴⁶ When he ran out of personal funds with which to pay private providers, he sought service from a local state health facility. The hospital refused Soobramoney treatment because his general physical condition did not qualify him for treatment under the criteria or guidelines used by the hospital to determine eligibility for such treatments. Suffering from a terminal illness and in need for renal dialysis to prolong his life, Soobramoney brought a constitutional application seeking an order for the hospital to provide him with access to dialysis treatment.⁵⁴⁷

The central issue in this case was whether South African health authorities had violated the right to health of the claimant when refusing renal dialysis treatment to a patient suffering from terminal illness and whether there has been a violation of the right to life.⁵⁴⁸ The Constitutional Court of South Africa (CCSA) preferred a utilitarian approach to the analysis of the constitutional right to health provided under section 27 (1) of the Constitution; that the available machines be allocated to those who would benefit most.⁵⁴⁹ Under the hospital's guidelines, the claimant was refused the desired treatment. The claimant relied on the Indian case of *Paschim Banga*⁵⁵⁰, to claim the constitutional right of access to treatment.⁵⁵¹ On the contrary, the CCSA adopted the restrictive English reasonableness approach enunciated in *R v Cambridge Health Authority*.⁵⁵²

The Court stated that *Soobramoney's* case was not an "emergency" in the sense of a sudden catastrophe, but rather an "ongoing state of affairs". Instead, the case falls under sections 27(1) and (2) of the Constitution which deal with the allocation of non-emergency medical treatment.⁵⁵³ Obligations imposed on the state regarding access to health care are dependent upon the resources available, as stated in sections 27(1) and (2). Because of limited resources the hospital had adopted a policy of admitting only those patients who could be cured within a short period and those with chronic renal failure who were eligible for a kidney transplant. The CCSA declared

⁵⁴⁶ *Ibid* para 2.

⁵⁴⁷ *Ibid* para 2.

⁵⁴⁸ *Ibid* para 3.

⁵⁴⁹ *Ibid* para 3.

⁵⁵⁰ (1996) AIR SC 2426/ (1996) 4 SCC 37.

⁵⁵¹ *Ibid* para 1.

⁵⁵² 1995 2 All ER 129.

⁵⁵³ *Supra* 502 para 2.

that it could not interfere with decisions taken in good faith by political organs and medical authorities as to how to allocate budgets and decide on priorities.⁵⁵⁴

The significance of *Soobramoney* case is that this was the first case in South Africa in which the CCSA had to decide on the constitutional right to health for everybody in light of the problem of scarce resources for the funding of the health care system.⁵⁵⁵

The Court accepted that rationing of resources is integral to health service delivery in the public sector even though this might support ongoing inequities between the private and the public sector. However, the Court implied that there might be grounds for the challenge of executive policies if such policies were unreasonable or if they were not applied fairly and reasonably.⁵⁵⁶

Academic responses to the CCSA ruling in *Soobramoney*, tend to criticise this judgment. For instance, Michelme⁵⁵⁷ has noted that the ruling failed to provide a substantive benchmark for the right to health for the claimant and other future litigants who might be in the same dire situation.⁵⁵⁸ This argument is predicated upon the presupposition that that the CCSA adopted a conflating narrow reading of the right to health in section 27 (1) (2).⁵⁵⁹ However, this view stands in contrast to the one propagated by Bilchitz⁵⁶⁰ who maintains that the CCSA ruling was consistent with the universality accepted notion that the realisation of socio-economic rights is determined by the availability of resources. This view recognises the constraints that government faces when implementing its positive obligation of fulfilling the right to health.⁵⁶¹

Following the *Soobramoney* case, the CCSA has, occasionally, expressed a more interventionist approach.⁵⁶² In the *Government of the Republic of South Africa v Grootboom*,⁵⁶³ the Constitutional Court addressed the standard of reasonableness.⁵⁶⁴

⁵⁵⁴ *Ibid* para 3.

⁵⁵⁵ Pieterse "Resuscitating socio-economic rights: constitutional entitlements to health care service" 2006 *SAJHR* 12 474.

⁵⁵⁶ *Ibid* 475 para 2.

⁵⁵⁷ Michelman "The constitution, social rights and reason: a tribute to Etienne Mureinik" 1998 *SAJHR* 510.

⁵⁵⁸ *Ibid* 510 para 2.

⁵⁵⁹ *Ibid* 511 para 1.

⁵⁶⁰ Bilchitz "Poverty and fundamental rights: the justification and enforcement of socio-economic rights" <http://solbookom.com/xexo136943.pdf> (accessed on 12/06/2015).

⁵⁶¹ *Ibid* 215 para 1.

⁵⁶² *Ibid* 215 para 2.

⁵⁶³ 2001(1) SA 46 (CC).

⁵⁶⁴ *Ibid* para 2.

Although *Grootboom* was not a case dealing with the right to health, it relates to the issue of resources, similar to *Soobramoney*.⁵⁶⁵ In *Grootboom*, a group of homeless people applied for temporary state housing. Although the housing authority had developed a detailed housing policy, there were gaps regarding short-term emergency accommodation.⁵⁶⁶ The CCSA held that, although the programme initiated by the government to provide access to housing had satisfied all the other requirements of the reasonableness test, it was nevertheless unreasonable in that "no provision was made for relief to the categories of people in desperate need".⁵⁶⁷ The CCSA, therefore, found the government in violation of section 26(2) of the Constitution.⁵⁶⁸ Accordingly, a declaratory order was made requiring the government to act to meet the obligations imposed by section 26(2). In sum, in *Grootboom*, the CCSA utilised the egalitarian principle which enables the achievement of social justice by ensuring that the marginalised have access to adequate housing.⁵⁶⁹

3.5.4 *Minister of Health v Treatment Action Campaign*

The second case in which the right to health was litigated in South Africa is *Minister of Health and Others v Treatment Action Campaign and Others*.⁵⁷⁰ The case emanated from public discontent with the scarcity of antiretroviral drugs called nevirapine at some government hospitals. The scarcity of the antiretroviral drugs was attributed to a narrow government programme for the prevention of mother-to-child transmission of HIV (PMCT). The programme had been devised and implemented by the Minister of Health, in consultation with provincial health authorities on behalf of the government. It entailed administering a single oral dose of the drug to the mother and a single oral dose to the baby at the time of birth. The programme was not universal but restricted by government to 18 pilot sites.⁵⁷¹

⁵⁶⁵ *Ibid* para 2.

⁵⁶⁶ *Ibid* para 2.

⁵⁶⁷ *Ibid* para 25.

⁵⁶⁸ Pillay "Rights, roles and resources: an analysis of women's housing rights – implications of the Grootboom case" https://www.westerncape.gov.za/text/2003/womens_housing_rights.pdf (accessed 02/02/2016).

⁵⁶⁹ Bilchitz "Towards a reasonable approach to the minimum core: laying the foundations for future socio-economic rights jurisprudence" 2003 *SAJHR* 19 6.

⁵⁷⁰ 2002 (5) SA 703 (CC).

⁵⁷¹ *Ibid* para 4.

Further, doctors working at public health facilities outside the 18 sites were banned from prescribing nevirapine.⁵⁷² The restrictions did not, however, apply to the private health sector. The consequence of the ban was that only 10% of babies born at public health facilities and their mothers had access to nevirapine.⁵⁷³ The government did not state when the programme would be widened to cover all public health sector. The South African government gave two main reasons why it was limiting the nevirapine programme. One of the reasons was to do with its concerns about the health impact of nevirapine despite the fact that that nevirapine had been successfully registered as a safe medication.⁵⁷⁴

The other intention is linked to the need to study the feasibility and cost of providing a comprehensive package for PMTCT to all the public health facilities.⁵⁷⁵ In this regard, the pilot sites would serve as centres for ascertaining the capacity of the government to provide, on a universal basis, not only nevirapine, but also attendant services, and supplementary therapy, including the following: voluntary HIV and AIDS testing and counselling services; follow-up services; formula milk where bottle-feeding was substituted for breast-feeding; antibiotics; and vitamin supplements.⁵⁷⁶ The data gathered from the pilot sites would assist the government in developing a universal comprehensive health programme.⁵⁷⁷

At the close of 2001, the decision by government to restrict the programme to the pilot sites was challenged in the High Court by a number of applicants of which the TAC were the principal applicants.⁵⁷⁸ The applicants' argument was that the restrictions on the nevirapine programme constituted a number of breaches of the Constitution, but in the main the right to health provided under section 27 (92) of the Constitution. The High Court proceeded on the basis that section 27 was determinative of the issues and ruled in favour of the applicants.⁵⁷⁹ The court held that government had breached sections 27(1) and 27(2) in that it acted unreasonably

⁵⁷² *Ibid* para 4.

⁵⁷³ *Ibid* para 4.

⁵⁷⁴ *Ibid* para 4.

⁵⁷⁵ *Ibid* para 5.

⁵⁷⁶ *Ibid* para 5.

⁵⁷⁷ Liebenberg "The International Covenant on Economic, Social and Cultural Rights and its implications for South Africa" 1995 *South African Journal on Human Rights* 359 7.

⁵⁷⁸ *Ibid* 359 para 6.

⁵⁷⁹ *Ibid* 359 para 6.

(a) in refusing to make nevirapine available in the public health sector, where the attending doctor had considered it medically indicated, and (b) in not setting a timeframe for a universal programme for PMTCT.⁵⁸⁰

The CCSA interpreted the state's obligations in terms of section 27 of the Constitution in the light of the international obligations provides by the right to health to ensure access to essential medicines.⁵⁸¹ Applying the principle of reasonableness, the CCSA disagreed with the government and ordered the government to provide a set of services, including counselling, and to lift the ban imposed on nevirapine availability to patients.⁵⁸² The *TAC* case was a watershed case in litigation over the right to health in South Africa. It reveals that the Court has generally preferred the English reasonableness test to the core health services doctrine advocated by its Colombian and Indian counterparts. In this way, the CCSA has maintained its restrictive approach to the right to health, with the *TAC* case being one notable exception⁵⁸³

The CCSA was unanimous in finding that the government was in breach of sections 27(1) and 27(2) of the Constitution.⁵⁸⁴ The Court was of the view that the policy of restricting nevirapine to 18 sites was unreasonably rigid and inflexible. Government had a positive duty under section 27(2) of the Constitution to take reasonable measures within its available resources to progressively realise the right of access to health care services in section 27(1).⁵⁸⁵ However, its policy unreasonably denied mothers and their new-born babies at public health facilities outside the pilot sites the opportunity to receive therapy that is potentially life-saving to the baby. In terms of cost, the therapy was within the available resources of the state.⁵⁸⁶

The CCSA maintained that the available medical evidence showed that the drug could be administered without any known harm to the mother or child. Any side-

⁵⁸⁰ *Ibid* 400 para 6.

⁵⁸¹ *Ibid* 401 para 7.

⁵⁸² Christiansen "Adjudicating non-justiciable rights: socio-economic rights and the South African Constitutional Court" 2007 *Columbia Human Rights Law Review* 321 339.

⁵⁸³ *Ibid* 339 para 4.

⁵⁸⁴ *Ibid* 339 para 4.

⁵⁸⁵ *Ibid* 340 para 1.

⁵⁸⁶ *Ibid* 240 para 2.

effects of the drug were greatly outweighed by the expected benefits.⁵⁸⁷ The court took cognisance of the fact that by the time the appeal was heard, government had substantially augmented the budget for HIV and AIDS such that nevirapine was manifestly affordable by the state. The court also took cognisance that nevirapine was simple to administer and that the World Health Organisation has recommended its use for PMTCT without qualification.⁵⁸⁸ In essence, the CCSA ordered the government without delay to :(a) Remove the restrictions that prevented nevirapine from being made available for the purpose of PMTCT at public health facilities outside the pilot sites (b) Permit, facilitate and expedite the use of nevirapine for PMTCT at state expenses.

3.5.5 *Minister of Health v New Clicks South Africa*

In *Minister of Health v New Clicks South Africa*,⁵⁸⁹ the court declared regulations which sought to limit pharmaceutical profit margins as unconstitutional for a range of reasons, which related mostly to the legality principle and administrative law.⁵⁹⁰ However, much of the finding appeared to be informed by the Court's sense that the regulations would infringe on the right to health by causing the closure of certain rural and courier pharmacies which served the interests of vulnerable patients.⁵⁹¹ Hoexter⁵⁹² observes that the *New Click* case demonstrates that even if the government give access to certain essential medicines free of charge in the public health sector, it is still under a constitutional duty to take steps towards reducing the prices of these essential medicines in the private sector in line with the obligation imposed by the right to health.⁵⁹³

3.6 Summary

This Chapter has demonstrated that access to essential medicines as part of the right to health is protected in South Africa. Section 27 in particular provides legal protection to the right of access to health care services with its accompanying core aspect of access to essential medicines. There exist also a lot of health related

⁵⁸⁷ Davis "Adjudicating the socio-economic rights in the South African Constitution: towards deference lite?" 2006 *South African Journal on Human Rights* 301 323.

⁵⁸⁸ *Ibid* 323 para 1.

⁵⁸⁹ 2006 (2) SA 311 (CC).

⁵⁹⁰ *Ibid* para 1.

⁵⁹¹ Hoexter "Judicial policy revisited: transformative adjudication in administrative law" 2008 *South African Journal on Human Rights* 24 286.

⁵⁹² *Ibid* 286 para 2.

⁵⁹³ *Ibid* 286 para 3.

legislation, case law and policies which protect access to essential medicines. The National Health Act, Medical Schemes Act, Medicines and Related Substances Control Amendment Act among others, are some of the legislation which protects the right to health. These legislative measures were instituted pursuant of section 27 (2) of the Constitution.

This Chapter has demonstrated that access to essential medicines is domestically protected under Section 27 via the right to have access to health care services. This direct imperative obliges the South African government to respect, promote and fulfil the right to health within the available resources. Significantly, the domestic protection of the right to health care services implies that access to essential medicines, as an essential component of the right to health, is judicially enforceable in South Africa. The *Minister of Health and Others v Treatment Action Campaign* indicates that the CCSA has adopted a reasonable test in order to measure the compliance of the State to its obligation under section 27.

CHAPTER FOUR

Intellectual property protection in South Africa: Do patents preclude or facilitate access to essential medicines?

4.1 Introduction

This chapter presents an account on the epidemiological health crisis plaguing South Africa. It then establishes the nexus between the epidemiological health crisis, lack of access to essential medicines and patent protection. This chapter further looks at various intellectual property theories which are the bedrock for justifying the extension of patents to essential medicines. It further examines the implication of Trade Related Intellectual Property Rights Agreement (TRIPS) responsible for the introduction of patents on essential medicines in South Africa.⁵⁹⁴ The TRIPS established minimum standards of intellectual property protection to be applied for all World Trade Organisation (WTO) members including South Africa.⁵⁹⁵ In addition, this chapter deals with other legal rules besides TRIPS which govern patent protection in South Africa, their present status and the effects they have on access to essential medicines. The ultimate goal of this chapter is to examine the development of South African patent law to see if it has led to the realisation of the right to health in the context of accessing cheap essential medicines, including generics.

4.2 The epidemiological picture of the health crisis

South Africa is in the midst of an epidemiological crisis emanating from a number of epidemics described in the Lancet Report.⁵⁹⁶ The six major diseases confronting

⁵⁹⁴The TRIPS Agreement is annex 1C of the Marrakesh Agreement Establishing the World Trade Organisation, signed in Marrakesh, Morocco on 15 April 1994. The Agreement sets out the minimum standards of protection to be provided by each Member. Each of the main elements of protection is defined, namely the subject-matter to be protected, the rights to be conferred and permissible exceptions to those rights, and the minimum duration of protection. The Agreement sets these standards by requiring, first, that the substantive obligations of the main conventions of the WIPO, the Paris Convention for the Protection of Industrial Property (Paris Convention) and the Berne Convention for the Protection of Literary and Artistic Works (Berne Convention) in their most recent versions must be complied with. With the exception of the provisions of the Berne Convention on moral rights, all the main substantive provisions of these conventions are incorporated by reference and thus become obligations under the TRIPS Agreement between TRIPS Member countries http://www.wto.org/english/tratop_e/trips_e/t_agm0_e.htm (accessed 02/06/2015).

⁵⁹⁵Corea: *Intellectual Property rights, the WTO and Developing Countries: The TRIPS Agreement and Policy Options* (2000)3.

⁵⁹⁶Mayosi *et al* "The Lancet South Africa team Health in South Africa: changes and challenges since 2009" <http://dx.doi.org/10.1016/S0140-> (accessed 04/06/2015).

South Africa are: Human Immunodeficiency Virus (HIV and AIDS),⁵⁹⁷ Tuberculosis (TB)⁵⁹⁸ Maternal, Infant and child mortality,⁵⁹⁹ Non-communicable diseases (NCDs)⁶⁰⁰, Injury and violence, Neglected Tropical Diseases (NTDs). In *Minister of Health and Others v Treatment Action Campaign and Others*,⁶⁰¹ the Constitutional Court described the impact of the HIV and AIDS pandemic as:

*An incomprehensible calamity and the most important challenge facing South Africa since the birth of our new democracy and government's fight against "this scourge" as a top priority. It has claimed millions of lives, inflicting pain and grief, causing fear and uncertainty, and threatening the economy...*⁶⁰²

In spite of South Africa's efforts to tackle HIV and AIDS, 51 % of the deaths are still HIV related.⁶⁰³ The HIV prevalence is twenty three times the global average, while the TB infection rate is among the highest in the world.⁶⁰⁴ Moreover, the TB and HIV and AIDS co-infection rate is one of the highest in the world, being, at 73%.⁶⁰⁵ As a result of the higher HIV and AIDS rate life expectancy in South Africa has declined

⁵⁹⁷These terms sometimes are used interchangeably. The terms refer to human immunodeficiency virus (HIV) which leads to the acquired immune (immuno-) deficiency syndrome (AIDS). In *Hoffmann v South African Airways* 2001 (1) SA 1 (CC) Ngcobo J, in his judgment sets out how the disease is spread and its impact upon humanity.

⁵⁹⁸TB is an infectious disease caused by the bacillus *Mycobacterium tuberculosis*. It typically affects the lungs (pulmonary TB) but can affect other sites as well. The disease is spread in the air when people who are sick with pulmonary TB expel bacteria, for example by coughing. In general, a relatively small proportion of people infected with tuberculosis will develop TB disease; however, the probability of developing TB is much higher among people infected with HIV. TB is also more common among men than women, and affects mostly adults in the economically productive age group. See World Health Organisation, Global Tuberculosis Report, 2013. http://apps.who.int/iris/bitstream/10665/91355/1/9789241564656_eng.pdf (accessed 12/06/2015).

⁵⁹⁹Ndlovu "The WTO TRIPS Agreement and Access to medicines in South Africa twenty years into democracy" <http://www.speculumjuris.co.za/files/pdf/SJ2314FPLonias.pdf> (accessed on 13/06/2015).

⁶⁰⁰In 2011, the UN made a political declaration on the prevention and control of NCDs. The declaration acknowledged that access to essential medicines, technologies, and vaccines for NCDs is a serious problem especially in developing countries. UN Resolution 64/265, of 2011 http://www.un.org/en/ga/ncdmeeting2011/pdf/NCD_draft_political_declaration.pdf (accessed 22/06/2015).

⁶⁰¹2002 (5) SA 703 (CC).

⁶⁰²Chirwa "Minister of Health and Others v Treatment Action Campaign and Others: Its Implications for the Combat against HIV and AIDS and the Protection of Economic, Social and Cultural Rights in Africa" 2003 *East African Journal of Peace and Human Rights* 174 5.

⁶⁰³UNAIDS "The Gap Report" http://www.unaids.org/sites/default/files/media_asset/UNAIDS_Gap_report_en.pdf (accessed 22/06/2015).

⁶⁰⁴Department of Health "National Health Policy Paper in South Africa" <http://www.bowman.co.za/FileBrowser/ContentDocuments/NHI.pdf> (accessed 06/14/2015).

⁶⁰⁵*Ibid* 2 para 2.

over a number of years. HIV and AIDS has also contributed significantly to high maternal and child mortality rates.⁶⁰⁶

4.2.1 Child and Maternal Health

South African health care system has achieved a noteworthy progress in reducing child and maternal deaths over the past decades.⁶⁰⁷ But with thousands of preventable deaths that continue to occur annually, mainly in marginalised area, such progress is still deeply inadequate.⁶⁰⁸ Currently, South Africa carries the highest mortality and neo-natal mortality rate than any of the developing countries.⁶⁰⁹ The maternal mortality stands at a ratios 5, peri-natal mortality 6 and neonatal mortality 7 rates far much higher than other developing countries.⁶¹⁰ This astronomical increase of maternal mortality in South Africa is mainly attributed to the impact of HIV/AIDS pandemic.⁶¹¹ There are also deaths that are largely due to non-AIDS related factors but preventable causes.

4.2.2 Non-communicable Diseases (NCDs).

The terrible toll of HIV and AIDS pandemic has been overshadowed by a fast growing rate of NCDs, which are an even more substantial cause of morbidity and premature mortality.⁶¹² NCDs such as high blood pressure, diabetes, chronic heart disease, chronic lung diseases, cancer and mental illnesses continue to ravage

⁶⁰⁶Chirwa “The right to health in international law: its implications for the obligations of state and non-state actors in ensuring access to essential medicine” 2003 *South African Journal on Human Rights* 547.

⁶⁰⁷The globally statistics on the mortality rate of children under the age of five has dramatically declined. However, preventable diseases are the main causes of under-five deaths. Nearly 7 million children under the age of five died in 2011, including almost 3 million in their first month of life. Sub-Saharan region in which South Africa is geographically situated contributed 48.7 % to global child mortality rate. South Asia contributed 33.9 % and only 1.4% while only 1.4% of deaths occur in high-income countries. Providing child nutrition, clean water, access to essential medicines and vector control could have prevented such a death tragedy. See U N “The Millennium Development Goals Report 2014” <http://www.un.org/millenniumgoals/2014%20MDG%20report/MDG%202014%20English%20web.pdf> (accessed 06/06/2015)

⁶⁰⁸Gostin et al “Towards a framework convention on global health: a transformative agenda for global health justice” 2013 *Yale Journal of Health Policy, Law, and Ethics* 13 9.

⁶⁰⁹*Ibid* 9 para 1.

⁶¹⁰*Ibid* 9 para 1.

⁶¹¹*Ibid* 9 para 2.

⁶¹²Globally, according to the WHO, malaria deaths fell from 810,000 in 2004 to 655,000 in 2010, with forty-three countries reducing disease incidence by more than half over the past decade. Still, malaria persists as a leading cause of death for children in Africa. Climate change, coupled with growing resistance to anti-malaria medications, pose major threats to sustaining progress over the long term, although a vaccine may be launched for children in Africa by 2015. See World Health Organisation “World Health Organisation Statistics 2014” http://apps.who.int/iris/bitstream/10665/112738/1/9789240692671_eng.pdf?ua=1 (accessed 14/06/2015).

South Africa.⁶¹³ NCDs have contributed to 28% of the total burden of disease. They are largely driven by four risk factors, namely, alcohol, smoking, poor diet, and lack of exercise. The epidemiologic transition, from HIV and AIDS to non-communicable diseases as the greatest killers, is unmistakable. NCDs are on track to cause 70% of all deaths in South Africa by 2020.⁶¹⁴

4.2.3 Neglected Tropical Diseases (NTDs)

Neglected tropical diseases (NTDs) are infectious diseases that thrive in impoverished environments.⁶¹⁵ They can be broadly classified into two categories namely: endemic, chronic and disabling diseases such as river blindness and sleeping sickness.⁶¹⁶ Besides causing pre-mature death, NTDs have a negative impact on social-economic development and the quality of life. The need to tackle NTDs has become a topical issue generating an extensive public health debate in South Africa and other international platforms such as the United Nations (UN).⁶¹⁷ For instance, there are current efforts to include NTDs in the post-2015 UN sustainable development goals.⁶¹⁸

4.2.4 Injury and violence

Injury and violence are also contributing significantly to the burden of disease.⁶¹⁹ Of note is the significant proportion of injuries associated with road accidents and interpersonal violence, particularly, violence against women and children. These are

⁶¹³ *Ibid* 17 para 2.

⁶¹⁴ *Supra* 12.

⁶¹⁵ The NTDs are a group of diseases commonly found among marginalised communities. South Africa's vulnerability to these diseases emanates from the greatest concentration of poverty mainly in the poverty stricken rural areas. In South Africa, the most prevalent NTDs are infection with the soil-transmitted *helminths* which is high in provinces such as the Limpopo and KwaZulu-Natal provinces as well as Cape Town province. See Mkhize "The neglected triple disease burden and interaction of helminths, HIV and tuberculosis: An opportunity for integrated action in South Africa" 2014 *South African Medical Journal* 16 http://www.scielo.org.za/scielo.php?pid=S0256-95742014000400005&script=sci_arttext (accessed 16/07/2015).

⁶¹⁶ Wilsdon et al "Evidence on access to essential medicines for the treatment of HIV/AIDS" http://www.ifpma.org/fileadmin/content/Publication/2011/CRA_Access_to_Essential_Medicines_HIV_DS_October2011.pdf (accessed 14/07/2015)

⁶¹⁷ House of Commons "Report for the All-Party Parliamentary Group on Malaria and Neglected Tropical, Diseases" http://www.who.int/neglected_diseases/diseases/NTD_Report_APPMG.pdf (accessed 12/06/2015).

⁶¹⁸ Holmes "WHO Strategic and Advisory Group on Neglected Tropical Diseases" Neglected tropical diseases in the post-2015 health agenda" http://www.who.int/neglected_diseases/Vol_383_May_24_2014.pdf (accessed 14/06/2015).

⁶¹⁹ Statistics South Africa "Mortality and causes of death in South Africa, 2013: findings from death notification" <http://www.statssa.gov.za/publications/P03093/P030932013.pdf> (accessed 14/07/2015).

driven largely by high alcohol consumption and other social factors such as poverty and unemployment.⁶²⁰

4.3 Domestic call for expanding access to essential medicines

The domestic statistics given above indicate that there is an epidemiological crisis in South Africa. Perhaps the most astonishing part is the existence of essential medicines developed by pharmaceutical companies for treating, preventing or eradicating much of the diseases causing the epidemiological crisis.⁶²¹ For instance, the invention of antiretroviral medicines (ARVs), new classes of medicines and their use could radically change the burden of diseases in South Africa.⁶²² Although many of these essential medicines are not a cure, combined with purposeful legislative framework, they have the potential to decrease the rates of mortality and morbidity which emanates from the high burden of diseases.⁶²³

Consequently, there are clear loud voices calling for expanding access to essential medicines in order to bring to an end to the epidemiological health crisis.⁶²⁴ Civic organisation such as Treatment Action Campaign have also joined this push by invoking the right to health as the panacea to South African health crisis.⁶²⁵ This has resulted in the African National Congress (ANC) led government to adopt a policy called the National Strategic Plan (NCP) on HIV, Sexually Transmitted Infections (STIs) and TB 2012-2016 which spells out access to essential medicines as its

⁶²⁰ *Ibid* 26 para 4.

