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The impact of the Trade-Related Aspects of Intellectual Property Rights (TRIPS) on the right to health and the right to development: A study of the implementation of TRIPS in Zimbabwe

Ropafadzo Blessing Munemo

209531877

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Supervisor: Ms Clydenia Stevens

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I, Ropafadzo Blessing Munemo declare that:

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ABBREVIATIONS

ACHPR	African Charter on Human and People's Rights
AIDS	Acquired Immune Deficiency Syndrome
ARIPO	African Regional Intellectual Property Organisation
ARV	Antiretroviral
AYC	African Youth Charter
CEDAW	Convention on the Elimination of All forms of Discrimination Against Women
CRC	Convention on the Rights of the Child
CRPD	Convention on the Rights of Persons with Disabilities
DCs	Developing Countries
DRD	Declaration on the Right to Development
FTAs	Free Trade Agreements
GATS	General Agreement on Trade in Services
GATT	General Agreement on Tariffs and Trade
HIV	Human Immune Virus
ICCPR	International Covenanton Civil and Political Rights
ICESCR	International Covenant on Economic, Social and Cultural Rights
IPRs	Intellectual Property Rights
ITO	International Trade Organization
LDCs	Least Developed Countries
OAU	Organisation Of African Unity
OHCHR	International Human Rights Committee
R & D	Research and Development
RTAs	Regional Trade Agreements
SADC	Southern Africa Development Community

SDGs	Sustainable Development Goals
SDT	Special and Differential Treatment
SPS	Sanitary and Phytosanitary Measures
TBT	Technical Barriers to Trade
UDHR	Universal Declaration of Human Rights
UNC	United Nations Charter
UNDHR	United Nations Declaration on Human Rights
UNDRTD	United Nations Declaration on the Right to Development
WHO	World Health Organisation
WIPO	World Intellectual Property Organisation
WTO	World Trade Organisation

ABSTRACT

The right to health and the right to development are intertwined socio-economic rights that affect the well being and growth of a country's populace. Most developing and least developed countries face challenges in ensuring access to essential medicines *vis a vi* the realisation of the right to health and full potential tof development. Patents, provided for under the TRIPS Agreement are partly to plae for the lack of access to essential medicines as they account for the excessive pricing of medicines.

Zimbabwe being a developing country currently facing dire economic and political challenges but being obliged under the International and Regional Human Rights Conventions it subscribed to, has to ensure the progressive realisation of the right to health and development. However, as a member of the TRIPS Agreement, there are limitations to the country's ability to ensure access to medicines and healthcare for developmental purposes.

This thesis has outlined the problematic provisions of the TRIPS Agreement and Zimbabwe's attempt to use the flexibilities provided to its advantage. Zimbabwe has only put into use the flexibility of compulsory licensing and parallel importation to a limited extent; hence the recommendation that even though the country has domesticated the Agreement to its advantage, the country needs to explore other flexibilities comprehensively and promote the realisation of the rights to health and development.

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CHAPTER 1: INTRODUCTION

1.1 Background

Zimbabwe is a developing country, and of late, due to political reasons, the country's economy has deteriorated beyond imagination. In these dire times, basic needs such as health care are compromised, and the government finds itself in a dilemma as it fails to ensure the progressive realisation of the right to health.[1] The right to development which is directly linked to the right to health is close to becoming defunct as health provision deteriorates and life expectancy sharply decreases with a mere 8, 9% annual budget being allocated to the health sector instead of the recommended 15%.[2] Doctors have gone on strike complaining about the poor state of hospitals and their inability to provide sufficient medical assistance to patients due to the non-availability of medicines and equipment.[3] In 2019, Zimbabwe once again[4] declared a state of national emergency due to the devastating damages by Cyclone Idai.[5] Further, there is an acute shortage of essential medicines due to the high costs and demand exceeding supply.[6] In addition, access to essential medical services and supply has drastically deteriorated due to the COVID-19 pandemic.[7]

The realisation of the need to protect intellectual property in the form of patents, copyrights and industrial designs was a welcome development intended to improve technology through the

[1] Since 2018, there has been an outcry on the state of health care facilities, infrastructure and the lack of enjoyment of the right to basic health care as enshrined in the Constitution see: Zimbabwe Human Rights NGO Forum & Zimbabwe Association of Doctors for Human Rights (ZADHR) an article titled "Statement on the Collapse of the Health System And Withdrawal of Labour by the Doctors in Zimbabwe**"** available at http://www.hrforumzim.org/news/forum-and-zadhr-statement-on-the-collapse-of-the-health-system/ accessed on 31 Dec 2020.

[2]Zimbabwe is a signatory to the Abuja Declaration and was part of the leaders that agreed in 2001 to allocate at least 15% of their annual budget to improve the health sector see the, 'Abuja Declaration: Ten Years On' available at https://www.who.int/healthsystems/publications/abuja_declaration/en/ accessed on 30 December 2020.

[3] Statement on the collapse of the health system and withdrawal of Labour by the Doctors in Zimbabwe available at http://kubatana net/2018/12/31/statement-collapse-health-system-withdrawal-labour-doctors-zimbabwe/ accessed on 30 December 2020.

[4] Zimbabwe declared a national state of emergency against AIDS in 2002. See Zimbabwe government takes emergency action against HIV/AIDS available at https://www.msf.org/zimbabwe-government-takes-emergency-action-against-hivaids accessed on 30 December 2020.

[5] In 2018, a state of emergency was declared after an outbreak of cholera and typhoid due to contaminated water sources.WHO assessed the overall public health risk to be high at the national level and moderate at the regional and low at global levels; Emergencies preparedness, response Cholera – Zimbabwe (5 October 2018) available at https://www.who.int/csr/don/05-october-2018-cholera-zimbabwe/en/ accessed on 31 December 2020.

[6] E F M.'tHoen 'TRIPS, Pharmaceutical Patents and Access to Essential Medicines: Seattle, Doha and Beyond' (2003) 39, 68.

[7] Grant Murewanhema et al, 'Essential health service delivery in Zimbabwe during the COVID 9 pandemic: perspectives and recommendations' (2020) 35:2 *Pan African Medical Journal* 143,143.

promotion of research. During the period of transition and introduction of intellectual property rights, there seemed to be a balance struck between the protection of intellectual property rights and the realisation of other human rights. The advancement in trade and continuous need to protect inventions led to the incorporation of the protection of intellectual property in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).[8] The TRIPS Agreement provisions ought to comply with the 'substantive provisions' of the Paris Convention.[9] However, the question that lingers now is whether protecting intellectual property rights promotes the realisation of other human rights such as the right to health under the new international provisions and the right to development. These rights are enshrined in international and regional instruments further discussed in Chapter 3.

The TRIPS Agreement[10] grants pharmaceutical companies the right to protect their medicines or inventions from the competition and result in them setting prizes that may maximise profits, to the detriment of many developing countries (DCs).[11] In the same voice, the Doha Declaration on TRIPs and Public Health of 2001 recognise the gravity of public health issues afflicting many countries, especially DCs and least developed countries (LDCs) and offers protection against patents by ensuring an interpretation and implementation of the TRIPs Agreement, which is supportive of WTO Members' right to protect public health and access to medicines.[12]As such, the ability to promote access to medicines is important, especially to low-income countries where it may be too expensive for those in need of them, thus, significantly affecting access to medicine.[13]

The patent protection provided for under the TRIPS Agreement may affect the accessibility of medicines which are of vital importance in the fight against, for example Human Immune Virus (HIV)/Acquired Immune Deficiency Syndrome (AIDS), malaria and tuberculosis[14] which prevail

[8] TRIPS Agreement of 1994 which came into effect on 1 January 1995 available at www.wto.org/English/tratop_e/trips_e/intel2_e htm accessed on 8 July 2021. Any reference to TRIPS Agreement is as amended on 23 January 2017.
[9] Article 2.1 & 9.1 of TRIPS Agreement.
[10]Article 28 (1) of TRIPS Agreement.
[11]Article 28 (1) (a) & (b) of TRIPS Agreement.
[12]DOHA Declaration 2001 paragraph 4.
[13]S Ozawo et al , 'Access to medicines through health systems in low- and middle-income countries', (2019) 34:*3 Health Policy and Planning* iii1, iii2.
[14] Low income and middle income countries reportedly spend billions of dollars in fighting against HIV/AIDS, malaria and tuberculosis including health assistance funding. *See* A E Micah *et al* 'Health sector spending and spending on HIV/AIDS, tuberculosis, and malaria, and developnt assistance for health: progress toards Sustainable Development Goal 3' (2020) 396:10252 *The Lancet* 693, 693.

in DCs. Although the TRIPS Agreement[15] provides for flexibilities, which address the issues of production and export of generic medicines, which covers accessibility,[16] these provisions may not work in practical situations and may be just there on paper.[17] It is unclear how these provisions or safeguards provided for by TRIPS Agreement may be used. Mainly because patents continue to present barriers to access to medicines through high prices of drugs set up by countries holding the patents.[18] This in turn make access to medicines in DCs problematic.[19]

Against this background, the International Human Rights Committee(OHCHR)[20] specifically the Committee on Economic Social and Cultural Rights [21] guarantees the implementation of the right to health and how it is to be respected, protected and fulfilled.[22] In the same spirit the OHCHR calls for the progressive realisation[23] of the right to health and the accessibility of essential medicines without discrimination of any kind.[24] As such, there has to be a common ground between the protection of intellectual property rights in particular patents and guaranteeing access to medicines.

The right to development is directly linked to the discussion, hence a detailed discussion under Chapter 3. The United Nations Declaration of Human Rights (UNDHR) reiterates the promotion of universal respect for the observance of human rights and fundamental freedoms.[25] It also emphasises social progress and achievement of a better standard of living as focused on by the

[15]Article 31 of TRIPS Agreement .
[16] Article 31 of TRIPS Agreement.
[17] World Trade Organization Council for Trade-Related Aspects of Intellectual Property Rights 'Waiver from certain provisions of the TRIPS Agreement for the prevention, containment and treatment of COVID-19 – responses to questions' IP/C/W/672 (2021) 1. *Also see* Ellen F.M' T Hoen 'TRIPS Pharmaceutical Patents and Access to Essential Medicines Seattle, Doha and Beyond' (2003) 39, 41.
[18] Tahir Amin 'The problem with high drug prices isn't 'foreign freeloading,' it's the patent system' found at https://www.cnbc.com/2018/06/25/high-drug-prices-caused-by-us-patent-system html accessed on 1 March 2021. According to this author, the U.S. prescription drug market, monopolies are yielding reckless pricing schemes and prohibitively expensive drugs for Americans (and people around the world) who need them.
[19] A. A Ekeigwe, Drug manufacturing and access to: the West African story. A literature review of challenges and proposed remediation (2019) 5:3 Springer Open Access 1, 4.
[20] International Human Rights Committee available at www.ohchr.org/en/hrbodies/ccpr/pages/ccprindex.aspx accessed on 8 July 2021.
[21] Committee on Economic Social and Cultural Rights available at www.ohchr.org/EN/HRBodies/CESCR/pages/cescrindex.aspx accessed on 8 July 2021.
[22] International Covenant on Economic, Social and Cultural Rights (ICESCR) (December 16, 1966), U.N. Doc. A/RES/21/2200 entry into force 3 January 1976 (ICESCR) Article 12.
[23] Article 2 (1) of ICESCR.
[24] Article 2(2) of ICESCR .
[25]Universal Declaration of Human Rights, adopted 10 December 1948, Preamble para 10.

right to development.[26] On a regional level, the African Charter on Human and Peoples' Rights (ACHPR) states that 'the right to development and civil and political rights and social, economic and cultural rights cannot be dissociated from each other'.[27] The normative basis of the right to development states:

> All peoples have the right to their economic, social and ultural development with due regard to their freedom and identity and in the equal enjoyment of the common heritage of mankind. States shall have the duty, individually and collectively, to ensure the exercise of the right to development.[28]

Furthermore, the right to development denotes a progression of development, leading to the realisation of all human rights through a rights-based approach.[29] The ACHPR uniquely codifies the right to development as legally binding on states that ratified and or signed the convention, thereby making it an obligation for states to ensure the progressive realisation of the right.[30]All this entails that the right to health cannot be alienated from the right to development. Both rights are interlinked, and a healthy being has the capacity for personal development as well as assisting the nation, or other individuals develop. In this background, the thesis will look at TRIPS provisions and their effects on the right to health *vis a vis* right to development.

1.2 Problem Statement

It remains an issue that patent protection is advantageous to developed countries but a burden to developing and LDCs. It hinders progress to ensuring access to health. The protection also presents challenging barriers to the use of flexibilities provided for in TRIPS, such as counterfeiting Free Trade Agreements (FTAs). M Ford[31] argues that the TRIPS Agreement has brought about a negative impact of unequal access to medicines. According to Grooms, 'TRIPS has unintentionally encouraged inequality when discussing access to pharmaceuticals'.[32] Thus, the question raised in this thesis is whether the flexibilities provided for in the agreements such as

[26]Mesenbet Assefa Tadeg 'Reflections on the Right to Development: Challenges and Prospects' (2010) 10 *African Human Rights Law Journal* 325, 328.
[27]African Charter on Human and Peoples' Rights Preamble, para 9.
[28] Article 22 of ACHPR.
[29]Article 6 of Declaration of Human Rights.
[30]K Arts & A Tamo 'The Right to Development in International Law: New Momentum Thirty Years Down the Line?' (2016) 63 *Neth Int Law Rev* 221, 232.
[31] S Ford 'Compulsory Licensing Provisions under the TRIPS Agreement: Balancing Pills and Patents' (2000) 4 *American University International Law Review* 941, 957.
[32] J Grooms 'Has TRIPS caused inequalities in countries' access to pharmaceuticals?' (2016*)* Department of Economics University of Florida Pomona College 1, 34.

the Doha Declaration and other agreements such as FTAs can be used to ensure better access to health for DCs and LDCs in particular Zimbabwe.

The protection of patents under the TRIPS Agreement by manufacturing companies which are mainly from developed countries affect the fundamental issue of research and development because it then remains in large pharmaceutical companies. In contrast, the diseases affecting developed countries may differ from those affecting DCs.[33] On the other hand, it is argued that member states may use these flexibilities when it is necessary to protect public health and access to medicines, and a patent may not be used as a license to abuse the market.[34] However, it remains questionable whether these flexibilities are helping countries in need and whether the patents are not being used to the advantage of developed countries to shift the market into a position favourable to them.

Interestingly, India, one of the countries with no patent protection provisions post TRIPS era, has managed to be the provider of generic drugs over the years to most developing and LDCs.[35] The TRIPS Agreement also aims at reducing barriers to international trade,[36] as evidenced by the provisions of flexibilities. However, the thesis will discuss the extent to which the TRIPS Agreement has managed to reduce such barriers with specific regards to Zimbabwe. Blakeney is of the opinion that the TRIPS Agreement is both a burden: complying with various intellectual property obligations and an opportunity: promotes technological innovation and dissemination.[37]This thesis, therefore, discusses the burdens and opportunities of the TRIPS Agreement to reveal which one outweighs the other.

The TRIPS Agreement negative impact on DCs and LDCs goes to the root of development; hence the thesis also focuses on the right to development. It is challenging to promote individuals development and, at the same time, maintain the stringent patent provisions under the TRIPS Agreement. The realisation of the right to development encompasses equal opportunity for all to

[33] M Motari et al 'The role of intellectual property rights on access to medicines in the WHO African region: 25 years after the TRIPS agreement' (2021) 21:490 BMC Public Health 1,6.
[34] E Munyuki and R Machemedze 2010 'Implementation of TRIPS flexibilities by east and southern African countries: status of patent law reforms by 2010, EQUINET Discussion Paper 80.EQUINET Harare 4-7.
[35] T Bazzle, 'Pharmacy of the developing world, reconciling intellectual property rights in India with the right to health: TRIPS, India's patent system and essential medicine' (2011) 42*GJIL* 785, 800.
[36] TRIPS Agreement Preamble.
[37] M Blakeney and S Mengistie 'Intellectual Property and Economic Development in Sub-Saharan Africa'(2011) 14 *JWIP* 238, 264.

access basic resources, education, health etc.[38] It then means that the infringement of the right to health through poor access to medicines due to the monopoly created by patents negates the process of the realisation of the right to development.

The purpose of this thesis is to review and discuss the TRIPS Agreements' provisions and their impact on access to health and development in Zimbabwe.

1.3 Summary of the research topic and key questions to be answered

This thesis will discuss the TRIPS Agreement provisions and their impact on access to health and the right to development in Zimbabwe. It will also discuss how the TRIPS Agreement, together with other relevant agreements such as bilateral and regional Free Trade Agreement (FTAs) entered in protecting intellectual property rights: patents in particular, have created a favorable platform for developed countries in access to health and realisation of the right to health and how it has not been of many benefits to DCs and LDCs in the same area.[39] It is also worth noting that the research will also focus on how the right to development is then affected directly or indirectly when the right to health is affected.

The research questions to be answered may be outlined as follows:

- How did TRIPS become part of the multilateral trade system?
- To what extent is the right to health and access to medicines protected internationally, regionally and nationally in Zimbabwe? How have the TRIPS provisions impacted the right to health and access to medicines in DCs and LDCs? How is the right to development affected by the negative or positive impacts on the right to health?
- To what extent has Zimbabwe benefited from the TRIPS Agreement?
- To what extent has Zimbabwe utilised the TRIPS flexibilities to its advantage to ensure access to medicines and realisation of the right to health and development?
- What recommendations and conclusions can be derived from India and South Africa for Zimbabwe to improvre its patent law and improve realization of the right to heath and development?

[38]Declaration on the Right to Development Article 8.
[39]Y A Vawda 'After the *Novartis* judgment - 'Evergreening' will never be the same again!' 2014 (18) *Law Democracy & Development* 305,312.

1.4 Aim and relevance of the study

This thesis aims to explore the TRIPS Agreement and the difficulties in implementing flexibilities in the same agreement as a result of FTA's heightened enforcement measures and the threat of trade sanctions Zimbabwe.[40] When the Paris Convention for the Protection of Industrial Property introduced patent protection, it made provision for the use of compulsory licenses to prevent abuse from exclusive rights conferred by patents.[41]

An analysis of Zimbabwe will be done to show the extent to which the country utilise TRIPS flexibilities as well as how far it has gone to implement them into its domestic legislation. In addition, the thesis will look at whether the domesticated TRIPS provisions have been utilized for the realisation of the right to development and the right to health. India and South Africa will be used as a basis for recommendations from what yielded results for them. For example:

- Zimbabwe amended its Patent Act in 1994 when the TRIPS Agreement came into effect to ensure compliance with the requirements and in 2002 used the flexibilities through an HIV/AIDS pandemic notice of Declaration of Period of Emergency.[42] However, there are still debates that more need to be done to ensure better medicine access.
- Zimbabwe also declared a state of emergency during the Cholera pandemic in 2018. The health delivery system has also reached its worst in 2018-2019, with medication highly-priced, thereby affecting people's right to health and right to development. The thesis will explore how Zimbabwe has utilised the TRIPS Agreement to its advantage during these dire times.
- South Africa also has Patent Act 57 of 1978, which was last amended in 2002 and in 2000, the South African government was taken to court [43]when it tried to use flexibilities by over 30 drug companies who were challenging the pharmaceutical legislation which had been put into place.[44] Similat to Zimbabwe, debates are ongoing on the use of flexibilities.

[40] B Baker & T Avafia 'The Evolution of IPRs from Humble Beginnings to Modern Day Trips Plus Era: Implications for Treatment access (2011) 14.
[41]Paris Convention for the Protection of Industrial Property 1967, Article 5A.
[42] M Khor 'Patents, compliances and access to medicines some recent experiences' (2010) 14.
[43]*Pharmaceutical Manufacturers Association of South Africa and Another: In re Ex Parte President of the Republic of South Africa and Others* (CCT31/99) [2000] ZACC 1; 2000 (2) SA 674; 2000 (3) BCLR 241 (25 February 2000).
[44]C. M. Correa and G Velásquez 'Access to medicines: Experiences with compulsory licenses and government use – the case of hepatitis c' (2019) 14.

- India is one of the countries that seems to have done more as its Patent Act of 1970 has specific provisions of the flexibilities such as parallel import, compulsory licensing, and provisions to oppose an application for a patent before and after it is granted.[45]

These examples and more recent ones[46] will be explored to examine how Zimbabwe has utilised the flexibilities and the difficulties experienced in doing so. It will further explore both positive and negative impacts the TRIPS Agreement has had on the country.

Lastly, the thesis will explore the impact of the TRIPS Agreement and its subsequent agreements on WTO members, specifically Zimbabwe, on access to medicines and realisation of the right to health and right to development.

1.5 Literature review

The right to health is a very broad principle recognised by various international conventions, treaties and declarations, including the ICESCR of 1966 and the ACHPR of 1981. The discussion on the right to health in this thesis will focus on the constitutional right to health in Zimbabwe and how it is promoted in line with the international conventions referred to above. According to Mercurio, there is a need to prioritise public health regardless of constraints from pharmaceutical patent owners' protection over medicines and strive to strike that appropriate balance between patent protection and lifesaving medicines which the TRIPS Agreement seems to have failed to do.[47] As Peter K Yu states, the TRIPS Agreement was never meant and 'should not prevent members from taking measures to protect public health'.[48]

DCs and LDCs are the most affected by life-threatening diseases such as malaria, tuberculosis, and even cholera. There definitely is a great need to strike a balance between patent protection for promotion of research and development and ensuring access to medicines. The objectives of the TRIPS Agreement under Article 7 of the Agreement clearly state that 'the protection and enforcement of intellectual property rights should balance between innovation and dissemination

[45] M Azam *Intellectual Property &Public Health in the Developing World* Cambridge, UK: Open Book Publishers, (2016) 129.
[46] See Chapter 5.
[47] B Mercurio 'Resolving the Public Health Crisis in the Developing World: Problems and Barriers of Access to Essential Medicines' (2006) 5 *NJIHR* 1, 5.
[48] P K Yu, 'The Objectives and Principles of the TRIPS Agreement' (2009) 46 *Houston Law Review* 980, 981.

of technology for the benefit of both owner and user of such knowledge'.[49] The TRIPS Agreement intended to strike a balance that promotes social and economic welfare. The creation of monopolies over patents, therefore, is ultra vires to the intention and ignorant of Article 7[50] through its failure to maintain a balance between producers and consumers.

As such, the Doha Declaration of 2001, mainly paragraph 5, reinforces the principle of flexibility which was initially provided for in the TRIPS Agreement Article 31. This theory interlinks with the accessibility to medicines as it ensures that non-patent holder countries access medicines through the use of the flexibilities. Baker and Avafia explicates that the principle is also derived from the school of thought that medicines are essential to one's wellbeing. They should not be subject to a monopoly.[51]

TRIPS brought about a new era of patents whereby big pharmaceutical owners have the privilege to patent their work and decide who can make generic drugs and when. Drahos and Braithwaite argue that TRIPS has given owners of patents the power to unilaterally price products without considering costs of production,[52] thereby commercialising their products and affecting access to medicines by the poor in DCs. Baker and Avafia explicate that, the principle of commercialisation of medicine negatively impacted on research and development of diseases affecting the poor as financial assistance on research and development fail to focus on research to control neglected diseases.[53]

On the other hand, TRIPS was introduced as a tool meant to equalise opportunities towards accessibility of medicines in both developed and DCs. There is, however, a clear imbalance between DCs focus on survival and development; and developed countries' focus on expanding their economy through TRIPS.[54] This is detrimental to the goal of DCs to provide cheaper drugs, thereby creating better access to medicines. Khor echoes the lack of reciprocal benefit, where rich countries gain mostly and DCs bear all costs through the payment of royalties to IPR holders which further reduces consumeraccess and affects their health.[55]

[49] Article 7 of TRIPS Agreement.
[50] Ibid.
[51] B Baker & T Avafia (note 40 above; 7).
[52] P Drahos & J Braithwaite 'The Corner House 'Who Owns the knowledge Economy? Political Organising Behind TRIPS' (2004) 2.
[53] B Baker & T Avafia (note 40 above; 17).
[54] B Lal Das 'The WTOs Doha Negotiations: An Assessment' (2008) 2.
[55] M Khor 'Implications of some WTO rules on the realisation of MDG's' (2005) 13-14.

The emerging of TRIPS-Plus overriding and undermining provisions of TRIPs such as flexibilities, compulsory licensing and special provisions brings about a challenge to access of medicines in DCs. Sell argues that the developed countries are including provisions for TRIPS-Plus such as prohibitions of parallel importation, restricted conditions for compulsory licensing and patent term extensions in the FTAs they are signing with DCs to continue with the monopoly associated with patents.[56] Smith *et al*. comment that TRIPS-Plus and the FTAs associated with it has put constraints on developing countries ability to oppose the patent application or review the extension of patent protection.[57] Furthermore, Smith *et a*l. explains that DCs' hope for foreign technology and investment results in the countries signing bilateral agreements containing TRIPS-Plus provisions, which they have to abide by lest they suffer from developed countries imposed sanctions.[58]

The contrast between TRIPS and TRIPS-Plus, and DCs and developed countries needs, especially with regards to health or access to medicines, is holistic and may only be dealt with by looking at the diverse views of different authors.

1.6 Research methodology

The research will be desk-based. It will draw information from journal articles, newspapers, discussion papers and other online material dealing with the impacts of IPRS on access to medicine and the realisation of the right to health and development. Case law, case studies and legislation from the three countries will also be made use of to highlight the developments made so far in terms of protection of the right to health and development as well as the use of TRIPs flexibilities to promote the rights. The research will also consider international conventions, agreements such as TRIPS, ICESCR, ACHPR and other appropriate literature such as journals, articles and newspapers.

1.7 Structure of the dissertation

Chapter 1 Introduction: This is an introduction to the topic and includes the research questions and a research methodology to be used**.** It gives an insight into what is contained in the following

[56] S K Sell 'TRIPS-Plus Free Trade Agreements and Access to Medicines' (2007) 28 *Liverpool Law Review* 41, 59.
[57] R D Smith, C Correa & C Oh 'Trade, TRIPS and pharmaceuticals' (2009) 373 *Lancet* 684, 687.
[58] Ibid 687.

chapters and, through the literature review, outlines the conflicting views of different authors on the research questions.

Chapter 2 TRIPs: Provides background and or brief history of the Trade-Related Aspects of Intellectual Property from the General Agreement on Tariffs and Trade (GATT) through the World Trade Organisation (WTO). It will also outline the provisions of the Trade-Related Aspects of Intellectual Property that are relevant to this thesis, particularly patents, flexibilities, compulsory licensing and special provisions. The Chapter is an overall discussion of how TRIPS became part of the multilateral trade system.

Chapter 3 The right to development and the right to health. This Chapter fully explores the extent to which the right to development and the right to health and access to medicines are perceived and protected Internationally and Regionally**.** It also focuses on how the right to health and the right to development being co-existing and intertwined are affected by TRIPS provisions in DCs and LDCs. Of importance also to this Chapter will be the provisions of the World Health Organisation (WHO) constitution and different scholarly arguments regarding the right to development. Case law such as the *Social and Economic Rights Action Centre (SERAC) & Another v Nigeria* (2001) AHRLR 60 (ACHPR 2001) and *Centre for Minority Rights Development (Kenya) and Minority Rights Group International on behalf of Endorois Welfare Council v Kenya* (2003) will also be used to illustrate the application of the right to health and the right to development.

Chapter 4 Country case study-Zimbabwe: a general overview of how Zimbabwe as a developing country facing economic/financial challenges, has domesticated the TRIPS Agreement and other international, regional conventions prementioned in Chapter 3; particularly in regards to the rights to health and development. Furthermore, with the recent developments of natural disasters, specifically COVID 19 pandemic; Cyclone Idai affecting communities; some deaths from Cholera, the volatile economic and political situation and a rise in new HIV/AIDS infections as well as a state of emergency being declared: the chapter seeks to explore how Zimbabwe has implemented the TRIPS Agreement; Patents provisions to its benefit in furtherance of the right to development and the right to health**.**

Chapter 5 Recommendations and Conclusions: This Chapter will discuss the findings made and the recommendations for Zimbabwe from South Africa and India. It will also be the concluding chapter of the thesis.

1.8 Limitation of the study

This thesis is only limited to Zimbabwe as the case study, with India and South Africa being referred to in the final Chapter for recommendations. India and South Africa are relevant to the extent they have adopted TRIPS regulations into their domestic laws and implemented them and usage of flexibilities provided for to their benefit. Zimbabwe can learn some lessons regarding the TRIPS Agreement from South Africa and India, which are currently classified as developed countries and have utilised the TRIPS Agreement to their advantage at some point in time.

1.9 Conclusion

As indicated above, the TRIPS Agreement and the monopoly that comes with it has far-reaching consequences to DCs and LDCs, such as the non-availability of essential medicines. Therefore, it is essential to determine whether such flexibilities provided for in the TRIPS Agreement are enough to surmount and counter the problems faced by DCs and LDCs as a result of the same Agreement. This chapter is a basic overview of the chapters to follow.

CHAPTER TWO: BACKGROUND DISCUSSION ON TRADE RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS

2.1 Introduction

The World Trade Organisation (WTO) TRIPS standardises the protection of intellectual property, including pharmaceutical patents.[59] It took 47 years for TRIPS to materialise, from the GATT negotiations, Uruguay Round and finally its formation as part of the WTO *acquis* in 1994.

The GATT negotiations subsequently led to the creation of the WTO and marked the end of the failed attempt to create an International Trade Organization (ITO) in 1948.[60] The GATT negotiation rounds also brought about a new perspective of international trade encompassing intellectual property rights to a higher degree. Protection and harmonisation of intellectual property rights promotes trade by enforcing transparency and enhancing global cooperation in trade.[61] However, it was left to individual countries to deal with their intellectual property rights feuds. This means that before the TRIPS Agreement was adopted, IPRs negotiations were strictly considered territorial,[62] created by national laws and seeking protection abroad was not easy when different laws applied.[63]

During the 47 years of round negotiations that led to the creation of the WTO, the World Intellectual Property Organization (WIPO), was established in 1967, coming into existence in 1970.[64] However, even before GATT round negotiations had started, intellectual property rights had been recognised in the early 19th century under the Paris and Berne Conventions, which were later adapted into WIPO.[65] Within all this turmoil to formulate a better functioning global trade

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[59] E F. M't Hoen 'TRIPS, Pharmaceutical Patents and Access to Essential Medicines: Seattle, Doha and Beyond' (2003) 39.

[60] The GATT years: from Havana to Marrakesh available at http://www.wto.org/english/thewto_e/whatis_e/tif_e/fact4_e.htm, accessed on 18 January 2021.

[61] A Kur & M Levin *Intellectual Property Rights in a Fair World Trade System* (2011) 11.

[62] Territorial means that the scope of an IP right is limited to the territory of the state granting it. The enforcement of IP rights is regulated by national or regional legislation and within defined territorial borders. See L.T.C. Harms *A Casebook on the Enforcement of Intellectual Property Rights* 4th ed WIPO (2018) 12.

[63] W Martin & L A Winters 'The Uruguay Round: a milestone for the developing countries' in W Martin et al (eds) *The Uruguay Round and the developing countries* (1996) 1, 24. For example, a drug patented in Zimbabwe would only be protected against any infringement in Zimbabwe and anyone anywhere else in the world would not need the patent holder's permission to produce the same drug.

[64] G Dutfield & U Suthersanen *Global Intellectual Property Law* 2 ed(2008) 29.

[65] V.B Kerry & K Lee 'TRIPS The Doha declaration and paragraph 6 decision: what are the remaining steps for protecting access to medicines?' *Global Health* 3**,** 3 (2007) doi: 10.1186/1744-8603-3-3. 1, 4.

regulating organisation, intellectual property rights protection also developed. This was due to the gravity of international trade and the need to acknowledge creators and inventors globally and not merely nationally. As such, intellectual property rights protection grew as the multilateral trade system was introduced.

Against this background, this chapter reveals how TRIPS became part of the WTO by discussing the chronological events from GATT to WIPO.[66] This chapter aims to determine how TRIPS became part of the multilateral trade system. Firstly, the chapter will discuss the history and background of the WTO. It will chronologically synchronise the stages of negotiations done and reveal the bigger picture or important negotiations leading to the formation of the WTO. Secondly, the formation of TRIPS and incorporation into the WTO will be discussed. Lastly, throughout the discussion, the focus will be directed on patents and the provisions of TRIPS promoting access to medicines such as flexibilities, compulsory licensing and special provisions.

2.2 Intellectual property in the General Agreement on Tariffs and Trade

2.2.1 From Geneva Tariff Conference to Tokyo Round

During the GATT years, eight rounds of tariff negotiations were held between 1947 and 1994.[67] The original intention after WWII was to create an agency for the United Nations called ITO in 1947 in Havana, Cuba.[68] This period is regarded as the beginning of trade liberalisation whereby international trade in different forums would be open worldwide.[69] The first negotiation round was the 1947 Geneva Tariff Conference marking the beginning of tariff negotiations which considered granting concession if the country providing the biggest part of the product requested a tariff reduction.[70]

The second round of GATT was the Annecy Tariff Conference of 1949, running from April to 10 August 1949.[71] It aimed at facilitating accession to GATT and enabled negotiations between the

[66] Overview: the TRIPS Agreement available at http://www.wto.org/english/tratop_e/trips_e/intel2_e.htm, accessed on 10 January 2021.
[67] GATT bilateral negotiating material by Round available at www.wto.org/English/docs_e/gattbilaterals_e/indexbyround_e.htm accessed on 8 July 2021.
[68]The GATT years: from Havana to Marrakesh available at http://www.wto.org/english/thewto_e/whatis_e/tif_e/fact4_e.htm, accessed on 10 January 2021.
[69]General Agreement on Tariffs and Trade October 30, 1946 available at https://www.loc.gov/law/help/us-treaties/bevans/m-ust000004-0639.pdf , 639-640 accessed on 22 June 2021.
[70] Fifitieth Anniversary of the Multilateral Trading system. WTO/GATT Chronology of events available at https://www.wto.org/english/thewto_e/minist_e/min96_e/chrono.htm, accessed on 10 January 2021.
[71] Ibid.

Contracting States and the States which had not participated in the first round.[72] It was followed by the Torquay Round held at Torquay, United Kingdom, from September 1950 to April 1951.[73] This round focused on tariff reduction and reproduced Article 17 of the Havana Chatter, promoting equal treatment of all parties under the Most Favoured Nation principle[74], which is still part of the TRIPS Agreement today.[75] Similar to the Torquay Round the Geneva Tariff Conference came fourth (1955 to 1956) and also focused on tariff reduction. The Dillon Round followed from 1960-1961, concerned with tariff renegotiations consequential to the launching of the European Economic Community (ECC) and the round was the last of the traditional tariff negotiating conferences.[76] Further, the Kennedy Round of 1964-1967 followed introducing that developed countries may not expect reciprocity from less developed countries under the principle of reciprocity.[77] The issue of reciprocity is still controversial under TRIPS, with DCs complaining that patents make it difficult for them to access much-needed medicines in their countries. In contrast, rich countries hold the patents.[78]

Furthermore, the Kennedy Round had a linear rule of 50% reduction in tariffs and greatly led to a reduction of bilateral tariffs.[79] Lastly, the Tokyo Round (1973-1979) followed, aimed at promoting increased participation by developing countries in the global trading system, and it allowed developed countries to 'accord differential treatment in favour of DCs in the tariff and non-tariff areas', which today is still part of WTO.[80] The Tokyo Round also resulted in three important developments, being:

a. DCs agreed to limited market access commitments and relatively few tariff bindings,

[72] A Hoda,'Tariff Negotiations and Renegotiations under the GATT and the WTO Procedures and Practices*:* World Trade Organization'*(*2002) 25.
[73] The World Trade Review available at http://worldtradereview.com/webpage.asp?wID=434, accessed on 10January 2021.
[74] Principles of the trading system available at www.wto.org/English/thewto_e/tif_e/fact2_e.htm accessed on 8 July 2021. See also Article 4 of TRIPS Agreement.
[75] Hoda (note 72 above) 27.
[76] The World Trade Review available at http://worldtradereview.com/webpage.asp?wID=436, accessed on 10 January 2021.
[77]Hoda (note 72 above) 30.
[78] This matter will be elaborated at a later stage of the thesis.
[79] B Norwood 'The Kennedy Round: A Try at Linear Trade Negotiations' (1969) 12 *University of Chicago Journal of Law & Economics* 297, 301 available at http://www.jstor.org/stable/724755?seq=9, accessed on 20 January 2021.
[80] The Tokyo Round: a first try to reform the system available at www.wto.org/english/thewto_e/whatis_e/tif_e/fact4_e htm, accessed on 20 January 2021.

b. It was agreed that only signatories would benefit from the new non-tariff measure agreements[81] and

c. A new framework was established to define and codify key legal rights and obligations of DCs under the GATT.[82]

The Differentiation Treatments,[83] according to the Tokyo Round, included but were not limited to enhanced access to markets, the non-reciprocal principle whereby DCs would benefit from multilateral trade agreements without being recquired to offer mutual contracts. It aslo included the 'freedom to create preferential regional and global trading arrangements on their terms' without complying with the GATT requirements.[84] A particular achievement of the Tokyo Round was the 'Enabling Clause', also known as the 'Decision on Differential and More Favourable Treatment, Reciprocity and Fuller Participation of Developing Countries'.[85] The enabling clause allowed countries to give different and favourable treatment to DCs as well as offer non-reciprocal favoured treatment to products originating in DCs.[86]

2.2.2 The Uruguay Round

The seven preceding rounds of negotiations led to one of the most significant rounds, the Uruguay Round of 1986-1993. Although it was one of the most protracted rounds, it brought about a huge turnaround in international trade. It was suggested by the United States of America (USA) in 1982 to extend GATT's coverage to areas of international trade growing but not covered by existing provisions.[87] These 'new' areas were intellectual property protection and trade in services. As such, the Uruguay Round aimed at addressing the inadequacies of GATT and outstanding

[81]A Keck and P Low*Special and Differential Treatment in the WTO: Why, When and How?*, WTO Staff Working Paper ERSD-2004-03 (2004) 5.
[82] MD M Hasan 'Special and Differential Treatment in the WTO: Its content and competence for facilitation of development' *NAUJILJ* (2016) 43.
[83] Article XVIII and part VI of the GATT states that any subsidizing contracting party shall notify in writing contracting parties of the nature, estimated effect on the quantity of exported from or imported into its territory and the circumstances surrounding the subsidization and shall take measures to minimise the prejudice and threats to interests of contracting and other prties. Also, Article III of GATT 1994 which is an overview of the general principle on non-discrimination; prohibits discrimination between domestic and like imported products of member countries.
[84]M Gibbs *Special and Differential Treatment in the context of globalization*, G15 Symposium on Special and Differential Treatment in the WTOAgreements (1998) 2.
[85] Hasan (note 82 above) 47.
[86] Ibid.
[87] J J Schott & W Buurman *The Uruguay Round: An Assessment* (1994) 4.

problems.[88] In December 1988, the Montreal meeting was held, and disputes over intellectual property, agriculture and textiles blocked the progress of the meeting. As such a review of GATT was set for later in April 1989.[89] Until December 1993, further negotiations were still ongoing to finalise the Final Act, which was signed by most of the 123 participating governments on 15 April 1994 at a meeting in Marrakesh, Morocco.[90]

Particular achievements of the Uruguay Round included; 'a trade-weighted average tariff cut of 38%, the conclusion of the Agreement on Agriculture, adoption of the General Agreement of trade in Services ,TRIPS and establishment of the World Trade Organization'.[91]

During the Uruguay Round, most nations did not have intellectual property laws and a clear understanding of the subject. Furthermore, there was no neutral ground in terms of application of intellectual property laws as individual countries had different methodologies of dealing with intellectual property rights. The need for a more accommodating agreement, sensitive to international trade growth and expansion, then put in motion negotiations giving birth to TRIPS.