⁶²¹ The epidemiological health crisis resulted in the adoption of a plan to expand access to essential medicines. In 1996, after an extensive policy assessment, the National Drug Policy (NDP) was hatched as a panacea to the problem of lack of access to essential medicines. The objective of the NDP is to expand access to essential medicines through promoting the availability of safe and effective medicines at the lowest possible cost by: (a) monitoring and negotiating medicines prices (b) rationalising the medicines pricing system and (c) promoting the use of generic medicines. See World Health Organisation “Essential medicine and health products information portal”

⁶²² Matthew et al “Evolving human rights and the science of antiretroviral medicine” 2015 *Health and Human Rights Journal* 17 76, <http://0-eds.b.ebscohost.com.wam.seals.ac.za/eds/pdfviewer/pdfviewer?sid=81c74efb-3c89-42b6-b3fb-5e91b46350ce%40sessionmgr112&vid=1&hid=114> (accessed 15/06/2015)

⁶²³ *Ibid* 76 para 1.

⁶²⁴ The need to expand access to essential has also been highlighted by the court in the context of the failure of the state to provide inmates with ARVs in prisons. See *Van Biljon v Minister of Correctional Services*, 1997 (4) SA 441 (CC) and *N v Government of Republic of South Africa* 2006 (6) SA 543 (D).

⁶²⁵ Park “Using law to accelerate treatment access in South Africa: an analysis of patent, competition and medicines law” http://www.undp.org/content/dam/undp/library/hivaids/English/using_law_to_accelerate_treatment_access_in_south_africa_undp_2013.pdf (accessed 12/06/2015).

indispensable component.⁶²⁶ The insistence on improving access to essential medicines is premised upon the notion that intellectual law patents inhibit access to medicines specifically for the marginalised groups in South Africa

It is further important to note that the latest 2013 Draft National Policy on Intellectual Property⁶²⁷, published by the Minister of Trade and Industry, indicates that lack of access to essential medicines is caused by a number of factors chief among them is the high cost of patented essential medicines.⁶²⁸ This development has drawn a lot of debate on the desirability of patents as catalyst for encouraging further research and invention of essential medicines.⁶²⁹ In South Africa, the common forms of intellectual property are trademarks, copyright patents and designs. Other forms of intellectual property such as geographical indicators, trade secrets and plant breeder's rights are also recognised.⁶³⁰

4.4 Establishing the linkage between the right to health and intellectual property

Historically, the concept of the right to health and intellectual property originated from the same place which is Western European societies.⁶³¹ This means that the two concepts interrelate in many ways.⁶³² Intellectual property rights are regarded as rights which mainly fall within the category of private law while the right to health is a part of human rights which is regarded as public law designed to impose duties

⁶²⁶Catherine and Rutter "Treatment Action Campaign, Fix the patent laws, the Economic and Social Case for Patent Law Reform in South Africa" <http://www.health-e.org.za/wp-content/uploads/2014/02/The-Economic-and-Social-Case-for-Patent-Law-Reform-in-South-Africa.pdf> (accessed 15/07/2015).

⁶²⁷Director General, Department of Trade and Industry "Draft National Policy on Intellectual Property, Invitation on the Public to make Comment on National Policy on Intellectual Property" <http://ip-unit.org/wp-content/uploads/2013/09/DRAFT-IP-POLICY.pdf> (accessed 06/10/2014).

⁶²⁸*Ibid* 2 para 2.

⁶²⁹Muswaka, "The impact of patent protection and lack of generic competition on the right of access to medicines in South Africa: explicating corporate responsibilities for human rights" 2014 *Mediterranean Journal of Social Sciences* 5 230.

⁶³⁰Teljeur " Intellectual property rights in South Africa: An Economic Review of Policy and Impact" http://www.tips.org.za/files/Teljeur_IPRs_paper_2003.PDF (accessed 16/08/2015).

⁶³¹Chapman "A human rights perspective on intellectual property, scientific progress, and access to the benefits of science" http://www.wipo.int/edocs/mdocs/tk/en/wipo_unhchr_ip_pnl_98/wipo_unhchr_ip_pnl_98_5.pdf (accessed 12/07/2015).

⁶³²Maleche and Day "Right to health encompasses right to access essential generic medicines: challenging the 2008 Anti-Counterfeit Act in Kenya" 2014 *Health and Human Rights Journal* 16 101.

primarily on States.⁶³³ Although there is no formal institutional linkage between the right to health and intellectual property regime, the impact of intellectual property has been a major subject of discussion at international platforms such as United Nations (UN) and the World Health Organization (WHO).⁶³⁴ A general consensus which emerged from these international discussions is that intellectual property protection potentially infringes on right to health, life and the enjoyment of the benefits of scientific progress.⁶³⁵

4.5 Defining Patents

By way of definition, patents are exclusive rights vesting in the patentee for an invention which is the product or process that provides a new way of doing something, or offers a new technical solution to a problem.⁶³⁶ Patents give rights to prevent others from making, using, selling or importing the invention.⁶³⁷ In the area of health, patents are a necessity since they are given after the process of clinical testing as a way of showing the authenticity of a particular medicine.⁶³⁸

4.5.1 An overview of the South African Pharmaceutical Sector

South Africa has the largest pharmaceutical sector in Africa mainly dominated by multinational companies.⁶³⁹ Many of these multinational pharmaceutical companies are attracted to South Africa by the availability of cheap raw materials and a

⁶³³Vawda “Pharmaceutical Innovation, Incremental Patenting and Compulsory Licensing Country Case Study: South Africa”<http://idl-bnc.idrc.ca/dspace/bitstream/10625/47912/1/IDL-47912.pdf> (accessed 16/08/2015).

⁶³⁴Elbeshbishi “TRIPS and Public Health: What Should African Countries Do?”
<http://repository.uneca.org/bitstream/handle/10855/13219/bib.%2054458.pdf?sequence=1> (accessed 26/07/2015).

⁶³⁵Cullet “Patents and Medicines: the relationship between TRIPS and the human right to health” (2003) 79 *International Affairs* 79 139.

⁶³⁶It is interesting to note that the etymological roots of the term “patent” can be traced back to the Latin term *patentes*, meaning “open letters.” Originally, patents were issued by the sovereign and addressed “to all whom these presents shall come.” In other words, patents consisted of some dignity, office franchise, or other privilege granted by the sovereign to the patentee. Nard et al: *The Law of patents*(2008)<http://intellect21.cdu.edu.au/wpcontent/uploads/2011/12/Nard.%20The%20law%20of%20Patents.pdf> (accessed 23/07/2015).

⁶³⁷Ostergard: *The development dilemma: the political economy of intellectual property rights in the international system* (2003).

⁶³⁸Department of Trade and Industry “Draft National Policy on intellectual Property” 2013 <http://ip-unit.org/wp-content/uploads/2013/09/DRAFT-IP-POLICY.pdf> (accessed 25/07/2015).

⁶³⁹Wen and Matsaneng “Patents, Pharmaceuticals and Competition: benefiting from an effective patent examination” <http://www.compcom.co.za/wp-content/uploads/2014/09/Patents-Pharmaceuticals-and-Competition-Yu-Fang-Wen-and-Thapi-Matsaneng-Annual-Competition-Conference-2013.pdf>(accessed 29/07/2015).

favourable geographical location.⁶⁴⁰ South African location on major shipping routes makes it convenient for many pharmaceutical companies to transport their products using cheap sea transport.⁶⁴¹ It is because of the foregoing factors that many multinational pharmaceutical companies have constructed permanent manufacturing facilities in South Africa whilst others have their headquarters and distribution centres in the country.⁶⁴² Indeed, this means that South Africa has the capacity to manufacture essential medicines including generic. Currently, generics medicines are being manufactured by pharmaceutical companies such as Adcock Ingram, Aspen Pharmacare, and Enaleni, among others.⁶⁴³

It must be noted that many of the multinational pharmaceutical companies mentioned above have patents on essential medicines.⁶⁴⁴ The huge financial costs of research and development needed to develop medicines; in order to combat the epidemiological health crisis, requires the intervention and participation of pharmaceutical companies who are capable of shouldering the financial burdens, in the field of bio-medical research. These corporate entities are not charitable research organisations they are mainly driven by the desire to make profit from their efforts through marketing of the products or processes derived from the research. A means of effectively achieving this is to obtain intellectual property right in the form of patents over such products or processes.⁶⁴⁵ From a public health perspective,

⁶⁴⁰Klug "Access to medicines and the transformation of the South African state: exploring the interactions of legal and policy changes in health, intellectual property, trade, and competition law in the context of South Africa's HIV/AIDS pandemic" 2012 *Journal of the American Bar Foundation, Law and Social Inquiry* 16 290.

⁶⁴¹*Ibid* 292 para 2.

⁶⁴²Kolawole "Using the right to health to enforce the corporate responsibilities of pharmaceutical companies with regard to access to medicines" [http://www.ghdnet.org/sites/default/files/Using%20the%20Right%20to%20Health%20to%20Enforce%20the%20Corporate%20Responsibilities%20of%20Pharmaceutical%20Companies%20with%20Regar0o%20Access%20to%20Medicines_0.pdf](http://www.ghdnet.org/sites/default/files/Using%20the%20Right%20to%20Health%20to%20Enforce%20the%20Corporate%20Responsibilities%20of%20Pharmaceutical%20Companies%20with%20Regard%20to%20Access%20to%20Medicines_0.pdf) (accessed 12/06/2015).

⁶⁴³Supra 600 para 1.

⁶⁴⁴Cullet "Human Rights and Intellectual Property Rights in the TRIPS Era" 2007 *Human Rights Quarterly* 29 403.

⁶⁴⁵Odunsi "Pharmaceutical industry, patenting, human rights and access to treatment in developing countries: another look at commercialisation of bio-medical research" https://docs.google.com/viewer?a=v&q=cache:b9wiu0tvflgj:siteresources.worldbank.org/intrad/resources/ssekalala.pdf+&hl=en&gl=us&pid=bl&srcid=adgeesqx2tf5c5o0066drvzpkdgmisaic78n3xcgklpmtkpr7s1o7jcwml65zel768lztzc7wbtfz10uaoajxodgesxqkyxzywgbjtwavxs3p99pb1vqtpveojbohluuqdooyfvz_&sig=ahietbri8piapqpayzwey3tvddznetvu7q (accessed 23/07/2015).

patents are found to present barriers to medicine access, particularly more so in the case of essential medicines.⁶⁴⁶

4.5.2 Statistics on the South African patented essential medicines

As already indicated above, many of the pharmaceutical companies have their medicines patented. Wen and Matsaneng⁶⁴⁷ noted that that the South African patented medicine market is expected to expand from R16.02 billion in 2012 to R22.16 billion by 2016.⁶⁴⁸ An analysis of South African patented medicine market reveal that pharmaceutical companies use the patent monopoly to charge higher prices for a number of patented essential medicines far much higher than in other countries.⁶⁴⁹ For instance, in 2012, Imatinib, a cancer medicine that has been patented in South Africa cost R867 per tablet in South Africa while in India it cost R86. India rejected an application for patenting this medicine as it was a new formulation of an old medicine. Linezolid is a TB medicine that has been patented in South Africa, it costs R676 per tablet in the private sector and R264 in public sector, while in India, the generic version of this medicine costs R9.39.⁶⁵⁰

In *Hazel Tau and Others v GlaxoSmithKline and Boehringer Ingelheim*,⁶⁵¹ a case which revolves around excessive pricing of essential medicines, particular ARV medicines for the treatment of HIV infection, the Competition Commission found that GlaxoSmithKline and Boehringer Ingelheim were using their exclusive rights in the patents to deny appropriate licences to other manufacturers, whilst simultaneously keeping their own prices high.⁶⁵² Although the case falls within the realm of competition law, it substantiates the general notion that patents have the potential to make essential medicines unaffordable thus infringing on the right to health for the marginalised people of South Africa.

⁶⁴⁶ *Ibid* 3 para 2.

⁶⁴⁷ Wen and Matsaneng "Patents, pharmaceuticals and competition: benefiting from an effective patent examination system" <http://www.compcom.co.za/wp-content/uploads/2014/09/Patents-Pharmaceuticals-and-Competition-Yu-Fang-Wen-andThapiMatsanengAnnualCompetitionConference-2013.pdf> (accessed on 07/06/2015).

⁶⁴⁸ *Ibid* 3 para 1.

⁶⁴⁹ Muswaka "The impact of patent protection and lack of generic competition on the right of access to medicines in South Africa: explicating corporate responsibility for human rights" 2014 *Mediterranean Journal of Social Science* 229 17.

⁶⁵⁰ *Supra* 608 3 para3.

⁶⁵¹ CPTech's 2003.

⁶⁵² *Ibid* 1 para 2.

4.6 The justification for the recognition of patents: The Debate

4.6.1 The Utilitarian Theory

There are essentially four major theories deployed to justify the recognition of patent protection claims on essential medicines in South Africa.⁶⁵³ The first justification revolves around the perceived economic benefits emanating from patents rights. Patent rights are needed as practical incentives for the enormous risky investments that pharmaceutical companies pour in the laborious process of inventing new medicines or improving the existing ones.⁶⁵⁴ This justification is utilitarian in nature in that it is based on the benefits arising from a temporary monopoly granted to pharmaceutical companies.⁶⁵⁵ However, such benefits must be examined in light of supra-competitive pricing that typically excludes the marginalised patients from accessing the newest essential medicines.⁶⁵⁶

In terms of the utilitarian theory, ordinary market forces do not result in optimal levels of innovation, if competitors can routinely copy and market new technologies without bearing any of the investment costs associated with the original invention.⁶⁵⁷ The inventor necessarily needs to recuperate its sunk costs, but cannot do so in competition with copiers who market at or near the marginal cost of production.⁶⁵⁸ The rational response to this risk of unfettered copying and competitive failure is either not to invest in research and development at all, or to keep inventions secret, which in turn decreases the dissemination of knowledge that supports future inventive activity.⁶⁵⁹

⁶⁵³Fisher “Theories of intellectual property” <http://cyber.law.harvard.edu/people/ffisher/ipttheory.pdf> (accessed 09/06/2015).

⁶⁵⁴Perot “Maximising utility: applying utilitarian theory to international patent” 2014 *The King’s Student Law Review* 58 9.

⁶⁵⁵Essentially, the utilitarian theory is largely supported by arguments coined by pro-utilitarian philosophers such as Jeremy Bentham. According to Jeremy Bentham laws are morally right if they can bring happiness or benefit to the greatest number of people. See [Stanford Encyclopedia of Philosophy](http://plato.stanford.edu/entries/utilitarianism-history/) “The history of utilitarianism” <http://plato.stanford.edu/entries/utilitarianism-history/> (accessed 09/06/2015).

⁶⁵⁶Sonderholm “A critique of an argument against patent rights for essential medicines” 2014 *Ethics and Global Politics* 119–136. <http://www.ethicsandglobalpolitics.net/index.php/egp/article/view/23213> (accessed 26/06/2015).

⁶⁵⁷Zaharia “Review of intellectual property and human development: current trends and future” 2014 *Berkeley Journal of International Law* 32 510.

⁶⁵⁸Lemley “Property, intellectual property, and free riding” 2005 *Texas Law Review* 83 1031.

⁶⁵⁹*Ibid* 1034 para 1.

Many protagonists of the utilitarian theory have supported the necessity of patents in order to recoup the costs of research by quoting the studies made by DiMasi and others.⁶⁶⁰ These studies estimate that the average costs of research for a selected number of new medicines was USD 803 million per successful drug in the year 2000. According to Forbes Magazine, the average cost of research is USD4 to USD11 billion per drug as of 2012.⁶⁶¹ However, independent researchers such as Light and Warburton⁶⁶² have questioned the authenticity of the costs of research incurred during the invention of new medicines submitted by DiMasi and others. Light and Warburton have found out that research costs were much lower than USD56 million per year in the same period.⁶⁶³

4.6.2 The fundamental Justice theory

The fundamental theory is based on the natural right of the inventor (fundamental justice).⁶⁶⁴ The theory states that justice inherently requires society to transfer to the inventor the right of control.⁶⁶⁵ The theory puts primacy on the inventor's inherent property right in their invention. The theory is supported by Lockean theory that individuals own themselves, and by extension, the fruits of their labour.⁶⁶⁶ The association of labour and an item created by that labour thus creates a property interest in the creator.⁶⁶⁷ It follows that inventors should be granted a right to exclude others from the use of their invention via a patent system.⁶⁶⁸ Hence, this theory is used to protect the inventor's invention as a fundamental non-material right worthy of protection.

⁶⁶⁰Vawda "Achieving social justice in the human rights/intellectual property debate: realising the goal of access to medicines" 2013 *AHRLJ* 13 510.

⁶⁶¹*Ibid* para 90.

⁶⁶²Brody and Light "Efforts to undermine public health – the inverse benefits law: how drug marketing undermines patient safety and public health" 2011 *American Journal of Public Health* 16 399.

⁶⁶³*Ibid* 399 para 1.

⁶⁶⁴Hughes "The Philosophy of Intellectual Property" http://pages.uoregon.edu/koopman/courses_readings/phil123-net/property/hughes_phil_ip.pdf (accessed 12/06/2015).

⁶⁶⁵Brennan and Rebecca *et al* "A human rights approach to intellectual property and access to medicines" <http://apps.who.int/medicinedocs/documents/s20952en/s20952en.pdf> (accessed 14/06/2015).

⁶⁶⁶Liu "Patent, but where is home and global justice? A Rawlsian and Senian inquiry" 2015 *Chicago-Kent Journal of Intellectual Property* 14 179.

⁶⁶⁷*Ibid* 179 para 2.

⁶⁶⁸*Ibid* 179 para 3.

4.6.3 Economic justification theory

In the same vein, the economic justification theory stipulates that patents are given when the sovereign is acting on behalf of the public.⁶⁶⁹ In other words, patent rights should be granted when the patenting transaction is one from which the public expects to benefit. If it looks like the public will suffer prejudice as a result of granting a patent, the patent can be legitimately denied. This theory regards the patent system as a tool to increase society's welfare.⁶⁷⁰ Most often, this societal welfare is viewed in economic terms, the goal being to maximize society's aggregate wealth. The theory can be traced back to the ancient civilisations in particular the Greeks. The Greeks believed in the idea of an incentive-based system wherein a potential inventor is encouraged to disclose something new and useful to society.⁶⁷¹

The incentive could take the form of a prize reward or exclusive right in the inventor's contribution.⁶⁷² The patent grant is intended to incentivise and promote the progress of science and useful arts. This incentive spurs innovation, with the innovation ultimately benefitting the society that grants the patent.⁶⁷³ A second economic justification of the patent regime is that the adoption of intellectual property rights spurs foreign direct investment and thus economic development and industrialisation in low and middle-income countries.⁶⁷⁴ Maskus⁶⁷⁵, a renowned researcher, has maintained that Foreign Direct Investments (FDI) decisions are not necessarily based on intellectual property rights considerations. According to him, FDI decisions are based on the following criteria (a) infrastructure (b) human capital, and regulatory issues.⁶⁷⁶

⁶⁶⁹Ramalho "Intellectual property and social justice"<http://www.ivir.nl/publicaties/download/163> (accessed on 14/06/2015).

⁶⁷⁰*Ibid* 249 para 2.

⁶⁷¹Nard and Tom *et at. American patent law with European and TRIPS comparative perspectives.* http://www.turinip.com/coursedocuments/documents2007/archive/2007edition/patents/Nard1WIPO_Class_Course_Book.pdf-1 (accessed on 16/06/2015).

⁶⁷²*Ibid* 9 para 2.

⁶⁷³Rochelle and Dreytus *et at: Law and global governance series: balancing wealth and health: battle over intellectual property and access to medicines in Latin America* (2014) 16.

⁶⁷⁴*Ibid* 17 para 1.

⁶⁷⁵Vawda "Achieving social justice in the human rights/intellectual property debate: Realising the goal of access to medicines" 2013 *AHRLJ* 13 81.

⁶⁷⁶*Ibid* 81 para 2.

4.6.4 Theory of Immaterial Property Rights

This theory provides that the basis for the recognition of patents rights is that the product is an expression of the inventor's mind.⁶⁷⁷ The basic underlying concept of this theory is that the object of patents should be sought in the product of the author or inventor's mind rather than merely looking at the personality. The theory maintains that as long as a creation only exists as an idea in its inventor's mind, it belongs to inventor.⁶⁷⁸ Therefore, the theory seeks to protect patents as non-material property of an inventor capable of negotiation and economic trafficking.

4.7 Objections and criticism of intellectual property theories

4.7.1 Issues of monopolies and market distortion

However, a more fundamental critique of the intellectual property theory is that they encourage high prices of essential medicines by imposing patents which gives pharmaceutical companies the right to ban others from using their innovation thus creating innovation based monopolies.⁶⁷⁹ Westerhaus⁶⁸⁰ has observed that patents render essential medicines inaccessible for most of the people without promoting innovation.⁶⁸¹ Indeed, this is detrimental from a right to health perspective because many people will be denied access to essential medicine.⁶⁸²

4.7.2 Patent Linkages

Furthermore, the theories of intellectual property law do not recognise that patents can be detriment to access to essential medicines when coupled with patent linkage.⁶⁸³ Patent linkage refers to the way in which patents are linked to domestic regulatory and marketing approval, which is often associated with data exclusivity for the patent holder.⁶⁸⁴ This data exclusivity allows patent holders to delay the generic market entry by preventing generic companies from using clinical trial and other key

⁶⁷⁷Brody and Light *et al* "Efforts to undermine public health – the inverse benefits law: how drug marketing undermines patient safety and public health" 2011 *American Journal of Public Health* 6 399.

⁶⁷⁸*Ibid* 399 para 1. .

⁶⁷⁹Hollis "Me-too drugs: is there a problem"http://www.who.int/intellectualproperty/topics/ip/en/Me-toDrugs_Hollis1.pdf (accessed 17/06/205).

⁶⁸⁰Castro and Westerhaus "Access to generic antiretroviral: inequality, intellectual property law, and international trade agreements" <http://www.scielo.br/pdf/csp/v23s1/10.pdf> (accessed on 23/06/2015).

⁶⁸¹*Ibid* 596 para 1.

⁶⁸²*Ibid* 596 para 2.

⁶⁸³Butler "Human rights and the trade organisation: the right to essential medicines and the TRIPS Agreement" 2007 *Journal of international law and policy* V 5.5.

⁶⁸⁴*Ibid* 5.5 para 2.

data for a set number of years from the date of regulatory approval, which can often exceed the life of the original patent.⁶⁸⁵

4.7.3 Patent evergreening

Linked to the above, the strengthening of intellectual property is also associated with the problem of evergreening.⁶⁸⁶ Evergreening is a method by which pharmaceutical manufacturers keep essential medicines updated, with the intent to maintain patent protection for longer periods of time than would normally be permissible under the law.⁶⁸⁷ It refers to increasing the life of the patent or the patent term beyond 20 years to reap the benefits for a much longer period of time. Evergreening has the end effect of hindering access to essential medicines by maintaining a patent monopoly which is supposed to have expired.⁶⁸⁸

4.7.4 Deprivation of indigenous knowledge

Another objection raised against extending patents on essential medicines is that they can be used as a tool to legitimatise the monopoly of indigenous traditional knowledge (TK) by multinational corporations, without authorisation.⁶⁸⁹ The basic premise underlying indigenous TK is that it mostly prioritises the interest of the community over those of the individual.⁶⁹⁰ This prime characteristic of indigenous knowledge is undermined by patents which transfer knowledge ownership from

⁶⁸⁵Brody and Light “Efforts to undermine public health – the inverse benefits law: how drug marketing undermines patient safety and public health” 2011 *American Journal of Public Health* 8 399.

⁶⁸⁶Darrow “Debunking the “evergreening” patents myth” http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2050696 (accessed on 26/06/2015).

⁶⁸⁷*Ibid* 131 para 2.

⁶⁸⁸Chalmers “Evergreen or Deciduous? Australian Trends in relation to the ‘evergreening’ of Patents” 2006 *Melbourne University Law Review* 30 29.

⁶⁸⁹Grenier provides a succinct definition of indigenous knowledge as the unique, traditional knowledge existing within and developed around specific conditions of women and men indigenous to a particular geographic area. In other words, what makes the knowledge indigenous is its inalienable link to the native people or aborigines of a particular locality. One of the characteristics of indigenous knowledge is that it is unique to the cultural system of such communities in a given locale. Krikorian and Kapczynski “Access to knowledge in the age of intellectual property” https://mitpress.mit.edu/sites/default/files/titles/free_download/9781890951962_Access_to_Knowledge_in_the_Age_of_Intellectual_Property.pdf (accessed on 28/06/2015).

⁶⁹⁰Currently, South Africa has adopted what is called anti-appropriation mechanism in order to protect TK. Such mechanism employed includes policies such as the 2013 Policy Framework for the Protection of Indigenous Traditional Knowledge through the Intellectual Property System. However, advocates of Indigenous TK have decried that such measures are not adequate to caution TK from being misappropriated by multinational corporations. In, 2013, South Africa enacted the Intellectual Property Amendment Act of 2013 in an attempt to close the lacuna in the law which exposed TK to misappropriation by multinational companies. However, the efficacy of this legislation is still much to be tested. Amechi “Leveraging traditional knowledge on the medicinal uses of plants within the patent system: the digitisation and disclosure of knowledge in South Africa”2015 *PELJ* 1 1727.

community based into a more developed commodity lucrative for commercial trafficking.⁶⁹¹

Critics against patents also cite instances in which they have been granted erroneously without complying with the novelty requirement.⁶⁹² Although this is not an appropriate use of a patent system, it appears that individuals have filed patent applications claiming that they invented a certain medicine that was not in fact invented by them but rather derived from other technology that was not new but well known.⁶⁹³ Although patent applications are examined for novelty, the examination is no better than the collection of information available to be examined. The situation is even compounded by the fact that bringing a legal challenge against such patents can be expensive and time consuming.⁶⁹⁴

4.8 A brief historical evolution of South African patent laws

Historically, many of the current patent laws which have a bearing on access to essential medicines can be traced back to 1800's when settlers from the Netherlands colonised the Western Cape of South Africa.⁶⁹⁵ The Dutch settlers came with Roman-Dutch law. When the British Empire took over the Cape of South Africa in 1806, they did not impose their legal system, at least not completely.⁶⁹⁶ Instead, the existing Roman-Dutch common-law remained in force, but was eventually overlaid with a heavy English law influence. The resulting South African legal system is regarded as a true hybrid of both English law and Roman-Dutch legal principles.⁶⁹⁷ The present patent laws of South Africa mirror this successive colonial history.⁶⁹⁸

⁶⁹¹ *Ibid* 1727 para 1.