This marked the replacement of the GATT by the WTO and the beginning of TRIPS.[92] The need for more accommodating agreements brought about the birth of WTO and new agreements such as TRIPS to deal with extended issues not covered by GATT.[93] The WTO ensured trade takes place according to multilateral trade rules and lower barriers to trade.[94] In doing so, it governed intellectual property rights under the TRIPS Agreement, which came into effect in 1995 to ensure that the same rules apply globally.

[88] U A Mwalimu 'Implications of WTO/TRIPS in East Africa-with special emphasis on Pharmaceutical Patents' (2002) 1, 2.
[89] Schott (note 87 above) 6.
[90] The Uruguay Round available at http://www.wto.org/english/thewto_e/whatis_e/tif_e/fact5_e.htm, accessed on 21 January 2021.
[91] The World Trade Review, 8th Round (Uruguay Round, 1986-1994) available at http://worldtradereview.com/webpage.asp?wID=439, accessed on 20 January 2021.
[92] The Uruguay Round available at http://www.wto.org/english/thewto_e/whatis_e/tif_e/fact5_e.htm, accessed on 20 January 2021.
[93] N Grimwade 'The GATT, the Doha Round and Developing Countries' in H Katrak et al (ed) *The WTO and Developing Countries* (1994) 11, 17.
[94] Ibid 12.

2.3 The World Trade Organisation (WTO)

As alluded to earlier, the WTO was established by the Marrakesh Declaration of 15 April 1994[95], under which Ministers welcomed the establishment of protection of trade-related intellectual property rights. Furthermore, it also 'reinforced multilateral trade provisions in agriculture, textiles and clothing and established trade in services', as was intended to by the Uruguay Round of negotiations.[96] It is the successor of GATT: brought about by the end of Uruguay Round, 'an organisation for trade opening, a forum for governments to negotiate a trade agreement and settle trade disputes'.[97] The rules and principles of the WTO apply to the TRIPS Agreement, as part of the single package or single undertaking, which encompasses GATT as modified by the Uruguay round, agreements and arrangements in a single institutional framework.[98]

As alluded to earlier, the WTO took on issues GATT did not cover, such as trade in services and intellectual property protection.[99] In doing so the WTO further outlines principles of liberalisation and permitted exceptions, including individual countries commitment to lower tariffs and trade barriers.[100] The WTO also continues to encourage non-discrimination, transparency, predictability in trade and the most favoured nation principle.[101] All of this forms the backbone of TRIPS and other related agreements under WTO. It further has the primary purpose of opening trade for the benefit of all.[102] The WTO has brought many changes after GATT, including dispute resolution and specific reference to intellectual property rights.

2.4 The Trade-Related Aspects of Intellectual Property Rights (TRIPS)

The TRIPS Agreement was incorporated into the WTO in 1995 after debates on economic development, trade and globalisation in the 1990s, which ultimately shaped discussions on

[95] http://www.wto.org/english/docs_e/legal_e/marrakesh_decl_e.htm accessed on 20 January 2021

[96]http://www.wto.org/english/docs_e/legal_e/marrakesh_decl_e htm accessed on 20 January 2021.

[97]World Trade Organization: Who we are, available at http://www.wto.org/english/thewto_e/whatis_e/who_we_are_e.htm accessed on 20 January 2021.

[98] J Whalley 'Developing countries and system strengthening in the Uruguay Round' in W Martin et al (eds) *The Uruguay Round and the developing countries* (1996) 409, 426.

[99] R M Stern 'The Multilateral Trading System' IPC Working Paper Series No.57 (April 2007) 12.

[100] Understanding the WTO: what we do available at http://www.wto.org/english/thewto_e/whatis_e/what_we_do_e.htm, accessed on 20 January 2021.

[101] Aid for Trade at a Glance 2009: Maintaining Momentum available at http://www.wto.org/english/res-e/booksp-e/aid4trade09-e.pdf accessed on 20 January 2021.

[102] World Trade Organization available at http://www.wto.org/english/thewto_e/whatis_e/wto_dg_stat_e.htm, accessed on 20 January 2021.

traditional knowledge, folklore and access to essential medicine.[103] The TRIPS Agreement protects intellectual property rights (IPRs) which have for a long time been the subject of many international conventions and agreements under the World Intellectual Property Organisation (WIPO), which came before the WTO.[104] T therefore, the TRIPS Agreement was born from the inclusion of IPRs in the Uruguay Round, representing a major extension in rulemaking into an area that was not covered by GATT.[105]

When conversing about the TRIPS Agreement, it is essential to go back to the foundation of intellectual property rights formulated in the early 19th Century, with such conventions as the Berne and Paris Conventions as well as WIPO. To show how far intellectual property rights have come and to clarify where the changes called for under GATT were based on, a brief discussion of the first two conventions will be given. Even though that was the foundation, as global trade extended with the eight negotiations rounds under GATT, so did the need to expand laws protecting IPRs.[106] GATT negotiations set evolution in motion, which resulted in the addition of new rights to be protected under intellectual property.

From the outset, the TRIPS Agreement incorporates the Paris Convention 1967, the Berne Convention, the Rome Convention 1961 and the Treaty on Intellectual Property in Respect of Integrated Circuits 1989.[107] Although the Paris and Berne Conventions have so far been revised, they were the first international treaties to be negotiated for intellectual property rights.[108]

The Paris Convention was firstly known as the Paris Union and Convention for the Protection of Industrial Property, which came into force in 1883 with no standard protection terms but covered patents, industrial designs and trademarks[109] and highlights the basis of patent protection in TRIPS. The Paris Convention gave birth to the core principles[110] found in TRIPS, such as the National

[103] T J Lybbert 'On assessing the cost of TRIPS implementation' (2002) 1 *World Trade Review: Economics, Law & International Institutions* 309, 309.
[104] C Michalopoulos *Developing Countries in the WTO* 1 ed (2001) 129.
[105] Ibid.
[106] C A P Braga 'Trade-related intellectual property issues: the Uruguay Round agreement and its economic implications' in W Martin et al (eds) *The Uruguay Round and the developing countries* (1996) 341, 341.
[107] The World Trade Review: Agreement on Trade Related Aspects of Intellectual Property available at http://worldtradereview.com/webpage.asp?wID=649, accessed on 20 January 2021.
[108] Braga (note 106 above) 342.
[109] Dutfield & Suthersanen (note 64 above) 23-24.
[110] P Pusceddu 'Assessing Access to Medicines in Preferential Trade Agreements: From the Trans-Pacific Partnership to the Comprehensive and Progressive Agreement for Trans-Pacific Partnership' (2018) 49 *IIC* 1048,1052.

Treatment[111] and flexibilities, including compulsory licenses[112] and special agreements.[113] Rather, the Berne Convention focused on copyright in 1886 when it started[114] and is the backbone of copyright in TRIPS. The Berne Convention was adopted to form the core provisions for copyright protection under TRIPS.[115]

WIPO was introduced in 1967, situated at the heart of the intellectual property and administering the conventions with the Paris Convention being revised by the Stockholm Act in 1967 and Berne Convention by the Paris Act of 1971, which is how TRIPS adopted them.[116] However, efforts by WIPO to promote international harmony toward IPR protection failed since most of the conventions required the use of national treatment; lacked minimum standards for protection or coverage of subject matter and WIPO lacked disciplinary measures for non-compliance in the absence of a dispute resolution board.[117] This prompted the beginning of IPR negotiations under GATT and led to the TRIPS Agreement under WTO in 1995, which has so far gone some revision under the Doha Round of 2001.[118]

2.4.1 Relevant TRIPS provisions

The purpose of TRIPS is to standardise the minimum IPR protection worldwide, extend protection to sectors previously not covered by laying down rules and procedures on the acquisition and enforcement of IPRs, and provide for a dispute settlement mechanism.[119] The Preamble to TRIPS provides:

> Desiring to reduce distortions and impediments to international trade, with the need to promote effective and adequate protection of intellectual property rights, and to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade; recognises the special needs of the least-developed country Members in respect of maximum

[111]Article 2 of Paris Convention .
[112]Article 5A of Paris Convention.
[113] Article 19 of Paris Convention.
[114] J Whalley 'Developing countries and system strengthening in the Uruguay Round' in W Martin et al (eds) *The Uruguay Round and the developing countries* (1996) 409, 426.
[115]Trade Related Aspects of Intellectual Property Rights, Article 9-10.
[116] J J Schott & J W Buurman (note 87 above) 115.
[117] Braga (note 106 above) 342.
[118] The Doha Round available at http://www.wto.org/english/tratop_e/dda_e/dda_e.htm#development, accessed on 20 January 2021.
[119] C Michalopoulos, Developing Countries in WTO 1ed (2001) 138.

> flexibility in the domestic implementation of laws and regulations to enable them to create a sound and viable technological base.[120]

According to Dutfield, the Preamble of TRIPS affirms members' need to create effective and satisfactory protection of intellectual property rights.[121] In doing so, members still have to observe the public policy objectives.[122] Thus, the agreement aims at balancing intellectual property rights with trade whereby as much as IPR's are recognised and protected, they may not be allowed to hinder progress in international trade or work against uplifting least developed and DCs through trade.

Further, the TRIPS Agreement's objectives aim to 'reduce distortions and impediments to international trade, promote effective and adequate protection of intellectual property rights, and ensure that measures and procedures enforcing intellectual property rights do not bar legitimate trade'.[123] Article 7 of the TRIPS Agreement states that:

> The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.[124]

This shows that the TRIPS Agreement, as much as it protects IPRs, promotes the dissemination of knowledge and balancing the rights/interest between intellectual property rights holders and non-holders. It also supports the protection of IPR's to such an extent that protected intellectual property may still be used for social and economic development[125] as long as non-holders of IPR's maintain their obligations, for example, paying royalties to the patent holder.[126]

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[120] TRIPS Agreement Preamble.
[121] Dutfield &Suthersanen (note 64 above) 34.
[122] Public policy objectives refers to the regulations, laws, constitutional provisions that are meant to solve public problems of economic, political or social nature. It therefore entails that TRIPS have to strike a balance between protection of intellectual property rights and continue to promote, uplift human rights such as the right to health and development. Public policy objectives entail maintaining goals meant to protect and develop the public in general.
[123] Article 7 of TRIPS Agreement which states that promotion o f innovation and dissemination of technology should to the mutual benefit of producers and users and to a balance of rights and obligations.
[124] Article 7 of TRIPS Agreement.
[125] A Slade 'The 'Objectives' and 'Principles' of the WTO Trips Agreement: A Detailed Anatomy.' (2016)12:10 *Osgoode Legal Studies Research Paper No 50* 1,9.
[126] Article 7 of TRIPS Agreement.

Members of TRIPS are bound by the provisions of the agreement and have to implement the provisions within their legal system and practice.[127] Article 8, entitled "Principles", identifies the rights of Members to embrace methods promoting public health, interest and prevent the abuse of intellectual property rights, provided that such methods are in line with the provisions of the TRIPS Agreement.[128] Furthermore, Article 8 adds on Article 7, and they should be read together to create a much more comprehensive protection and balance of rights in intellectual property.

Further, the TRIPS Agreement is also governed by the fundamental rules from Article 3 on National Treatment and the Most-Favoured-Nation treatment of foreign nationals.[129] These rules in Article 3 and 4 cover substantive standards of 'protection' whereby protection entails:

> matters affecting the availability, acquisition, scope, maintenance and enforcement of property rights as well as those matters affecting the use of intellectual property rights specifically addressed in the Agreement.[130]

The national treatment clause prohibits discrimination between nationals of a Member country and the nationals of other Member countries.[131] On the other hand, the most-favoured-nation treatment clause prohibits discrimination between other Members' nationals even though exceptions to this rule exist and are allowed as it was in WIPO.[132] The thesis recognises the value and importance of the protection of IPRs but argues that such protection of IPRs should be beneficial to both developed and DCs and not create a monopoly over drugs manufactured by developed countries.

[127] Article 1 of TRIPS Agreement .
[128] Article 8 of TRIPS Agreement.
[129] Article 74of TRIPS Agreement.
[130] Article 2,3 & 4 of TRIPS Agreement .
[131] Overview of the TRIPS Agreement available at http://www.wto.org/english/tratop_e/trips_e/intel2_e.htm, accessed on 26 January 2021.
[132]Overview of the TRIPS Agreement available at http://www.wto.org/english/tratop_e/trips_e/intel2_e.htm, accessed on 26 January 2021.

2.4.2 Patents

The term patents refer to;

> the protection of any new, innovative invention capable of industrial application[133] whereby the applicant is given exclusive rights of making, using, offering for sale, selling and importing the patented invention[134] for a minimum period of 20 years counted from the filing date.[135]

Further, Michalopoulos describes patents as the protection of inventions pursued through the provision of a reward in the form of a monopoly or market exclusivity for a period of time long enough to profit patent holder.[136] It has been argued by Drahos et al. that patents give owners unilateral power to price products without considering cost production, thereby hindering access to medicines.[137] On the other hand, patents may be described as primary protection to industrial property meant to encourage innovation, design and making of technology.[138]

Patents bring about stringent intellectual property rights, resulting in monopoly by pharmaceutical manufacturers who unilaterally charge exorbitant prices for their patented drugs without looking at production cost.[139] This means that patents mainly benefit developed countries such as the USA, which own the biggest pharmaceutical companies.[140] Yet, they are the least affected by diseases such as malaria and tuberculosis known as 'neglected diseases' affecting DCs.[141] The greatest challenge brought about by patents is the lack of effective access to medicines. They heighten the commercialisation of medicine[142] and make the availability of drugs dependant on patent holders.[143]

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[133] Article 27.1 of TRIPS Agreement.
[134] Article 28 of TRIPS Agreement .
[135] Article 33 of TRIPS Agreement .
[136] C Michalopoulos 'Special and Differential Treatment of Developing Countries in Trips' (2004) 7.
[137] P Drahos & J Braithwaite, 'The Corner House: Who Owns the Knowledge Economy? Political Organising Behind TRIPS' 2004, 2.
[138] Centre for WTO Studies: Indian Institute of Foreign Trade 'Frequently Asked Questions' (2010) 3.
[139] P Drahos & J Braithwaite, 'The Corner House: Who Owns the Knowledge Economy? Political Organising Behind TRIPS' (2004) 8.
[140] Celgen an American company has sought over 105 patents over one of the most expensive cancer drugs on the market, Revlimid and pharmaceutical companies in the United States of America add on new patents to prolong a drug's exclusivity, even when the additions aren't fundamentally new, non-obvious, and useful as the law requires heeby promoting evergreening and restricting access of the drugs by developing countries. See Amin Tahir 'The problem with high drug prices isn't 'foreign freeloading,' it's the patent system' available at https://www.cnbc.com/2018/06/25/high-drug-prices-caused-by-us-patent-system.html accessed on 1 March 2020
[141] B K Baker & T Avafia, 'The Evolution of IPRS from Humble Beginnings to Modern Day TRIPS-Plus Era: Implications for treatment access' (2011) 17.
[142]S Sell 'TRIPS-Plus free trade agreements and access to medicines' (2007) *Liverpool Law Review* 41, 54.
[143] Ibid 50.

One argument is that patents are mainly related to the pharmaceutical industry, many originating from developed countries with a goal of getting profits and refunds for the expenses incurred during research processes and protection for the research results.[144] The monopoly created by patents gives a patent holder the freedom of choice on the decision to commercialise or manufacture the product in more developed countries; usually resulting in patent holder manufacturing in a developed country and importing to low DCs.[145] Ultimately, for the general populace to enjoy their right to health, they have to purchase the research results of the pharmaceutical industry, mainly in the form of medicines. Prices of pharmaceutical inventions tend to be high and usually not affordable to most; due to the inherent monopoly associated with pharmaceutical products.[146]

2.4.3 Flexibilities

The Doha Declaration explicitly outlines the flexibilities and their main aim is to prevent TRIPs from barring members from taking measures to protect public health.[147] The Declaration states explicitly that TRIPS will not prevent members from protecting public health, and members may create exceptions to their IPR laws to allow for the manufacturing of life-saving drugs by a third party without the approval of the patent holder.[148]

Relevant in this respect is Article 31 of TRIPs, which provides for flexibilities whereby the use of patented matter is allowed only in cases of national emergency or extreme urgency.[149] The condition is that the user of the patented matter should have made efforts first to obtain authorisation from the patent holder to use the patented matter and where the user fails to obtain such authorisation, he should notify the holder as soon as reasonably possible.

The three specific flexibilities provided for under TRIPs are compulsory licensing, parallel imports and the bolar provision which are discussed further below.

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[144] E Lisdiyono & M. N. B. Asyhar Assalmani 'Community Right to Health on Pharmaceutical Patents' (2017) 8.7 *International Journal of Civil Engineering and Technology* 920, 921.
[145]A Kaur & R Chaturvedi 'Compulsory Licensing of Drugs and Pharmaceuticals: Issues and Dilemma' (2015) 20 *Journal of Intellectual Property Rights* 279, 279.
[146] E Lisdiyono & M. N. B. Asyhar Assalmani (note 144 above) 922.
[147] World Trade Organization, Declaration on the TRIPS Agreement and Public Health (Doha Declaration), WT/MIN(01)/DEC/2, Ministerial Conference, Fourth Session, Doha, 9-14 November 2001, paragraph 4 & 5, http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e htm accessed on 10 March 2021.
[148] Centre for WTO Studies: Indian Institute of Foreign Trade 'Frequently Asked Questions' (2010) 6.
[149] Article 31 of TRIPS Agreement.

2.4.4 Compulsory licensing

Kyung-Bok Son states that compulsory licensing occurs when the government allows someone other than the patent holder to produce patented products without the consent of the patent owner.[150] As such, compulsory licensing may be described as the 'granting of a license by a government to use a patent without the patent holder's permission' [151] to allow non-patent holders to make generic drugs.

Significant to the discussion is Article 30 and 31 of TRIPS which outline conditions under which compulsory licensing may be used, and one of the condition is in the event of a national emergency or a large-scale outbreak of a disease. The compulsory license was only limited to domestic use, meaning benefits would be confined to countries with manufacturing capacities.[152] The Doha Declaration moved away from this discriminatory concept and allowed for compulsory licensing to be issued to produce drugs for export to countries with no manufacturing capacity.[153] Notably, compulsory licensing arguably (depending on what side you are) is a remedy to the lack of access to medicines by the poor in DCs and LDCs[154] who do not have the capacity to manufacture their drugs. Further, it is the link between the protection of innovation and access. It brings about competition on the market, thereby reducing the price of patented products through the availability of generic products.

Compulsory licensing positively puts companies under compulsory licensing to be more innovative and remain ahead of their competitors, thereby enhancing innovativeness.[155] The main focus for this will be to improve access to patented, expensive medicines by the public; mostly in DCs. This is achieved by increasing competition due to compulsory licensing, whereby competition increases the supply and brings the drug price levels down.[156]

Although most DCs benefit from this provision, it also brings about some challenges. Creating a 'grey market' whereby a patented product designed and meant for a particular market ends up

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[150] K Son 'Importance of the intellectual property system in attempting compulsory licensing of pharmaceuticals: a cross-sectional analysis' (2019) 15:42 *Globalization and Health*1,1.
[151] Ibid 5.
[152] Article 31(f) of TRIPS Agreement.
[153] Kaur & Chaturvedi (note 145 above) 280.
[154] W A Reinsch 'Compulsory Licensing: A cure for distributing the cure?' available at www.csis.org/analysis/compulsory-licensing-cure-distributing cure accessed on 8 July 2021.
[155] Kaur & Chaturvedi (note 145 above) 284.
[156] R Thapa 'Waiver Solution in Public Health and Pharmaceutical Domain under TRIPS Agreement' (2011) 16 *Journal of Intellectual Property Rights* 470, 474.

being sold at a lower price than its original price in another market poses a danger of counterfeiting.[157] Other challenges include the lack of motivation to patent holders to continue improving their products and differences between countries on what constitutes a national emergency.

Lastly, the introduction of TRIPS-Plus by developed countries has hindered progress and the use of compulsory licensing. Notably, the formation of Free Trade Agreements (FTAs) between developed countries who are the majority holders of patents and developed countries threaten DCs with sanctions and withdrawal of support when acceding to WTO if they use compulsory licensing.[158] The thesis opinions that compulsory licensing is the best flexibility to be utilised by DCs, but stringent conditions designed by developed countries under FTAs and TRIPS-Plus make it very difficult for DCs to utilise the flexibility. The thesis will also consider whether Zimbabwe, despite of the above-mentioned hindrances, has successfully utilised this flexibility to promote the rights to health and development.

2.4.5 Special provisions

Special and differential treatment (SDT) is another terminology used to describe the special provisions available for DCs and LDCs.[159] The special provisions include longer time periods to implement agreements, parallel imports and the Bolar provision, mentioned earlier.[160] As such, SDT allows DCs and LDCs to focus on their needs and allow justifiable deviation from obliging with the basic principles of WTO, such as disregarding the principle of reciprocity enshrined in TRIPS.[161]

Further, parallel imports refer to charging lower price in one country than another, whereby DCs can import cheaper drugs from a cheaper country than buying locally at higher prices. This gives DCs greater priority and allows them to pay attention to their own needs.[162]

The Bolar provision is a regular exception permitting the use of the patented invention without the owner's permission to obtain marketing permission of a generic product before the patent

[157] Kaur & Chaturvedi (note 145 above) 283.
[158]R D Smith et.al 'Trade TRIPS 7 pharmaceuticals' (2009) 373 *Lancet* 684, 688.
[159]Special and differentiation treatment provisions available at www.wto.org/English/tratop_e/devel_/dev_special_differential_provisions_e.htm accessed on 8 July 2021.
[160]See section 2.4.3 under Chapter 2.
[161]Hasan (note 82 above) 41.
[162] E F. M't Hoen (note 59 above) 39.

expires.[163] The thesis is of the view that these special provisions edify the use of compulsory licenses and ensure that the DCs and LDCs also have access to much needed patented products, especially drugs/medicines produced by DCs. However, the thesis further argues that it remains difficult for DCs and LDCs to implement the special provisions due to lack of resources and or fear political/economic sidelining by countries holding the patents.

2.5 Developing countries, least developed countries and intellectual property rights

Intellectual property rights protection under TRIPS meant a reduction in ability by DCs and LDCs to use technical data to uphold public interest goals such as well-being, nourishment and environmental preservation.[164] The introduction of patent protection meant that DCs and LDCs could no longer freely borrow technology or produce generic medicines from DCs inventions. This posed a great danger to the development and well-being of the DCs and LDCs populace. It was more so with regards to HIV and AIDS, malaria and tuberculosis, given their dominance in and impact on low income countries.[165]

As Brian Martin stated, intellectual property retards innovation and exploits the least developed and developing populace.[166] In other words, the DCs and LDCs were against the protection of innovation and technology due to their incapacity and financial inability to promote research and development independently. For these countries to develop, there was and still is need to borrow from what has been done by their predecessors. They do not have the financial capacity to build from scratch, and even the payment of royalties for them to be able to use inventions from developed countries was rightfully foreseen as a hindering block to their development.

DCs and LDCs argument that nations pursuing to develop technically have often borrowed and learned from those already possessing the knowledge remains valid to date.[167] An historical analysis of intellectual property protection in pharmaceutical products demonstrates how most of

[163] Prof B K Baker, 'A full description of WTO TRIPS flexibilities available to ARIPO member states and a critique of ARIPO'S comparative study analyzing and making recommendations concerning those flexibilities' (2019) 25.
[164] B U Ihugba & I S Onyesi 'International Intellectual Property Agreements as Agents of Sustainable Development of Developing Countries' (2016) 9 *African Journal of Legal Studies* 1,3.
[165] Africa: a region where most developing countries are ,is said to be the most affected region by HIV/AIDS with East and Souther Africa alone recording approximately 800 00 new infections in 2017 available at https://www.afro.who.int/health-topics/hivaids accessed on 4 November 2020.
[166] B Martin, 'Against Intellectual Property', *Information Liberation*, London: Freedom Press (1998) 29.
[167] M Shugurov 'The TRIPS Agreemet, International Technology Transfer and Development: some lessons from strengthening IPR protection' (2016) 3:1 *BRICS Law Journal* 90,92.

the industrialised countries were the fist to introduce patent legislation in this field.[168] This was after they had reached a certain level of technological capability and international competitiveness.[169] Intellectual property rights and mainly the protection of patents would encumber access to essential drugs through an increase in drug pricing.[170]

Although the TRIPS Agreement makes provision for flexibilities, discussed in detail above, which enable DCs and LDCs to use it to their advantage, there are still some problems regarding those flexibilities. The disproportionate power relations between DCs and LDCs [171] make it very difficult for the countries to use TRIPS to their advantage or develop regulatory approaches suitable for their developmental stage.[172] Developed countries have introduced mechanisms to refrain DCs and LDCs from utilising flexibilities to their advantage. These include bilateral and regional free trade agreements and economic partnership agreements (also known as TRIPS Plus) which offer DCs and LDCs short term advantages; an example being limited grounds for the use of compulsory licenses at higher remuneration levels.[173]

As much as DCs and LDCs try to use flexibilities, threats of sanctions, economic dependency on developed countries, hope for foreign and technology investments, and the need for support when negotiating accession into WTO force the countries to accept TRIPS-Plus.[174] As a result; DCs and LDCs end up facing problems including but not limited to non- materialisation of expected benefits due to non-implementation by developed countries, exorbitant prices of medicines due to escalated

[168] C Juma, 'Intellectual Property Rights and Globalization: Implications for Developing Countries,' Science, Technology and Innovation Discussion Paper No. 4, Center forInternational Development, Harvard University, Cambridge, MA, USA (1999) 2.
[169]. Ibid.
[170] B Baker and T Avafia, The Evolution of IPRs from Humble Beginnings to the Modern Day TRIPS-plus Era: Implications for Treatment Access. Working Paper prepared for the Third Meeting of the Technical Advisory Group of the Global Commission on HIV and the Law, 7-9 July 2011 (2011) 12.
[171]An example is that of the USA and its countries being the most powerful politically and having the largest pharmaceutical companies. Such countries have used their political standing and advanced economic development to work strongly against the least developed and developing countries' use of TRIPS flexibilities. South Africa's introduction of Medicines and Related Substances Control Amendment Act 90 of 1997 which authorised parallel importation of cheaper drugs was strongly opposed by more than thirty nine pharmaceutical companies.
[172] S Sell 'TRIPS-Plus free trade agreements and access to medicines' (2007) 28:1 *Liverpool Law Review* 41,56 &58
[173] Baker & Avafia (note 141 above) 14.
[174] RD Smith, C Correa, & C Oh: 'Trade, TRIPS and pharmaceuticals' (2009) 373 (9664)*The Lancet* 684, 688.

standards of intellectual property maintained by developed countries and lack of reciprocity[175] in terms of benefits between them and developed countries.[176]

The exclusion of pharmaceutical drugs from patenting by DCs and LDCs pre-TRIPS era was a means to upholding access to drugs.[177]An open pharmaceutical market encouraged competition and affordable medicines to the general populace in DCs and LDCs. The implementation of TRIPS-Plus is problematic. It promotes higher pricing by intellectual property rights owning companies, which reduces consumers' access and affects their health, development, and welfare.[178] However, waiver of the TRIPS Agreement or its domestication alone may not be enough to help countries implement the same.[179] Such waiver or domestication needs tobe complemented with measures to address the challenges that go with their enactment, including the inadequate capacity to develop regulations, weak IP institutions, and weak enforcement, among others.[180]

2.6 Conclusion

The development of TRIPS has been proven to come a long way, with the significant and final step being the Marrakesh Declaration, which introduced the WTO holding TRIPS as one of its so many agreements. This chapter has traced the development of international trade (intellectual property protection) since WWII and shows the expansion and growth that has been experienced in the global economy. This discussion has also outlined the objectives and principles of TRIPS based on the GATT background to link the two and identify why there was a need for change from GATT to WTO even though GATT still applies in certain circumstances.

Notably, TRIPS brought about the more strict application of patents affecting access to medicines mainly by the population in DCs such as Zimbabwe. The flexibilities provided for under Article 30 & 31 of the TRIPS Agreement enhanced by the Doha Declaration are a much-appreciated

[175] Developing countries pay for the costs in form of royalties, high priced medicines while developed countries continue to enjoy the benefits and pushing for TRIPS-Plus agreements which continue to hinder access to LDCs & DCs.
[176] M Khor, 'Implications of some WTO rules on the realization of MDGS' (2005) 13.
[177] M G Catteneo 'Intellectual Ptoperty Rights and Health Rights: a feasible reform proposal to facilitate access to drugs in developing countries'(2017) 11:5 *World Academy of Science, Engineering and Technology International Journal of Law and Political Sciences* 1339, 1345.
[178] Khor (note 176 above) 14.
[179] M Eccleston-Turner and M Rourke 'The TRIPS Waiver is Necessary, but it Alone is not Enough to Solve Equitable Access to COVID-19 Vaccines' (2021) 25:9 *American Society of International Law* 1,3.
[180] B M Ncube *et al* 'Establishment of the African Medicines Agency: progress, challenges and regulatory readiness' (2021) 14:29 *Journal of Pharmaceutical Policy and Practice* 1,2.

mechanism supporting competition in drug production and thereby lessening monopoly by patent holders. Even though there are challenges brought by the flexibilities; these may relatively be dealt with by for example using special packaging, barcoding and stamping of generic products. Countries also need to be informed on the use of flexibilities so they do not restrict themselves by signing FTA's and bilateral agreements sanctioning them from use of such flexibilities. Ultimately, TRIPs is colliding with the right to health, the right to development and access to medicine, which will be discussed in the next chapter. TRIPS-Plus makes it even more difficult for DCs to promote the right to health and development. This is more so due to the fact that DCs and LDCs are economically dependent on and politically inferior to developed countries, which own most of the patents and are behind the introduction of TRIPS-Plus. The DCs and LDCs fear sanctions and withholding of economic benefits by developed countries, which would leave them isolated and incapable of accessing cheaper drugs, so they cannot oppose TRIPS-Plus.

CHAPTER 3:

AN ANALYSIS OF THE RIGHT TO HEALTH AND THE RIGHT TO DEVELOPMENT

3.1 Introduction

The least DCs and LDCs are most affected by infectious diseases, including malaria,[181] HIV/AIDS[182] and tuberculosis. They do not have the capacity to ensure the realisation of the right to health and development.[183] On the other hand, developed countries have the capacity to manufacture pharmaceuticals and export to DCs and LDCs .[184] However, research indicates that developed countries have a monopoly over their pharmaceuticals, and due to lack of competition, their drugs become very expensive for the countries that need them most. Against this background, this chapter, therefore, focuses on the right to development, the right to health and whether the TRIPS Agreement positively or negatively affects such rights.

The rights to health and development are best described as socio-economic or third-generation rights, that give people access to certain basic needs essential for human beings to lead a dignified life.[185]Socio-economic rights play a major role in ensuring that people whose access to resources, opportunities or services have been blocked can access such through enforcement of the rights. According to Khoza, the rights are critical and include other rights such as the educational, employment, health and social security rights and they should be guaranteed by states without discrimination.[186]

The TRIPS Agreement grants patents to inventors as a reward and motivation to produce more intellectual work,[187] which includes pharmaceuticals and medicines. Granting patents in the

[181] During the WHO Regional Committee for Africa meeting in Brazzaville (August 2019) it was acceded that the African region has a troubling high burden of vector-borne diseases, primarily malaria; information available at https://www.afro.who.int/news/african-health-ministers-agree-all-fronts-push-control-rise-vector-borne-diseases accessed on 4 November 2020.

[182] Africa: a region where most developing countries are ,is said to be the most affected region by HIV/AIDS with East and Souther Africa alone recording approximately 800 00 new infections in 2017 as available https://www.afro.who.int/health-topics/hivaids accessed on 4 November 2020.

[183] M Jurua 'Access to Drugs at Risk: Securing Access to Medicines for Least Developed Countries' (2017) XLII, No. 1 *Africa Development* 101, 113.

[184] T Kongolo, *African Contributions in Shaping the World Wide Intellectual Property System* 1 ed (2016) 218.

[185] S Khoza , Socio-Economic Rights in South Africa: A resource book (2007) available at https://repository.uwc.ac.za/xmlui/handle/10566/254 accessed on 10 September 2020.

[186] Ibid.

[187] E Lisdiyono & M.N.B. Asyhar Assalmani 'Community Right to Health on Pharmaceutical Patents' (2017) 8:7 *International Journal of Civil Engineering and Technology* 920,920.

pharmaceutical world may curb people's access to health[188] as the relationship between health, innovation, and the law continues to become forceful. Pharmaceutical patents grant a monopoly to patent owners mostly affecting the poor and burdening public access to health, qualifying TRIPS Agreement as the cause of lack of access to medicines.[189]

Notably, human rights are interdependent, indivisible and interrelated.[190] The Right to Development is intertwined with the right to health in the sense that development focuses on people's well-being. Adding on, the ability to progress from one level to another and such development is only attainable in a healthy environment or when people are at their best attainable health status. A denial of any of the indivisible and interdependent human rights is equal to the denial of the right to development.[191]

The importance of the right to health[192] and development is further captured in their judicialisation, making them enforceable through the courts.[193] To give a comprehensive study on the right to health and the right to development, this chapter will discuss and analyse international, regional and national provisions relevant to the right to health and development. The main focus will be on WTO (TRIPS); Patents, WHO provisions on health, Article(s) 12 ICESCR, Article(s) 15, 16, 18 and 22 of the ACHR, Article 1 of the International Covenant on Civil and Political Rights (ICCPR)[194], Declaration on the Right to Development as well as Article 25 and 27(2) of the Universal Declaration of Human Rights (UDHR).[195] An analysis of case law will also give a deeper understanding of what the two rights entail.

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[188] M G Catteneo, 'Intellectual Ptoperty Rights and Health Rights: a feasible Reform Proposal to facilitate access to drugs in developing countries'(2017) 11:5 *World Academy of Science, Engineering and Technology International Journal of Law and Political Sciences* 1339, 1339.
[189]Ibid, 1340.
[190] Vienna Declaration and Programme of Action (A/CONF.157/23), as quoted in Fact Sheet No 31 for Word Health Organisation and Office of the United Nations High Commissioner for Human Rights 6.
[191] Declaration on the Right to Development, Preamble.
[192] R Dittrich et al 'The International Right to Health: What Does It Mean in Legal Practice and How Can It Affect Priority Setting for Universal Health Coverage?' (2016) 2(1) *Health Systems & Reform* 23, 23.
[193] See *Minister of Health* v. *Treatment Action Campaign* (2002) 5 SA 721 (CC) in which the court was said to be under a duty to ensure effective relief is granted where a breach of any right has taken place and *Centre for Minority Rights Development (CEMIRIDE) (on behalf of the Endorois) v Kenya* (Communication 276/2003) in which the people of Endrois took the Government of Kenya to court to ascertain their right to development and the African Commission on Human and Peoples' Rights was of the view that the exclusion of the beneficiaries of a development project or lack of consultation with them was tantamount to violation of their RTD.
[194] International Covenant on Civil and Political Rights (1967) 6 ILM 368.
[195] Universal Declaration of Human Rights of 10 December 1948 available at www.un.org/en/about-us/universal-declaratio-of-human-rights accessed on 8 July 2021.

In essence; this Chapter is an analysis of the international and regional provisions of the rights to health and development, a discussion on how TRIPS provisions impact on the right to health and access to medicines in DCs and LDCs and how the right to development is directly or indirectly interlinked to the right to health.

3.2 The right to health

The right to health involves bringing to end discrimination in all healthcare settings.[196] This entails that everyone, no matter who they are or where they are from, get the quality health care they need and deserve. It is an inclusive right, subject to availability of resources with a claim to a set of 'social engagements, standards, establishments, laws and an enabling environment that can best secure timely satisfaction of such'.[197]

Health is one of the very basic needs of people which is considered to be 'important to the highest degree'.[198] The government of every nation has an obligation to intervene and provide public access to medicines and other pharmaceutical products to the people.[199] However, such an obligation is based on the progressive realisation[200] of the right. Progressive realisation of a right entails the development of societal resources; necessary for the realisation by everyone; of the right recognised. It exists independently of increase in resources but requires the equitable and effective use of nationally or internationally available resources.[201] The availability of resources which is usually the key area affected by TRIPS, play a significant role in the publicaccess to health.

The right to health is more than just the provision of essential health services but includes tackling underlying determinant factors of health such as adequate education, housing and food.[202] It is a

[196] Human Rights and health available at https://www.who.int/news-room/fact-sheets/detail/human-rights-and-health accessed on 5 October 2021.
[197]Ibid.
[198] WTO Agreements and Public Health 'A joint study by the WHO and the WTO Secretariat (2002) 31.
[199] E Lisdiyono & M.N.B. Asyhar Assalmani 'Community Right to Health on Pharmaceutical Patents' (2017) 8:7 *International Journal of Civil Engineering and Technology* 920,923.
[200] The term entails that a right has to be realised over time and the progress towards full realisation of such right is dependent on the availability of resources. However, the responsible state is expected to take the minimum possible time to reach full realisation of the right and taking into consideration extra needs of the marginalised groups. *See* L Chenwi 'Unpacking "progressive realisation", its relation to resources, minimum core and reasonableness and some methodological considerations of assessing compliance (2013) *De Jure* 742, 743 &747. It does not mean that a country's difficult financial situation absolves it from taking action to realise the right to health.
[201]J Tasioula 'The Minimum Core of the Human Right to Health' Washington DC,The World Bank Research Paper(2017) 4.
[202] Article 25 of the UDHR.

qualification to all the other human rights and includes access, without discrimination, to all health-related services.[203]

Under the right to health, one is entitled to the protection of the health system which results in an equal opportunity to enjoy the best level of health and freedoms to control their health, free from any interference.[204]

3.2.1 International laws on the right to health

The right to health was first expressed in the preamble of the World Health Organisation (WHO) Constitution of 1946, which highlighted that:

> The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without discrimination by race, religion, political belief, economic or social conditions.

This was two years before the UDHR of 1948.[205] In the UDHR, the United Nations declared that everyone has the right to a standard of living, social security and services.[206] Furthermore, Article 27(2) of the UDHR acknowledges that IPRs should also be protected while promoting other socio economic rights. On the other hand, the ICESCR provides that:

> all member States are to recognise their people's right to take part in cultural life; enjoy the benefits of scientific progress and its application and benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author.[207]

This provision entails that ordinary individuals ought to benefit from any scientific progress made in member countries. This connotes that the protection of intellectual property should not hinder the people's access to medicine and research and development should not be used as an excuse to deny people's right to health but rather should promote the right to health.

Article 12 of the ICESCR further states that:

1. 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*.

[203]*Egyptian Initiative for Personal Rights and Interights v Egypt II (2011) African Human Rights Law Report* (90) 134.
[204] Human Rights and Health found at https://www.who.int/news-room/fact-sheets/detail/human-rights-and-health accessed on 5th January 2020.
[205] UDHR (note 195 above).
[206] UDHR (note 202 above)
[207]Article 15 1(c) of ICESCR.