⁶⁹² Berger "Strengthening pharmaceutical innovation in Africa" <http://www.nepad.org/system/files/str.pdf> (accessed 24/06/2015).

⁶⁹³ *Ibid* 28 para 2.

⁶⁹⁴ Oxfam "Trading away access to medicines –how the European trade agenda continues to undermine access to medicines" https://www.oxfam.org/sites/www.oxfam.org/files/file_attachments/bp-trading-away-access-medicines-290914-en.pdf (accessed 25/07/2015).

⁶⁹⁵ Pechacek "The past, present, and future of South Africa's patent system" <http://web.wmitchell.edu/cybaris/wp-content/uploads/2012/09/pechacek.pdf> (accessed 26/06/2015).

⁶⁹⁶ *Ibid* 28 para 1

⁶⁹⁷ Klopper: *Law of Intellectual Property in South Africa* Durban (2011) 4.

⁶⁹⁸ Burrell: *Burrell's South African Patent and Design Law* (1999) 43.

4.9 The Impact of TRIPS Agreement on access to essential medicines

The major legal instrument largely responsible for the introduction of patents on essential medicines in South Africa is TRIPS.⁶⁹⁹ TRIPS is an international trade agreement designed to liberalise trade while protecting the private rights of intellectual property owners by reducing piracy and misappropriation.⁷⁰⁰ When South Africa became a member of WTO in 1995, it was automatically bound by the TRIPS Agreements. Since then, South Africa has made serious amendment to the chief legislation which governs patents, the Patents Act⁷⁰¹ in order to make it compatible with the provisions of the TRIPS Agreement.⁷⁰² The TRIPS Agreement requires states parties to establishment minimum standards of intellectual property protection in their respective national spheres. Geographically, as of April of 2015, the TRIPS Agreement has been ratified by 161 nations.⁷⁰³

4.9.1 Normative content

According to Article 7 of TRIPS, among the objectives of this treaty is the protection and enforcement of intellectual property rights.⁷⁰⁴ This 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.⁷⁰⁵ The three objectives mentioned above primarily focus on technological development and may have excluded other forms of intellectual property; the latter two cover nearly all forms of intellectual property rights.⁷⁰⁶

⁶⁹⁹Champagne “Access to essential medicines in developing countries: the role of international intellectual property law and policy in the access crisis” 2012 *Albany Law Journal of Science and technology* 22 90.

⁷⁰⁰TRIPS, supra 1, Preamble. The overarching ideology of TRIPS was to reduce trade barrier by protecting intellectual property rights. The very first line of TRIPS Preamble reads as following: to reduce distortions and impediments to international trade.

⁷⁰¹Act 1978, as amended up to Act number 49 of 1996. This is the major piece of legislation governing intellectual property in South Africa.

⁷⁰²*Ibid*, Preamble.

⁷⁰³WTO “Understanding the WTO: the organization Members and Observers”https://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm (accessed on16/06/2015).

⁷⁰⁴Article 7.

⁷⁰⁵Forman “Trading health for profit: bilateral and regional free trade agreements affecting domestic property rules on pharmaceuticals” in Cohen., JC et al; (eds.) http://iatp.org/files/451_2_100411.pdf (accessed 12/06/2015).

⁷⁰⁶Peter “The objectives and principles of the TRIPS agreement” <http://www.peteryu.com/correa.pdf> (accessed 13/06/2015).

Despite the lofty objectives set out in Article 7 of the TRIPS Agreement, concerns have been raised as to whether these objectives are achievable within the context of developing countries. For instance, civil organisations such as Treatment Action Campaign (TAC) and Médecins Sans Frontières (MSF) have noted that following the adoption of TRIPS, South Africa witnessed a massive de-industrialisation in its pharmaceutical sector.⁷⁰⁷ This view is supported by a research conducted by Naude and Luiz,⁷⁰⁸ which states that between 1994 and 2007 about 35 pharmaceutical manufacturing plants in South Africa, belonging mainly to transnational companies were closed.⁷⁰⁹ Indeed, the above finding stands in contradistinction to the notion that strong intellectual property protection leads to technological transfer and improved access to essential medicines.⁷¹⁰

The meaning of the objectives of TRIPS becomes more explicit when examined within the context of the negotiating history of Article 7.⁷¹¹ As Peter⁷¹² points out that, the brainchild of TRIPS negotiations were the developed countries that were pushing to protect the contributions of authors and inventors.⁷¹³ On the contrary, the promotion of these contributions was something that was of peripheral interest to the less developed countries.⁷¹⁴ In addition, the provision, together with Article 7 of TRIPS, confirms the broad and unfettered discretion that members have to pursue public policy objectives.⁷¹⁵

In terms of Article 8(1) parties to the TRIPS Agreement are allowed to formulate or amend their laws as well as adopt measures necessary to protect public health and nutrition, and promote the public interest in sectors of vital importance to their socio-

⁷⁰⁷Pfumorodze “The WTO TRIPS Agreement and access to medicines in Southern Africa” 2011 *Botswana Law Journal* 13 90.

⁷⁰⁸Naude and Luiz “An Industry Analysis of Pharmaceutical Production in South Africa” <http://reference.sabinet.co.za/document/EJC131412> (accessed 12/06/2015).

⁷⁰⁹*Ibid* 33 para 1.

⁷¹⁰*Ibid* 34 para 3.

⁷¹¹Harris “TRIPS’ rebound: an historical analysis of how the TRIPS Agreement can ricochet back against the United States” 2004 *Northwestern Journal of International Law and Business* 25 108.

⁷¹²Supra 46.

⁷¹³De “So much to do, so little done? the right of access to anti-retroviral drugs post-Grootboom” <file:///C:/Users/SMotamakore/Downloads/So%20much%20to%20do%20so%20little%20done%20%20The%20right%20of%20access%20to%20anti-retroviral%20drugs%20post-Grootboom.pdf> (accessed 24/06/2015).

⁷¹⁴Pogge “Harnessing the power of pharmaceutical innovation “in Cohen at al: 2006, 142-149; Pogge,T et al. “Incentives for global public health: Patent law and access to essential medicines” 2008 *Public Health Ethics* 73 82.

⁷¹⁵Supra 46.

economic and technological development.⁷¹⁶ However, such measures have to be consistent with the provisions of the agreement. Correa⁷¹⁷ suggests that such measures include measures inside and outside the intellectual property regime.⁷¹⁸

The major provision which authorises patents on essential medicines is embodied in Article 27 (1).⁷¹⁹ Article 27 (1) obliges member states to make patents available for all inventions including products or processes in all fields of technology. Sarah Joseph⁷²⁰ points out that TRIPS effectively expanded the scope of patents to cover human rights sensitive areas such as essential medicines which many countries had previously excluded because of public health concerns.⁷²¹ Article 27 (1) would oblige South Africa to provide patent protection for a minimum of twenty years on new medicines.⁷²² This has enabled pharmaceutical manufactures to monopolise the industry by ensuring that there is only a single supplier of new medicines. The monopoly created in the absence of strict price regulation results in the price of essential medicines going up, a problem which impedes the realisation of the right to health.⁷²³

However, Article 27(2) allows member states to exclude certain inventions from patentability provided that the prevention of the commercial exploitation of those inventions “is necessary to protect *ordre public* or *morality*, including protecting human, animal or plant life, health in order to avoid serious prejudice to the environment.”⁷²⁴ Article 73 further enables member states to pursue their essential security interests and to fulfil obligations under the United Nations Charter in relation to the maintenance of international peace and security.⁷²⁵

⁷¹⁶Article 8 (1).

⁷¹⁷Correa “Implications of the Doha declaration on the TRIPS agreement and public health” http://www.who.int/medicines/areas/policy/WHO_EDM_PAR_2002.3.pdf (accessed 01/07/2015).

⁷¹⁸*Ibid* 43 para 4.

⁷¹⁹Correa “Intellectual property rights and inequalities in health outcomes” <http://infojustice.org/download/gcongress/ipandhumanrights/Correa%20article.pdf> (accessed 02/07/2015).

⁷²⁰Joseph: *Blame it on WTO? A human rights critique* (2011) 214.

⁷²¹*Ibid* 215 para 3.

⁷²²Article 27 (1).

⁷²³Muswaka “The impact of patent protection and lack of generic competition on the right of access to medicines in South Africa: explicating corporate responsibility for human rights” 2014. *Mediterranean Journal of Social Science* 5 229.

⁷²⁴Wang “Ancillary orders of compulsory licensing and their compatibility with the TRIPS Agreement” 2014 *Marquette Intellectual Property Law Review* 18 97.

⁷²⁵Article 73.

Article 30 of TRIPS provides for an exception to patent rights, referred to as compulsory licensing.⁷²⁶ In terms of this provision, member states may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with the normal exploitation of the patent or do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.⁷²⁷ Article 31 further delineates a list of requirements, which need to be met in order for a compulsory license to be issued, this includes the requirements that the person seeking the license must first attempt to obtain a voluntary license from the patent holder, and the patent holder must receive sufficient remuneration costs.⁷²⁸

4.9.2 Doha Declaration on TRIPS Agreement and Public health

The TRIPS rules mentioned above have generated an international debate on their overall impact on the human right to health, in particular access to essential medicines in developing countries.⁷²⁹ Developing countries have regarded the TRIPS patent rules as an impediment to accessing essential medicines. These developing countries cited TRIPS patent rules as the primary reasons for limiting the availability and affordability of essential medicines. In response to the issue of access to essential medicines, the WTO adopted the Doha Declaration on the TRIPS Agreement and Public Health in 2001.⁷³⁰ The Doha Declaration stated that TRIPS 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.⁷³¹

⁷²⁶The term "compulsory license" refers to the grant of permission for an enterprise seeking to use another's intellectual property without the consent of its proprietor. The grant of a compulsory patent license typically requires the sanction of a governmental entity and provides for compensation to the patent owner. Compulsory licenses in the patent system most often relate to pharmaceuticals and other inventions pertaining to public health, but they potentially apply to any patented invention. Thomas "Congressional Research Service, Compulsory Licensing of Patented Inventions" http://ipmall.info/hosted_resources/crs/R43266_140114.pdf (accessed 20/07/2015).

⁷²⁷Cullet "Patents and medicines: the relationship between TRIPS and the human right to health" <http://ielrc.org/content/a0301.pdf> (accessed 22/06/2015).

⁷²⁸Article 31.

⁷²⁹WTO "Decisions of the General Council on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public health" WT/L/2003 Decision https://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm (accessed 21/07/2015).

⁷³⁰Halliburton "Drug resistance, patent resistance: Indian pharmaceuticals and the impact of a new patent regime" 2009 *Global Public Health* 3 515.

⁷³¹Hoeh "The global politics of pharmaceutical monopoly power, drug patents, access, innovation and the application of the WTO Doha Declaration on TRIPS and Public Health"

The Doha Declaration was celebrated as a historic achievement in that it recognised public health problems and stressed the need of the adjustments of the provisions of TRIPS in order to meet these needs.⁷³² Paragraph six of the Declaration, stated “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.”⁷³³ The Doha Declaration mandated the Council for TRIPS to find an expeditious solution to the problem of access to essential medicines.⁷³⁴

In 2003, as a follow up to Doha Declaration, WTO released a General Council Decision, which became known as the “Paragraph 6 Waiver”.⁷³⁵ Paragraph 6 Waiver addressed and modified the language of Article 31(f) of TRIPS, which originally required that in order to use compulsory licensing the use “shall be authorised predominantly for the supply of the domestic market of the member authorising such use.”⁷³⁶ In order to alleviate this requirement, paragraph six waived the domestic market requirement imposed under Article 31(f), stating that:

*the obligation of exporting member under article 31(f) of the TRIPS Agreement shall be waived to the extent necessary to enable a pharmaceutical product produced or imported under a compulsory license in that member to be exported to the markets of those other developing or least-developed country parties to the regional trade agreement that share the health problem in question.*⁷³⁷

http://www.msfaaccess.org/sites/default/files/MSF_assets/Access/Docs/ACCESS_book_GlobalPolitics_tHoen_ENG_2009.pdf (accessed 23/07/2015).

⁷³²Abbott “Compulsory licensing for public health needs: the TRIPS Agenda at the WTO after The Doha Declaration on Public Health”<http://quno.org/geneva/pdf/economic/Occassional/Compulsory-Licensing.pdf> (accessed 24/07/2015).

⁷³³UNDP “Discussion Paper, Doha Declaration Ten Years on and Its Impact on Access to Medicines and the Right to Health 20 December 2011”
http://www.undp.org/content/dam/undp/library/hiv aids/Discussion_Paper_Doha_Declaration_Public_Health.pdf (accessed 25/06/2015).

⁷³⁴*Ibid* 24 para 1.

⁷³⁵Correa “Implementation of the WTO General Council decision on paragraph 6 of the Doha Declaration on the TRIPS agreement and public health”
http://www.who.int/medicines/areas/policy/WTO_DOHA_DecisionPara6final.pdf (accessed 27/06/2015).

⁷³⁶*Ibid* 1 para 1.

⁷³⁷*Ibid* 1 para 2.

In 2005, WTO approved the changes to the TRIPS Agreement proposed by Paragraph 6 Waiver.⁷³⁸ The deadline for these changes to be formally accepted by two-thirds of the WTO members and built into the TRIPS Agreement was extended from December 2011 to December 2013.⁷³⁹ However, since the acceptance of the Paragraph 6 Waiver, the implementation of compulsory licensing by developing countries has been almost non-existent.⁷⁴⁰ Further, post-TRIPS and the Paragraph 6 Waiver, cost and access to essential medicines remain a crucial problem in South Africa, this is evidenced by the continued inability of South Africa to provide proper access to antiretroviral therapy for HIV and AIDS patients.⁷⁴¹ It is also regrettable to note that South Africa does not take full advantage of these flexibilities permitted by TRIPS to grant compulsory licenses or parallel importation in the public health interest in order to enable access to essential medicines.

4.9.3 Reaction to Doha declaration on TRIPS Agreement and public health

The non-generic manufacturing pharmaceutical companies reacted harshly to the Doha Declaration and to the use of compulsory licensing.⁷⁴² These pharmaceutical companies pushed their western government to exert political muscles in form of threats of imposing economic sanction on developing countries that elect to use TRIPS flexibilities provided under the Declaration.⁷⁴³ South Africa has been the biggest recipient of these hash threats against the use of TRIPS flexibilities. This is because the South African pharmaceutical sector is saturated by pharmaceutical companies which are of western origin.⁷⁴⁴

The non-generic pharmaceutical manufacturing companies also argued that the Doha Declaration on Public Health would result in unlawful deprivation of their

⁷³⁸Pusceddu "Access to medicines in developing countries and free trade agreements: the case of the US-DR-CAFTA with focus on Costa Rica" 2014 *Journal of Intellectual Property Rights* 104 1.

⁷³⁹ICO "East Europe and Central Asia Union of PLWH within the project "Promoting universal access to treatment for people living with HIV, as an inalienable human right" http://ecuo.org/media/filer_public/2013/12/26/analytical_report_ecuo_trips_eng.pdf (accessed 22/06/2015).

⁷⁴⁰Gupta "Compulsory Licensing under TRIPS: how far it addresses public health concerns in developing nations" 2010 *Journal of Intellectual Property Right* 357 15.

⁷⁴¹*Ibid* 358 para 3

⁷⁴²Correa: *Implications of the Doha Declaration on the TRIPS Agreement and Public Health* Geneva: World Health Organisation (2002) 13.

⁷⁴³*Ibid*.

⁷⁴⁴Treatment Action Campaign "The economic and social case for patent law reform in South Africa". <http://www.health-e.org.za/wpcontent/uploads/2014/02/TheEconomicandSocialCaseforPatent-Law-Reform-in-South-Africa.pdf> (accessed 06/06/2015).

intellectual property.⁷⁴⁵ They argued that certain provisions in international instruments recognise intellectual property protection as a human right.⁷⁴⁶ These pharmaceutical companies substantiated their view by Article 15 (1) b of the International Covenant on Economic Social and Cultural rights (ICESCR) which recognises the right to the “protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is author”.⁷⁴⁷ However, this view has received a lot of criticism, mostly because this one clause is compensated by article 15(1) (b) of ICESCR, which protects everyone’s right “to enjoy the benefits of scientific progress and its applications”.⁷⁴⁸

In the same light, Shermers,⁷⁴⁹ a human rights scholar, argued against the notion that patents are human rights. Shermers maintains that considering patents as human rights is irreconcilable with the need to balance the interests of consumers and rights holders in circumstances where human rights and consumer interests clearly deserve priority, such as when it concerns access to essential medicines.⁷⁵⁰ This view is supported by Drahos⁷⁵¹ who submits that patents rights are distinguishable from fundamental human rights in that “human rights are of such importance that their international protection includes the right, perhaps even the obligation, of international enforcement”, a claim which cannot be made for patents.⁷⁵²

The foregoing stance is backed by the Economic, Social and Cultural Rights Committee, (ESCR) which provides that intellectual property regimes, although

⁷⁴⁵Chapman “Approaching intellectual property as a human right: obligations related to Article 15 (1) *Copyrights Bulletin xxx 4* <http://unesdoc.unesco.org/images/0012/001255/125505e.pdf> (accessed on 06/06/2015).

⁷⁴⁶This view was much relied upon in the *Nelson Mandela v Big Pharma*. In this case Pharmaceutical companies sued South African government for violating TRIPS and the right to property guaranteed under the South Africa Constitution when the South African government enacted legislation which suspended certain antiretroviral patents to guarantee the public’s access to essential medicines. Fisher and Rigamonti “The South Africa AIDS Controversy a case study in patent law and policy” <http://cyber.law.harvard.edu/people/ffisher/South%20Africa.pdf> (accessed 9/06/2015).

⁷⁴⁷Article 24 (1) of the ICESCR.

⁷⁴⁸Phillipe “Human Rights and Intellectual Property Protection in the TRIPS Era” 2007 *Human Rights Quarterly* 29 403.

⁷⁴⁹Vawda “Achieving social justice in the human rights/intellectual property debate: Realising the goal of access to medicines” 2013 *AHRLJ* 13 55.

⁷⁵⁰*Ibid* para 55 para 1.

⁷⁵¹Drahos “Intellectual property and human rights” <https://www.anu.edu.au/fellows/pdrahos/articles/pdfs/1999iPandhumanrights.pdf>(accessed 25/06/2015).

⁷⁵²Shoell “Why can’t the poor access life-saving medicines? an exploration of solving the patent issue” 2002 *Minnesota Intellectual Property Review* 4 163.

they traditionally provide protection to individual authors and creators, are increasingly focused on protecting business and corporate interests and investments', and thus fall outside the ambit of human rights protection.⁷⁵³ Accordingly, article 15(1) b should always be interpreted to prioritise human rights over property rights. Even within the WTO, member states have unanimously agreed that the TRIPS Agreement should be interpreted 'in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all.⁷⁵⁴

However, there are numerous commentators who depart from the view that intellectual property rights are human rights, arguing instead that these rights necessarily result in a more limited role in international law for human rights norms, in particular the right of access to medicines.⁷⁵⁵ In the light of the potential conflict between this human rights regime and the intellectual property/trade regime as exemplified by TRIPS Agreement, and in view of lack of a clear normative hierarchy, these commentators contend that dispute settlement in the trade arena must yield to the dictates of intellectual property rights enshrined in international economic rules.⁷⁵⁶

Conversely, the generic pharmaceutical manufacturing companies welcomed the Declaration, in particular the freedom of countries to decide the grounds for compulsory licensing.⁷⁵⁷ The generic manufacturers did, however, express concern about possible unilateral pressure to influence countries not to make the full use of the Declaration.⁷⁵⁸ The industry suggested that the advanced WTO Members should commit themselves to the Declaration in practice by refraining from exerting unilateral pressure.⁷⁵⁹ Similarly, the generic manufacturers expressed disappointment

⁷⁵³Drahos "Developing countries and international intellectual property standard-setting" 2002 *Journal of intellectual property* 5 766.

⁷⁵⁴*Ibid* 766 para 2.

⁷⁵⁵Moon "Medicines as global public goods: the governance of technological innovation in the new era of global health" 2009 *Global Health Governance* 7 2.

⁷⁵⁶*Ibid* 7 para 2.

⁷⁵⁷United Nations Development Programme "Discussion Paper, the Doha Declaration ten years on and its impact on access to medicines and the right to health"http://www.undp.org/content/dam/undp/library/hiv/aids/Discussion_Paper_Doha_Declaration_Public_Health.pdf (accessed on 27/07/2015).

⁷⁵⁸Ferrera "Access to affordable hiv/aids drugs: the human rights obligations of multinational pharmaceutical corporations" 2002 *Fordham Law Review* 71 1134.

⁷⁵⁹Brennan and Distler *at et* "A human rights approach to intellectual property and access to medicines. global health justice partnership, policy paper"<http://apps.who.int/medicinedocs/documents/s20952en/s20952en.pdf> (accessed 29/07/2015).

that there was no resolution of the issue that arises when a country with limited production capacity that issues a compulsory license for a medicine cannot find an efficient, affordable, and reliable source of medicines, due to TRIPS restrictions on production and export of medicines.⁷⁶⁰

4.9.4 Compulsory licencing After the Doha Declaration

Although the Doha Declaration on TRIPS and public health was important for drawing attention to the use of compulsory licencing as an option for creating access to essential medicines, most developing countries have not made use of compulsory licencing due to political pressure from the developed countries.⁷⁶¹ Indeed, this means that developing countries have been deprived of a pertinent tool which could be utilised to improve access to essential medicines by giving manufacturers the right to produce generic medicines.⁷⁶² South Africa, as it shall be seen in the forthcoming discussion, has not used compulsory licencing to bring about access to essential medicines.⁷⁶³ Perhaps, as alluded to in the South African 2013 Draft National Policy on Intellectual Property, the current South African patent legal framework is too rigid for it to achieve the desired public health goal, hence the call for reform.⁷⁶⁴

4.10 Current patenting regime in South Africa

As indicated in the preceding discussion, the major legal instrument governing patents in South Africa is the Patents Act. The Patents Act empowers the Registrar of Patents to accept, publish and register patent applications.⁷⁶⁵ This means that the

⁷⁶⁰ *Ibid* 16 para 2.

⁷⁶¹ Correa, notes that the Doha Declaration on TRIPS and Public health, although it was a landmark decision, it was far from being perfect. The declaration did not deal adequately with essential issues such as how to ensure that products manufactured under a compulsory license could be exported to countries without domestic production capacity. Correa "Implementation of the WTO decision on paragraph 6 of the Doha declaration on the TRIPS agreement and public health" <http://apps.who.int/medicinedocs/documents/s17521en/s17521en.pdf> (accessed 23/06/2015).

⁷⁶² Abbott and Reichman "access to essential medicines: lessons learned since the Doha Declaration on the TRIPS Agreement and Public Health, and Policy options for the European Union"

⁷⁶³ Ndlovu "The WTO TRIPS Agreement and access to medicines in South Africa twenty year into democracy" <http://www.speculumjuris.co.za/files/pdf/SJ2314FPLonias.pdf> (accessed 24/06/2015).

⁷⁶⁴ Pouris and Pouris "Patents and economic development in South Africa: managing intellectual property rights" <http://www.sajs.co.za/sites/default/files/publications/pdf/355-6888-1-PB.pdf> (accessed 26/06/2015).

⁷⁶⁵ Patent disputes are filed in the Court of the Commissioner of Patents. Only judges of the North Gauteng High Court, Pretoria may sit as a Commissioner. Proceedings before the Commissioner are governed by the rules and procedures of the High Court. The Commissioner is vested with authority under the Patents Act to make essentially all substantive determinations under the Patents Act, including infringement and revocation proceedings and applications for compulsory licences. The

Act makes the Companies and Intellectual Property Registry Office (CIPRO) to be the custodian of all patent applications that are filed within the Republic of South Africa.⁷⁶⁶ An individual can privately file a provisional patent application. However, only a patent attorney can file a non-provisional patent application and assist in drafting the patent specification.⁷⁶⁷

4.10.1 Substantive examination and non-substantive patent system

One of the major criticisms of the South African Patent Act is that it is premised upon the principle of non-substantive examination of patent before applications are approved.⁷⁶⁸ The significance of having a system that allows substantive examination is that there are examiners who are responsible for examining the quality of the patent before a patent is approved.⁷⁶⁹ In spite of its noteworthy benefits, the extent of examination varies from country to country.⁷⁷⁰

4.10.2 The implication of a non-substantive examining patent system

One of the demerits of having a non-substantive system is that it does not look at the quality of the patent result in the approval of patents that are of inferior quality.⁷⁷¹ Granting more inferior patents leads to less generic competition, which will then in turn, make the prices of essential medicines to go up. In terms of section 40 of Patent Act, any application accompanied by a provisional specification, is examined to ensure that the documents lodged are legible and capable of reproduction only.⁷⁷² Basically, non-substantive examining patent system promotes unwarranted patents

Patents Act also creates a Patent Examination Board, comprising the registrar of patents and appointees from the law societies, university law schools and the South African Institute of Intellectual Property Law. South Africa acceded to the Patent Cooperation Treaty in 1999, and it is understood that the majority of patent applications are now being filed via the Patent Cooperation Treaty. According to data from the World Intellectual Property Organization, which administers the Patent Cooperation Treaty, the vast majority of patent applications in South Africa are filed by foreign entities. See <http://patentsearch.cipc.co.za/> (accessed 26/06/2015).

⁷⁶⁶Musungu *et al* *Utilising TRIPS flexibilities for Public Health Protection through South-South Regional Frameworks* (2004) 3.

⁷⁶⁷*Ibid* 3 para 2.

⁷⁶⁸Hassim "Intellectual property regime and access to medicines –the regulatory gap" <http://www.compcom.co.za/wp-content/uploads/2014/09/IP-Regulations-competition-conference-draft-3.pdf> (accessed on 20/06/2015).

⁷⁶⁹*Ibid* 3 para 4.

⁷⁷⁰Shoell "Why can't the poor access life-saving medicines? an exploration of solving the patent issue" 2002 *Minnesota Intellectual Property Review* 4 162.