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

A perusal of Article 12 of ICESCR shows that the government is duty-bound to guarantee that every person achieves the maximum standard of health. The Covenant confirms that;

> every state is obliged to take meaures, independently and through international assistance and cooperation, particularly economic and technical, to the maximum of its available resources, with a view to achieving the full realisation of the right to health progressively.[208]

It is, therefore, the duty of the state to ensure that resources are set aside specifically for development and attainment of the right to health.

Under the international human rights laws, states are obliged to adequately prepare for pandemics and maintain international cooperation, which is defined as sharing; medical equipment, best medical equipment and practices, knowledge and minimizing the economic and social impacts of the public health through joint action crisis.[209]

The 2006 Convention on the Rights of Persons with Disabilities (CRPD)[210] brings out an important notion about the right to health when it states that persons with disabilities have the right to the enjoyment of the highest attainable standard of health without discrimination on the basis of disability.[211] The Convention on the Rights of a Child, further discussed under Chapter 4 also protects children's right to health. The connotation of the above is that the right to health is

[208]Article 2 (1) of the ICESR.
[209] L Montel 'The Right to Health in Times of Pandemic: What Can We Learn from the UK's Response to the COVID-19 Outbreak?' (2020) 22:2 *Health and Human Rights Journal* 227, 235.
[210] The right to health is also recognised in other international instruments such as the 1979 Convention on the Elimination of All Forms of Discrimination against Women under articles 11 (1) (*f*), 12 and 14 (2) (*b*), the 1989 Convention on the Rights of the Child articles 24, 1990 International Convention on the Protection of the Rights of All Migrant Workers and Members of Their Families Articles 28, 43 (*e*) and 45 (*c*).
[211] Article 25 of the Convention on the Rights of Persons with Disabilities

qualitative, meant for all, and should not be subject to a person's social, economic, or political status.

3.2.2 The right to health under the World Health Organisation(WHO)

The WHO stipulates that the right to health is the highest attainable standard of health whose achievement is central and dependent upon the realisation of other human rights.[212]An example of the above is the right to access to medical drugs signifying the specification of the human right to health. It can be argued that the fulfilment of the right to health directly depends on the public's access to medicines and other pharmaceutical products.[213] Under the WHO, health has been documented as an essential characteristic of human and economic development[214] and this description stamps the relationship between the right to health and development.[215]

3.2.3 Provisions under the World Trade Organisation(WTO)

International trade plays a pivotal role in peoples' attainment and access of the right to health as countries depend on each other for resources and products relevant to promoting the right to health. Although the main focus is on TRIPS and patents, the WTO has many agreements relating to health and health policies. These include TRIPS, Agreements on Technical Barriers to Trade (TBT)[216], Sanitary and Phytosanitary Measures (SPS)[217] and General Agreement on Trade in Services (GATS)[218], but this research will only focus on TRIPS.

3.2.4 Relevant Provisions under TRIPS

The WTO regards TRIPS as a balancing mechanism between inventors' rights and the people's access to medicine. TRIPS is the determinant factor to the availability of medicines, one of the core factors of the right to health, as it controls the pricing and accessibility through patenting. The

[212] WHO: Human Rights and Health at http://www.who.int/mediacentre/factsheets/fs323/en/ accessed on 12 December 2020.
[213] Catteneo (note 153 above) 1341.
[214] The African Health Monitor, 'Health Financing in the African Region' Issue # 17 (2013).
[215] Constitution of The World Health Organisation 1995; according to the Constitution's preamble health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity, which elements are also equally important for the realisation of the right to development.
[216] Technical Barriers to Trade available at https://www.wto.org/english/tratop_e/tbt_e/tbt_e.htm accessed on 28 June 2021.
[217] Sanitary and Phytosanitary Measures available at https://www.agriculture.gov.au/market-access-trade/wto/sps accessed on 28 June 2021.
[218] General Agreement on Trade in Services available at https://www.wto.org/english/tratop_e/serv_e/gatsqa_e htm accessed on 28 June 2021.

protection of intellectual property is considered under WTO as a way to encourage research into new and more effective treatments and at the same time allowing governments' some flexibility to ensure that the medicines are available at affordable prices.[219] However, the flexibilities provided for under TRIPS does not fully ensure access to medicines[220] by developing, and LDCs as these countries do not have the capacity to manufacture their pharmaceuticals. Thus the Doha Declaration positively introduced an amendment to TRIPS in line with promoting the right to health.[221] Despite this effort by the Doha Declaration to ensure promotion of human rights under Article 31*bis,* the challenge that remains is that it fails to consider the importation costs to be met by usually resource poor members hence its poor implementation.[222]

The Declaration on TRIPS and Public Health (DOHA) of 2001 is one of the mechanisms under WTO designed to promote access to the right to health and strike a balance between the protection of patents and access to medicines. The Declaration confirmed and put into perspective the autonomous right of governments to take measures to protect public health by giving primacy to public health over private intellectual property.[223] Although access to medical products was guaranteed under Doha, not all of the problems associated with intellectual property protection and public health were solved. The less developed countries continue to suffer the same predicament due to the introduction of TRIPS-Plus regulations and Regional Trade Agreements (RTAs) which tend to hinder the use of such flexibilities. Therefore, it remains difficult to have access to medicines and promote the right to health under such stringent trade conditions.

The WTO also recognises the right to health through its Sustainable Development Goals (SDGs), which set targets to be achieved by 2030 in areas such as poverty reduction and health.[224] The

[219]The WTO can support the environment and health available at https://www.wto.org/english/thewto_e/whatis_e/10thi_e/10thi08_e htm; accessed on 10th September 2020.
[220] Committee on Economic, Social and Cultural Rights **'**Statement on universal affordable vaccination for COVID-19, international cooperation and intellectual property' E/C.12/2021/1 paragraph 10.
[221] Article 31*bis* of the TRIPS Agreement allows low cost generic medicines to be produced and exported under a compulsory licence exclusively for the purpose of serving the needs of countries that cannot manufacture those products themselves; found at https://www.wto.org/english/tratop_e/trips_e/pharmpatent_e.htm accessed on 10 September 2020.
[222] V G Nicholas 'Trip-ing Up: the failure of TRIPS Articl 31*bis*' (2020) 24:1 *Gonzaga Journal of International Law* 1, 22.
[223] E F M.'t Hoen,'Practical Applications of the Flexibilities of the Agreement on Trade-Related Aspects of Intellectual Property Rights Lessons beyond HIV for access to new essential medicines (2018) 29.
[224] Refer to SDG 1 –No Poverty & SDG 3-Good Health and Wellbeing.

SDGs stress that trade plays a significant role in promoting sustainable development.[225] This initiative by WTO also confirms that the right to health and development are intertwined, and one cannot be achieved without the other.[226] The economic situation and lack of development in infrastructure, especially hospitals, has resulted in alienation of the right to health in Zimbabwe.

TRIPS being the regulating agreement of member countries in terms of trade in pharmaceuticals, has broad adverse effects on the right to health. For example, during the COVID-19 era, a report from the World Economic Forum indicates that 59 WTO members did not report their restrictions on exports, breaking trade regulations[227] and some countries/custom territories banned or limited exports of medical supplies critical for the COVID-19 pandemic.[228] Considering the situation in Zimbabwe, a country with no capacity to produce its pharmaceuticals and depends on imports, the pricing of medication by patent holders is too high. People fail to afford the medications being priced in United States Dollars, a currency dominating the manufacturing companies but foreign in the country of consumption.

3.3 Regional laws on the right to health

The ACHPR of 1981[229] is one of the regional instruments confirming the right to health and the state's responsibility to ensure that the right is attainable to all.[230]Article 18 of ACHPR also makes it an obligation for the state to protect the family's physical and mental health.

In the case of *Social and Economic Rights Action Centre (SERAC) & Another v Nigeria*[231]the African Commission on Human and Peoples' Rights employed the typology of "respect, protect, promote, and fulfil" as a standard of determining the obligations of states under the ACHPR. Further, it recognised that in many situations, 'the need to ensure the meaningful enjoyment of

[225] SDG 8 supports Trade-led inclusive economic growth enhances a country's income-generating capacity, which is one of the essential prerequisites for achieving sustainable development, SDG 9 which promotes trade investment between developing and developed countries thereby promoting development via technology transfer.
[226] SDG 3 talks on health and well -being and prioritises on access to affordable medicines as a way of promoting sustainable development.
[227] L Forman & J C Kohler 'Global health and human rights in the time of COVID-19: Response, restrictions, and legitimacy' (2020) 19:5 *Journal of Human Rights* 547, 552.
[228] A Shalal '80 Countries Are Hoarding Medical Supplies—Here's Why It Damages the Global Response to COVID-19' (2020) available: https://www.weforum.org/agenda/2020/04/wto-report-80-countrieslimiting-exports-medical-supplies accessed on 14 March 2021.
[229]Article 16 which states that every individual shall have the right to enjoy the best attainable state of physical and mental health.
[230]Ibid and Article 19 of ACHPR which states that all people are equal.
[231] *Social and Economic Rights Action Centre (SERAC) & Another v Nigeria(2001) AHRLR 60 (ACHPR 2001*).

socio-economic rights would require action from the state in terms of more than one of the different duties'. The Commission ruled that the Ogoni government's failure to prevent pollution and ecological degradation had violated the people's right to health.[232] This case emphasises the importance of States in maintaining their obligations to promote the realisation of socio-economic rights such as the right to health.

The Protocol to the ACHPR on the Rights of Women (2003/2005) under Article 14 also makes it an obligation for states to protect women's rights to health and a healthy and sustainable environment as provided for under Article 18. The provisions in this Protocol highlight the importance of protecting the right to health, albeit in vulnerable groups such as women.The African Youth Charter (2006/2009) (AYC) further states under Article 16 that states are obliged to fulfil the implementation of and secure access[233] of the youth to their right to the best attainable spiritual, physical and mental health.[234]

In addition to that, there are at least 115[235] Constitutions including the Constitution of the Republic of South Africa, 1996 and the Constitution of Zimbabwe Amendment (No. 20) Act 2013, that provide for the protection of the right to health.

An illustration of the protection of the right to health under a national constitution is found in the Kenyan case of *P.A.O & 2 Others v Attorney General*[236] in which Judge Mumbi Ngugi upheld the Constitutional right to the highest attainable standard of health as is guaranteed under Article 43(1) of the Kenyan Constitution against patent holders intellectual property rights to protection against counterfeit drugs. The court held that the absence of a clear differentiation between the words counterfeit and generic in the Anti Counterfeit Act 2008 was detrimental to access of generic drugs by mainly those affected by HIV/AIDS and depended on the generic drugs to realise their rights to health and life.[237] The Judge was of the opinion that 'there can be no room for ambiguity where the right to health and life of petitioners and many other Kenyans affected by HIV/AIDS at stake'.[238]

[232] Ibid par 53.
[233] Article 16(2) of AYC .
[234] Article 16(1) of AYC.
[235] Fact Sheet No 31 of the World Health Organisation (10).
[236] *P.A.O & 2 Others v Attorney General* (2012) eKLR.
[237] Ibid par 87.
[238] P.A.O (note 235 above par 84).

The importance of protecting and ensuring the realisation of the right to health by all; without discrimination which is prevalent in all the regional instruments was highlighted in the *Purohit case.*[239] The Commission read into Article 16 of the African Charter the duty upon Governments to use the available resources and ensure the progressive realisation of the right to health without discrimination of any kind.[240]

The African Commission, in applying regional law to cases dealing with the right to health, has also maintained that the right to health is not a stand-alone right but also depends on the realisation and protection of other socio-economic rights[241] and is pivotal to the wellness and life of all.[242]

3.4 The Right to Development

3.4.1 Brief history and recognition of the Right to Development

There are different schools of thought concerning history, specifically the alpha of the right to development. Ngang states that the right to development was initially proclaimed by Dodou Thiam a Senegalese Minister who advocated for the denunciation of the old colonial past and putting in its place the right to development.[243] Another author, Ramcharan, states that the idea was conceived by a Senegalese jurist Keba M'Baye in 1972 in an inaugural lecture at the International Institute of Human Rights in Strasbourg by Senegalese.[244]

The Universal Declaration of Human Rights (UDHR) of 1948 is, however, known to be the precursor to the right to development as it was the first to address the right to development.[245] It prohibited discrimination and hence encouraged development as one of the key elements to development is equity. The right to development was initially recognised by the UN General Assembly, as a human right, in November 1979 through a resolution.[246] The right to development was then first proclaimed by the Organisation of African Unity (OAU) and later included in the

[239] *Purohit and Moore v. The Gambia, Communication No. 241/2001 (2003.*
[240]Ibid par 84.
[241] *SERAC* (note 230 above) par 51-52.
[242] *Purohit* (note 238 above) par 80.
[243] C C Ngang, Differentiated Responsibilities under International Law and the Right to Development Paradigm for Developing Countries (2017) 265, 278.
[244] B G Ramcharan *Mordenizing the UN Human Rights System* (2019) 127 International Studies in Human Rights 86.
[245] The Universal Declaration of Human Rights 1948 was the first instrument to make provisions for the right to development under Article(s) 22, 26 and 29.
[246] S P Subedi, 'Declaration on the Right to Development' (2021) *United Nations Audio Visual Library of International Law* 1,2.

ACHPR of 1981.[247] The ACHPR under Article 22; expressly confirms the right to development and is the only legally binding international document recognising the right.[248]

In 1986, the United Nations Declaration on the Right to Development (UNDRTD) was adopted and it recognised the Right to Development as a fundamental principle of humanity.[249] According to Piron, RTD was later reaffirmed in the 1993 Vienna Declaration and Programme of Action and the 2000 Millennium Declarations.[250] The Vienna Declaration and Programme of Action endorse; 'the right to development, as established in the Declaration on the Right to Development, as a universal and inalienable right and an integral part of fundamental human rights'.[251]

Despite the long existence of the right, the Millennium Declaration of 2000 aims to make the right to development a reality for everyone and ensure that every human being is freed from lack. The commitment of the Millennium Declaration was recalled by the Durban Declaration and Programme Action, which also affirms the solemn commitment of all states to promote universal respect for human rights and the elimination of all forms of discrimination.

Regionally, the African Charter also provides for the right under Article 24, which 'states that all peoples shall have the right to a general satisfactory environment favourable to their development'. The effect of the recognition of the right by the African Charter is that it becomes legally binding on all (African) states and makes it mandatory for states to fulfil their obligations towards elevation and implementation of the right to development.[252]

The ICESCR and the ICCPR transformed the provisions of the Universal Declaration into legally binding treaties, thereby solidifying the implementation of all human rights, including the right to health and development.[253] The ICESCR outlines a holistic approach to realising the right to development through successful recognition and implementation of socio-economic rights such as

[247] Ibid.
[248] D M Chirwa & L Chenwi, *The Protection of Economic, Social and Cultural Rights in Africa: International, Regional and National Perspectives* Cambridge University Press 1st ed (2016) 118.
[249] The Declaration states that the human being is the epitome of development, see Articles 2(1), 4(2) & 8 (1).
[250] K Arts & A Tamo 'The Right to Development in International Law: New Momentum Thirty Years Down the Line?' (2016) 63 *Neth Int Law Rev* 221, 227.
[251]Vienna Declaration paragraph 10.
[252] K Arts & A Tamo (note 250 above, 226).
[253] What is the Universal Declaration of Human Rights? Available at humanrights.gov.au/our-work/what-universal-declaration-human-rights accessed on 9 July 2021.

the right to an adequate standard of living[254] and the right to primary health care.[255] Further, the realisation of these rights by State parties ought to be realized through all suitable means, mostly the adoption of legislative measures, maximising use of existing funds, and through international assistance and cooperation.[256] The provisions of the Convention out rightly promote the realisation of the right to development as development encompasses the realisation of all other core human rights.

3.4.2 An overview of the Right to Development

The right to health connotes the mental, physical and social well-being of an individual. The characteristics of the right to health have an element of development that pertains to the social, cultural and political wellness hence the importance of the right to development in this chapter.

Ramcharan(s) defined the right to development as, 'a human right that has the objective of satisfying the on-going enhancement of the well-being of persons by growing their competences and their freedom'.[257]The authors also share the same view with Sengputa[258] that the right to development as a right to a route of development. All human rights and fundamental freedoms can fully and gradually be realised in a genuinely participatory manner to ensure equitable distribution for improved human well-being.[259]The right to development in DCs is aligned to an expression of self-determination, a pursuit for emancipation from domination and a claim for justice and equity in the development process.[260]

It is a composite right that integrates other rights, and by that virtue, it is recognised in the International Bill of Rights.[261] As rightfully stated by Ngang, the right to development implies neither a solicitation for development assistance nor the right to economic growth except to the extent that economic growth is consistent with human rights.[262] The obligation to promote the right to development according to the Declaration of the Right to Health falls upon the relevant state

[254] Article 11 of ICESCR
[255]Article 12 of ICESCR
[256]Article 2 of ICESCR clearly outlines the joint obligation between states and international organisations or countries towards realisation of human rights.
[257]R Ramcharan & B Ramcharan *Asia and the Drafting of Universal Declaration of Human Rights* 1st ed (2019) 148.
[258] A Sengupta, The Human Right to Development (2004) 32:2*Oxford Development Studies* 179,180.
[259] R Ramcharan & B Ramcharan (note 257 above).
[260] C C Ngang'Towards a Right to Development Governance in Africa'(2018) 17:1 *Journal of Human Rights* 107,108.
[261]T A Mensenbet, 'Reflection on the right to development: Challenges and prospects' (2010) 10:2 *African Human Rights Law Journal* 325, 327.
[262] Ngang (note 243 above) 281.

and internationally that obligation is fulfilled mostly through humanitarian work done by developed countries.[263] International organisations with international legal personality are bound by general norms of international law[264]. As specialised UN Agencies, they are bound by their subscriptions to the UN Charter; and through the obligations of member states under international human rights.[265]

The right to development, similar to the right to health, is a third-generation socio-economic right which is interdependent on other human rights.[266]The state has an obligation to ensure the progressive realisation of the right through the implementation of policy and legislative measures, just as is ith the right to health.[267]It is in itself a paradigm of development ensuring equality and non-discrimination in the access of basic rights by individuals. The characteristics of development are that it is equitable, non-discriminatory, participatory, accountable and transparent, and the characteristics are complemented with overarching themes of equity and choice.[268]

It also entails that the State consults with its people and provides for their participation in any development processes.[269] The Right to Development has evolved to the extent that it has been recognised constitutionally in some states. The Constitution of Cameroon (1996) is one of the first African Constitutions to recognise the right to development by explicitly affirming it in its its preamble.[270] Recently, the Draft Convention on the Right to Development of 2020 was unveiled,

[263]Article 3 of the Declaration on Right to Development.
[264]Article 22 of the ACHPR says States shall individually and collectively share the duty to ensure exercise of the right to development.
[265] Article 1 (3) of the United Nations Charter outlines one of the purposes of the Charter is to achieve international co-operation in solving international problems of an economic, social, cultural, or humanitarian character, and in promoting and encouraging respect for human rights and for fundamental freedoms for all without distinction as to race, sex, language, or religion; and. All member states are bound by such principles.
[266] Failure to protect the people of Ogoni by the Nigerian State was said to have violated their right to food which is incorporated in the right to development, *SeeSocial and Economic Rights Action Centre (SERAC) & Another v Nigeria*(2001) AHRLR 60 (ACHPR 2001) para 64
[267] A K Sengupta 'Conceptualizing the right to development for the twenty-first century. Office of the High Commissioner for Human Rights, Realizing the right to development: essays in commemoration of 25 years of the United Nations Declaration on the Right to Development. United Nations, New York and Geneva' (2013) 67,67.
[268]*Centre for Minority Rights Development (Kenya) and Minority Rights Group International on behalf of Endorois Welfare Council v Kenya*(2003) 27[th]Activity Report of the African Commission para 277.
[269]Ibid.
[270] The Preamble of the Constitution contains a proclamation of the right to development and the people's determination to promote it.

and it seeks to validate and strengthen the right to development on the international community, which is yet another evolution in the positive.[271]

3.5 Objections to the Right to Development

According to Menserbet, the main objection to the idea of a right to development stems from the fact that development is not likely to be fulfilled for all[272] , and this argument curtails a layman's thinking whereby the right to development would only be for the already wealthy with access to state resources needed in furthering their developed status. However, Sen contends that 'practicability should not be a benchmark by which the cogency of human rights is measured when the objective itself is to work towards expanding their feasibility and full realisation'.[273] As already highlighted above, the right to development is a vector of all other human rights, and interrelationship is its cornerstone; hence the feasibility of all the other human rights is also its feasibility.[274]

Stevens *et al.* state that Vandenbogaerde questions the value of the right to development and also calls for its dissolution as it is not relevant to current human rights discussions.[275] This objection by Vandenbogaerde is ignorant of the interrelationship and interdependence nature of human rights, especially socio-economic rights under which the right to development falls. The same argument can also be dismissed as the right to development represents the procedure of enabling economic and social, cultural and political development, thereby being far from being a standalone right.

The legal significance of the right to development is also criticised by Donnelly, who argues that the right is unsubstantiated as there is no legal or even ethical reason for a right to development.[276] Mubangizi counters Donnelly's argument when he argues that there is an undeniable acute

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[271] N Schrijver, 'A new Convention on the human right to development: Putting the cart before the horse?' (2020) 38:2 *Netherlands Quarterly of Human Rights* 84,89.
[272] T A Mensenbet, 'Reflection on the right to development: Challenges and prospects' (2010) 10:2 *African Human Rights Law Journal* 325,338.
[273] B A Andreassen & S Marks (eds) Development as a human right: Legal, political and economic dimensions (2006) 241.
[274] C Stevens & N Ntlama 'An Overview of South Africa's institutional framework in promoting women's right to development' (2016) 20 *Law Democracy & Development* 46,51.
[275]Ibid 59.
[276] J Donnelly "In search of the unicorn: the jurisprudence and politics of the right to development" 1985 *California Western International LJ* 473 ,477 as quoted inC Stevens & N Ntlama, ' An Overview of South Africa's institutional framework in promoting women's right to development' (2016) 20 *Law Democracy & Development 46,* 59.

relationship between human rights and development, whereby the achievement or attainment of other human rights should be the yardstick to measure development.[277]

Mere suspicion by the developed countries that this right may burden the developed countries with unavoidable obligations to provide development aid to countries that cannot on their own realize the right to development of their inhabitants is another cause of objection of the right.[278]

3.6 TRIPS versus the rights to health and development

All human rights are universal, indivisible, interdependent and interrelated according to the Vienna Declaration.[279] The realisation of the right to development is inclusive of the economic, social, cultural and political process whose primary purpose should be the constant improvement of the wellbeing of the entire population and all individuals, including the poor and women.[280] The interrelationship between the right to health and development entails that even the slightest violation of one by TRIPS results in the violation of the other.

Considering that access to drugs is a corollary of the right to health (that is considered as inviolable by Art. 25 of UDHR), and according to the aim of ICESCR, a concrete and substantial violation of international law and a conflict between conventional norms exists when TRIPS minimises the accessibility by DCs and LDCs to drugs paramount to their people's development.[281] Thus, it could be argued that the limitation of access to drugs by the TRIPS Agreement in the DCs and LDCs, directly impacts on the physical and mental well-being of the populace. Further, it negatively affects their right to development which is depended on the realisation of other socio-economic rights.

The system of patenting medical products entails that before a country can procure products, embark on research and development or negotiate for licensing, there should be up-to-date domestic patent information, including the patent status, which is still very difficult to obtain in

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[277] J C Mubangizi "A human rights-based approach to development in Africa: opportunities and challenges" (2014) 39 (1) *J Soc Sci* 67 ,67-69- 72 as quoted inC Stevens & N Ntlama, ' An Overview of South Africa's institutional framework in promoting women's right to development' *Law Democracy & Development* Vol 20 (2016) 46, 59.

[278] N Schrijver, 'A new Convention on the human right to development: Putting the cart before the horse?' (2020) 38:2 *Netherlands Quarterly of Human Rights* 84,85.

[279] Vienna Declaration and Programme of Action 1993 available at www.ohchr.org/en/professionalinterest/pages/vienna.aspx accessed on 10 July 2021.

[280] C Stevens & N Ntlama (note 274 above) 57 .

[281] P. K. Yu 'Intellectual Property and Human Rights in the Nonmultilateral Era' (2012) 64 *Florida Law Review*1045,1048

many, particularly in DCs.[282] Sometimes the information is not readily available, or it will be expensive to acquire due to various reasons comprising of lack of capacity and resources in national patent offices as well as lack of communication between the relevant authorities and language barriers.[283] This then becomes a barrier to more accessible access to medicines as without appropriate information, the danger of legal suits may be too grave for DCs to ignore.

The number of new essential drugs under patent protection might increase, but the drugs will remain out of reach to people in DCs because of high prices. As a result, the access gap between DCs and LDCs will widen, thereby depriving the populace of their right to health. Once that happens, 'the right to development which encapsulates realisation of all human rights and is central to economic, political, social and cultural empowerment'[284] then becomes difficult to realise and implement

DCs and LDCs mostly rely on generic drugs to maintain a status of physical and mental health in their countries but TRIPS through patenting negatively affects local manufacturing capacity and removes major sources of generic, innovative, quality drugs on which DCs depend. Patents also impede rather than promote R&D in DCs and LDCs for diseases such as malaria and tuberculosis because emerging countries often do not provide sufficient profit potential to motivate R&D investment by the pharmaceutical industry, so they prefer to remain in developed countries.[285] As a result, DCs and LDCs continue to lag in human rights realisation and implementation. In Zimbabwe, a developing country without the capacity to develop their own medicines and a signatory to TRIPS, people are dying in hospitals, and the majority cannot afford the drugs which are priced in United States Dollars. The maternal death rates continue to escalate due to the lack of proper health care.[286] As a result, people are deprived of the right to development as a poor state of health engulfs them.

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[282] H L Williams, 'How do patents affect research investments?'(2017) 9 *Annual Review of Economi*cs 441, 447. This was termed as the disclosure theory.
[283] Ibid.
[284] Stevens & Ntlama (note 274 above) 49.
[285] Ellen't Hoen et al 'Driving a decade of change: HIV/AIDS, patents and access to medicines for *all' (*2011) *14:15 Journal of the International AIDS Society* 1,7.
[286] Z Murwira and B Chidakwa 'The Chronicle 9 January 2020: ED concerned by maternal mortality rate. . . Calls for investment in strengthening skills of midwives, doctors' in which the President of Zimbabwe is quoted saying the Government is concerned about the high maternal mortality in Zimbabwe with 651 deaths for every 100 000 live births available at https://www.chronicle.co.zw/ed-concerned-by-maternal-mortality-rate-calls-for-investment-in-strengthening-skills-of-midwives-doctors/ accessed on 9 January 2020.

The flexibilities provided for under TRIPS are being overshadowed by TRIPS Plus agreements, which tighten patent protection, limit compulsory licensing and exceptions that facilitate the prompt introduction of generics.[287] TRIPS and TRIPS Plus area divide and conquer mechanism destroying DCs collective bargaining power. DCs and LDCs are left isolated, and due to fear of being barred from trade benefits by developed countries, there is no collective bargaining in terms of better trade conditions. The fear of isolation limits the extent of use of flexibilities to promote the right to health and development by DCs. According to Vawda and Baker, foreign states have an obligation to ensure that international agreements do not adversely affect the right to health.[288] The DRD also states that international / developed states must assist in the realisation of the right to development.[289] Through TRIPS, developed countries are ignoring their obligations to ensure the realisation of human rights in the DCs and LDCs .

Furthermore, Article 6 of the DRD acknowledges that failure to observe civil and political rights, as well as economic, social and cultural rights, is an obstacle in itself to development. Marks and Malhotra also state that human rights, including the right to development, pursue the realisation of the full human potential for all human beings, including resistance to trade and investments practices aimed at increasing profits but that generate inequality and harm people.[290] Patenting of drugs under TRIPS is an obstacle to development as it aims at increasing profits of huge pharmaceutical companies but at the same time ignoring the research and development of diseases such as malaria and tuberculosis that affect most least developed and DCs.

The violation of the right to development under TRIPS falls within the concept of how the economic policies in a globalised world cannot be set in isolation from international interactions and interdependence.[291] The TRIPS, therefore, continues to violate the realisation of human rights in general through its stringent patenting conditions that affect the realisation of the right to health and development in DCs and still have to be made part of national laws. TRIPS-Plus fails to

[287] World Health Organization: *Globalization, TRIPS and Access to Pharmaceuticals.* March 2001. Available at www.who.int/medicines/library/edm_general/6pagers /PPM03%20ENG.pdf accessed on 20 September 2019.
[288] Y A Vawda & B K Baker, 'Achieving Social justice in the human rights/ intellectual property debate: Realising the goal of access to medicines' (2013) 13 *African Human Rights Law Journal* 55, 66.
[289] Article 7 of the DRD.
[290] S Marks & R Malhotra 'The future of the right to development' (2002) 1, 13
[291] J C Pereira 'Environmental issues and international relations, a new global (dis)order – the role of International Relations in promoting a concerted international system' (2015) 58 (1) *Rev. Bras. Polít. Int.* 191, 192.

maintain a fair trade policy which TRIPS tried to create through flexibilities that put into cognisance the development needs of DCs.

3.7 Conclusion

The interdependence of human rights is very clear from the above. The ripple effects of patents have also been outlined, and the argument that patents enable pharmaceutical companies to seek new drugs has been dismissed because most patented drugs, such as the AIDS drug in the United States of America, were developed using public funding.[292] In addition, the argument of promoting new development is denied as there is a need to promote and protect the current generation rights as much as the future generation's rights are being protected. It is, therefore, better if an international tiered valuing and compulsory licensing framework could be created through a convention by WHO to ensure worldwide development and access to health needs due to proper pricing per state. Overall, countries ought to implement human-centred policies and employ a bottom to top based approach in implementing the realisation of all human rights and, ultimately, the right to development.

[292] R L Ghio 'Assessing the Impact of IPRs on Development: A view from the Developing World', (2011) 23 *Journal of International Development* 1013, 1015.

CHAPTER 4:

TRIPS, THE RIGHT TO HEALTH AND THE RIGHT TO DEVELOPMENT IN ZIMBABWE

4.1 Introduction

Zimbabwe is a developing country[293] in the Southern Region of Africa with a high prevalence rate on HIV/AIDS, [294] malaria and tuberculosis infections.[295] Furthermore, as a signatory to the TRIPS Agreement, [296] the country is entitled to conform to the Patents provision in TRIPS, pay royalties and employ the flexibilities provided therein to its advantage.[297] The country has suffered recent setbacks on its implementation of the right to health due to cholera outbreaks and a natural disaster; Cyclone Idai.[298] Further, the dire economic and political situation is another major determinant to access to the right to health and development. The country situation is very volatile such that there is close to no respect of the rule of law,[299] which is paramount for furthering or realising the right to health and development.

The protection of IPs is widely acknowledged in Zimbabwe as cross-sectoral in nature, cutting through education, health, trade and many other sectors as well as being a means to economic

[293] The country is a signatory of the Global System of Trade Preferences among Developing Countries (GSTP) found on http://rtais.wto.org/UI/PublicShowMemberRTAIDCard.aspx?rtaid=146 accessed on 14 November 2020.
[294] Statistics as of 2018 showed that approximately 1, 3 million people lived with HIV/AIDS in Zimbabwe. See HIV and AIDS in Zimbabwe found on https://www.avert.org/professionals/hiv-around-world/sub-saharan-africa/zimbabwe#footnote65_3t5pahg accessed on 18 November 2020.
[295] Zimbabwe is ranked of the '30 high burden TB countries', see https://www.avert.org/professionals/hiv-around-world/sub-saharan-africa/zimbabwe accessed on 18 November 2020.
[296]Zimbabwe has been a signatory to WTO and TRIPS since March 5 1995 see https://wipolex.wipo.int/en/legislation/profile/ZW accessed on 18 November 2020.
[297] Article 1 of the TRIPS Agreement makes it an obligation for member states to give effect to the provisions of the Agreement. These provisions include Patents protection and payment of royalties under Article 27 of the Agreement payment of royalties
[298] An article titled 'Cyclone-affected communities in Zimbabwe being vaccinated againstcholera' published on 16 April 2019 gave an overview of how the Zimbabwe Ministry of Health and Child Care with support from UNICEF and the World Health Organization (WHO), launched an Oral Cholera Vaccine as a proactive, preventative measure against cholera after the floods. Article is available onhttps://www.afro.who.int/news/cyclone-affected-communities-zimbabwe-being-vaccinated-against-cholera accessed on 22 November 2020.
[299] T Gumpo and A Sibanda, 'ED must respect rule of law to win FDI', Newsday of 26 April 2018 found on https://www.newsday.co.zw/2018/04/ed-must-respect-rule-of-law-to-win-fdi/ accessed on 18 November 2019.

development.[300] Thus, it is the Government's obligation to ensure that international conventions and or agreements such as TRIPS (which the country have acceded to) are domesticated and are aligned to the country's constitution in favour of the people's needs.

Therefore, this chapter will discuss Zimbabwe's position as a signatory to TRIPS and to what extent it has employed the flexibilities to further its obligation as a country in promoting the right to health and the right to development. The chapter focuses on the extent the TRIPS Agreement has benefited Zimbabwe and on how the country has managed to utilise the flexibilities to its advantage to ensure access to medicines and realisation of the right to health and ultimately peoples' right to development.

The Chapter will firstly outline the background of Zimbabwe as a developing country and then discuss the relevant treaties and legislation governing Zimbabwe under the rights to health and development. To provide a detailed answer to the research question, the chapter will also focus on TRIPS implementation in Zimbabwe and how the country has since utilised flexibilities provided in the treaty to promote the realisation of the rights to health and development.

4.1.1 A brief background on Zimbabwe

Born out of a liberation struggle and finally achieving independence and a sovereign state status in April 1980, Zimbabwe has evolved over the years and signed some highly regarded international agreements or conventions such as TRIPS, as fully discussed in this Chapter. As a member of the WTO,[301]as well as other agreements such as regional trade arrangements, discussed further under section 4.4 below, Zimbabwe has made recognised arrangements towards further liberalisation of trade in favour of the right to health and development. Indeed, the country ought to protect the right to health both internationally, regionally and nationally as discussed later in this chapter.[302]

[300] A Ncube, 'Zimbabwe Launches its national IP policy and implementation strategy' 28 June 2018 found on https://www.aripo.org/zimbabwe-launches-its-national-ip-policy-and-implementation-strategy/ accessed on 18 November 2020.

[301] According to the World Trade Organisation, Zimbabwe has been a member since 5 March 1995. See 'Understanding WTO: The Organisation. Members and Observers found at https://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e htm accessed on 29 Janaury 2021.

[302] Dr. M Tekere , J Hurungo and M Rusare , 'Study prepared for FAO Trade and Development Studies Centre, Harare' found at http://www.fao.org/3/y4632e/y4632e0y htm and accessed on 18 November 2020.

The birth of WTO in 1995[303] corresponded with the end of Zimbabwe's economic reform period, during which it carried out self-directed and independent trade liberalisation policies.[304] The trade liberalisation advocated by the WTO was a welcome development to developing countries including Zimbabwe.[305] The trade liberaliation assisted to strengthen national efforts towards economic growth, employment creation, increased exports and incorporation of the country into the world economy.[306] When Zimbabwe initially joined the WTO on the 5th of March 1995,[307] it was classified as a developing country so it enjoyed some concessions regarding compliance, longer implementation periods, and exemption from some commitments, grace periods and technical support towards meeting its obligations.[308] With that advantage of having more time to implement the WTO Agreements, the thesis will discuss; below in this chapter; whether Zimbabwe, which has a dualistic approach to international human rights law has incorporated necessary provisions in its domestic law for the furtherance of the right to health and development. This means that international law only become part of Zimbabwe's national law if it has been expressly adopted as such by way of legislative action.[309]

4.2 International and Regional Law governing Zimbabwe in terms of the Rights to Health and Development

Zimbabwe acceded to WIPO Convention in December 1981, Paris Convention (Industrial Property), since April 1980, Berne Convention (Literary and Artistic Works), since April 1980, Patent Corporation Treaty (PCT) (Patents), since June 1997, World Trade Organisation Member and signatory to TRIPS Agreement since March 1995.[310] Zimbabwe is also a member of the African Regional Intellectual Property Organisation (ARIPO) and Harare Protocol on Patents, Industrial and Designs: 1984, which will be discussed in detail below.

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[303] The WTO was established on 1 January 1995. See Fact-file accessed from https://www.wto.org/english/thewto_e/whatis_e/who_we_are_e.htm accessed on 29 January 2021.

[304] Tekere , Hurungo and Rusare (note 302 above).

[305] Global Trade Liberalization and the Developing Countries available at www.imf.org /external/np/exr/ib/2001/110801.htm#ii accessed on 10 July 2021

[306] Ibid.

[307] Zimbabwe has been a member since 5 March 1995. See 'Understanding WTO: The Organisation. Members and Observers found at https://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm accessed on 29 Janaury 2020

[308] This is as according to the special differentiatial treatmeant discussed under 2.4.5.

[309] Section 327 (2) of the Constitution of Zimbabwe Amendment (No. 20) Act 2013.

[310] This has already been discussed in the preceding Chapter and will not be discussed further in this Chapter save to indicate that Zimbabwe is bound by their provisions.

According to Mude, Zimbabwe is a member of the United Nations (UN) and thus has obligations under the United Nations Charter (UN Charter) to protect the rights of Zimbabweans in accordance with rules of state responsibility[311] which includes promotion and encouragement of human rights[312] for all without dissimilarity.[313] This then entails that the Government of Zimbabwe has both international and regional obligation to protect and promote the rights to health and development for all individuals equally as will be explained further below. The national obligation of the country to protect the right to health and development will be discussed under section 4.6 of this chapter.

4.2.1 Convention on the Elimination of All Forms of Discrimination Against Women (CEDAW)

CEDAW came into force in 1981, but Zimbabwe signed and ratified the convention on 13 May 1989, accepting the responsibility to protect the rights of women. Under CEDAW, States Parties are obliged to 'take all suitable methods to eradicate discrimination against women to ensure to them equal rights with men in the field of education and in particular to ensure, on the basis of equality of men and women'.[314] According to Article 10 (h) of CEDAW;

> h) Access to specific educational information to help to ensure the health and well-being of families, including information and advice on family planning.[315]

When Zimbabwe acceded to CEDAW, it accepted the obligation to realise women's right to health and this obligation is further highlighted under Article 12 (1) of CEDAW, which states as follows:

> 1. 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.

[311] T Mude, 'The History of International Human Rights Law in Zimbabwe'(2014) 2 (1) *Journal of Social Welfare and Human Rights* 53, 62.
[312] United Nations Charter; Article 1 (3) states that one of the purpose of UN is to achieve international co-operation in solving international problems of an economic, social, cultural, or humanitarian character, and in promoting and encouraging respect for human rights and for fundamental freedoms for all without distinction as to race, sex, language, or religion
[313] United Nations Charter; Article 55 (c) aims at promoting universal respect for, and observance of, human rights and fundamental freedoms for all without distinction as to race, sex, language, or religion.
[314]Article 10 of CEDAW.
[315] Article 10 (h) of CEDAW.