⁷⁷¹*Ibid* 157 para 1.

⁷⁷²*Supra* 157 para 2.

which go against the competition policy.⁷⁷³ A sound competition policy would condemn a patent system which does not encourage innovation but instead conveys market power.⁷⁷⁴

In the same vein, patents on essential medicines which do not encourage innovation have the potential to impose costs on the public health needs. When unwarranted patents convey market power on pharmaceutical companies, this may lead to depriving consumers of the benefits of competition without compensating value.⁷⁷⁵ The reasoning behind this is that the non-protection should then leave room for competition policy to spur innovation and provide consumers with what they want at optimal prices, quantity, and quality.⁷⁷⁶

In addition, a non-substantive examining patent system has been seen as the reason why South Africa is considered as having the cheapest patent registration system in the whole world.⁷⁷⁷ According to Wen and Matsaneng⁷⁷⁸, it is fairly easy in South Africa for pharmaceutical companies to get patents when their application documentation is framed using proper legal language.⁷⁷⁹ Statistically, between 2010 and 2011, the CIPC received 7 245 applications for patent protection and 5 296 patents were granted, 32 were not granted not on the basis of quality but because they did not meet the documentation required by the Patent Act when filed.⁷⁸⁰ Indeed, this foregoing data reveal that South Africa granted more patents than other countries which have a substantive examination system.⁷⁸¹

⁷⁷³Baker “Placing access to essential medicines on the human rights agenda” in JC Cohen et al (eds) *The power of pills: Social, ethical and legal issues in drug development, marketing and pricing* (2006). <http://www.ahrlj.up.ac.za/vawda-y-a-baker-b-k>(accessed 21/06/2015).

⁷⁷⁴*Ibid* 77 para 4.

⁷⁷⁵Erika “The human right to health and HIV/AIDS: South Africa and south-south cooperation to reframe global intellectual property principles and promote access to essential medicines” 2011 *Indiana Journal of Global Legal Studies* 18 1440.

⁷⁷⁶*Ibid* 1440 para 2.

⁷⁷⁷Supra 600.

⁷⁷⁸*Ibid* para 7.

⁷⁷⁹*Ibid* para 7.

⁷⁸⁰Medicines Sans Frontiers “Benefits of substantive examination for pharmaceutical patent claims in IP forum, South Africa,” https://www.thedti.gov.za/business_regulation/presentations/pharmaceutical_patent_claims.pdf (accessed 29/06/2015).

⁷⁸¹Treatment Action Campaign “The economic and social case for patent law reform in South Africa” <http://www.health-e.org.za/wp-content/uploads/2014/02/The-Economic-and-Social-Case-for-Patent-Law-Reform-in-South-Africa.pdf> (accessed 30/07/2015).

Consequently, the failure to have a substantive examination patent system has resulted in South Africa granting more patents on essential medicine which has a negative impact on the protection of public health than other developing countries. Wen and Matsaneng have submitted that South Africa is more willing to grant patent monopolies on essential medicines than even developed countries such as United States of America or European states.⁷⁸² Indeed, this means that South Africa's patent laws have fallen short in promoting the right to health. Thus, pro-public health patent law reforms would be needed to better promote access to essential medicines in South Africa.

4.10.3 Defining subject matter

Further, the Patents Act defines the subject matter as the "an invention is capable of protection provided that it is new, inventive and is capable of use or application in trade or industry or agriculture."⁷⁸³ The Patents Act also distinguished inventions that may not be patentable and therefore are not inventions for purposes of the Act. Section 25 of the Patent Act provides that:

*A patent may, subject to the provisions of this section, be granted for any new invention which involves an inventive step and which is capable of being used and applied in trade or industry or agriculture*⁷⁸⁴

There is no definition of what an "invention" is, only certain exclusions of what does not constitute an invention are provided.⁷⁸⁵ This is evidently a much wider construction of "invention" than that contained in the previous Act.⁷⁸⁶ It can be argued that the wider definition of an invention adopted by the Patent Act may be regarded as a lacuna which opens a flood gate for inventions which are not necessary supposed to be regarded as such.⁷⁸⁷

⁷⁸²Supra 600.

⁷⁸³Essentially, this section incorporates the patentability requirements embodied in section 27 (1) of TRIPS which provides that an invention is a patentable subject matter if it meets the three conditions for patentability which are "any invention whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application". However, it must be noted that the TRIPS agreement does not define the standard for novelty, so member countries adopt their own standard.

⁷⁸⁴Section 25 (1).

⁷⁸⁵Bombach "Can South Africa fight Aids? reconciling the South African Medicines and Related Substances Act with the TRIPS Agreement" 2001 *Boston University International Law Journal* 19 275.

⁷⁸⁶*Ibid* 275 para 1.

⁷⁸⁷ Supra 35.

4.10.4 Novelty

The novelty requirement is designed to ensure that knowledge that already exists in the public domain is not subjected to a statutory monopoly, which would be unjustified and would undermine the very basis for the grant of patent protection.⁷⁸⁸

Novelty can be interpreted narrowly or broadly, and a distinction is drawn between 'relative' novelty and 'absolute' novelty.⁷⁸⁹ Relative novelty is determined by whether an alleged invention exists only within the country in which the patent is sought. In contrast, absolute novelty is determined by whether an alleged invention exists anywhere in the world. South African novelty requirement is relative novelty.⁷⁹⁰ This means that the patentability criterion is not much stricter. From the perspective of access to essential medicines absolute novelty standard is preferable.⁷⁹¹ This is because relative novelty standard is often cited as a loop hole which enables poor quality patents that endanger manufacturing of generic medicines.⁷⁹²

However, this does not mean that any new invention is automatically patentable. Section 25(4) of the Patent Act provides for the patentability of a patent in that a patent shall not be granted for an invention the publication or exploitation of which would be generally expected to encourage offensive or immoral behaviour; or for any variety of animal or plant or any essentially biological process for the production of animals or plants, not being a micro-biological process or the product of such a process⁷⁹³. This serves as a general limitation in South Africa for granting patent protection of inventions.⁷⁹⁴

⁷⁸⁸Pfumorodze "WTO TRIPS Agreement and access to medicines in South Africa" University of B

⁷⁸⁹Brand "Intellectual Property and abuse of Dominant Position in South African Competition Law" 2005 *South African Law Journal* 910 16.

⁷⁹⁰*Ibid* 16 para 2.

⁷⁹¹The lack of strict patentability requirements has been highlighted as one of the problems besieging South African Intellectual Property Law. See Burgern "A Court's Dilemma: When patents conflict with public Health" 2007 *Virginia Journal of law and technology* 13 4.

⁷⁹²Anderson "Global pharmaceutical patent law in developing countries- amending TRIPS to promote access for all" <http://infojustice.org/04fcfb43-bd19-42dd-9d771a300e5c4ed7/finaldownload/downloadid4a654441e42ac9f8b4847838419b6c62/04fcfb43bd1942dd9d7> (accessed 17/07/2015).

⁷⁹³*Ibid* 23 para 1.

⁷⁹⁴Anderson "Unnecessary deaths and unnecessary costs: Getting patented drugs to patients most in need" <http://scholarship.law.cornell.edu/cgi/viewcontent.cgi?article=1021&context=facpub> (accessed 23/07/2015).

4.10.5 Compulsory licencing and parallel importation

As indicate in the preceding discussions, being able to grant compulsory licenses or parallel importation in the public interest enables States to provide access to essential medicines in case of an epidemic or other national emergency.⁷⁹⁵ In 1996, South Africa enacted the Medicines and Related Substances Control Amendment Act,⁷⁹⁶ whose thrust was to *inter alia*, empowers the Minister of Health, for purposes of protecting the right to health, to prescribe conditions necessary for increasing access to affordable essential medicines through the importation of cheaper generic medicines or granting compulsory licencing to a third party, regardless of the consent or objection of the patent owner.⁷⁹⁷ From a human rights perspective, it can be suggested that the amendments clearly discipline trade with the demands of the right to health.

However, in February 1998, the amendment was challenged by a group of Pharmaceuticals Manufacturers Association (PMA) in the case of *Pharmaceutical Manufacturers' Association v President of the Republic of South Africa*.⁷⁹⁸ The PMA averred that the amendments authorising parallel imports or compulsory licensing to enable access to cheap generic medicines infringed the right to patents protected under the TRIPS Agreement.⁷⁹⁹ The PMA claimed that the relevant provisions violated the rights of its members to intellectual property under the Constitution, to freedom of trade, occupation and profession and to freedom of expression.⁸⁰⁰

Having a critical examination on the first argument advanced by PMA that the amendment deprived patentees of their right to property in form of intellectual property devoid of compensation and in total disregard of section 25 of the South African Constitution, one would note that deprivation is dispossession of property which is not anywhere equivalent to expropriation of property. The South African

⁷⁹⁵Brinkhof "On patents and human rights" in Grosheide W (ed) (2010) *Intellectual Property and Human Rights: A Paradox*.

⁷⁹⁶Act 90 of 1997

⁷⁹⁷Generally, non-voluntary license holder is not exempt from paying royalties to the patent holder, but is allowed, generally for a specified period to manufacture the product in question. See Correa "Pharmaceutical innovation, incremental patenting and compulsory licencing" <http://apps.who.int/medicinedocs/documents/s21395en/s21395en.pdf> (accessed on 18/07/2015).

⁷⁹⁸TPD 4183/98 (March 2001).

⁷⁹⁹Article 27 (1) of TRIPS.

⁸⁰⁰The Constitution of the Republic of South Africa, 1996. protects the right to property in section 25 either incorporeal or corporeal. Section 16 protects the right to freedom of expression which includes artistic creation and lastly section 22 protects the right to freedom of trade and occupation.

Constitution puts a demarcation between deprivation of property and expropriation. In *Agri South Africa v Minister for Minerals and Energy*,⁸⁰¹ the Constitutional Court opined, that:

*Deprivation always takes place when property or rights therein are either taken away or significantly interfered with, the same is not necessarily true of expropriation. Deprivation relates to sacrifices that holders of private property rights may have to make without compensation, whereas expropriation entails state acquisition of that property in the public interest and must always be accompanied by compensation. Therefore, there is more required to establish expropriation although there is an overlap and no bold line of demarcation between sections 25(1) and 25(2)*⁸⁰²

An analysis of the above quotation reveals that deprivation of property ought not be arbitrary and may only take place “in terms of law of general application” whereas expropriation of property is not only required to be “in terms of law of general application”, but also “for a public purpose or in the public interest” and “subject to compensation”.⁸⁰³ It can be submitted that by implication the compensation issue raised by PMA in its pleadings would be considered only if there is expropriation and not deprivation of property.

Further, in order for PMA to be successful in an action for compensation of this nature, South African courts have long insisted, over and above proof that the property or right in question must have passed over to the State.⁸⁰⁴ In other words, in addition to the clear requirements under section 25(2) of the Constitution, the courts have emphasised that interference with property rights which does not result in transfer of property to the State, is not compensable as of constitutional right. Additionally, for the FMA to succeed in its action it has to prove that the deprivation is arbitrary.⁸⁰⁵

⁸⁰¹ 2013 (4) SA 1 (CC).

⁸⁰² *Ibid* para 48.

⁸⁰³ Section 25 (2).

⁸⁰⁴ *Mwakyembe and Kanja at et* “Implications of the TRIPS Agreement on the access to cheaper pharmaceutical drugs by developing countries: case study of South Africa vs The pharmaceutical companies”http://www.turinip.com/coursedocuments/documents2007/archive/2007edition/papers/papers2001/Kanja_unkhondiaMwa-1 (accessed on 23/07/2015).

⁸⁰⁵ *Ibid* 13 para 2.

In *FNB v CSARS*⁸⁰⁶ the Constitutional Court held that a deprivation of property is arbitrary when the law does not provide sufficient reason for the particular regulatory deprivation in question, or when it is procedurally unfair.⁸⁰⁷ This means that an intricacy of relations must be reflected in testing whether there is an adequate regulatory reason for deprivation.⁸⁰⁸ A closer examination of the relationship between the means employed and the ends sought by the legislative scheme; the relationship between the purpose of the deprivation and the nature of the property; as well as the extent of the deprivation in respect of that property must be made.⁸⁰⁹

In *Prinsloo v Van der Linde*,⁸¹⁰ the Constitutional Court had to interpret the meaning of “arbitrary” as manifest naked preferences that serve no legitimate governmental purpose. Sunstein⁸¹¹ further unpacks the term “arbitrariness” by stating that it occurs when one group or person is treated differently from another solely because of a raw exercise of political power; no broader or more general justification exists.⁸¹² However, it can be submitted that given the extent of the devastation emanating from the epidemiological health crisis shown in the preceding discussion, such an argument would be without merits since there is a legitimate justification of public health which sanctions the deprivation of property. Due to immense pressure from Civil Organisations NGOs such as MSF and Oxfam, PMA dropped their claim.⁸¹³ Significantly, the case demonstrates civil society’s alertness against private actors seeking to reduce access to essential medicines.⁸¹⁴

In the same vein, PMA later challenge price control regulations that were promulgated pursuant to the amendments made to Medicines and Related

⁸⁰⁶ 2002 (4) SA 768 (CC).

⁸⁰⁷ See also *Offit Enterprises (Pty) Ltd and Another v Coega Development Corporation (Pty) Ltd* 2011 (1) SA 293 (CC) para 39-41.

⁸⁰⁸ See also *Shoprite Checkers (Pty) Limited v Member of the Executive Council for Economic Development, Environmental Affairs and Tourism: Eastern Cape and Others* (2015) ZACC para 23.

⁸⁰⁹ *Ibid* para 77.

⁸¹⁰ 1997(3) SA 1012 (CC).

⁸¹¹ Sunstein “Naked preferences and the Constitution” 1984 *Columbia Law Review* 1693.

⁸¹² *Ibid* 1663 para 2.

⁸¹³ Heapcoalition “The critical role of civil society in shaping the market for antiretroviral therapy and direct-acting antiretroviral” <http://static1.1.sgspcdn.com/1d4b5c2c-4a4d-4896-9948-9a8d162923f6/finaldownload/downloadid251490accdf3eea7fbc0dda776602215/1d4b5c2c4/26101791e+of+cs+formatted+final+201504+01.pdf?token=bthygrirutolqj5zhrhcfiisv8u%3d> (accessed 15/07/2015).

⁸¹⁴ *Ibid* 3 para 2.

Substances Control Act.⁸¹⁵ The amendments imposed limits on the profit margins of retail pharmacists in relation to prescribed essential medicines.⁸¹⁶ In *Pharmaceutical New Clicks South Africa (Pty) Ltd v Minister of Health and Another*⁸¹⁷, the Cape High Court affirmed the legitimacy of the purpose of the regulations, which it saw as obviously being aimed at complying with the state's obligations to increase access to essential medicines through assuring their affordability in terms of section 27(2) of the Constitution.⁸¹⁸ Unfortunately, the regulations were subsequently invalidated by the South African Constitutional Court (CCSA) for not having complied with the principle of legality and for not having prescribed an 'appropriate' fee for pharmaceutical products.⁸¹⁹

In spite of the developments mentioned above, the use of parallel importation as a device to improve access to essential medicines has been very low in South Africa.⁸²⁰ Parallel importation occurs when a patented product is imported by a person other than the patent holder without the patentee's authorisation.⁸²¹ The imported essential medicines are generally purchased from a foreign licensee who produces the product at lower prices than the original patent holder or local licensee.⁸²² This unique feature of parallel importation makes it to be at longheads with patent holder in cases where a patent holder has selected an exclusive distributor in the country in question.⁸²³

4.11 Jurisprudence on cases of patent induced excessive pricing

4.11.1 Introduction

This section of the dissertation presents a discussion on the seminal cases of excessive pricing of essential medicines which went through the Competition

⁸¹⁵Section 27 "Access to essential medicines"<http://www.section27.org.za/wp-content/uploads/2010/04/Chapter14.pdf> (accessed 17/07/2015).

⁸¹⁶Ibid 445 para 2.

⁸¹⁷2006 (8) BCLR 872.

⁸¹⁸Ibid 410 para 784.

⁸¹⁹Ibid 411 para 785.

⁸²⁰Musungu "Access to art and other essential medicines in Sub-Saharan Africa: intellectual property and relevant legislations" <http://apps.who.int/1d4b5c2c-4a4d-4896-9948-9a8d162923f6/finaldownload/downloadid-81a479d00f89d4890bcb4d9bf0ee89a9/1d4b5c2c-4a4d-4896-9948-9a8d162923f6/medicinedocs/documents/s18248en/s18248en.pdf>(accessed 23/07/2015).

⁸²¹Ibid 3 para 1.

⁸²²Ibid 3 para 2.

⁸²³Teljeur "Intellectual property rights in South Africa: an economic review of policy and impact" http://www.tips.org.za/files/Teljeur_IPRs_paper_2003.PDF (accessed 25/07/2015).

Commission.⁸²⁴ The Competition Act, which is the major piece of legislation which relates to anti-competitive practices, has been invoked in many scenarios of excessive pricing in the context of access to essential medicine. Because South Africa's Competition law is relatively young and still evolving, it has not been largely tested in the area of intellectual property. Be it as it may, there are critical cases which have gone through the Competition Commission which indicates that patents have a far reaching impact on access to essential medicines.⁸²⁵

4.11.2 *Hazel Tau v GlaxoSmithKline and Boehringer Ingelheim (BI)*

This case revolved around a complaint which was lodged against the GlaxoSmithKline (GSK) and Boehringer Ingelheim (BI) groups of pharmaceutical companies with the South Africa's Competition Commission by the Civic Organization and a group of concerned individuals.⁸²⁶ This complaint was lodged as part of a national campaign to expand access to essential medicines for HIV and AIDS, which included taking steps to ensure access to continuous supply of affordable HIV-related medicines.⁸²⁷ The Complaint was anchored on section 49B(2)(b) of the Competition Act, which permits any person to submit a complaint against an alleged prohibited practice. The complainants argued that the two companies acted in violation of competition law by charging excessive prices for certain of their ARV medicines to the detriment of consumers. The respondents,

⁸²⁴The South African competition law framework is designed to promote competition in the interests of the public. The preamble to the Competition Act, 1998 confirms: That an efficient, competitive economic environment, balancing the interests of workers, owners and consumers and focused on development, will benefit all South Africans. This means that the Competition Act prohibits anti-competitive conduct by firms operating in South Africa. However, patents are a legislated, but partial exception to the general rule. According to section 45(1) of the Patents Act, a patent gives a pharmaceutical company the exclusive right to the "making, using, exercising, disposing or offering to dispose of, or importing the invention, so that he or she shall have an enjoy the whole profit and advantage accruing by reason of the invention" for a period of 20 years. Generally, patent regimes are designed in part to restrain competition for a limited period of time to promote investment in new inventions, including essential medicines, and to promote disclosure that permits earlier future innovation. See <http://www.who.int/intellectualproperty/documents/thereport/ENPublicHealthReport.pdf> (accessed on 23/06/2015).

⁸²⁵UNDP "Regional issue brief: intellectual property rights and access to medicines" http://www.google.co.za/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&ved=0ahUKEwiArZjEt6nJAhWI7hoKHRXBAGgQFggeMAA&url=http%3A%2F%2Fwww.hivlawcommission.org%2Findex.php%2Fregionaldiain%2Fafrika%2Fregionalissuesbriefintellectualpropertyrightsandaccesstomedicines%2Fdownload&usq=AFQjCNHalAaYCI_QRyFY8OaldGI04Cgm9Q&bvm=bv.108194040,d.bGQ (accessed 24/06/2015).

⁸²⁶CPTech's 2003 reports for the RSA Competition Commission, in *Hazel Tau et al. v GSK, Boehringer* <http://www.section27.org.za/wpcontent/uploads/2010/10/TauvGSKevidenceAndLegalSubmissions.pdf> (accessed 19/06/2015).

⁸²⁷*Ibid* 5 para 15.

GSK and BI are registered South African pharmaceutical companies with a patent on essential medicines, specifically ARV.⁸²⁸

The complainants alleged that GSK and BI, which were pharmaceutical companies, had engaged in excessive pricing of ARVs to the detriment of consumers, as prohibited by section 8(a) of the Competition Act, 89 of 1998.⁸²⁹ The complainants further argued that excessive pricing of ARVs is directly responsible for premature, predictable and avoidable deaths of people living with HIV and AIDS, which includes both children and adults.⁸³⁰ The ARVs in respect of which excessive pricing was alleged were as follows (a) Lamivudine (b) Combivir and Nevirapine. The complainants also alleged that in so far as these ARVs are concerned, the respondents were dominant firms as contemplated by section 7 of the Competition Act.⁸³¹ In the result, the prohibition in the Act against excessive pricing to the detriment of consumers was applicable.⁸³² The complainants argued that even when full allowance was made for the costs of research and development, the incentive to develop new essential medicines, higher profits and licensing fees, the prices of these patented medicines remained excessive and unjustifiable.⁸³³

It is important to note that although arguing in terms of the Competition Act, the complainants based their arguments firmly within the larger framework provided by the public health emergency of HIV and AIDS in South Africa, as well as the constitutional protection of the right to health previously discussed in chapter three of this dissertation.⁸³⁴ At the time that the complaint was lodged, the South African government had yet to commit itself to the development and implementation of a

⁸²⁸ *Ibid* 6 para 17.

⁸²⁹ *Ibid* 7 para 18.

⁸³⁰ *Ibid* 8 para 19.

⁸³¹ *Ibid* 15 para 23.

⁸³² Klug "Access to medicines and the transformation of the South African State: exploring the interactions of legal and policy changes in health, intellectual property, trade, and competition law in the context of South Africa's HIV/AIDS pandemic" 2012 *Law and Social Inquiry* 37 1747.

⁸³³ United Nations Development Programme "Medicines for whom? intellectual property law and the global fight for treatment, HIV and the law: risks, rights and health September 2012" https://www.google.co.za/search?q=file%3a%2f%2f%2fc%3a%2fusers%2f%2fdownloads%2fselectedbibliography%2520%2520iptrips.pdf&rlz=1c1nchb_enza654za654&oq=file%3a%2f%2f%2fc%3a%2fusers%2f%2fdownloads%2fselectedbibliography%2520%2520iptrips.pdf&aqs=chrome..69i58j69i57.12071j0j4&sourceid=chrome&es_sm=93&ie=utf-8 (accessed 29/07/2015).

⁸³⁴ Section 27 (1) of the Constitution of South Africa which provides the right to health was also used

public sector ARV treatment programme.⁸³⁵ This meant that access to essential medicines in the public sector was not available. In a country where a large number of people are dependent on the public sector for the realisation of the right to health, this meant no access to ARV medicines was undesirable.⁸³⁶

There were only three options available to people in South Africa for accessing essential medicines, namely: out-of-pocket purchase from private pharmacies; medical scheme cover; and employer-funded workplace treatment programs for uninsured workers.⁸³⁷ By challenging the high prices of essential medicines, the complaint sought to ensure that people living with HIV and AIDS who are working can afford to buy medicines to save their lives; that treatment for people living with HIV and AIDS is available and that employers are able to pay for the treatment of workers on a sustainable basis.⁸³⁸ Given the paucity of jurisprudence on the use of competition law to increase access to essential medicines, the lack of clarity in the Competition Act regarding the patent law and competition policy interface, and the inherent risks of litigation, the complainants decided to tread cautiously.⁸³⁹

The Complainants' aim was to make the best use of the available legal framework to ensure access to a sustainable supply of affordable ARV. In terms of section 39(2) of the South African Constitution "every court, tribunal or forum, when interpreting any legislation ... must promote the spirit, purport and objects of the Bill of Rights".⁸⁴⁰ It must be appreciated that 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.⁸⁴¹ The Complainants indicated that there was a dramatic

⁸³⁵ Amollo "Women's socio-economic rights in the context of HIV and AIDS in South Africa: thematic focus on health, housing, property and freedom from violence" <http://etd.uwc.ac.za/xmlui/bitstream/handle/11394/1736/Amollo.pdf?sequence=1> (accessed on 28/09/2015).

⁸³⁶ Collins-chase "The case against trips-plus protection in developing countries facing aids epidemics" [https://www.law.upenn.edu/journals/jil/articles/volume29/issue3/CollinsChase29U.Pa.J.Int'lL.763\(2008\).pdf](https://www.law.upenn.edu/journals/jil/articles/volume29/issue3/CollinsChase29U.Pa.J.Int'lL.763(2008).pdf) (accessed 26/06/2015).

⁸³⁷ Abbott and Flynn *et al.* *Using competition law to Promote Access to Health Technologies: A guidebook for low- and middle-income countries* (2014) 4.

⁸³⁸ *Ibid* 6 para 2.

⁸³⁹ *Ibid* 6 para 3.

⁸⁴⁰ The Constitution of South Africa, 1996.

⁸⁴¹ Klug "Access to medicines and the transformation of the South African State: exploring the interactions of legal and policy changes in health, intellectual property, trade, and competition law in the context of South Africa's HIV/AIDS Pandemic" 2012 *Law and Social Inquiry* 37 297.

difference in prices between what is charged to the private sector generally in South Africa and what was available outside of South Africa in terms of generic alternatives. Generic ARVs are not sold in South Africa because of the protection of patent law.⁸⁴²

The question that arose, and which was the subject of this complaint, is whether the prices charged by the respondents are excessive to the detriment of consumers within the meaning of section 8(a) of the Act.⁸⁴³ In addition, the complainants submitted that the existence of patent protection is not a justification for charging of a price which in all the circumstances was excessive and to the detriment of consumers. They argued that patent protection does not entitle a firm to charge a price which bears no reasonable relation to the economic value of the good concerned. The Competition Commission tested whether the GSK and BI had established dominance as contemplated by section 7 of the Competition Act and found out that dominance existed in respect of the South African market for each particular ARV that was the subject of this complaint.⁸⁴⁴

4.11.2.1 Determining excessive pricing

The Competition Commission utilised section 8(a) of the Competition Act which prohibits a dominant firm from charging “an excessive price to the detriment of consumers” to see if the two pharmaceutical companies were charging excessive prices for their essential medicines.⁸⁴⁵ The Competition Commission expressed that the mere existence of patent protection did not justify charging a price that bore no reasonable relation to the economic value of the particular medicine concerned.⁸⁴⁶ In determining excessive pricing, the Competition Commission considered the following factor (a) whether the relation between the price charged for a particular medicine and the economic cost value of that good was reasonable within the meaning of the Act included what the price of the good would be in a competitive market in the

⁸⁴² *Ibid* 233 para 2.