The progressive realisation of the right to health under this convention also makes it mandatory for the country to ensure that all classes of women[316] have access to health care facilities and services provided thereto.[317] Abiding by this provision would achieve both access to right to health and development at once for Zimbabwe; as a healthy society equals to high development potential and most women are at the core of attaining development in communities.

4.2.2 Convention on the Rights of the Child (CRC)

In 1989, the General assembly adopted the Convention on the Rights of the Child, which came into force in 1990. [318] Zimbabwe signed and ratified the CRC in 1990.[319] The Convention protects children against discrimination[320] and accepts their civil and political, economic, social and cultural rights.[321] These accepted rights include the right to health and development, which are intertwined. Article 24 of CRC summarises the obligation of state parties towards the promotion and realisation of children's rights to health. It states that the right of the child to health and to facilities for the treatment of illness and rehabilitation of health is of paramount importance.[322] The state also has an obligation to take suitable measures to abolish harmful traditional policies detrimental to the child's right to health.[323] It is essential to note that development of a child and the community at large is also dependant on the physical and mental health status of the individuals. This chapter will elaborate on the extent to which Zimbabwe has managed to protect children' right to health and development in its national legislation.

4.2.3 International Covenant on Economic Cultural and Social Rights (ICESCR)

The Government of Zimbabwe also signed and ratified this human rights instrument on 13 May 1991, which aims at ensuring the protection of the right to health by state parties. Article 12 of the

[316] The term means all women, whether biological, anatomical, genetic, gender performance, and/or gender identity working with any combination or standing alone. Working or not working, married or not. See E Meyer 'Designing Women: The Definition of "Woman" in the Convention Designing Women: The Definition of "Woman" in the Convention on the Elimination of All Forms of Discrimination Against Women on the Elimination of All Forms of Discrimination Against Women' (2016) 16:2 *Chicago Journal of International Law* 553,557.
[317] Article 14 (b) of CEDAW.
[318] Convention on the Rights of the Child Adopted and opened for signature, ratification and accession by General Assembly resolution 44/25 of 20 November 1989 entry into force 2 September 1990 (CRC).
[319] Zimbabwe has been a signatory since March 1990 and ratified the Convention in September 1990 found at https://treaties.un.org/Pages/ViewDetails.aspx?src=IND&mtdsg_no=IV-11&chapter=4&lang=en accessed on 29 January 2020.
[320]Article 2 of CRC.
[321] Article 4 of CRC.
[322]Article 24 (1) of CRC.
[323]Article 24 (3) of CRC.

convention states 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'.

The provisions of this convention are discussed in detail under chapter 3. The question that remains to be answered is how Zimbabwe has utilised TRIPS in its national legislation to ensure that Article 12 is put into the concept. In addition, under Article 2 (1) of the ICESCR,

> A State Party is required to take legislative and other steps to the maximum of its available resources, with a view to achieving progressively the full realization of the rights recognized in the Covenant, including the right to health.

In light of the above, Zimbabwe has an obligation to its people to ensure their health needs are met through the provision of adequate health facilities, access to medicines as well as qualified medical personal. Furthermore, in 1993, the Vienna Declaration on Human rights and Programme of Action, which proclaims the universality of human rights and reaffirms the obligation on all states, including Zimbabwe, to promote and respect human rights, came into being.[324] It increased the expectations on Zimbabwe to promote human rights.

4.3 TRIPS Agreement and Zimbabwe

Under the TRIPS agreement, Zimbabwe's primary focus is the right to health, particularly ensuring access to medicine. The country has since domesticated the provisions of TRIPS in legal texts such as the Patent Act.[325] However, remittances for royalties have been suspended due to the 'severe hard currency shortage' experienced in Zimbabwe since the year-end of the 19th century.[326]

Of major concern are the pharmaceutical companies stringent limitations imposed through the TRIPS agreement on the right of countries to deliver health care to their general public and to procure drugs at reasonable prices.[327] In this regard, Zimbabwe campaigns for the right of DCs to provide health care, develop pharmaceutical industries and secure drugs at reasonable prices for the majority of people to be respected.[328] T Hoen *et al.* confirms Zimbabwe's advocacy by sharing how the 2001 chair of the TRIPS Council, Boniface Chidyausiku a Zimbabwean, proposed a

[324] Vienna Declaration of 1993 (note 278 above).
[325] Patents Act Chapter 23:06.
[326] Zimbabwe available at 2001-2009.state.gov/e/eeb/ifd/205/42203 htm.
[327] S Ahmadiani and S Nikfar 'Challenges of access to medicine and theresponsibility of pharmaceutical companies:a legal perspective' (2016) 24:13 *DARU Journal of Pharmaceutical Sciences* 1, 1.
[328] Tekere , Hurungo and Rusare (note 302 above).

special session on access to medicines.[329] The advocacy resulted in the adoption of the Declaration on TRIPS and Public Health by the WTO Ministerial Conference in Doha. Importantly, this gave birth to the 'Doha Declaration', which confirmed the pre-eminence of public health in intellectual property legislation.[330]

To date, Zimbabwe has put to use the TRIPS flexibilities a couple of times. Firstly, during the years 2002-2005, the country employed compulsory licenses to secure Antiretroviral (ARVs) medicines, including specific ARVs for treating HIV/AIDS. Zimbabwe also continues to employ parallel importation to import cheaper drugs from India and South Africa due to the high costs of manufacturing the drugs in the country.[331]

4.4 Regional Instruments

This section will outline the Regional instruments that govern Zimbabwe in terms of the right to health and development. As an African Country and a Member of SADC, regional instruments are important to the realisation of the right to health and development as they offer guidelines how the government should fulfil that obligation. A review of these regional instruments will also assist in determining how and whether Zimbabwe has utilised the TRIPS Agreement.

4.4.1 African Charter on Human and People's Rights (ACHPR)

The ACHPR was approved by the Organisation of African Unity (OAU) in 1981, came into force in 1986 and is also known as the Banjul Charter.[332] Zimbabwe ratified the charter in 1986.[333] Article 16 of the Charter states that:

> 1. Every individual shall have the right to enjoy the best attainable state of physical and mental health
>
> 2. States 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.

The ACHPR is also the only legally binding international document recognising the right to health.[334]

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[329] E F. M. 't Hoen , T Kujinga & P Boulet 'Patent challenges in the procurement and supply of generic new essential medicines and lessons from HIV in the southern African development community (SADC) region' (2018) *Journal of Pharmaceutical Policy and Practice* 1, 8.
[330] Ibid 8.
[331] M Gwarisa 'Importing ARVs cheaper for Zim – IP Experts available at https://healthtimes.co.zw/2017/12/29/importing-arvs-cheaper-zim-ip-experts/ accesed on 5 May 2020.
[332] History of the African Charter available at www.achpr.org/hotac accessed on 10 July 2021.
[333] Ratification table:- ACHPR available at www.achpr.org/ratificationtable?id=49 accessed on 10 July 2021.
[334] Article 22, African Charter on Human and People's Rights.

Article 2(1) (e) of the OAU Charter provides that member states should promote international co-operation having due regard to the UDHR. Article 2 (2) (d) recognises the right to health and obliges the Member States to coordinate and harmonise their general policies in specific fields, which include health. In balancing the right to health and IPRs, the ACHPR also recognises the protection of IPRs which may only be limited for public need or community interest.[335] As a result, Zimbabwe as a member of ACHPR, is obliged to promote the right to health and expected to abide by the specific provisions of the Charter. The thesis is of the view that Zimbabwe has failed to abide by the provisions of the ACHPR, which is evident in the inadequate health systems in the country, further discussed under section 4.5.1.

4.4.2 African Regional Intellectual Property Organisation (ARIPO)

In addition, the country subscribes to the African Regional Intellectual Property Oganisation (ARIPO),[336] which provides an easy path for medicines patenting. The Harare Protocol on Patents, Industrial and Designs 2020 empowers ARIPO to grant patents to member states and such granted patents are subject to 'applicable national law on compulsory licenses, forfeiture or use of patented inventions in the public interest.[337]This entails that Zimbabwe has to abide by the terms and conditions guiding patent protection even within the Southern Africa Region, and there is then more reason to employ the TRIPS flexibilities and incorporate the into national law.

4.4.3 Southern Africa Development Community (SADC)

Zimbabwe is one of the 16 countries that form the Southern Africa Development Community (SADC), whose main objective is to achieve economic growth and sustainable development.[338] The SADC is made up of countries in a region highly burdened with malaria, tuberculosis and HIV/AIDS[339] hence the need for utilisation of TRIPS flexibilities to promote the realisation of the right to health. As a SADC member, Zimbabwe can utilise TRIPS compulsory or government use licence to produce generic versions of patented medicines for local use.[340] It can also export to

[335] Article 14 of ACHPR.
[336] E F. M. 't Hoen , Kujinga & Boulet (note 329 above) 2.
[337] Section 3 (12) of the Harare Protocol on Patents, Industrial and Designs 2020.
[338] https://www.sadc.int/themes/economic-development/ accessed on 28 November 2020.
[339] E F. M. 't Hoen , Kujinga & Boulet (note 329 above) 2.
[340] Article 31, TRIPS (as amended in January 2017).

other SADC countries[341] where there will be no infringement of an existing patent. Still, Zimbabwe should have implemented TRIPS flexibilities in its national law to be able to use the exception.[342]

Zimbabwe as a member of SADC, which has an aim of promoting economic growth and sustainable development[343], is obliged to ensure that it abides by the regional and international human rights provisions for the best of its populace. Being a SADC member; Zimbabwe needs to regularise and expand its use of the TRIPS flexibilities as a developing country without enough technology for R&D towards the infectious diseases mentioned above affecting the country.

4.4.4 Abuja Declaration

The Abuja declaration, which Zimbabwe is a member, also forms part of the regulating conventions in terms of health. According to the Abuja Declaration, state members should allocate 15% of their yearly budget to health.[344] The Abuja, 15% target, remains an elusive target for the country as the public health sector allocation currently stands at 8,9%.[345] To promote the right to health, Zimbabwe has to conform to the provisions of the Abuja Declaration and as it is, the country is failing to do so.

4.5 Political, Social and Economic situation in Zimbabwe

The idiom, 'history repeats itself', is well-founded in the case of Zimbabwe. The country is on a roller-coaster whereby more than three decades after independence, people continue to experience the same political, social and economic challenges they have been experiencing during the pre-independence era.[346]As is generally accepted, the health of a nation is a sensitive expression of the prevailing socio-economic conditions, and that disproportions in disease experience reflect differences in both living conditions and access to health care.[347] Zimbabwe is also embedded in political instability- there is little economic or social development, and the health delivery system

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[341] These include South Africa and Zambia as indicated under the Members List found on https://www.sadc.int/member-states/ accessed on 29 January 2021.
[342] Article 31 *bis* (3) TRIPS as amended in January 2017.
[343] United Nations Zimbabwe, Sustainable Development Goal Nuber 8 vailable at https://zimbabwe.un.org/en/sdgs/8 accessed on 28 June 2021.
[344] Abuja Declaration: Ten Years On' available at https://www.who.int/healthsystems/publications/abuja_declaration/en/ accessed on 30 December 2020.
[345] V Langa & Jena 'Scale up 2020 health budget, govt urged found' at https://www.newsday.co.zw/2019/10/scale-up-2020-health-budget-govt-urged/ accessed on 22 November 2020.
[346] P Zvomuya, 'Zimbabwe: Of protests, prayer and legacy' published on 5 August 2017 at https://www.africaportal.org/features/zimbabwe-protests-prayer-and-legacy/ accessed on 22 November 2020.
[347] D Sanders 'Equity in Health: Zimbabwe Nine Years On', (1990) 5:1 *Journal of Social Development in Africa* 5, 6.

is in its worst condition.[348] There is a poor health delivery system, and medical personnel continue to leave the country due to poor remuneration leaving service providers incapacitated to render services to the people.[349]

The Zimbabwean Government is like new wine in old bottles – there are new drivers of power, but the old regime is still in existence. What has only changed are the names and the people, but the governing system remains the same.[350] There is a strong presence of corruption which when coupled with poor governance also present in the country; stimulate incompetence, distort competition and leave the structure susceptible to unwarranted influence, fraud and abuse.[351] All of these make access to health products encubersome. The severe socio-economic difficulties presently being experienced by Zimbabwe including hyperinflation, negative real interest rates, and a chronic shortage of foreign exchange is also worth mentioning.[352]

Noticeably, the cost of health care in Zimbabwe remains one of the highest in the region. With recent developments of medical health facilities charging in United States Dollars or demanding payment at the equivalent of the Zimbabwean Dollar, most people are being denied access to health care.[353] The current government has denied many people access to basic and quality health care as medicines are being charged in United States Dollars. In contrast, the majority of the people earn salaries in local currency. There has not been any mechanism to ensure that pharmaceutical products are charged in the local currency and remain available.

The lack of willingness by the government to introduce social, political and economic reforms makes the country continue to surge in repression of human rights.[354] Hence this can have daring

[348] E Mirzayev 'How Corruption Affects Emerging Economies' available at https://www.investopedia.com/articles/investing/012215/how-corruption-affects-emerging-economies.asp accessed on 29 January 2021.
[349] Y Yuksekdag 'Health Without Care? Vulnerability, Medical Brain Drain, and Health Worker Responsibilities in Underserved Contexts', (2018) 26 (1)*Health Care Anal* 17, 27.
[350] R Nagvekar, 'Not Free, Not Fair, Not Credible: Did Britain Back a Zimbabwean Autocrat's Re-election? March 27 (2019) found at https://thepolitic.org/not-free-not-fair-not-credible-did-britain-back-a-zimbabwean-autocrats-re-election/ accessed on 18 November 2020.
[351] K K Kidia, 'The future of health in Zimbabwe', *Global Health Action* (2018) 11.
[352] Zimbabwe's medicines and basic commodity prices keep escalating as they are being charged at an exchange rate with the black market rate of the United States Dollar which is now an illegal tender for domestic transactions in the country. Seehttps://www.sadc.int/member-states/zimbabwe/ accessed on 18th November 2020.
[353] P Mbanje 'Draw health lessons from successful countries, Zim urged' accessed from http://www.cwgh.co.zw/draw-health-lessons-from-successful-countries-zim-urged/ on 22 November 2020.
[354] A T Magaisa 'Big Saturday Read: Two years after the coup- Part 1' found at https://www.bigsr.co.uk/single-post/2019/11/09/Big-Saturday-Read-Two-years-after-the-coup---Part-1 accessed on 18 November 2020.

effects on the nations' positive health and development sustainability. The Government has neglected to hold inclusive dialogue and develop sustainable policies and plans to the dire economic, political and social situation the country is facing. The country has been experiencing instability and lack of human rights respect as evidenced by the August 1, 2018, tragedy whereby the military shot and killed six unarmed citizens following protests over disputations on the 30 July elections.[355] The death of more than 15 people following the peaceful stay away organised by the Zimbabwe Congress of Trade Unions in 2019 is also evidence of political instability in the country.[356] Furthermore, over 300 state arrests on allegations of committing public violence, the arrest of 7 civil society leaders on their way from a transitional workshop in the Maldives and charged them with subversion in May 2019 and the assault and death of other civilians including vendors over peaceful protests.[357]

In Zimbabwe, it has become the norm that instead of the politicians developing the country; they rather fly out to neighbouring countries such as South Africa and India to seek medical attention.[358] Ordinary citizens suffer from the consequences of such extravagant spending, corruption[359] and high living standards of the political elite, and any hope of the realisation of their right to health or development is squashed.

Democratic space[360] continues to shrink in Zimbabwe and worsened by banning demonstrations in all major towns signalling a 'state of emergency'.[361] Recently, Zimbabwe was ranked number

[355] B Mhlanga 'Aug 1 shootings were preplanned' available at www.newsday.co.zw/2018/11/aug-1-shootings-were-preplanned/ accesed on 18 March 2020.

[356] O Manayiti 'ZCTU mobilises for stayaway- the big interview' available at https://www.thestandard.co.zw/2019/07/21/zctu-mobilises-stayaway/ accesed on 18 March 2020.

[357]Joint Statement on the Escalating Human Rights Violations in Zimbabwe' accessed from http://kubatana net/2019/09/18/joint-statement-on-the-escalating-human-rights-violations-in-zimbabwe/ published on 18 September 2020.

[358] It has bee argued several times that the fact that the former President of Zimbawe, Robert Gabriel Mugade used to travel outside Zimbabwe for his medical needs and ended up dying in a foreign hospital shows his loss of confidence in the current health provision system. See Strong Healthcare System Crucial found on https//:www.dailynews.co.zw/articles/2019/09/20 accessed on 28 June 2021.

[359] Corruption and missuse of funds is reported to be one of the reasons why there is poor case management of COVID-19. ***See*** T Dzinamarira *et al* 'Coronavirus Disease 2019 (COVID-19) Response in Zimbabwe: A Call for Urgent Scale-up of Testing to meet National Capacity' (2020) *Clinical Infectious Diseases ViewPoint s* 1,6.

[360] "The term refers to the arena that exists between the state and the individual in which people interact to hold the state accountable, shape public debate, participate in politics and express their needs and opinions" see L Horner and A Puddephat, 'Democratic Space in Asia-Pacific: Challenges for Democratic Governance Assistance and Deepening Civic Engagement' (2011) 1,1.

[361]A T Magaisa, 'Big Saturday Read: The question of political reforms' available at https://www.bigsr.co.uk/single-post/2019/10/05/Big-Saturday-Read-The-question-of-political-reforms on 5th October 2020.

two for the worst inflation index.[362]According to Bauman, Zimbabwe was considered the breadbasket of Africa until a controversial land reform which crippled its economic stability. As such, economic sanctions, loss of major trade partners as well as the collapse of agriculture have had negative impacts on the economy and development.[363] In essence, without political reforms, Zimbabwe's economy will continue to deteriorate, and the general populace social, economic and political rights will never be realised. Thus, understandable that Zimbabwe is ranked 155 out of 190 countries according to the World Health Organization (WHO)'s rankings of the world's health systems due to its weak and unreliable infrastructure of the public healthcare sector. [364]

4.5.1 Effects of the current political, social and economic situation in Zimbabwe on the rights to health and development

Zimbabwe as stated above under 4.4.1; is a signatory and state party to the ACHPR wherein article 16 expresses the Right to Health. Having also signed and ratified the CEDAW which provides for far-reaching rights to women, including the provision of adequate and quality maternal health services as discussed above, the government is obliged to secure resources and ensure the progressive realisation of the rights to health and development. However, the shortage of basic equipment in maternal clinics and hospitals indicate these rights are far from being realised. The shortage of necessary equipment and proper health facilities is a sign of infringement of the people's right to development.