⁸⁴³ UNDP: *Using competition law to promote access to health technologies a guidebook for low- and middle-income countries* (2014) 226. http://www.undp-globalfund-capacitydevelopment.org/media/468621/undpusing_competition_law_to_promote_access_to_medicin_e-05-14-2014.pdf (accessed on 13/07/2015).

⁸⁴⁴ *Ibid* 226 para 2.

⁸⁴⁵ Section 1 of the Competition Act defines an excessive price as “a price for a good or service which which bears no reasonable relation to the economic value of that good or service; and higher than its market value.

⁸⁴⁶ Dipika Jain and Jonathan J. Darro “An exploration of compulsory licensing as an effective policy tool for antiretroviral drugs in India” 2013 *Health Matrix* 23 213.

absence of patent protection including a normal rate of profit in that context.⁸⁴⁷ A reasonable allowance for the recovery of research and development costs, relevant to the production of the good concerned, which other producers and sellers of the equivalent good in a competitive market would not have incurred.⁸⁴⁸

The Competition Commission maintained that the health consequences of lack of access to essential medicines deprive people of the enjoyment of their constitutionally protected rights to life, dignity and the right to health.⁸⁴⁹ It also deprives children of their right to have their best interests treated as paramount. The right to dignity is foundational to our constitutional order and, with the right to life, is regarded as one of the most important rights. Access to essential medicines allows people to live dignified lives.⁸⁵⁰ These rights are firmly entrenched in the Constitution and are also recognised by international law. The Commission accepted that research-based companies should be given a reasonable opportunity to recover their true research and development costs. However, such incentive to innovate must be reasonable when viewed in the context of the need to expand access to essential medicines.⁸⁵¹

4.11.2.3 Competition Commission's decision

Simply put, the Commission found that GSK and BI used their exclusive rights in the patents to deny appropriate licenses to other manufacturers, whilst simultaneously keeping their own prices high. By early December 2003, within two months of the Commission's referral announcement, GSK and BI had entered into separate settlement agreements with the complainants and the Commission respectively. In essence, the two groups of companies agreed to open up the market for generic competitors. For the first time in South Africa, generic versions of on-patent drugs were to become commercially available.

⁸⁴⁷ *Ibid* 213 para 3.

⁸⁴⁸ Wu "Transnational pharmaceutical corporations legal and moral responsibilities in relation to access to medicines" 2012 *Asian Journal of WTO and International Health Law and Policy* 7 77.

⁸⁴⁹ *Ibid* 7 para 2.

⁸⁵⁰ *Ibid* 8 para 1.

⁸⁵¹ *Ibid* 8 para 3.

4.11.3 Treatment Action Campaign v Bristol-Myers

This second case is almost similar to the one discussed above. However, *Treatment Action Campaign v Bristol-Myers Squibb*⁸⁵² revolve around civil society actors threatening to lodge an excessive pricing complaint against Bristol-Myers Squibb (BMS) for charging inflated prices for a product that was off patent, but for which the patent holder still held a de facto monopoly and was charging far lower prices in some developed countries. The matter was settled out of court with BMS agreeing to lower prices by approximately 80%.⁸⁵³

4.11.4 Evaluating the Lesson learnt

It can be suggested that the preceding jurisprudence perpetuates a growing understanding that protection of the right to health necessarily entails limits of Intellectual property protection. The two cases presented above indicates that patent monopoly can lead to anticompetitive practices which have the potential to restrict access to essential medicines including, *inter alia*, restrictive licensing agreements, patent ever greening etc.

4.12 Factors other than patents which influence access to essential medicines

4.12.1 Political will and commitment

Lack of access to essential medicines may result from a deliberate lack of support and commitment of political leaders and policy makers.⁸⁵⁴ Policy makers and political leaders play a critical role in designing appropriate policies whose aim is to increase access to essential medicines. These role players should not wait for epidemiological health crisis to worsen. Instead, they should focus on responding quickly, mobilising public finances in order to procure new medicines to tackle epidemics.⁸⁵⁵ Although South Africa leaders have recognized the problem of access to essential medicines

⁸⁵²4183/98.

⁸⁵³UNDP: *Compendium of judgments background material, judicial dialogue on HIV, human rights and the law in Asia and the Pacific* (2013).

⁸⁵⁴Zinatul *et al* "Pharmaceutical patents and access to essential medicines in sub-Saharan Africa" 2011 *African Journal of Biotechnology* 16 34.

⁸⁵⁵*Ibid* 16 para 35.

and it is actually the direction and support at the highest level of political leadership and unflinching commitment that is lacking to end the problem⁸⁵⁶.

The attitude of policy makers, society and national government towards the need to improve access to essential medicines has not changed significantly.⁸⁵⁷ From the days of President Thabo Mbeki, who openly doubted the efficacy of anti-retroviral medicines, government attitude has been a major deciding fact in the matrix of accelerating access to essential medicines.⁸⁵⁸ Currently, some government officials are preoccupied with the feeling that death is inevitable and that nothing much could be done to take South Africa out of this predicament.⁸⁵⁹

The situation is also exacerbated by the notion that the available essential medicines which cannot cure some disease are so expensive, and their accessibility to everyone including the marginalised groups is impossible.⁸⁶⁰ This argument is anchored on the budgetary implications of expanding access to essential medicines to everyone.⁸⁶¹ This attitude to a larger extent is responsible for the very few attempts made to aggressively enhance access to essential medicines by securing newer essential medicines whose effectiveness is beyond doubt.⁸⁶²

4.12.2 An inadequate health infrastructure

South Africa is a developing country whose health delivery infrastructure is still inadequate.⁸⁶³ Having an insufficient health delivery infrastructure has some devastating effects on accelerating access to essential medicines. When there are no hospitals in some rural area, or proper storage and distribution facilities, the effect of this is that even inexpensive essential medicines are not used or may be misused

⁸⁵⁶Aginam “Global health governance, intellectual property and access to essential medicines: opportunities and impediments for south-south cooperation” http://ghgi.org/Aginam_final.pdf (accessed 24/07/2015).

⁸⁵⁷Fisher and Rigamonti “The South Africa AIDS controversy: a case study in patent law and policy” <http://cyber.law.harvard.edu/people/ffisher/South%20Africa.pdf> (accessed 26/07/2015).

⁸⁵⁸*Ibid* 3 para 1

⁸⁵⁹*Ibid* 3 para 2.

⁸⁶⁰Treatment Action Campaign “The future of global health: ingredients for a bold and effective U.S. Initiative”<http://www.treatmentactiongroup.org/1d4b5c2c4a4d489699489a8d162923f6/finaldownload/downloadida951f65ba2272eefa6483797200575d6/1d4b5c2c4699489a8d162923f6/sites/tagone.drupalgardens.com/files/future%20of%20global%20health.pdf>(accessed 23/07/2015).

⁸⁶¹Supra 817.

⁸⁶²Supra 817.

⁸⁶³Jason “A robust health data infrastructure” http://healthit.gov/1d4b5c2c-4a4d-4896-9948-9a8d162923f6/finaldownload/downloadid-ea884e39f9a05bdbdfa29494d536e011/1d4b5c2c-4a4d-4896-9948-9a8d162923f6/sites/default/files/ptp13-700hhs_white.pdf (accessed 24/07/2015).

and contribute to the emergence of drug resistant pathogens or virus.⁸⁶⁴ A UN study indicates that there is inadequate health data infrastructure in developing countries which is vital for capturing information which can be used in the process of manufacturing quality medicines.⁸⁶⁵ This means that there is generally lack of infrastructure which includes hospitals, trained personnel to facilitate access to essential medicines etc.

4.12.3 Lack of Public health literacy

Lack of access to essential medicines can also be linked to the lack of educational programmes to help people see the need to have access to essential medicines in order to reduce the impact of the epidemiological health crisis.⁸⁶⁶ This problem is also compounded by a lack of infrastructure and suitable educational systems in many rural areas undoubtedly inhibiting access to essential medicines. An enlightened public has long been recognized as a necessity for improving access to essential medicines.⁸⁶⁷ A lot of people still believe that diseases are caused by “witchcraft attack” and prefer to go to local witch doctors and herbalist than going for treatment in clinics and hospitals.⁸⁶⁸

4.12.4 Corruption

There is a general consensus among legal scholars that corruption hinders access to essential medicines.⁸⁶⁹ The UN together with the African Union has acknowledged the devastating problem and consequences of corruption by adopting the African Union Convention on Preventing and Combating Corruption.⁸⁷⁰ This Convention clearly indicates that corruption remains a major stumbling block to achieve full

⁸⁶⁴ *Ibid* 4 para 3.

⁸⁶⁵ *Ibid* 4 para 4.

⁸⁶⁶ WTO “Regional issues brief: intellectual property rights and access to medicines 2011” http://www.google.co.za/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&ved=0CBwQFjAA&url=http%3A%2F%2Fwww.hivlawcommission.org%2Findex.php%2Fregionaldialoguesmain%2Fasiapacific%2Fregionalissuesbriefintellectualpropertyrightsandaccesstomedicines%2Fdownload&ei=WZayVIGvD8aAUcyPgqG&usq=AFQjCNGbLfSQ-ROXq4B34Mq4mMTtIELx3A&sig2=pTQU6a4y2vgFDeS_IKJqXQ (accessed 11/01/2015).

⁸⁶⁷ World Health Organisation “Access to essential medicines’ http://www.who.int/healthinfo/systems/WHO_MBHSS_2010_section4_web.pdf (accessed 29/07/2015).

⁸⁶⁸ *Ibid* 10 para 2.

⁸⁶⁹ William “The antecedents and effects of national corruption” <http://0inksource.ebsco.com.wam.seals.ac.za/FullText.aspx?> (accessed 29/07/2015).

⁸⁷⁰ The convention was established to promote and strengthen the development in Africa by each State Party, of mechanisms required to prevent, detect, punish and eradicate corruption and related offences in the public and private sectors and to coordinate and harmonize the policies and legislation between State Parties for the purposes of prevention, detection, punishment and eradication of corruption on the continent http://www.africa-union.org/Officialdocuments/TreatiesConventions_Protocols/Convention_on_Combating_Corruption (accessed 24/07/2015)

enjoyment of socio-economic rights.⁸⁷¹ The impact of corruption on access to essential medicines can be illustrated as following. For example if funds set aside to purchasing essential medicines are diverted and used for personal benefit, the result is that the right to health will be hindered.⁸⁷² Although South Africa has enacted anti-corruption laws, as well as taking policy measures, corruption is still a menace.⁸⁷³

4.13 Summary

In a word, this chapter, through an extensive discussion on the epidemiological health crisis, has demonstrated that there is a problem of access to essential medicines in South Africa. It is safe to posit that this problem of access to essential medicines emanates primarily from varied factors which include non-patents ones. However, patents on essential medicines also inhibit access to essential medicines. The patents rules imposed by the WTO TRIPS Agreement on South Africa have led to the strengthening of intellectual property rights. The strengthening of intellectual property is not good news from access to essential medicines perspective. It has been associated with problem of pharmaceutical monopolies and market distortion, patent linkage, evergreening and deprivations of the use indigenous knowledge. All these problems are detrimental to the achievement of access to essential medicines.

This chapter has also noted that there are flexibilities in TRIPS with the potential to significantly improvement access to essential medicines in South Africa. Interestingly, there has been little interest by South Africa to take full advantage of the TRIPS flexibilities. This is exhibited by the fact that the Patent Act which is the chief legislation governing intellectual property in South Africa does not incorporate TRIPS flexibilities. On the other side, South African Competition Commission has not

⁸⁷¹Vuuren "South Africa: Democracy, Corruption and Conflict Management" <http://democracy.cde.org.za/wpcontent/uploads/2014/05/democracyworkssouthafricaconferencepaperdemocracy-corruption-and-conflict-management-by-hennie-van-vuuren-pdf-.pdf> (accessed 24/07/2015).

⁸⁷²Pillay "Corruption – the challenge to Good Governance: a South African Perspective" http://www.casac.org.za/?wpfb_dl=71 (accessed 25/07/2015).

⁸⁷³There is a plethora of legislation enacted in South Africa to combat corruption. For instance, the Prevention and Combating of Corrupt Activities Act 12 of 2004, the Prevention of Organised Crime Act 121 of 1998, the Financial Intelligence Centre Act 31 of 2001, the Protected Disclosures Act 26 of 2008, the International Cooperation in Criminal matters Act 75 of 1996, the Criminal Procedure Act 51 of 1977, the Public Finance Management Act 1 of 1999, the Municipal Finance Management Act 56 of 2003, the Companies Act 70 of 2008. It must be noted that although we have such a plethora of legislation corruption is still a problem that is deeply entrenched in the South African society. See Bruce "Control, discipline and punish: addressing corruption in South Africa" https://www.issafrica.org/uploads/SACQ48_Bruce.pdf (accessed on 30/01/2016).

been hesitant in making rulings that ensure a significant degree of the realisation of the right to health through expanding access to essential medicines for HIV/AIDS patients. However, these attempts to use Competition law to protect the right to health are fraught with problems. Therefore, the following chapter will provide concrete recommendations which can be utilised to ameliorate this situation.

CHAPTER FIVE

Conclusion, recommendations and areas of further research

5.1 Introduction

From the theoretical and normative legal fabric proffered in this dissertation, a deduction can be made that the right to health is a paramount human right. It guarantees access to essential medicines. Access to essential medicines is a *sine qua non* for combating infectious diseases presently plaguing South Africa and without it is impossible to improve public health. The right to health provides sufficient legal obligations which obligate South African government to provide access to essential medicines. South African government is required to respect, protect and fulfil the obligation to provide access to essential medicines consistent with the right to health. The preceding chapters have also demonstrated that patents, among other factors, determine the accessibility, affordability and availability of essential medicines in South Africa. In the absence of a strong regulatory framework, patent can cause problems such as pharmaceutical monopoly, patent evergreening, patent linkages among other factors, which inhibit access to essential medicines.

Chapter two showed that the right to health, with its component of access to essential medicines, find its protection within the gamut of international human rights instrument such as the ICESCR, CEDAW, CRC and other regional human rights instruments. These international human rights instruments impose the tripartite duties to respect protect and fulfil the right to health. It has been shown that South Africa is a state party to both the ICESCR and the African Charter and other international human rights instruments which enjoin it to provide access to essential medicines at the domestic level. Therefore, in terms of this aforementioned corpus of international human rights instruments, South African government should provide access to essential medicines progressively in line with its available resources.

An analysis of chapter three shows that the right to health has been incorporated in the national constitution and laws of South Africa. The right to health is domestically protected under section 27 of the Constitution and other health related legislation as well as policies. This direct constitutional protection of the right to health places an obligation upon South African government to respect, promote and fulfil the right to

health within the available resources. This means that access to essential medicines as part of the fulfilment of the right to health is indeed enforceable through the South African Courts.

Chapter four, through giving an account on the epidemiological health crisis, has demonstrated that there is a problem of access to essential medicines in South Africa. This chapter has shown that the problem of access to essential medicines emanates primarily from varied factors which include non-patents ones. However, patents on essential medicines also inhibit access to essential medicines. The patents rules imposed by the WTO TRIPS Agreement on South Africa have led to the strengthening of intellectual property. The strengthening of intellectual property has caused pharmaceutical monopolies and market distortion, patent linkage, evergreening and deprivations of the use indigenous knowledge. All these problems have impacted negatively on access to essential medicines.

Chapter four has also noted that there are flexibilities in TRIPS which provides a potential avenue for improving access to essential medicines situation in South Africa. However, there has been little interest by South Africa to take full advantage of the TRIPS flexibilities. This is exhibited by the fact that the Patent Act which is the chief legislation governing intellectual property in South Africa fails to fully incorporate such TRIPS flexibilities. Chapter four has also demonstrated that South African Competition Commission has not been hesitant in making rulings which ensure a significant degree of the realisation of the right to health through expanding access to essential medicines for HIV and AIDS patients. However, these attempts to use Competition law to protect the right to health have been fraught with problems due to the complexity of determining excessive pricing and use of competition lexicon.

5.2 Summary of important findings of the study

On the question relating to the nature, scope and content of the right to health under international law, the study concludes that access to essential medicines is an important component of the right to health. This means that South African government is obliged to provide access to essential medicines because it has ratified a number of international instruments that protect the right to health. It has ratified the ICESCR, CEDAW, CRC and other regional human rights instruments. It

has been shown that South Africa is also a state party to the African Charter which enjoins it to provide access to essential medicines at the domestic level.

According to the CESCR, General Comment 14, access to essential medicines is a fundamental component of the right to health. The CESCR stated that the right to health in article 12.2 (d) of the ICESCR includes the provision of essential medicines “as defined by the WHO Action Programme on Essential Drugs”. The African Commission resolution on Access to Health Needed Medicines in Africa, together with Reports from the UN Special Rapporteur on the right to health, recognise that access to essential medicines is a part of the right to health. The preceding binding international human rights instruments and non-binding resolutions impose the tripartite duties to respect, protect and fulfil the right to health.

South Africa has also demonstrated its commitment towards providing access to essential medicines by incorporated the right to health into its Constitution and legislation in particular, the National health Act, the Medicines schemes Act, Medicines and Related Substances Control Act. South Africa has further sought to protect the right to health by the means of creating policy documents to advance access to health care, which includes essential medicines. Policy documents such as the White Paper on Health, the National Telemedicine Policy, and the partially implemented National Health Insurance have been adopted by South Africa to ensure the progressive realisation of the right to health. Further, the right to health has also been interpreted through case law, such as *Minister of Health v Treatment Action Campaign*, where the courts emphasising that access to essential medicines is a vital cog of the right to health.

Further, on the question relating to the impact of South Africa patent laws on the right to health, in particular access to essential medicines, the study concludes that excessive patenting of essential medicines inhibits access to them specifically for the marginalised groups who cannot afford to buy expensive medicines. The study concludes that the epidemiological health crisis presented in chapter four shows that access to essential medicines is a necessity in South Africans. The patent rules imposed on South Africa by TRIPS Agreement, together with the Patent Act, favour the protection of pharmaceutical patents to the detriment of the right to health in particular access to essential medicines. The study also concludes that patents

cause problems such as pharmaceutical monopoly, patent evergreening, patents linkages among other factors which endanger access to essential medicines. Therefore, South African patent laws stand in contradistinction to the international norms and standards imposed by the right to health, which require South Africa to provide access to essential medicines.

This chapter, therefore, posit recommendations predicated on the recognition of the right to health as a fundamental human right over patent rules in order to solve the problem of access to essential medicines. Patent protection on essential medicines must comply with the normative framework imposed by the right to health to be human rights compliant. This means that South African should deploy measures: either legislation or policy, in the context where essential medicines are patented, to guarantee access to them for the marginalised groups. Such measures must be taken by the legislature, the judiciary, and the executive together with the civil societies.

However, such measures must not only be in line with the Constitution of South Africa but must also be in line with international instruments to which South Africa is a party to. It must be noted that this dissertation does not suggest that the recognition of the right to health as a supreme right over patents laws is an end in itself, because law cannot be regarded as everything, however, it is not nothing either.⁸⁷⁴ This means that the right to health if combined with purposeful policies can go a long way in improving access to essential medicines in South Africa.⁸⁷⁵ It is also important to note that the recommendations proffered in this dissertation cannot adequately tackle the problem of access to essential medicines in South Africa. Thus, areas for further research have been identified in order to compliment the proposed recommendations, in an endeavour to expand access to essential medicines.

⁸⁷⁴MacKinnon, *Feminism unmodified: Discourses on life and law* (1987) 116.

⁸⁷⁵It must be appreciated that law can be used easily as a tool for oppression or for emancipation. However, whatever its uses, law can be an urgency for social engineering, therefore, providing an important source of empowerment, as well as an important site of legitimate resistance. See Musungu "Access to art and other essential medicines in Sub-Saharan Africa: intellectual property and relevant legislations" https://www.opensocietyfoundations.org/sites/default/files/artafrica_20090313.pdf (access ed 28/09/2015).

5.3 Legal and practical recommendations to lack of access and innovation

5.3.1 South African domestic courts should invoke the right to health

There is a plethora of cases existing in foreign jurisprudence providing an important model on how South African courts can increase access to essential medicines through the utilisation of the right to health to reinterpret or dismantle patents laws that impede access to medicines.⁸⁷⁶ Although such cases are drawn mainly from countries such as India, Kenya, Brazil and Colombia, they are a necessary compendium of judgments which provide an insight into the utility of the right to health within the context of patent protection.⁸⁷⁷ Therefore, this part intends to provide a discussion on how South African courts can expand access to essential medicines via the right to health.⁸⁷⁸

As Pieterse⁸⁷⁹ asserts:

*Rights are powerful and empowering. They enable individuals and marginalized groups within society to assert themselves against powerful entities in the public and private spheres and, thereby, to draw societal attention to their plight. Where the objects of rights include social goods or services, the rights further recast claims for access to such goods or services as moral and legal imperatives, rather than 'mere' cries for help. As such, rights at once impact on the manner in which society views delivery of social goods and services and demand accountability from those responsible for this delivery.....*⁸⁸⁰

A central concept which emanates from Pieterse's submission is that the force of the right to health or rights in general, is engraved in their nature, not simply as just

⁸⁷⁶In some instances these patents were accused of causing a surge in the prices of essential medicines by creating unnecessary monopoly thus violating the right to health and by extension other fundamental human rights. For instance, a Kenyan court struck down an "anti-counterfeiting" law on the basis that it violated the right to health in the Kenyan constitution. See Hoen: *The global politics of pharmaceutical monopoly power: drug patents, access, innovation and the application of the WTO Doha Declaration on TRIPS and Public Health* (2009) 91.

⁸⁷⁷UNDP: *Compendium of Judgments background material judicial dialogue on hiv, human rights and the law in asia and the pacific Bangkok* (2013).

⁸⁷⁸Brennan "To adjudicate and enforce socio-economic rights: South African domestic courts are a viable option" 2009 *QUTLJJ* 9 69.

⁸⁷⁹Pieterse: *Can rights cure? the impact of human rights litigation on South Africa's health system*, (2014) 1.

⁸⁸⁰*Ibid* 1 para 1.

moral persuasions but as law itself.⁸⁸¹ This view recognises the practical normative role of the right to health, which is in a large part, an indispensable component of social engineering.⁸⁸² The view is largely backed by legal scholars such as Judith Shklar⁸⁸³ who proposes, that civilisation advances when what is commonly perceived as misfortune becomes considered injustice instead.⁸⁸⁴ The implication is that human rights have the potential to determine what is considered appropriate and legitimate.⁸⁸⁵

The contemporary power of human rights as tools for social change is clearly manifested by the successful dismantlement of slavery, apartheid, colonialism and the extension of women's suffrage.⁸⁸⁶ Section 2 of the Constitution of South Africa declares that the Constitution is the supreme law of the land and that any act or omission found to be inconsistent with the provisions of the Constitution is invalid to the extent of its inconsistency.⁸⁸⁷ This means that by extension, the superior character of the Constitution of South Africa vests the right to health with a higher normative and Constitutional status over patent rights.⁸⁸⁸ Based on the concept of the supremacy of the Constitution, the government of South Africa cannot justify trumping the right to health in preference of trade interests of pharmaceuticals companies.⁸⁸⁹ Therefore, the right to health contains a transformative power which has the potential to discipline injurious patents.

There are many ways by which the right to health can be deployed to expand access to essential medicines. First, the right to health can be invoked in patent claims litigation process.⁸⁹⁰ Where a pharmaceutical company alleges that the claim for a

⁸⁸¹ Wiley "Health law as social justice" 2014 *Cornel Journal of law and Policy* 47 2.

⁸⁸²Forman "'rights' and wrongs: what utility for the right to health in reforming trade rules on medicines? 2014 *Health and Human Rights Journal* 10, 38.

⁸⁸³Brennan et al " A human rights approach to intellectual property and access to medicines" 2013. <http://apps.who.int/1d4b5c2c4a4d489699489a8d162923f6/finaldownload/downloadid666384834525121e927c0d2e295cddb0/1d4b5c2c4a4d489699489a8d162923f6/medicinedocs/documents/s20952en/s20952en.pdf> (accessed 02/10/2015).

⁸⁸⁴*Ibid* 11 para 1.

⁸⁸⁵*Ibid* 11 para 2.

⁸⁸⁶Supra 39.para 3.

⁸⁸⁷Adusei "The right to health and constitutional imperatives for regulating the exercise of pharmaceutical patent rights in Sub-Saharan Africa" 2013 *African Journal of International and Comparative Law* 2 250.

⁸⁸⁸*Ibid* 251 para B 1.

⁸⁸⁹*Ibid* 251 para B 2.

⁸⁹⁰Pieterse: Can rights cure? the impact of human rights litigation on South Africa's health system. (2014) 143.

patent for the subject matter has been infringed because of the doubt in the efficacy of the so called new version of the medicines in contest, the court must not rush to protect such a claim but rather the right must be weighed against the need to ensure that the public has access to essential medicines.⁸⁹¹ In other words, the Court must strive to strike a balance between the need to promote research and development in the manufacturing of essential medicines and to minimise private monopoly which is detrimental to the right to health.⁸⁹² The implication is that patent rights must be balanced with the need to realise the right to health. This human rights based approach to intellectual property which is heavily premised on the need to protect the right to health has become common in countries such as India.⁸⁹³

The Indian courts have used the right to health to re-interpret the provisions of the Patents Act⁸⁹⁴ which governs intellectual property.⁸⁹⁵ In *Novartis AG v. Union of India*,⁸⁹⁶ a case which revolved around whether section 3(d) of the 2005 Patent Act was constitutional and in compliance with Article 27 of TRIPS that obliges India to provide patents for new inventions, the court held that section 3(d) was consistent with the legal obligations imposed by the right to health enshrined in the supreme constitution.⁸⁹⁷ However, the Indian court refused to decide on whether the aforementioned section complied with section 27 of TRIPS, stating that the proper platform for addressing this issue was the Dispute Settlement Board (DSB) established under the auspices of the WTO TRIPS Agreement.⁸⁹⁸ In delivering its judgment, the Indian High Court justified its decision on the basis of the supremacy of the right to health in the patent approval process by articulating that:

⁸⁹¹Esalimba “Norvatis persists in challenge to the Indian Patent Law; India rejects more AIDS drugs patents” <http://www.ip-watch.org/2009/09/02/novartis-persists-in-challenge-to-indian-patent-law-india-rejects-more-aids-drugs-patents/> (accessed 04/10/2015).

⁸⁹²Narula “The rights-based approach to intellectual property and access to medicine: parameters and pitfalls”http://lsr.nellco.org/cgi/viewcontent.cgi?article=1300&context=nyu_plltwp(accessed 05/10/2015).

⁸⁹³Sellin “Justiciability of the right to health - access to medicines the South African and Indian experience” 2009 *Erasmus Law Review* 2 465.

⁸⁹⁴*Ibid* 465 para 2.

⁸⁹⁵Act No. 15 of 2005.

⁸⁹⁶(2007) 4 MLJ 1153.

⁸⁹⁷*Ibid* 6 para 2.

⁸⁹⁸The DSB is mandated to settle trade disputes among WTO members and has the sole authority to establish panels of experts to consider the case, and to accept or reject the panels’ findings or the results of an appeal. It monitors the implementation of the rulings and recommendations, and has the power to authorise retaliation when a country does not comply with a ruling. See WTO, understanding the WTO. https://www.wto.org/english/thewto_e/whatis_e/tif_e/understanding_e.pdf (accessed 06/10/2015).

*We state that in this case we have already found, analysing the alleged offending provision, that it is not in violation of Article 14 of the Constitution of India. We have borne in mind the object which the Amending Act wanted to achieve namely, to prevent evergreening; to provide easy access to the citizens of this country to life saving drugs and to discharge their Constitutional obligation of providing good health care to its citizen.*⁸⁹⁹

As observed by the Court, the rationale for this approach was that the existing patent laws had been detrimental to other public interests which include the right to health.⁹⁰⁰ This necessitates the need to clearly identify certain inventions, the grant of patents to which would retard research, or industrial progress, or be detrimental to the national health or well-being, and to make those inventions not patentable.⁹⁰¹ The Indian approach has already proven to be successful in accelerating access to essential medicines.⁹⁰² Vawda⁹⁰³ notes that India has become the “pharmacy of the poor” with an increased drug manufacturing capacity owing to the significance of the human right based approach adopted by the Indian court.⁹⁰⁴ Although India has been constantly vilified by Western governments who feel that their commercial interests were endangered by this approach, India has stood its ground to defend its constitutionally protected right to health of its citizens.⁹⁰⁵

Similarly, in *Patricia Asero Ochieng and Ors. v. Attorney General*,⁹⁰⁶ a Kenyan High Court adopted a human rights based approach to the interpretation of patent rules.⁹⁰⁷ The case involved Kenyan nationals living with HIV and AIDS who petitioned the

⁸⁹⁹Lee “Trials and TRIPS-ulations: Indian Patent Law and *Novartis Ag V. Union of India*. <http://re.indiaenvironmentportal.org.in/74f152fde48849dca923006c01f59bf6/finaldownload/downloadidd52b6206c732188e485f2668916f873/74f152fde48849dca923006c01f59bf6/files/file/trials%20and%20trips.pdf> (accessed 09/10/2015).

⁹⁰⁰Bennett “Indian pharmaceutical patent law and the effects of *Novartis Ag v. Union of India*” 2014 *Washington University Global studies Law Review* 13 577.

⁹⁰¹Bhadoria “India Pharma 2020 propelling access and acceptance, realising true potential” <http://online.wsj.com/public/resources/documents/McKinseyPharma2020ExecutiveSummary.pdf> (accessed 10/10/2015).

⁹⁰²*Ibid* 15 para 1.

⁹⁰³Vawda “After the *Novartis* judgment - ‘evergreening’ will never be the same again!” 2014 *Law democracy and Development* 18 306.

⁹⁰⁴*Ibid* 307 para 3.

⁹⁰⁵Hogerzeil et al: *Is access to essential medicines as part of the fulfilment of the right to health enforceable through the courts?* (2006) 368.

⁹⁰⁶*Ibid* 308 para 4.

⁹⁰⁷*Ibid* 315 para 2.

court challenging that the provisions of Anti-Counterfeiting Act⁹⁰⁸ which were understood broadly to include generic medicines, thus limiting access to essential medicines.⁹⁰⁹ The petitioners argued that such a broad interpretation departed from a narrow one envisaged by section 27 of the TRIPS which only limits the use of the term to counterfeit trademark goods.⁹¹⁰ The petitioners further submitted that generic HIV medicines in transit to developing countries had in fact already been confiscated in other countries due to laws similar to the repugnant provisions of the Act.⁹¹¹

After examining the scope and content of the right to health under the auspices of Kenyan and International human rights instruments, the court enforced the right to health by declaring that:

*...if a law had the effect of limiting the accessibility and availability of HIV medicines, it would ipso facto threaten the lives and health of people living with HIV in violation of their rights under the Constitution*⁹¹²

The utilisation of the right to health obligations as a tool to overthrow injurious patents has been carried to greater heights by the Thailand Court. In the *AIDS Access Foundation v. Bristol Myers-Squibb and Department of Intellectual Property*⁹¹³ the Defendant, Bristol Myers-Squibb applied for a patent for didanosine, an HIV reverse transcriptase inhibitor effective against HIV and used in combination with other antiretroviral drug therapy.⁹¹⁴ The patent claim stated that it was a better formula for oral use and stipulated the dosage from about 5 to 100 mg per dose. The defendants later amended the patent claim to delete the dosage stipulation.⁹¹⁵

⁹⁰⁸ Act 13 of 2008.

⁹⁰⁹ Durojaye and Mirugi-Mukundi “Status’s obligations in relation to access to medicines: revisiting Kenyan High Court decision in *P.A.O and Others v Attorney-General and Another*” (2013) *Law democracy and Development* 17 24.

⁹¹⁰ *Ibid* 425 para 4.

⁹¹¹ The United Nations Special Rapporteur on the Right to Health submitted arguments as an *amicus* arguing that the definition of counterfeiting in the Act succinctly confused generic medicines produced in violation of intellectual property rights with those that have been legitimately authorised. The Rapporteur maintained that this would have a serious adverse impact on the availability, affordability and accessibility of essential medicines. The Kenyan Attorney General contested that the term “generic drugs” was not the same with counterfeit drugs. See *Ibid* 25 para 4.

⁹¹² *Ibid* para 4.

⁹¹³ No. 92/2545 (2002).

⁹¹⁴ *Ibid* 1 para 1.

⁹¹⁵ *Ibid* 1 para 1.

The Thailand Court held that medicines were fundamental to the well-being of human beings and were thus distinct from other patented inventions that people may or may not choose for consumption. It stressed that treatment for the life and health of human beings was more important than other property.⁹¹⁶ The Thailand Court noted that the Doha Declaration on the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and Public Health, adopted by the World Trade Organization in 2001, declared that the TRIPS Agreement was to be interpreted and implemented to promote the rights of Member States to protect public health, particularly access to essential medicines.⁹¹⁷

The Court held that deletion of the phrase from about 5 to 100 mg per dose from the patent claim was a material amendment that granted the Defendant protection for all dosage amounts of the medicine.⁹¹⁸ The Thailand Court further held that the phrase “material to the invention” includes amounts of the medicine.⁹¹⁹ The Court ruled that the phrase “material to the invention” includes both details of the invention and the patent claim itself.⁹²⁰ The defendant’s amended patent claim went beyond the scope stipulated in the original claim and the scope of invention was thus extended beyond what was disclosed in the details of the invention.⁹²¹ The Court held that the Defendant must register the amendment of the patent, to reintroduce the dosage stipulation, or the Department of Intellectual Property would amend the claim pursuant to the Court’s ruling.⁹²²

In the same vein, Courts in Venezuela have also employed the right to health as a solution to the problem of access to essential medicines. Although much of this burgeoning case law does not involve patent claims as the cause of litigation, it is very important because it demonstrates the utility of the right to health in litigation process.⁹²³ In *López, Glenda and Ors. v. Instituto Venezolano de los Seguros Sociales*, the litigants were HIV patients who were covered by the Venezuelan

⁹¹⁶ *Ibid* 5 para 17.

⁹¹⁷ *Ibid* para 18.

⁹¹⁸ Van Puymbroeck “Basic survival needs and access to medicines - coming to grips with trips: conversion + calculation” 2010 *Journal of law, Medicines and ethics* 38 533.

⁹¹⁹ *Ibid* 533 para 2.

⁹²⁰ *Ibid*.534 para 1.

⁹²¹ *Ibid* 534 para 2.

⁹²² *Ibid* 534 para 3.

⁹²³ *Ibid* 534 para 4.

Institute of Social Security (IVSS).⁹²⁴ They filed an amparo action against the IVSS requesting that it ensure a regular and consistent supply of HIV triple-therapy medicines and other medicines necessary for treatment of opportunistic diseases, and that IVSS cover the expense of all necessary medical tests. The litigants also requested that the effect of the Court's decision be extended to all people living with HIV covered by the IVSS.⁹²⁵

The central issue in this case was whether Venezuela had an obligation to ensure the petitioners had access to treatment for HIV consistent with the obligations imposed by the right to health?⁹²⁶ The court held that the right to health obligates the state to provide access to essential medicines.⁹²⁷ The Court further held that the State was responsible and ordered it to adopt all necessary measures to guarantee access to treatment for HIV for the Petitioners and all beneficiaries of the National Programme Against AIDS.⁹²⁸ The Court considered General Comment 14 of the United Nations Committee on Economic, Social and Cultural Rights, which interprets and elaborates the right to health in Article 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR).⁹²⁹ The Court stated that under General Comment 14, Venezuela had an obligation to provide a health system that ensured equal opportunity for everyone to enjoy the highest attainable standard of physical and mental health.

The court's finding in the preceding cases demonstrates the commitment on its part to protect and enforce the right to health in the context of patent claims and non-patent situations. Hence, these courts can be commended for putting emphasis on the supremacy of human rights, in particular the right to health over trade rules. South Africa can adopt this human rights based approach to intellectual property rules because it has the potential to effectively incorporate the right to health into the interpretation of patent law. It can further be suggested that South African courts when interpreting patent laws should have due regard to other rights that have a bearing on the right to health. These rights including but not limited to the rights to

⁹²⁴UNDP: *Compendium of judgments: background material judicial dialogue on HIV, human rights and the law in Asia and the Pacific* (2013)52.

⁹²⁵*Ibid* 52 para 2.

⁹²⁶*Ibid* 52 para 2

⁹²⁷*Ibid* 52 para 2.

⁹²⁸*Ibid* 52 para 2.

⁹²⁹*Ibid* 52 para 2.

life, human dignity, equality as all of these rights are interrelated, interdependent and mutually supporting. The interpretation of patent laws through the prism of the right to health or human rights in general, may lead to the evolution of a unique South African patent law jurisprudence which is in harmony with the normative content of the right to health.⁹³⁰

5.3.1.1 Impact of health-related litigation: concrete norm creation and reconfiguration

One of the important lessons which can be deduced from the above submission is that health related litigation is a viable tool for pursuing social justice.⁹³¹ Hogerzeil *et al*⁹³² have opined that juridical action can create social change by compelling governments to comply with obligations generated by the right to health under international and national law.⁹³³ Such an important utility is especially valuable in South Africa where as indicated chapter 4, the right to health is under threat because of excessive patenting and pricing of essential medicines.⁹³⁴ This means that health related rights litigation can be useful in holding a government accountable for its failure to realise the right to health within its jurisdiction.⁹³⁵ The basic premise of this argument is that people and institutions entrusted with powers and responsibilities have the obligation to exercise such public power within the confines of the law.⁹³⁶

It must be noted that health related litigation as a strategy to hold South Africa government accountable for the egregious infringement of the health cannot achieve the desired outcome, unless cases are brought to court by vocal individuals or any

⁹³⁰Deva has noted that there is a need to bind corporate entity's activities with human rights so that they comply with human rights obligations. See Deva: *Regulating corporate human rights violations* (2012) 1.

⁹³¹Mubangizi "The constitutional protection of socio-economic human rights in selected Africa countries: A comparative evaluation" 2006 *African Journal of Legal studies* 2 3.

⁹³²Hogerzeil *et al* "Is access to essential medicines as part of the fulfilment of the right to health enforceable through the courts? http://www.who.int/medicines/news/Lancet_EssMedHumanRight.pdf (accessed on 15/10/2015).

⁹³³*Ibid* 33 para 2.

⁹³⁴Gloppen "litigation as a strategy to hold governments accountable for implementing the right to health" 2008 *Health and human rights* 10 21.

⁹³⁵Mubangizi "The right to health care in the specific context of access to HIV/ AIDS medicines: What can South Africa and Uganda learn from each other? 2010 *African Human Rights Law Journal* 10 381.

⁹³⁶London "What is a human-rights based approach to health and does it matter? 2008 *Health human rights* 10 65.

other interest group such as non-governmental organizations.⁹³⁷ Other Non-governmental organisations should join hands with TAC, MSF and Section 27 who have an admirable history of providing *pro bono* work to the marginalised members of the society who are deprived of access to essential medicines.⁹³⁸ This gesture of goodwill can go a long way in helping many potential litigants who are ignorant of their rights or unable to meet litigation costs.⁹³⁹ This will also create an opportunity for Non-governmental organization to challenge the state in court to demonstrate that it has employed the available resources maximally towards the realisation of the right to health.⁹⁴⁰

The implication of this health-related litigation is that it provides a template on how South African courts can use the right to health to set recreate norms governing patent rules so that they become amicable to access to essential medicines or improve the flexibility of legal standards used in IP cases.⁹⁴¹ In other words, it erects a new norm which is cognisant of the pre-eminence of the constitutional right to health and help to establish a legal precedent that lower courts in South African can draw upon.⁹⁴² The outcomes of this health related litigation is a necessity for South African lower courts because it helps to articulate and refine a set of legal arguments that they can use to strike down patents rules which inhibit access to essential.⁹⁴³

Further, the articulation of human rights norms and standards in South Africa courts has an impact on other branches of government. As the *Treatment Action Campaign* case discussed earlier demonstrates that court cases often spur executive and legislative action. It can be noted that as a consequence of this health related litigation the executive and legislative branches began to make necessary steps and

⁹³⁷Pieterse “The potential of socio-economic rights litigation for the achievement of social justice: considering the example of access to medical care in South African prisons” 2006 50 *Journal of African Law* 50 118.

⁹³⁸Heywood “Drug access, patents and global health: ‘chaffed and waxed sufficient’” 2002 23 *Third World Quarterly* 23 217.

⁹³⁹Gorge “The human right to health and HIV/AIDS: South and South-South cooperation to reframe global intellectual property principles and promote access to essential medicines” (2011) *Indiana Journal of Global Legal Studies* 18 187.

⁹⁴⁰Hepcoalition “The critical role of civil society in shaping the market for antiretroviral therapy and direct-acting antiretroviral”http://hepcoalition.org/IMG/pdf/report_on_civil_society_april_1_2015_1-2.pdf (accessed 19/10/2015).

⁹⁴¹Gloppen “Litigating health rights: framing the analysis, in litigating health rights: can court bring more justice to health?” 2012 *Osgoode Hall Law Journal* 49 597.

⁹⁴²Wu “Raising the right to health concerns within the framework of international intellectual law” 2010 *Asian Journal of WTO and International Health Law and Policy* 5 141.

⁹⁴³*Ibid* 146 para 2.

action in line with the declaratory order granted by the court. In Brazil, the government has been prompted by health related-litigation to speak the language of human rights as a justification for its actions.⁹⁴⁴ For example, it has employed human right arguments to justify its compulsory license on HIV medication Efavirenz.⁹⁴⁵ In the press release announcing this compulsory license, the Brazilian government invoked the “fundamental human right to health.”⁹⁴⁶ In sum, it is pertinent to note that the articulation of the right to health norms at the judicial level can lead to the formation of new norms which are consistent with access to essential medicines.

5.3.2 Supporting initiatives of establishing a framework Convention on Global Health

As indicated in chapter four, many of the pharmaceutical companies are transnational companies making the problem of access to essential medicines beyond the control of South Africa only.⁹⁴⁷ The existing human rights framework, however, does not adequately address this issue. This means that South Africa should back initiatives to establish a framework convention on global health which improves global coordination, cooperation and collaboration in order to address the problem of access to essential medicines.⁹⁴⁸ It can be suggested that the convention may be anchored on Article 12 of ICESCR, General Comment No. 14, the UDHR, the Constitution of the WHO and other important human rights instruments.

It can be maintained that a global framework convention provide legally rules which place the right to health at the centre of global health policy and global governance

⁹⁴⁴Brennan et al “A human rights approach to intellectual property and access to medicines” Global Health Justice Partnership Policy Paper 1 September 2013 Yale Law School and Yale School of Public Health. <http://apps.who.int/medicinedocs/documents/s20952en/s20952en.pdf> (accessed 25/10/2015).

⁹⁴⁵Matthews “When framing meets law: using human rights as a practical instrument to facilitate access to medicines in developing countries” <http://www.pijip-impact.org/wp-content/uploads/2013/01/When-Framing-Meets-Law-Using-Human-Rights-as-a-Practical-Instrument-to-Facilitate-Access-to-Medicines-in-Developing-Countries-Matthews.pdf> (accessed 26/10/2015).

⁹⁴⁶*Ibid* 19 para 1.

⁹⁴⁷Grover the UN Special Rapporteur on the Right to Health has revealed that the idea, though young, is gaining momentum and it has been tabled upon at different international platforms such as the Workshop on Democratising Global Health Governance held in Geneva, May 2010 and the Regional Dialogue on the Right to Health which took place in Johannesburg, March 2011. See Kickbusch et al “A new governance space for health” http://www.globalhealthaction.net/index.php/gha/article/view/23507/pdf_1 (accessed 28/10/2015).

⁹⁴⁸Goskin “Towards a framework Convention on Global health” 2013 <file:///C:/Users/Downloads/WHO%20Bulletin%20Framework%20Convention%20Gostin%20et%20a%202013.pdf> (accessed on 28/10/2015).

for health.⁹⁴⁹ This instrument would clarify the obligations of non-state entities, including pharmaceutical companies, under the right to health.⁹⁵⁰ Such a framework convention has the potential to reform global health governance to strengthen the voice of the marginalized people who are most affected by global health burdens and inequities.⁹⁵¹ Further, the creation of the framework convention would be an inclusive, participatory, community-driven process that includes the participation of all relevant stakeholders.⁹⁵² This would provide an important platform for the participation of affected communities, particular those from the developing countries such as South Africa seeking to address the issue of access to essential medicines.⁹⁵³

It can be noted that the idea of creating a global framework convention is currently gathering a lot of momentum among legal scholars.⁹⁵⁴ Some scholars have suggested that the framework convention may include a chapter that addresses the impact of non-state entities on global health and the realization of the right to health.⁹⁵⁵ They envisage the development of the obligations of pharmaceutical companies from the soft law such as the "Norms on the Responsibilities of Transnational Corporations and Other Business Enterprises with Regard to Human Rights," which preceded the "Guiding Principles on Business and Human Rights: Implementing the United Nations 'Protect, Respect and Remedy' Framework" discussed earlier.⁹⁵⁶ Other commentators also suggest that the global framework should have three chief functions namely (a) adjudicatory, (b) investigatory, and (c) promotional.⁹⁵⁷

⁹⁴⁹Friedman and Gostin "Pillars for progress on the right to health: harnessing the potential of human rights through a framework convention on global health" 2012 *Health and Human Rights: An International Journal* 14 4 19.

⁹⁵⁰*Ibid* 4 para 1.

⁹⁵¹*Ibid* 4 para 2.

⁹⁵²Brolan *et al* "Global governance for universal health coverage: could a framework convention on global health hold it together?" 2013 *Global Health Governance* VI 7.

⁹⁵³*Ibid* VI para 2.

⁹⁵⁴Centre on Global Health Security "Analysing proposals for reform of the global health architecture"https://www.chathamhouse.org/sites/files/chathamhouse/field/field_document/20150803_GlobalHealthArchitectureSchaferhoffSchradeSuzuki.pdf (accessed 30/10/2015).

⁹⁵⁵Supra 868 para 7.

⁹⁵⁶Heywood and Shija "A global framework convention on health - would it help developing countries to fulfil their duties on the right to health? a South African perspective"<http://www.section27.org.za/wp-content/uploads/2010/11/Heywood-Shija.pdf> (accessed 29/10/2015).

⁹⁵⁷Médecins sans Frontières (MSF) *Access to Essential Medicines Campaign, Untangling the Web of Price Reductions: A Pricing Guide for the Purchase of ARVs for Developing Countries* (2005)3.

In the same vein, the adjudicatory function will consist of a judicial committee which will be responsible for making binding judicial decisions enforceable under international law.⁹⁵⁸ Since the judicial committee will be adjudicating claims against pharmaceutical companies' relation to access to essential medicines, it should be comprised of experts in human rights and the right to health, the pricing practices of pharmaceutical and intellectual property law.⁹⁵⁹ One representative from the State where the pharmaceutical company involved is domiciled should be a voting member of the judicial committee.⁹⁶⁰ The judicial committee should be given jurisdiction to hear all complaints involving pharmaceutical companies' conduct domiciled in states parties to the framework convention as well as those involving acts or omissions that occurred in the jurisdiction of a state party.⁹⁶¹

In the same light, empowering the judicial committee under the auspices of this proposed global framework with extra-territorial jurisdiction is essential to ensure full liability for violations of the right to health.⁹⁶² The framework convention could provide remedies to individuals and groups for the infringement of their right to health and failure to address deficits under the right to health in relation to access to essential medicines.⁹⁶³ The framework convention should provide sufficient compensation for such infringement which could be in form of guarantees of minimum monetary compensation for victims, non-repetition, commitments to research and development priorities for neglected diseases, and the granting of compulsory licenses.⁹⁶⁴ These remedies should be available under international law pursuant to adjudication by the judicial committee, and they should be incorporated into domestic law by South Africa and available pursuant to domestic litigation.⁹⁶⁵

⁹⁵⁸Toebes "The framework convention on global health: considerations in light of international law"<http://poseidon01.ssrn.com/delivery.php?id=672090112009084083110120092021087076109020070981230641101140950981061270350130150980030640681220990301055410491171260700288201508311303608708402800012110011310000010706911811811240071069016001064111089125127030001117&ext=pdf> (accessed 02/11/2015).

⁹⁵⁹Sidibé and Buse, "A framework convention on global health: a catalyst for justice" 2012 *Bulletin of the World Health Organization* 870.

⁹⁶⁰*Ibid* 870 para 3.

⁹⁶¹*Ibid* 80 para 3.

⁹⁶²Gostin "The quest for global justice in health: a review of global health law by Lawrence" 2015 *Yale Journal of Health Policy, Law, and Ethics* 5 4.

⁹⁶³*Ibid* 385 para 1.

⁹⁶⁴*Ibid* 385 para 2.

⁹⁶⁵*Ibid* 385 para 3.

Additionally, in order to sponsor remedies provided by the judicial committee, a convention fund may be created comprised of taxes levied on pharmaceutical companies by the state in which they are domiciled.⁹⁶⁶ Such an access to essential medicines tax may be based upon the companies' compliance with the obligations in the framework convention; companies with poor records would be required to pay more taxes than those who fare better under review by the convention body.⁹⁶⁷ The funds would be used to provide compensation to individuals or groups found by the judicial committee to be victims of violations of the right to health, including access to essential medicines.⁹⁶⁸ However, such remedies may be used to finance other remedies, including the granting of compulsory licenses, directed research and development of neglected disease.⁹⁶⁹ The financing of this sort may create an incentive for states parties to grant permission to the judicial committee to adjudicate complaints because it will reduce the costs associated with administering remedies under domestic law.⁹⁷⁰

Moreover, the convention body would also be charged with two investigative duties.⁹⁷¹ First, it would conduct annual reviews of the world's major pharmaceutical companies to determine their compliance with the right to health in relation to access to essential medicines.⁹⁷² This could take the shape of a rotating annual review similar to the Universal Periodic Review conducted by the Human Rights Council.⁹⁷³ This means that pharmaceutical companies would be required to report periodic on their compliance with the obligations under the framework convention, including activities undertaken to promote the right to health in relation to access to essential medicines.⁹⁷⁴ The convention body would also receive submissions from

⁹⁶⁶Halabi "Multipolarity, Intellectual property, and the internationalisation of public health law" 2014 *Michigan Journal of international law* 35 718.

⁹⁶⁷*Ibid* 718 para 2.

⁹⁶⁸*Ibid* 720 para 1.

⁹⁶⁹Schaferhoff: *Analysing proposals for reform of the global health architecture* (2015)22.

⁹⁷⁰*Ibid* 24 para 1.

⁹⁷¹Gostin, "Transforming global health through broadly imagined global health governance" 2010 *McGill Journal of Law and Health* 4 3.

⁹⁷²*Ibid* 9 para 2.

⁹⁷³*Ibid* 13 para 3.

⁹⁷⁴Haffeld and Røttingen "Examining the global health arena: strengths and weaknesses of a convention approach to global health challenges" 2010 *Journal of Law, Medicine and Ethics* 38 614.

stakeholders, including civil society and community based groups to be included in the review process.⁹⁷⁵

Secondly, the convention body would investigate urgent complaints and allegations received from individuals or groups concerning on going gross violations of the right to health in relation to access to medicines.⁹⁷⁶ Such a process may include fact-finding missions conducted by a task force from the convention body with the assistance of the Office of the High Commissioner for Human Rights and the Human Rights Council and communication with the pharmaceutical company involved.⁹⁷⁷ The mission's findings may be used as input into ongoing or future domestic litigation or adjudication by the judicial committee. The convention body may also serve a promotional function directed toward the identification and publication of best practices of pharmaceutical companies under the right to health in relation to access to essential medicines.⁹⁷⁸

In sum, the promotional activities would be used to clarify what is required of pharmaceutical companies in order to meet their obligations under the framework convention and to promote uniform practices and codes of conduct across the industry.⁹⁷⁹ For example, the convention body may coordinate stakeholder meetings involving states, pharmaceutical companies and affected communities in order to promote open dialogue and discussion concerning challenges and best practices.⁹⁸⁰ The convention body may also draft a template code of conduct for pharmaceutical companies, with the participation of affected communities, based on the former Special Rapporteur's Guidelines.⁹⁸¹ Pharmaceutical companies may use the template as the basis for their own codes of conduct. Indeed, this global convention can be a milestone towards the improvement of access to essential medicines.

⁹⁷⁵ *Ibid* 618 para 2.

⁹⁷⁶ Heywood and Shija "A global framework convention on health: would it help developing countries to fulfil their duties on the right to health?" <http://www.section27.org.za/wp-content/uploads/2010/11/Heywood-Shija.pdf> (accessed on 27/10/2015).

⁹⁷⁷ Global Fund "The framework document of the global fund to fight AIDS, Tuberculosis and Malaria," http://www.theglobalfund.org/documents/TGF_Framework.pdf (accessed 28/10/2015).

⁹⁷⁸ *Ibid* 13 para 12.

⁹⁷⁹ Burris and Anderson, "A framework convention on global health: social justice lite, or a light on social justice?" 2010 *Journal of Law, Medicine and Ethics* 38 3 580.

⁹⁸⁰ *Ibid* 581 para 1.

⁹⁸¹ *Ibid* 581 para 2.

5.3.3 Amending the Patent Act.

Legal scholars and policy makers generally agree that the provisions of the Patents Act which pose a threat to accessing to essential medicines need to be amended.⁹⁸² As stated before, the process of amending these provisions has already begun through the adoption of Draft Intellectual Policy. The Draft Intellectual Property Document contains several recommendations relating to how Intellectual property rules can be amicable to the issue of access to essential medicines.⁹⁸³ The policy document suggests that the government of South Africa should adopt a hybrid procedure for granting of patents by considering approving the establishment of a substantive search and examination system of patent applications to ensure that patents which are granted are not weak one.⁹⁸⁴ This has an advantage of providing a strict patenting procedure which ensures that competition principles are not unreasonably undermined.⁹⁸⁵

It can be suggested that the criteria of inventiveness, contained in the Patent Act must be changed to eliminate the granting of weak patents.⁹⁸⁶ South Africa should couch the provision relating to inventiveness in the same way that India has done. India has set the bar high by inserting section 3 (d) of the 2005 Patent Act precluding from patent any product that amounts to be 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. The Indian patent law also requires that any derivative of a known substance to differ significantly in properties with regard to efficacy to qualify for patent.⁹⁸⁷

This focus on "efficacy" distinguishes section 3 (d) from the minimum patentability standards required under Article 27(1) in TRIPS, which mandate that patents should be available for any inventions provided that they are new, involve an inventive step

⁹⁸²UNDP et al "Using competition law to promote access to health technologies: a guidebook for low- and middle-income countries" 30.

⁹⁸³Director General, Department of Trade and Industry "Draft National Policy on Intellectual Property, Invitation on the Public to make Comment on National Policy on Intellectual Property" <http://ipunit.org/wpcontent/uploads/2013/09/DRAFT-IP-POLICY.pdf> (accessed 28/10/2015).

⁹⁸⁴*Ibid* 10 para 2.

⁹⁸⁵*Ibid* 31 para 3.

⁹⁸⁶Bazzle "Pharmacy of the developing world: reconciling intellectual property rights in India with the right to health: trips, India's patent system and essential medicines" (2010) *George Town journal of international law* 42 785.

⁹⁸⁷*Ibid* 801 para 1.

and are capable of industrial application.⁹⁸⁸ The insertion of the efficacy requirement within the Patent Act will ensure that patents are not granted in circumstances where there is no innovation on the original or dependent patents. In addition, requiring evidence of efficacy could be a profitable move to combat the pernicious practice of "evergreening" pharmaceutical patents, a process whereby drug companies artificially extend their period of patent exclusivity by patenting trivial secondary elements of their patented medicines when the underlying patent is set to expire.⁹⁸⁹

The Draft Intellectual Property Document policy also recommends that South Africa should consider amending the Patent Act so that it has the pre-and post-opposition of patents.⁹⁹⁰ This provides a window to oppose weaker patents after or before they have been granted. The procedure has been used in India where it has proven to be useful in challenging patents which do not meet the requirement of novelty.⁹⁹¹ Currently, South Africa does not provide such a facility.⁹⁹² Further, the Draft Intellectual Property policy recommends that a cost and benefit analysis should be conducted before implementing some of the patent-related recommendations.⁹⁹³ A cost and benefit analysis should be conducted through the Regulatory Impact Assessment (RIA) process, and benchmarks should be based on similar economies such as India, Kenya, Brazil and Venezuela.⁹⁹⁴ The cost and benefit should not only be calculated in monetary terms, as access to public health does not necessarily translate into monetary value.⁹⁹⁵

On the issue of disclosure of information in patents, the Draft Intellectual Property policy recommends that on expiry of a 20 year patent monopoly, patent information must be disclosed for use by the public.⁹⁹⁶ It can be further suggested that there must

⁹⁸⁸ *Ibid* 801 para 2.

⁹⁸⁹ Hanefeld "Patent rights v patient rights: intellectual property, pharmaceutical companies and access to treatment for people living with HIV/AIDS in Sub-Saharan Africa" 2002 *Feminist Review* 72 84.

⁹⁹⁰ Director General, Department of Trade and Industry "Draft National Policy on Intellectual Property, Invitation on the Public to make Comment on National Policy on Intellectual Property" <http://ip-unit.org/wpcontent/uploads/2013/09/DRAFT-IP-POLICY.pdf> (accessed 28/10/2015).

⁹⁹¹ *Ibid* 13 para 1.

⁹⁹² *Ibid* 13 para 2.

⁹⁹³ Hoen " Access to cancer treatment A study of medicine pricing issues with recommendations for improving access to cancer medication" <https://www.google.co.za/#q=Access+to+cancer+treatment+A+study+of+medicine+pricing+issues+wit+h+recommendations+for+improving+access+to+cancer+medication> (accessed 29/10/2015).

⁹⁹⁴ *Ibid* 20 para 1.

⁹⁹⁵ *Ibid* 20 para 2.

⁹⁹⁶ *Ibid* 21 para 1.

be a provision welded in the Patent Act that penalise pharmaceutical companies seeking to conceal the information in a patent after the patent has expired. On misappropriation of indigenous knowledge, South Africa should develop a system which compels the disclosure of the origin of the genetic resource or knowledge, prior informed consent, benefit-sharing or co-ownership of the patents if indigenous knowledge was used.⁹⁹⁷

It can be suggested that when amending the Patent Act, South Africa should recognise the need to adopt a more health-sensitive patent policy including implementing a patent law containing a number of very significant safeguards, including: strict patentability criteria just like India as mentioned above to limit the number of patented medicines, coupled with an effective system which provides a possibility for anyone to oppose the granting of a patent. These drastic changes to the Patent Act will go a long way in tackling the problem of access to essential medicines.

5.3.4 Use of TRIPS flexibilities to protect the right to health

As indicated in chapter four, the WTO TRIPS Agreement has patents flexibilities designed to facilitate access to essential medicines.⁹⁹⁸ According to the Doha Declaration on the TRIPS Agreement and Public Health, developing countries like South Africa can use TRIPS flexibilities to expand access to essential medicines.⁹⁹⁹ The first flexibility is found in Article 30 of the TRIPS Agreement which provides for exceptions to the exclusive rights bestowed upon the patent holder, 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.¹⁰⁰⁰

Hestermeyer¹⁰⁰¹ notes that Article 30 provides two types of flexibilities that are research and regulatory related.¹⁰⁰² The research related flexibility permits

⁹⁹⁷ *Ibid* 21 para 2

⁹⁹⁸ Bird "Developing nations and compulsory license: maximising access to essential medicines while minimising investment side effects" 2009 *Journal of Law, Medicine and Ethics* 37 209.

⁹⁹⁹ Johnson "Strategies to balance patent law and low cost access to medicines" 2005 *Brown Journal of World Affairs* XII 169.

¹⁰⁰⁰ *Ibid* 169 para 2.

¹⁰⁰¹ Herstermeyer "*Human rights and the WTO: the case of patents and access to medicines*" (2007) 14.

¹⁰⁰² *Ibid* 14 para 2.

researchers to use the patented invention for further research without the consent of the patent owner. The regulatory related flexibility allows generic manufacturers to use the patented invention prior to the expiry of the patent. In order to effectively utilise these flexibilities South Africa should amend the Patent Act to incorporate these flexibilities contained in Article 30 of TRIPS Agreement.¹⁰⁰³ Another important flexibility under TRIPS is the ability to issue compulsory licenses in the event of a national emergency or a circumstance of extreme urgency stipulated in Article 31.¹⁰⁰⁴

Although compulsory licensing is a viable alternative of securing access to essential medicines, criticism has been levelled against the requirements of obtaining it.¹⁰⁰⁵ Many countries which have attempted to use it have complained that the requirements are cumbersome to export or importing essential medicines.¹⁰⁰⁶ A country exporting essential medicines is required to issue a compulsory license in order to export the medicines to the importing country facing a public health crisis.¹⁰⁰⁷ The requirements become even more obnoxious in circumstances where the essential medicines are patented in the importing country, the importing country is obliged to issue a second compulsory license. This explains why developing countries have submitted recommendations for changing the requirements of obtaining compulsory to TRIPS Council.¹⁰⁰⁸

Further, another plausible criticism against Article 30 and 31 is that the bipartite provisions although they can be said to be amicable to the problem of access to essential medicines, they do not take a pure right to health approach to intellectual property protection.¹⁰⁰⁹ These two provisions endeavour to strike a balance between the right to intellectual property and public health. From a human rights perspective,

¹⁰⁰³Ndlovu "The WTO TRIPS Agreement and access to medicines in South Africa twenty years into democracy"http://www.researchgate.net/publication/272293198_the_wto_trips_agreement_and_access_to_medicines_in_South_Africa_twenty_years_into_democracy (accessed 12/06/2014).

¹⁰⁰⁴Historically, developed countries such as Canada, the United Kingdom and the US have utilised compulsory licencing to provide essential medicines for either military or public use. Perhaps, it is plausible to say that South Africa should take heed to these successful stories and implement them within her domestic province. See Xiong "Pharmaceutical Patents in the TRIPS Agreement and the Right to Health- Can These Rights Be Reconciled?" 2013 *Austria Law Review* 36 140.

¹⁰⁰⁵Comides "European Union adopts regulation on compulsory licensing of pharmaceutical products for export" 2007 *The Journal of World Intellectual Property* 10 46.

¹⁰⁰⁶*Ibid* 140 para 2.

¹⁰⁰⁷Arno and Feiden: *Against the odds: the story of Aids drug development, politics and medicines* (1992) 6.

¹⁰⁰⁸Clarke et al "Patent pools: a solution to the problem of access to biotechnology patents?" <http://www.usptogov/web/offices/pa/dapp/opla/patentpool.pdf> (accessed 28/10/2015).

¹⁰⁰⁹*Ibid* 10 para1.

this shallow approach is unwarranted because it puts at par the right to health with intellectual property which is very misleading. It can be suggested that the right to health must be viewed as a supreme right capable of imposing a superlative norm which overrides all trade rules.¹⁰¹⁰

Notwithstanding the criticism, the use of Article 30 and 31 TRIPS flexibilities has been extensive.¹⁰¹¹ For instance, countries like Brazil and Thailand are using them for expanding access to essential medicines. Brazil is utilising compulsory licencing to secure access to second-line ARV medicines for treating HIV and AIDS.¹⁰¹² On the other hand, Thailand is employing compulsory licencing as a method for increasing access to NCDs. The Thailand case study provides an important model which can be emulated by South Africa.¹⁰¹³

Further, South Africa must support generic manufacturers through dispensing soft loans or any other incentives such as tax cuts to attract pharmaceutical companies who might want to produce generic medicines.¹⁰¹⁴ This must be coupled with public education campaigns to disseminate information about generic medicines to consumers.¹⁰¹⁵ Lack of generic information can be a hindrance for the poor to access these essential medicines.¹⁰¹⁶ It is estimated that one-third of the most expensive medications used to treat cardiovascular diseases has generic equivalents or a lower cost therapeutic alternative.¹⁰¹⁷ Astonishingly, prescribers, consumers, and physicians frequently lack accurate information about the cost of generic medicines and quality that would enable them to make cost-effective choices.¹⁰¹⁸ South Africa

¹⁰¹⁰Section 27 “South Africa: stop blindly handing out patents!” <http://www.section27.org.za/wp-content/uploads/2013/10/press-release-south-africa-stop-blindly-handing-out-patents.pdf> (accessed 29/10/2015).

¹⁰¹¹Du Plessis “The TRIPS Agreement and South African legislation: the case of the parallel importation of medicines” (1999) *Law, Democracy and Development* 4 62.

¹⁰¹²Baker “Arthritic flexibilities for accessing medicines: analysis of WTO action regarding Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health” 2004 *Indiana International and Comparative Law Review* 14 614.

¹⁰¹³Zaheer and Riaz “Flexibilities under TRIPS: implementation gaps between theory and practice” 2013 *Nordic Journal of Commercial Law* 1 3.

¹⁰¹⁴Tironi “Pharmaceutical pricing: a review of proposals to improve access and affordability of prescription drugs” 2010 *Annals of Health Law* 19 344.

¹⁰¹⁵*Ibid* 344 para 1.

¹⁰¹⁶*Ibid* 344 para 2.

¹⁰¹⁷*Ibid* 356 para 2.

¹⁰¹⁸*Ibid* 356 para 2.

could save a large amount of money through an education programme which informs consumers about cheap generic alternatives.¹⁰¹⁹

5.3.5 Amending South Africa's Competition Act

South African competition law has the potential to tame the monopoly created by patents to ensure that there is access to essential medicines.¹⁰²⁰ However, for Competition law to effectively discipline patent monopoly there is a need to ensure that it is aligned with the obligations imposed by the right to health. This can be achieved through making certain crucial legal changes to the chief legislation governing competition law in South Africa, the Competition Act.¹⁰²¹ From *Treatment Action Campaign v Bristol-Myers Hazel Tau and Others and GlaxoSmithKline and Boehringer Ingelheim* (GSK) discussed in chapter four, it was clear that in order for the complainants to succeed in challenging high pricing of essential medicines they have to overcome technical aspects such as defining market definition, proving existence of firm's dominance, and excessive pricing among others. Avafia and Berger¹⁰²² *et al*, note that with each requirement, the chances of mounting a successful challenge for proving unjustifiable pricing of essential medicines diminished.¹⁰²³

It can be suggested that as a way of eliminating such sophisticated requirements the Competition Act should be modified to ensure that it provides clearer direction on how it relates to patent monopoly and compulsory licencing.¹⁰²⁴ Currently, the Act is salient as to whether compulsory licensing is permissible or not. This is further worsened by the fact that section 58(1) of the Competition Act does not explicitly mention compulsory licensing.¹⁰²⁵ It is not clear whether or not its provisions permit the issuing of a compulsory license. Further, whether or not Section 58(1) is

¹⁰¹⁹Clark "Using law to fight a silent epidemic,: the role of health literacy in health care access, quality and cost" 2011 *Annals of Health Law* 20.

¹⁰²⁰Supra 939 para 13.

¹⁰²¹Avafia *et al* "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"<http://apps.who.int/medicinedocs/documents/s18249en/s18249en.pdf> (accessed on 23/07/2015).

¹⁰²²*Ibid* 10 para 1.

¹⁰²³*Ibid* 16 para 2.

¹⁰²⁴WHO *at et* "Promoting access to medical technologies and innovation intersections between public health, intellectual property and trade"https://www.wto.org/english/res_e/booksp_e/pantiwhowipowtweb13_e.pdf (accessed 24/07/2015).

¹⁰²⁵Sell "TRIPS-plus free trade agreements and access to medicines" 2007 *Liverpool Law Review* 28 41.

interpreted as empowering the Competition Commission or Tribunal to grant a compulsory license following a finding of prohibited excessive pricing of a patented product will depend on whether the Tribunal and the Appeal Court view the subsection as a closed list of permitted orders, and how, when and to what extent they interpret what is meant by an appropriate order.¹⁰²⁶

In the same vein, the above untenable situation can be reversed by inserting a clear provision which recognizes the granting of a compulsory license as appropriate relief for certain forms of prohibited conduct.¹⁰²⁷ Such an amendment will provide clarity and avoid unnecessary litigation.¹⁰²⁸ It is pertinent to note that the amendment of section 58 should provide the following minimum elements (a) an express recognition that the Competition Tribunal has the power to order the granting of compulsory licensing (b) detailed provisions relating to the amount of the royalty to be paid, such as 4% or 5%, for example; c) An express mechanism to adjust the royalty rate either upwards or downwards in exceptional circumstances, taking into consideration a range of factors, such as the actual research and development undertaken by the patentee in respect of the patented product concerned.¹⁰²⁹

Lastly, it can be suggested that the Competition Commission should use its powers enshrined in section 79 (1) of the Competition Act to design guidelines which outline its approach to patent law and competition law interface.¹⁰³⁰ Although such guidelines will not be binding per se, they will provide crucial direction for all role players, including both holders of exclusive rights in patents as well as consumers.¹⁰³¹ It can also be submitted that the Commission should be empowered to make resources available to complainants, such as access to certain information held by

¹⁰²⁶ *Ibid* 41 para1.

¹⁰²⁷ Abbott *et al.* *Using competition law to promote access to health technologies. A guidebook for low- and middle-income countries* (2014)5.

¹⁰²⁸ Elliott "Patents, international trade law and access to essential medicines, Canadian HIV/AIDS legal network" <http://www.aidslaw.ca/Maincontent/issues/cts/Patents-international-trade-lawandaccess> (accessed 27/09/2015).

pdf

¹⁰²⁹ Niada "The human right to medicine in relation to patents in Sub-Saharan Africa: some critical remarks" (2011) 15 *The International Journal of Human Rights* 15 700.

¹⁰³⁰ *Ibid* 7 para 2.

¹⁰³¹ Anderson "The conflict between intellectual property rights and the right to health of AIDS victims in South Africa" www.globalpolitics.net/essays/Lisa_Anderson.pdf (accessed 29/10/2015).

pharmaceutical companies that is ordinarily inaccessible.¹⁰³² This will go a long way in helping the complainants to build a strong case against pharmaceutical companies who abuse their patent monopoly by charging high prices on essential medicines.¹⁰³³ The development of guidelines with a clear cut approach of Competition law to patent law will be essential for harmonising the two areas of law and provide guidance to adjudicators.¹⁰³⁴

5.3.6 Price reductions and price differentiation

Price reduction or price differentiation is an important concept that can be used to improve access to essential medicines.¹⁰³⁵ The concept refers to a situation where pharmaceutical companies agree to sell their products at lower prices in developing countries.¹⁰³⁶ The concept implies that pharmaceutical company will be selling their medicines at production cost in low income countries whilst pursue this system in middle income countries, with prices there not at marginal costs, but slightly higher.¹⁰³⁷ The feasibility of this approach has already been proven by pharmaceutical companies such as the GSK who employ strategies such as offering discounts for certain types of customers, setting the prices of patented medicines according to the generic equivalents, issuing voluntary licenses to generic manufacturer and donating essential medicines as part of their corporate social responsibility programmes.¹⁰³⁸

It must be noted that due to increased globalisation and integration of world's market price differentiation has proven to be problematic.¹⁰³⁹ Pharmaceutical companies are shunning price differentiation because it is promoting parallel importation thus stifling

¹⁰³² Mackenzie and Langbridge "Expanding the frontiers of abuse of dominance - The Astrazeneca case and its implications for South Africa" <http://www.compcom.co.za/wp-content/uploads/2014/09/Astrazeneca-Conference-Paper-FINAL.pdf> (accessed 25/07/2015).

¹⁰³³ *Ibid* 18 para 1.

¹⁰³⁴ Avafia *et al* "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" <http://apps.who.int/medicinedocs/documents/s18249en/s18249en.pdf> (accessed on 23/07/2015).

¹⁰³⁵ The concept of price differentiation has its origin in the concept of equity pricing propounded WHO. The basic premise of this concept is to cushion developing countries from paying the same prices for medicines that developed countries with strong economies does. See World Health Organisation "Measuring medicine prices, availability, affordability and price components" http://www.who.int/medicines/areas/access/OMS_Medicine_prices.pdf (accessed 27/07/2015).

¹⁰³⁶ *Ibid* 214 para 1.

¹⁰³⁷ *Ibid* 214 para 2.

¹⁰³⁸ *Ibid* 215 para 2.

¹⁰³⁹ Cohen-Kohler and Illingworth: *Access to medicines and the role of corporate social responsibility: the need to craft a global pharmaceutical system with integrity* (2008) 363.

competition.¹⁰⁴⁰ Consequently, because of globalised markets, medicines with lower prices in poor countries will end up appearing on the markets of developed countries, thereby infringing the patent rights of pharmaceutical companies.¹⁰⁴¹

5.3.7 The use of voluntary mechanisms and corporate social responsibility

Over the years, external pressure exerted chiefly by UN, Consumers and Civil Organisations, has driven some pharmaceutical companies to adopt self-imposed codes of conduct meant to address concerns related to labour practices, environmental impacts, and human rights.¹⁰⁴² These codes exist in assorted form including corporate governance, corporate social responsibility initiatives, declaration principles, human rights guidelines, and other voluntary mechanisms.¹⁰⁴³ An important characteristic of some of these voluntary mechanisms is that they are grounded upon the recognition of the right to health as one of the fundamental human rights which must be respected in the course of pharmaceutical company's operations.¹⁰⁴⁴ Although these voluntary mechanisms are not enforceable *per se*, they can be regarded as a good starting points of exploring the panacea to the problem of access to essential medicines.¹⁰⁴⁵

It is crucial to note that a lot of these voluntary mechanisms may be understood to fall within the auspices of the corporate social responsibility, which can be loosely defined as any attempt to get corporations to behave responsibly on a voluntary basis out of ethical or bottom-line considerations.¹⁰⁴⁶ A good example of such attempts is the Sullivan Principles which offered guidance for Transnational Companies conducted business in South Africa during apartheid era.¹⁰⁴⁷ Many, if not

¹⁰⁴⁰ *Ibid* 363 para 1.

¹⁰⁴¹ *Ibid* 363 para 2.

¹⁰⁴² Droppert and Bennett "Corporate social responsibility in global health: an exploratory study of multinational pharmaceutical firms" 2015 *Globalisation and Health* 1186 1.

¹⁰⁴³ Moon "Respecting the right to access to medicines: implications of the UN Guiding Principles on Business and Human Rights for the pharmaceutical industry" 2013 *Health and human rights* 15 1.

¹⁰⁴⁴ Adusei "The right to health and constitutional imperatives for regulating the exercise of pharmaceutical patent rights in sub-Saharan Africa" 2013 *African Journal of International and Comparative Law* 2 250.

¹⁰⁴⁵ Wu "Transnational Pharmaceutical corporations legal and moral human rights responsibilities in relation to access to medicines" 2012 *Asian Journal of WTO & International Health Law and Policy* 7 79.

¹⁰⁴⁶ Oxfam *at et* "Beyond Philanthropy: the pharmaceutical industry, corporate social responsibility and the developing world" http://www4.dr-rath-foundation.org/pdf-files/beyond_philanthropy.pdf (accessed 24/07/2015).

¹⁰⁴⁷ The United Nations "The social responsibility of transnational corporations" http://unctad.org/en/Docs/poiteiitm21_en.pdf (accessed 01/02/2015).

all, of the world's biggest pharmaceutical companies have adopted a code of conduct issuing a separate statement addressing their efforts toward improving access to essential medicines.¹⁰⁴⁸ Interestingly, only one statement among an ocean of statements issued mention human rights or the right to health. From a right to health perspective, this weakness makes it impossible for one to rely on the sole use of these corporate social responsibility approaches in regulating pharmaceutical companies.¹⁰⁴⁹

Notwithstanding the above, the UN and other multilateral institutions have also embarked on a project of codifying the corporate social responsibilities.¹⁰⁵⁰ The former UN Special Rapporteur, Paul Hunt, has produced important reports and recommendations seeking to suggest how pharmaceutical companies should operate their business in a manner which promotes the right to health.¹⁰⁵¹ Further, the launch of a UN Global Compact, a voluntary initiative consisting of corporate entities devoted to align their businesses with human rights standards and norms will contribute towards the development of soft-law which promotes access to essential medicines.¹⁰⁵² John Ruggie,¹⁰⁵³ the Secretary-General on the issue of human rights and transnational corporations and other business enterprises, notes that companies need to adopt a human rights policy and that broad aspirational language may be used to describe respect for human rights, but more detailed guidance in specific functional areas is necessary to give those commitments meaning. All of the

¹⁰⁴⁸The Global Sullivan Principles, https://www.heartland.org/sites/all/modules/custom/heartland_migration/files/pdfs/6789.pdf (accessed 26/07/2015).

¹⁰⁴⁹Ferreira "Access to affordable HIV/AIDS drugs: the human rights obligations of Multinational pharmaceutical corporations" (2014) *Fordham Law Review* 71 1134.

¹⁰⁵⁰Forman and Kohler "Introduction: International law, access to medicines and pharmaceutical companies" 2012 http://www.academia.edu/2105696/Lisa_Forman_and_Jillian_Kohler_Introduction_International_law_access_to_medicines_and_pharmaceutical_companies_2012 (accessed on 27/06/2015).

¹⁰⁵¹Hunt "Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health," http://www.who.int/medicines/areas/human_rights/A63_263.pdf (accessed 27/10/2015).

¹⁰⁵²Supra, 984 para 3.

¹⁰⁵³Ruggie "Special representative of the secretary-general on the issue of human rights and transnational corporations and other business enterprises, protect, respect and remedy: a framework for business and human rights" <http://daccess-dds-ny.un.org/doc/UNDOC/GEN/G08/128/61/PDF/G0812861.pdf?OpenElement> (accessed 28/10/2015). See also United Nations Conference on trade and development "The social responsibility of transnational corporations" http://unctad.org/en/Docs/poiteiitm21_en.pdf (accessed 28/10/2015)

aforementioned expose the great potential that voluntary mechanisms have in improving access to essential medicines.¹⁰⁵⁴

Similarly, there are also other voluntary initiatives which have proven to be an important source of increasing access to essential medicines.¹⁰⁵⁵ For instance, large pharmaceutical companies like GSK have devised what they call an “access strategy” which is designed to enhance access to medicines by starting a new company for discovery and delivery of treatments for HIV.¹⁰⁵⁶ The same company has a culture of reducing prices of its medicines by more than half to make them available and affordable the marginalized communities such as least developing countries.¹⁰⁵⁷ Other pharmaceutical companies have also joined the wagon of utilizing corporate social responsibility to promote the right to health.¹⁰⁵⁸ The 2014 Access to Medicine Index, which analyses the access policy of large pharmaceutical companies, indicates that Gilead Sciences was the number one company with a policy that is amenable to the issue of access to essential medicines.¹⁰⁵⁹

In the same vein, South African can also expand access to essential medicines through appealing to the donor community.¹⁰⁶⁰ Although of lately, this strategy has been criticised by scholars because of its potential to create a dependency syndrome, it can go a long way in solving the problem of access to essential medicines.¹⁰⁶¹ There is a sizeable number of global institutions, developed countries and wealthy individuals who are running donor programmers designed to assist developing countries to improve their public health situations. A good example is the Children's Fund established by (UNICEF), created to tackle infant mortality by way of providing health care services such as essential medicines.¹⁰⁶² South Africa can also

¹⁰⁵⁴ *Ibid* 18 para 3.

¹⁰⁵⁵ Gruskin and Raad “Are drug companies living up to their human rights responsibilities? Moving Toward Assessment” (2010) *PLoS Med* 7 2.

¹⁰⁵⁶ GSK “Corporate Social Responsibility Report” <http://www.gsk.com/media/325170/cr-report-2013.pdf> (accessed 29/10/2015).

¹⁰⁵⁷ *Ibid* 8 para 1.

¹⁰⁵⁸ *Ibid* 8 para 2.

¹⁰⁵⁹ Access to medicines foundation “The Access to Medicine Index 2014” <http://apps.who.int/medicinedocs/documents/s21637en/s21637en.pdf> (accessed 30/10/2015).

¹⁰⁶⁰ GlaxoSmithKline “Intellectual Property and Access to medicines in Developing Countries” at <http://www.gsk.com/responsibility/index.htm> (accessed 01/02/2016).

¹⁰⁶¹ See Aginam “global health governance, intellectual property and access to essential medicines: opportunities and impediments for South-South Cooperation” http://ghgi.org/Aginam_final.pdf (accessed 01/02/2016).

¹⁰⁶² *Ibid* 7 para 1.

be a beneficiary of the Special Programme for Research and Training in Tropical Diseases created to tackle the problem of neglected tropical diseases expounded in chapter four of this study.¹⁰⁶³

Additionally, the government of Sweden, Denmark, United Kingdom (UK) and USA governments have launched various donor initiatives which include, International Development Cooperation Agency (Sida), the Danish International Development Agency (Danida), the UK Department for International Development (DFID) and the US Agency for International Development (USAID) to assist need countries with aid.¹⁰⁶⁴ South Africa can tap into the resources provided by these institutions to increase access to essential medicines.¹⁰⁶⁵ Currently, there is a web of philanthropists in the form of churches, individuals and civil organizations such as the Catholic Relief Foundation, Rockefeller foundation, Clinton foundation and the Bill and Melinda Gates Foundation among others that may help South Africa to secure access to essential medicines for its people.¹⁰⁶⁶

5.3.8 An Open Source

South Africa should embrace an open source system as a viable alternative to improving access to essential medicines.¹⁰⁶⁷ An open sources system is a public voluntary collaborative scheme where participants donate their time and expertise to come up with an invention or discovery which tackles a complex societal problem.¹⁰⁶⁸ The participants receive noble recognition for their inventions which is non-patent in nature. In other words, the results of the project are made available to all and can be modified by all, such that individual members re-contribute to the larger project.¹⁰⁶⁹ This concept has been used successful for software development.¹⁰⁷⁰ It is credited for the development of an operating system called Linux.¹⁰⁷¹ This operating system is

¹⁰⁶³World Health Organisation: *Handbook: quality practices in basic biomedical research* (2011) 4.

¹⁰⁶⁴Hogerzei *et al* "Non-communicable diseases promotion of access to essential medicines for Non-communicable diseases: practical implications of the UN political declaration" <https://www.ghdonline.org/uploads/AccessNCDsFeb2013.pdf> (accessed on 02/01/2016).

¹⁰⁶⁵*Ibid* 4 para

¹⁰⁶⁶*Ibid* para

¹⁰⁶⁷Alessandro: *Biotechnology in Brazil: promoting open innovation* (2010) 136.

¹⁰⁶⁸Kepler *et al* "Open source research-the power of US" 2006 *Austl. J. Chemistry* 59 291.

¹⁰⁶⁹Weilbaecher "Endemic in developing countries: how to incentivise innovation" 2009 *Annals Health Law* 18 281.

¹⁰⁷⁰*Ibid* 286 para 1.

¹⁰⁷¹*Ibid* 286 para 2.

the outcome of the industrious efforts made by a group of volunteers collaborating through the Internet with the source code made freely available for anyone to view, modify, or improve with the provision that the volunteers agreed to share their modifications openly.¹⁰⁷²

The open source system has been successfully used in the field of bioinformatics, where supercomputers are used to conduct biological research.¹⁰⁷³ The public shares the software code and databases. Even though the open source system seems to work well in precompetitive platform technologies such as biological research tools, the question remains as to whether it will also work further downstream, closer to the patient, where the development costs are greater and the potential benefits more direct.¹⁰⁷⁴ While pharmaceutical manufactures may be unwilling to participate in open source initiatives for the development of potentially highly profitable or blockbuster new essential medicines, open source may not meet resistance and may be effective in two areas.¹⁰⁷⁵ One is in the development of non-patentable compounds or essential medicines whose patents have expired. Since discovery involving these medicines and compounds cannot be protected, nor can they garner large profits, developers generally are less interested in pursuing research in these areas.¹⁰⁷⁶

The second area in which it can be successfully used is the one of neglected diseases because there is not a large enough market of paying customers to justify the expense involved in developing an essential medicine.¹⁰⁷⁷ Given that pharmaceutical companies and other essential medicines developers would not lose money by participating in open source projects in these areas, they may not be amenable to this system.¹⁰⁷⁸ The WHO called for support of open source initiatives so as to (a) promote upstream research and product development in developing countries support discovery science, including where feasible and appropriate, voluntary open-source methods, in order to develop to sustainable portfolio of new

¹⁰⁷² *Ibid* 286 para 2.

¹⁰⁷³ Petherbridge "Road map to revolution? patent-based open science" 2007 *Me. L. Revel* 59 333.

¹⁰⁷⁴ *Ibid* 333 para 2.

¹⁰⁷⁵ Munos "Can Open-Source R&D reinvigorate drug research" <http://www.nature.com/nrd/journal/v5/n9/pdf/nrd2131.pdf> (accessed 02/11/2015).

¹⁰⁷⁶ *Ibid* 724 para 4.

¹⁰⁷⁷ Bors *et al* "Improving access to medicines in low-income countries: a review of mechanisms" 2015 *The Journal of World Intellectual Property* 18 1.

¹⁰⁷⁸ *Ibid* 6 para 2.

products (b) promote and improve accessibility to compound libraries through voluntary means, provide technical support to developing countries and promote access to drug leads identified through the screening of compound libraries.¹⁰⁷⁹

Currently, there is a plethora of precedents which validates the use of open source system in developing essential medicines. A good example is called Open Source Drug Discovery (OSDD) which is presently in the pipe line in India through the Council of Scientific and Industrial Research (CSIR).¹⁰⁸⁰ Likewise, Brahma Chari, the head of the OSDD project stated that the aim is to establish a novel web-enabled open source platform-both computational and experimental to make the invention of cost effective and affordable essential medicines by employing the creative potential of college and university students along with senior scientists, a collective approach to the development of the essential medicines.¹⁰⁸¹ It is important to note that the project will receive one third of its funding from the government, one-third from international sources, and one-third from philanthropic organizations.

Consequently, OSDD has created a database of requirements for infectious disease drug development, whereby individual researchers can contribute to solutions for specific aspects of medicines invention.¹⁰⁸² The chemical entities thus developed will instantly become generics as the knowledge will be in public domain. This is diametrically opposite to the concept of intellectual property protection, which involves legal expenses to bar others from applying their minds on the invention.¹⁰⁸³ Another example which resembles an open source initiative is the Human Genome Project, which is a quest by the international community to place all of the resulting data in the public domain rather than allowing any individual researcher to have patent monopoly.¹⁰⁸⁴

¹⁰⁷⁹WHO “Global strategy and plan of action on public health, innovation and intellectual property” http://apps.who.int/gb/ebwha/pdf_files/A61/A61_R21-en.pdf (accessed 12/11/2015).

¹⁰⁸⁰Singh “India takes an open source approach to drug discovery” (2009) *Cell* 18 133.

¹⁰⁸¹Brahmachari “Open source drug discovery will lower costs” http://www.rediff.com/money/2008/feb/1_5inter.htm (accessed 15/11/2015).

¹⁰⁸²Supra 1009 para 3.

¹⁰⁸³Kapizynnski *et al* “ Addressing global health inequalities: an open licencing support for university innovation” <http://www.benkler.org/EALFinalBTLJ.pdf> (accessed on 16/11/2015).

¹⁰⁸⁴WHO “The world medicines situation”http://www.searo.who.int/LinkFiles/ReportsWorldMedicines_Situation.pdf (accessed 16/11/2015).

5.3.9 Patent pools

South African can make use of patent pools as a potential tool to accelerate access to essential medicines which is required to combat the epidemiological health crisis discussed in chapter four of this study.¹⁰⁸⁵ The WHO, UNITAID, and some pharmaceutical companies such as GlaxoSmithKline (GSK) have suggested the use of patent pools as a viable alternative for encouraging innovation. A patent pool can be defined as:

An agreement between two or more patent owners to pool their patents and to license them to one another or to third parties. The agreement usually offer standard licensing terms to licensees and allocate a portion of the licensing fees as royalties to patent owners according to a pre-set formula or procedure. Agreements between the members of the patent pool and third parties can be established directly through patentees and licensees or indirectly through an entity specifically created to administer the pool¹⁰⁸⁶

An essential characteristic of a patent pool is that it is a collective management strategy which is either voluntary or governmentally imposed.¹⁰⁸⁷ This collective management strategy has been praised for incentivising innovation through eliminating hurdles such as expensive transaction through streaming and centralizing of the licensing procedures. In other words, patent pools accelerate the process of obtaining licence thereby making it easy and simpler. James Love¹⁰⁸⁸ has observed that the increased use of patent pools fosters access to patented essential medicines by streamlines patent procedures thereby lower costs of them.¹⁰⁸⁹

There is an ocean of precedents which supports the use of patent pools as a method of expanding access to certain products specifically in the areas of garment industry,

¹⁰⁸⁵Nicol *et al* "Opening the dam: patent pools, innovation and access to essential medicines" In: Pogge *et al* :*Incentives for global public health: patent law and access to essential medicines* (2010) 235.

¹⁰⁸⁶Bermudez and Hoen "The UNITAID patent pool initiative: bringing patents together for the common good" 2010*The Open AIDS Journal* 4 37.

¹⁰⁸⁷Medicines Patent Pool, "Licenses in the pool 2013" <http://www.medicinespatentpool> (accessed 27/09/2015).

¹⁰⁸⁸Love "Measures to enhance access to medical technologies, and new methods of stimulating medical research and development" 2007 *University of California, Davis* 40 685.

¹⁰⁸⁹*Ibid* 685 para 2.

and aircraft manufacturing.¹⁰⁹⁰ For instance, the 1917 aircraft patent pool, which comprised of almost every aircraft manufacturer in the U.S, was formed after the US government noted that two aircraft patent holders, the Wright Company and the Curtiss Company, blocked the building of new airplanes just as the United States was entering World War 1.¹⁰⁹¹ Indeed, the MAA was created when the government threatened to compulsorily license the needed patented technology.¹⁰⁹²

However, one of the major problems of patent pools is that in the absence of strict regulation, they may cause an anti-competitive impact in South Africa.¹⁰⁹³ There is a lot of concrete evidence from foreign jurisprudence especially in United States which proves that patent pools can create a gigantic corporal entities capable of expand monopoly pricing.¹⁰⁹⁴ In *Standard Sanitary Manufacturing Co. v. United States*, the USA¹⁰⁹⁵ Supreme Court dissolved a patent pool because of anti-trust violations, including fixing prices and blocking unlicensed manufacturers.¹⁰⁹⁶ In 1945, in *Hartford-Empire Co. v. United States*,¹⁰⁹⁷ the U.S. Supreme Court dissolved a glass manufacturer patent pool because it comprised ninety-four percent of all glass made in the U.S. and was thus able to set and maintain unreasonably high glass prices.¹⁰⁹⁸

It is pertinent to note that while there are practical cases for patent pools in the aforementioned areas, they are largely untested in the area of essential medicines. Critics such as the Organisation for Economic Co-operation and Development (OECD) doubt whether patent pools can be applied effectively to the development of essential medicines or medical biotechnology industry.¹⁰⁹⁹ They are calling for an in depth study into the feasibility of patent pools in the field of biotechnology. The gist of the OECD view is that pharmaceutical companies rely heavily on their intellectual

¹⁰⁹⁰Sykes "TRIPS, Pharmaceuticals, developing countries, and the Doha 'Solution'" 2007 *Chicago Journal of International Law* 3 47.

¹⁰⁹¹Szakalski "Progress in the aircraft industry and the role of patent pools and cross-licensing agreements" 2011 *UCLA Journal of law and technology* 15 2.

¹⁰⁹²*Ibid* 3 para 2.

¹⁰⁹³Levy *et al* "Patent pools and genomics: navigating a course to open science?" http://www.bu.edu/jostl/files/2015/02/Marden_WEB_161.pdf (accessed 08/11/2015).

¹⁰⁹⁴*Ibid* 2 para 2.

¹⁰⁹⁵226 US.20 (1912) NO.554.

¹⁰⁹⁶*Ibid* 1 para 1.

¹⁰⁹⁷323 U.S. 386 (1945).

¹⁰⁹⁸*Ibid* 1 para 2.

¹⁰⁹⁹Herder "The Bioeconomy to 2030: designing a policy agenda. intellectual property issues in biotechnology: health and industry" <http://www.oecd.org/futures/long-termtechnologicalsocietalchallenges/40181372.pdf> (accessed 09/11/2015).

property and this might cause difficulties in the process of creating a pool. WHO has also raised its concern against patent pools by calling for research into the feasibility of patent pools in its Global Strategy proposal in the following provision: (a) developing possible new mechanisms to promote transfer of and access to key health-related technologies (b) examine the feasibility of voluntary patent.¹¹⁰⁰

Aside of the criticism displayed above, the Bulletin of the World Health Organization published in 2005 suggested the creation of a patent pool to facilitate the development of essential medicines to treat Severe Acute Respiratory Syndrome (SARS).¹¹⁰¹ The proposal contended that since the outbreak of SARS in late 2002, numerous organizations have filed patent applications that incorporate the genomic sequence of the SARS coronavirus, which likely would result in a fragmentation of intellectual property rights and thus hinder the development of a vaccine. A patent pool was recommended to help set a precedent for the use of patent pools in health care. This proposal has yet to be adopted.¹¹⁰²

Importantly, the prospects and challenges of a patent pool approach for the development of a malaria vaccine was analysed in a study published in 2007 in the Intellectual Property Handbook for Best Practices.¹¹⁰³ The authors of the study note that there is no safe essential medicine for treating malaria currently exists, and there is an increasing priority as malaria parasites are becoming resistant to known medicines.¹¹⁰⁴ A patent pools approach to developing treatment of malarial could have the following benefits in comparison with the existing treatments: (1) cost-effectiveness; (2) minimization of negative effects on the environment by reducing the need for pesticides to control mosquito populations; (3) assistance in solving the problem of drug-resistant parasites; and (4) the potential to save lives, which is of the utmost importance.¹¹⁰⁵

¹¹⁰⁰*Ibid* 7 para 3.

¹¹⁰¹Levy "Patent pools and genomics: navigating a course to open science" http://www.bu.edu/jostl/files/2015/02/Marden_WEB_161.pdf (accessed 11/11/2015).

¹¹⁰²*Ibid* 123 para 3.

¹¹⁰³Krattiger : *Intellectual property management in health and agricultural innovation a handbook of best practices* (2007) 25.

¹¹⁰⁴Mattioli "Power and governance in patent pools" 2014 *Harvard Journal technology* 27 457.

¹¹⁰⁵Van Overwalle *et al* "Models for facilitating access to patents on genetic inventions" <http://www.nature.com/nrg/journal/v7/n2/abs/nrg1765.html> (accessed 12/11/2015).

5.3.10 The Health Impact Fund

The Health Fund (HIF) is another panacea which solves the problem of access to essential medicines by providing an alternative to the current incentive system so that it no longer creates access barriers.¹¹⁰⁶ The HIF is a system that is to be entirely financed by governments, designed to replace patents by offering patent holders an opportunity to choose a reward, instead of patent monopoly.¹¹⁰⁷ The amount of the reward to be given to pharmaceutical manufacturers is determined by the global impact the newly discovered essential medicine would make on combating disease and improving health.¹¹⁰⁸ Pogge, one of the leading scholars in this area, envisage the establishment of an HIF which has at its disposition a large sum of money, which would reach as much as 6 billion US dollars annually.¹¹⁰⁹ This sizeable amount of money deposited by various governments into the fund will be given as a reward to any successful inventor of new essential medicines depending on the degree of the invention.¹¹¹⁰

The money that is used as a reward is generated through taxes.¹¹¹¹ This means that taxpayers will benefit from the system, as they will have access to low-cost medicines developed through it.¹¹¹² The HIF has a lot of merits than demerits. The system enables pharmaceutical companies to stop wasting resources on expensive litigation and patent registrations.¹¹¹³ It also allows the production of essential medicines at optimal level which is beneficial for patients in both rich and poor countries, since it directs research toward the medicines that can do the most

¹¹⁰⁶Pogge "Getting the incentives right: the health impact fund a concrete contribution to global and innovation in global health justice" <http://healthimpactfund.org/files/HIFeuropaPapierFES.pdf> (accessed 14/11/2015).

¹¹⁰⁷Pogge "The Health Impact Fund: better pharmaceutical innovations at much lower prices" http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1431180 (accessed 13/11/2015).

¹¹⁰⁸Pogge "The Health Impact Fund: more justice and efficiency in global health" https://devpolicy.anu.edu.au/pdf/papers/DP_7The_Health_Impact_Fund_More_justice_and_efficiency_in_global_health.pdf (accessed 14/11/2015).

¹¹⁰⁹Coles *et al* "Stakeholder views regarding a Health Impact Fund (HIF), to incentivise pharmaceutical innovation relevant to diseases of poverty" (2013) Global health Governance VI 6.

¹¹¹⁰Hollis "The Health Impact Fund: a useful supplement to the patent system?" 2008 *Public health Ethics* 1 2.

¹¹¹¹Pogge "Results based financing: the 'Health Impact Fund' as an example for smart pro-poor innovations" https://www.kfwentwicklungsbank.de/DownloadCenter/PDFDokumenteDevelopmentResearch/2012_01_MF_Pogge-Ergebnisbasierte-Finanzierung_E.pdf (accessed on 15/11/2015).

¹¹¹²Peterson *et al* "A critique in need of critique" 2010 *Public health Ethics* 3 178.

¹¹¹³ Supra 1037 para 3.

good.¹¹¹⁴ The HIF also cures the defects created by push and pull research fund mechanisms.¹¹¹⁵ Push research mechanism which occurs when money is given by the government to an institution, commonly universities, which is to discover and develop a new medicine whereas, pull mechanisms, occur when numerous inventors participate in some sought of research competition aimed at the development of a particular medicines and the one that comes with the best invention first is granted public financing.¹¹¹⁶

5.3.11 Other non-patent related solutions

In order to improving access to essential medicines there must be a sustained South African government commitment to public health systems.¹¹¹⁷ This higher commitment can be exhibited through designing an equitable public sector financing. An equitable public health sector financing is instrumental to the development of a good health delivery infrastructure.¹¹¹⁸ The South African government should embark on infrastructural projects such as building hospitals in remote rural area, storage and distribution facilities as well as trained personal to facilitate access to essential medicines. Additionally, the South African government must roll out educational programmes to help people see the need to have access to essential medicines such as generic ones.¹¹¹⁹ Such a move would enlighten the public on the options they have when they fail to purchase the newest versions of medicines because of high prices.

In addition, South African government should adopt legislative mechanism which provides adequate protection of TK.¹¹²⁰ Such legislative measures have the potential

¹¹¹⁴Pogge "The Health Impact Fund: A new paradigm in pharmaceutical innovation"<http://publicacions.iec.cat/repository/pdf/00000220%5C00000001.pdf> (accessed 16/11/2015).

¹¹¹⁵*ibid* 26 3. Another borne of contentions associated with push research is the risk of wasting resources which is associated with funding a particular institution at a time.

¹¹¹⁶Aginam "Global health governance, intellectual property and access to essential medicines: opportunities and impediments for South-South cooperation" (2010) *Global health Governance* IV 3.

¹¹¹⁷Dountio "Access to Medicines in Africa: Where there is a Will there is a Way" (2012) *Bridges Africa Review* 1 4.

¹¹¹⁸Zinatul *et at* "Pharmaceutical patents and access to essential medicines in sub-Saharan Africa" 2011 *African Journal of Biotechnology* 10(x) 12376-12388.

¹¹¹⁹WTO "Regional Issues Brief: Intellectual Property Rights and Access to medicines. 2011 http://www.google.co.za/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&ved=0cbwqfjaa&url=http%3a%2f%2fwww.hivlawcommission.org%2findex.php%2fregionaldialoguesmain%2fasiapacific%2fregionallissuesbriefintellectualpropertyrightsandaccesstomedicines%2fdownload&ei=wzayvigvd8aaucyppggg&usq=afqjcnqblfsqroxq4b34mq4mmttielx3a&sig2=ptqu6a4y2vgfdes_ikjxq (accessed 11/01/2015).

¹¹²⁰Sell "TRIPS and the access to medicines campaign" (2002) *Wisconsin International Law Journal*, 20 481.

to curb the appropriation and patented of TK with little or no compensation to the original knowledge holders and without their prior consent.¹¹²¹

5.3.12 Combating Corruption

There is no doubt that corruption impacts on access to essential medicines.¹¹²² When government official divert and embezzle public funds set aside to purchasing essential medicines, the result is that the realisation of the right to health will be hindered.¹¹²³ The actions of a public official who demands kickbacks as a pre-condition for purchasing essential medicines may lead to inaccessibility of such medicines.¹¹²⁴ In order to tackle this problem of corruption within the health sector, South African government should put in place institutional checks and balances at various public hospitals in the country. These institutional checks and balances would consist of clearly defined medicines procurement policy for public hospitals so that officials can make decisions based on uniform criteria rather than mere discretion.¹¹²⁵ Further, the policy should provide a selection processes which ensures that the most cost-effective and appropriate drugs for a population's health needs are chosen fairly.¹¹²⁶ The WHO Model List of Essential Medicines is a helpful framework in this regard for South Africa because it establishes priority areas of treatment and covers the most common diseases.¹¹²⁷

5.4 Areas for further research

5.4.1 Impact of Patents on the whole gamut of human rights

This study only focused on the utility of the right to health in the context of patent protection. It has explored the possible benefits which emanates from disciplining patents with the right to health obligations so as to increase access to essential medicines. The study departed from the basic premise that that human rights, in

¹¹²¹ *Ibid* 481 para 2.

¹¹²² Cohen "Pharmaceutical and corruption: a risk assessment". <http://www1.worldbank.org/publicsector/anticorrupt/corecourse2007/Pharmaceuticals.pdf> (accessed on 29/09/2015).

¹¹²³ Camerer "Poverty and Corruption in South Africa: government corruption in poverty alleviation programmes, iss monograph no. 15, costly crimes" <https://www.issafrica.org/publications/monographs/monograph-15-costly-crimes-commercial-crime-and-corruption-in-south-africa-edited-by-lala-camerer> (accessed 14/10/2015).

¹¹²⁴ *Supra* 1041 para 3.

¹¹²⁵ Marks "Access to essential medicines as a component of the right to health" health: a human rights perspective" (2009) https://cdn1.sph.harvard.edu/wpcontent/uploads/sites/580/2012/10/marks_access_to_essential_medicines-2009.pdf (accessed 19/11/2015).

¹¹²⁶ *Ibid* 8 para 2.

¹¹²⁷ *Ibid* 8 para 3.

particular the right to health, is a supreme right whose obligations must be complied with in patent -trade-related scenarios. However, the study did not explore in detail the possible impact of patents on the whole gamut of human rights. Therefore, the study recommends further research in this area. Such a further study would point a wholesome picture of the impact of patent on a broad constituency of human rights.

5.4.2 The impact of factors other than patents

This study has identified the role played by non-patent factors in determining access to essential medicines. The study has noted that factors such as political will and commitment, inadequate infrastructure, lack of health literacy, corruption and other factors limit access to essential medicines. However, the study did not delve much into the pros and cons of such non-patent factors on the realisation of the right to health, in particular access to essential medicines. Therefore, the study recommends a further research on the impact of non-patent factors on access to essential medicine. Such a study has the potential to shed more light on the intricate issues surrounding the problem of access to essential medicines.

5.4.3 The development of Competition law

This study has shown that competition law can be a useful instrument for eliminating patent monopoly, curbing excessive pricing of essential medicines and promoting fair competition. Unfortunately, this study did not venture much into addressing some of the current challenges faced by competition law in the area of access to essential medicines. The sophistication of competition law and policy, but more importantly, the lack of capacity to apply competition legislation and policy remains an unsolved issue in South Africa. This study, therefore suggests further research into this area to ensure that all these hurdles are overcome. Further research on how to develop Competition law to in order to protect the right to health provides a good opportunity to find other avenues of tackling the problem of access to essential medicines.

5.4.4 The right to health responsibilities of pharmaceutical companies

Much of the discussion presented in this study focused on the state obligation to provide access to essential medicines imposed by the right to health on South African as a state. This study did not delve much into obligations imposed on non-state actors. Because of the growing power of pharmaceutical companies, scholars have manifested a keen interest to bind the activities of pharmaceutical companies

with human rights obligations to ensure access to essential medicines. Therefore, a further study on the feasibility of extending human rights obligations on pharmaceutical companies will surely be desirable and a lucrative for the purpose of expanding access to essential medicines.

5.5 Summary

This dissertation has demonstrated that the right to health has the potential to discipline injurious patents which could make a noteworthy contribution in improving access to essential medicines for the marginalised people in South Africa. Needless to say, South African patent laws which are mainly influenced by TRIPS have come under attack as falling short of making essential medicines more accessible. Chief amongst the criticism is the failure of the South African Patent Act to meaningfully activate TRIPS –related flexibilities to enable access to essential medicines. The South African patent laws have been blamed for facilitating the granting of weak patents which are detrimental to the provision of access to essential medicines.

However, this dissertation has also shown that the right to health can be invoked in patent claims litigation process. It has proposed that South African courts must play their oversight role to ensure that a balance is struck between the need to promote research and development in the manufacturing of essential medicines and to minimize private monopoly which is detrimental to the right to health.¹¹²⁸ This means that any patent law which *ipso facto* threaten access to essential medicines must be weighed against the need to ensure that the marginalised groups have the opportunity to enjoy their right to health. This is the human rights based approach to intellectual property which forms the core of this chapter.

¹¹²⁸Narula “The rights-based approach to intellectual property and access to medicine: parameters and pitfalls” http://lsr.nellco.org/cgi/viewcontent.cgi?article=1300&context=nyu_plltwp(accessed 05/10/2015).

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