The Zimbabwean government's failure to protect, promote and fulfil the right to health in line with SDG number 3 discussed in Chapter 3 can be expressed as the lack of political will rather than lack of resources.[365] As a country that is rich in natural resources– including gold, coal, asbestos and nickel, amongst other minerals, the government could use such resources to improve service delivery in hospitals.[366] Contrary to the use of resources to promote development and realisation

[362] Pindula General News 'Zimbabwe's Inflation Rate Ranked 2nd, After Venezuela' (3 May 2019) available at https://news.pindula.co.zw/2019/05/03/zimbabwes-inflation-rate-ranked-2nd-after-venezuela-report/ on 29 January 2020.
[363] V Baumann 'Reforming Microfinance to Suit Developing Economies: The Right Way and the Zimbabwe.' (2015) 14:2 *Washington University Global Studies Law Review* 337, 338.
[364] CountryPolicy and Information Note Zimbabwe: Medical and healthcare issues Version 1.0 April 2019 p 8.
[365]Sustainable development goal 3 focuses on improving the right to health and well -being.
[366] G Mwonzora 'Political Will or Not? The Right to Health in Zimbabwe in the Era of SDGs'accessed from https://impakter.com/the-right-to-health-in-zimbabwe/ on 22 November 2020.

of rights, corruption has resulted in the abuse of resources to the extent that there is no realisation of SDG3 goals as expected.[367]

The social and economic well-being of individuals is at its worst, with people earning way less than enough to live a decent life and essential medicines being charged in forex.[368] Of importance is the fact that 90% of the country's workforce do not have medical aid, earn their salaries and wages in the bond note local currency. Concerningly, the demand of payment for medicine and some health care provisions in foreign currency essentially means denying people their Constitutionally given right to health.[369] The few pharmacies that are still accepting bond notes have since quadrupled their prices at levels of parallel market rates and these prices are beyond the reach of ordinary Zimbabweans.[370] As a result, many patients, some with chronic illnesses such as diabetes, HIV/AIDS, and hypertension, who should not miss their medication; are defaulting in taking the medication due to non-affordability.[371] Resultantly, many patients may lose their lives after developing serious health complications caused by failure to access medicines.[372]

During the COVID-19 era, the lack of appreciation and realisation of the right to health in Zimbabwe has been exposed. Healthcare workers failed to provide basic healthcare services to COVID 19 patience due to lack of supplies and protective clothing (PPE). Most emergency health cases were not given the prerequisite attention due to a total national lockdown.[373] The continued on and off strikes by doctors other healthcare service providers since 2019 and during the COVID-19 pandemic has left many patients stranded at public health institutions.[374] It has also put Zimbabwe in breach of WHO guidelines as women now resort to home-based labour facilities, exposing themselves and their newborn babies to death due to complications like excessive

[367]Ibid.
[368] According to Ajazeera news of 4 November 2019, a teacher earns equivalent of USD70.00 per month and a month's supply of ARVs costs USD60.00.
[369] T G Nhapi 'Socioeconomic Barriers to Universal Health Coverage in Zimbabwe: Present Issues and Pathways Toward Progress,' (2019) 35:1 *Journal of Developing Societies* 153,163.
[370] B A Mutingwende, 'Patience in dilemma as pharmacies demand foreign currency for medication:CWGH' available at spiked.co.zw/patients-in-dilema-as-pharacies-demand-foreign-currency-for-medication-cwgh/ accessed on 10 July 2021.
[371] Ibid.
[372] Challenges in the public health sector: CWGH accessed from https://www.zimbabwesituation.com/news/challenges-public-health-sector-cwgh/on 18 November 2019.
[373] G Murewanhema & R Makurumidze 'Essential health services delivery in Zimbabwe during the COVID-19 pandemic: perspectives and recommendations' (2020)35(2) *Pan African Medical Journal* 143,143.
[374] P Chipunza, Doctors turn back on Health Apex Council as published in the Herald Newspaper available athttps://www herald.co.zw/doctors-turn-back-on-health-apex-council/ accessed on 22 November 2020.

bleeding and obstructed labour.[375] Some mothers who might need proper medical care from qualified personnel to prevent transmission of HIV to their new-born babies are missing the opportunity[376] and exposing the children to infection with the HIV/AIDS virus at birth. The latest Zimbabwe Demographic Health Survey states that an estimated 614 women from every 100 000 who give birth die in the process, making it one of the highest in the world.[377] According to WHO data, the mortality rate is currently at 37/1000 live births and maternal mortality rate is at 440/10 000.[378]

Zimbabwe, like some countries[379], used the pandemic as a pretext to use excessive force, ignore human rights and harass vulnerable populations such as vendors; thus, the impact is often disproportionately experienced by poor and marginalized people.[380] The right to development aim is for the enjoyment of all civil, political, economic, social and cultural rights by the human person who is the centre subject of the right. The current socio-economic and political situation in Zimbabwe highlighted above negatively impacts the people's right to health and development. Decisions are made without consulting with the general populace or considering the impactsuch decisions may have on people. The country needs a development strategy that does not disregard or interfere with the protection and promotion of human rights.

4.6 Zimbabwe relevant legal framework

Zimbabwe is known as a common-law country, and international law/agreement can only become part of the domestic law of the country when it has been explicitly enacted into national law by an Act of Parliament.[381] In order to utilise the TRIPS flexibilities and promote the progressive

[375] Ibid.
[376] B Kanengoni ,S Andajani-Sutjahjo & E Holroyd 'Women's experiences of disrespectful and abusive maternal health care in a low resource rural setting in eastern Zimbabwe' (2019) 76 *Midwifery* 125,126.
[377] Ibid. Zimbabwe re- mains far from fully meeting the current Sustainable Development Goal 3 (SDG3) target for global maternal mortality rate (MMR) of less than 70 deaths per 100,0 0 0 live births (WHO, 2018).
[378] J Osler, 'Unpacking Zimbabwe's Wobbling Health System accessed from https://www.dailynews.co.zw/articles/2019/01/06/unpacking-zimbabwe-s-s-wobbling-health-system.
[379] In Uganda police officers killed protestors (used teargas and live bullets) and in India police beat journalist. See Covid-19 Triggers Wave of Free Speech Abuse available at https://www hrw.org/news/2021/02/11/covid-19-triggers-wave-free-speech-abuse accessed on 28 June 2021.
[380] L Forman & J C Kohler 'Global health and human rights in the time of COVID-19: Response, restrictions, and legitimacy' (2020) 19:5 *Journal of Human Rights* 547, 549.
[381] E Mandipa & G Manyatera, "Zimbabwe," (2014) 2 *African Disability Rights Yearbook* 287, 290.

realisation of the rights to health and development; Zimbabwe ought to have enacted the provisions of the international agreements protecting such rights into national law.

The Constitution of the Republic of Zimbabwe Amendment (No 20) Act 2013 is the supreme law of the country[382] , and its founding values include respect for human rights and the rule of law.[383] The Constitution enshrines the Declaration of Rights under Chapter 4.

4.6.1 The right to development under the Constitution of the Republic of Zimbabwe

The Constitution of Zimbabwe's[384] right to development is derived from the principle of equity under Section 56, which values equality and non-discrimination. Section 56 states that:

> (1) All persons are equal before the law and have the right to equal protection and benefit of the law.
>
> (3) Every person has the right not to be treated in an unfairly discriminatory manner on such grounds as their nationality, race, colour, sex, gender, disability of economic or social status.

The recognition of equality and non -discrimination by the supreme law of the country encompasses the core requirements of the right to development as provided under the ICESCR, ICCPR and the African Charter. In addition to the above, Section 73 of the country's Constitution has incorporated provisions of Article 24 of the African Charter, which states that all peoples shall have the right to a satisfactory general environment favourable to their development. Section 73 headed 'Environmental Rights' states that:

> (1) Every person has the right—
>
> (a) To an environment that is not harmful to their health or well-being; and
>
> (b) To have the environment protected for the benefit of present and future generations, through reasonable legislative and other measures that—
>
> (iii) Secure ecologically sustainable development and use of natural resources while promoting economic and social development.
>
> (2) The State must take reasonable legislative and other measures, within the limits of the resources available to it, to achieve the progressive realisation of the rights set out in this section.

[382] Section 2 of the Constitution of the Republic of Zimbabwe Amendment (No 20) Act 2013.
[383] Ibid (Section 3).
[384] Amendment (No 20) Act 2013.

The section also recognises the State's obligation to use the accessible resources and set in motion progressive realisation of the right. The domestication of the above mentioned regional provisions further highlights the obligation on Zimbabwe to promote, respect and realise its people's rights to health and development.

4.6.2 The right to health under the Constitution

Section 76 deals with the Right to health care and can be paraphrased as follows:

(1) Every Citizen and Permanent Residentof Zimbabwe has the right to access basic health-care services, which include reproductive healthcare services
(2) Every personliving with a chronic illness has a right to have access to basic health-care services for the illness.
(3) No personmay be refused emergencymedical treatment in any healthcare institution.
(4) The Statemust take reasonable legislative and other measures, within the limits of the resources available to it, to achieve the progressive realisation of the rights set out in this section.

The right to health is determined not only by access to health care and services but there are other underlying factors such as clean water, a clean environment and availability of food. Under Section 77 of the Constitution of Zimbabwe, the right to food and water is a fundamental 'component of the second element of the right to health as it relates to the right to live in healthy conditions'.[385] The relationship between the two rights is evidenced in Zimbabwe's experiences with cholera and typhoid outbreaks which have claimed more than 4000 lives . This was as a results of little access to potable water, inadequate sanitation services, and limited information on water quality.[386]

4.7 TRIPS in Zimbabwe

4.7.1 Patents Act Chapter 26:03

The Zimbabwean government has made progress in terms of aligning its laws to TRIPS by creating the opportunity to use the flexibilities through the enactment of the Patents Act Chapter 26:03

[385]Section 76 of the Constitution states that every person has the right to- (a) safe, clean and portable water; and (b) sufficient food.
[386] Zimbabwe, found on https://www.hrw.org/world-report/2019/country-chapters/zimbabwe accessed on 28 November 2020.

Sections 24A (parallel importation), 24B (bolar exception), 30 and 31 to 35 (compulsory licences and government use) of the Zimbabwean Patents Act.

In brief, the compulsory licence may be issued allowing the importation of generic drugs under sections 31 and 32 of the Act. The government can declare a national emergency and utilise section 35 to manufacture and sell the patented product for the relief of the State.

Section 24A of the Patents Act deals with the parallel importation of patented products. It provides that: 'a patented product which has been put on the market in another country by a patentee may be imported into Zimbabwe, without the consent of the patentee, if the cost of importing such product is less than the cost of purchasing from the patentee.'

This entails that Zimbabwe has incorporated Article 31 of TRIPS into its national law and is in a position to utilise such flexibility for the realisation of the right to health and development.

Section 24B of the Act is an implementation of the Bolar provision, and it states that:

> (1) Test batches of a patented product may be produced without the consent of the patentee six months before the expiry of the patent: Provided that the test batches shall not be put on the market before the expiry date of the patent.
>
> (2) Where test batches of a patented product have been produced in terms of subsection (1), the term of the patent of the original product shall not be extended.

This entails that where there is an opportunity for the country to develop a patented product for the progressive realisation of the right to health and development through research and development but before the expiration of such patent, the government can rely on this section.

Further, the Act allows the Registrar to grant a compulsory licence for a dependant patent over a prior patent where the invention of such dependant patent involves a practical/technological progress of considerable economic improvement.[387] The Patents Tribunal[388] may grant a compulsory licence on application if:

[387] Section 30A of Patents Act Chapter 26:03.

[388] Established in terms of the Intellectual Property Tribunal Act, 2001 (Chapter 26:08) (Act No. 5 of 2001). Section 3(1) of the Intellectual Property Tribunal Act outline the purpose of the Tribunal as that of hearing and determining references, applications, appeals and other matters in terms of the Industrial Designs Act [Chapter 26:02], the Patents Act (Chapter 26:03), the Trade Marks Act (Chapter 26:04), the Copyright and Neighbouring Rights Act (Chapter 26:05), the Geographical Indications Act (Chapter 26:0) or the Integrated Circuit Layout-Designs Act (Chapter 26:07).

> it is satisfied that the patent holder has not manufactured the products protected by the patents in Zimbabwe after the expiration of three years from the grant of the patent, and the applicant had previously unsuccessfully applied for a voluntary licence; to ensure that the patent is utilised in Zimbabwe.[389]

The Tribunal can also grant compulsory licences for products used as foods or medicines, where such a compulsory licence is necessary for ensuring that food and medicines remain available and accessible to the people at a low cost.[390] The original patentee under this section should be paid reasonable royalties.[391] Section 32 aims at promoting the realisation of the rights to health and development in Zimbabwe through the domestication of Article 31bis of TRIPS briefly discussed in Chapter 3.

Also of importance to this section, is Section 34 and 35 of the Patents Act, which regulate the government's use of patented inventions for the service of the state and in times of emergency. The Tribunal can grant a licence to a third party to manufacture and sell a patented invention for the State's or third party's benefit 'during any period of emergency the powers exercisable in relation to an invention' for any purpose including:

> for the maintenance of supplies and services essential to the life of the community; or, for securing a sufficiency of supplies and services essential to the well-being of the community; and generally, for ensuring that the whole resources of the community are available for use, and are used, in a manner best calculated to serve the interests of the community.[392]

Over the years the Zimbabwean government has, in accordance with the its Patents Act, regularly renewed the state of emergency on HIV/AIDS initially declared on on 27 May 2002.[393] The Patent Act has also been utilised to permit the production of generic drugs under compulsory licenses.[394] In addition to declaring a national emergency in 2002 as stated above, Zimbabwe also issued compulsory licenses to local companies such as Varichem to produce or import chaper ARV.[395]

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[389]Section 31 of the Patents Act.
[390]Section 32 of the Patents Act as amended by the General Laws Amendment (No. 2) Act 14 of 2002.
[391]Ibid
[392] Section 35 of the Patents Act.
[393] General Notice No. 240 of 2002.
[394] Zimbabwe has compulsory license on all ARVs see Reed Beall & Randall Kuhn 'Trends in Compulsory Licensing of Pharmaceuticals Since the Doha Declaration: A Database Analysis'(2012) 9:1 *Journal of Plos Medicine* 3.
[395] According to the article 'DOHA+10 TRIPS flexibilities and access to antiretroviral therapy: Lessons from the past, opportunities for the future'**, (**2011) 16-Varichem Pharmaceuticals [Pvt] Ltd, a Zimbabwe-registered company, was granted authority to use relevant patents. Under the terms of this authorization, Varichem was to "produce antiretrovirals or HIV/AIDS-related drugs and supply three quarters of its produced drugs to state-owned health

This local production of the drugs led to price reductions in the ARV Zerit from US$400 in 2001 to US$30 in 2002.[396]

There is limited to zero production of generic drugs in Zimbabwe due to lack of raw materials, machinery and poor technology[397], compared to countries with a more developed generic manufacturing capacity, such as Brazil or India.[398] This means that the prices charged by the pharmaceutical companies such as Varichem (Pvt) Ltd are essentially monopoly prices.

4.8 Conclusion

The deplorable state of the country's health system requires urgent attention, particularly giving priority focus to addressing the social, political and economic elements of health to achieve universal health coverage and development as provided for under TRIPS. Even though Zimbabwe is one of the few countries that have managed to create good national laws incorporating TRIPs flexibilities, the country still needs to fully explore such flexibilities to the benefit of its people. The use of flexibilities so far has been confined to when there was a state of emergency, for example when the country faced outbreaks of HIV/AIDS and cholera. Zimbabwe needs to employ the flexibilities to import cheaper drugs from other countries such as India. Instead of depending on the few pharmaceutical companies in the country that produce drugs under compulsory licences but still have monopolies. The right to health and development will only be progressively recognised if an open policy of transparency and accountability of resources, as well as use of TRIPS flexibilities, is adopted in Zimbabwe.

institutions.Datlabs, a pharmaceutical manufacturer, was authorized to import antiretroviral medications from Ranbaxy in India, while Omahn, an agent for the Indian manufacturer Cipla, was authorized to import Cipla products.

[396] 'Claiming our space: Using the flexibilities in the TRIPS agreement to protect access to medicines', Regional Network for Equity in Health in east and southern Africa, Equinet 1 Policy Series No.16 (2006) 2.

[397] Michael Gwarisa 'Importing AARVs cheaper for Zim – IP Experts available at https://healthtimes.co.zw/2017/12/29/importing-arvs-cheaper-zim-ip-experts/ accesed on 5 May 2020

[398] Ibid.

CHAPTER 5:

RECOMMENDATIONS AND CONCLUSION

5.1 Introduction

The thesis commenced with a brief background of the current dire situation in Zimbabwe to situate the challenges faced by this country that once was described as a significant agricultural exporter in Africa. Thereafter the study gave a detailed background of the history of TRIPS and the extent to which it changed the multilateral, regional and national landscape. This discussion aimed to provide background to Chapter 2, which elaborated on how the controversial agreement became part of the multilateral trade system. Having provided the historical and legal analysis of the TRIPS Agreement, discussion turned to the protection of the right to health and development; and how the two rights are affected by the TRIPS Agreement protection of Patents with a particular focus on Zimbabwe as the country of the case study.

In Chapter 4, this thesis outlined Zimbabwe's status under TRIPS and highlighted how the country had employed some of the flexibilities provided for under the Agreement. Chapter 5 will draw recommendations for Zimbabwe from India and South Africa in terms of how best the country can use TRIPS flexibilities to its advantage. These recommendations have been put into subheadings, to avoid generalisation of the same.

5.2 How can Zimbabwe improve the realisation of the right to health and development?

Zimbabwe's political, economic and social situation requires that it practices strict separation of powers whereby the judiciary, legislative and executive should be independent to provide realisation of civil, socio-economic and political rights. Recent reports indicate that the country's health system, due to prolonged neglect, is failing and literally on its knees.[399] This study recommends that Zimbabwe prioritise the right to health and put into perspective proper emergency pandemic tools for such times like the COVID 19 era. It is also imperative that a human rights-based approach be utilised in the governance of the country, whereby as stated in the

[399] M Makoni 'COVID-19 worsens Zimbabwe's health crisis' (2020)396 *The Lancet* 457, 457.

Endorois case, the people of the country are allowed to participate in the decision making and implementation as well as sharing of benefits from the development projects.[400]

It is recommended that Zimbabwe learns and borrow from India's strict invention requirements to avoid ever-greening. This will also encourage the development and exploitation of new inventions to secure the benefits thereof for the public.[401] As the Intellectual Property Rights Innovation & Public Health argued in its 2008 report, it is recommended that Zimbabwe abstains from concluding any bilateral trade agreements which may have provisions that restrict access to medicines.

Zimbabwe is also recommended to put to use parallel importation discussed under section 4.8[402], available to DCs such as itself under the WTO Ministerial Decision of 30 August 2003.[403] Although the country has utilised compulsory licensing, this flexibility has not been exploited to its fullest extent. Reportedly, only two pharmaceutical companies, one of them being Varichem have authority and the capacity to manufacture drugs which has a danger of prices remaining exorbitant due to lack of competition.[404] It is therefore recommended that Zimbabwe explores the use of compulsory licensing at a larger scale.

As a developing country, Zimbabwe might be pressured to associate with developed countries in return for trade benefits. It is therefore recommended that the country be alive to TRIPS Plus inclusive agreements, which may end up giving a monopoly to large pharmaceutical companies from developed countries. It is rather profound for DCs to conclude agreements on their own and seek support from international donors, NGO's or rely on foreign assistance to improve their ability to provide for their people.[405]

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[400] *Centre for Minority Rights Development (CEMIRIDE) (on behalf of the Endorois) v Kenya* (Communication 276/2003) .

[401] N. Rajagopala Ayangar, *Report on the revision of the Patents Law* (India, September 1959) 13

[402] Parallel Importation has been fully discussed under section 4.8.

[403] Decision removes final patent obstacle to cheap drug imports available at www.wto.org/English/news_e/pres03_e/pr350_e.htm accessed on 9 July 2021.

[404] [404] According to the article 'DOHA+10 TRIPS flexibilities and access to antiretroviral therapy: Lessons from the past, opportunities for the future'**, (**2011) 16-Varichem Pharmaceuticals [Pvt] Ltd, a Zimbabwe-registered company, was granted authority to use relevant patents. Under the terms of this authorization, Varichem was to "produce antiretrovirals or HIV/AIDS-related drugs and supply three quarters of its produced drugs to state-owned health institutions.Datlabs, a pharmaceutical manufacturer, was authorized to import antiretroviral medications from Ranbaxy in India, while Omahn, an agent for the Indian manufacturer Cipla, was authorized to import Cipla products.

[405] R L Ghio, 'Assessing the impact of IPRs on development: A view from the Developing World' (2011) 23*Journal of International Development* 1013, 1016.

As Martin Khor, said DCs who have limited capacity to manufacture their medicines and put them on the market under a reasonable price; like Zimbabwe should be given preference to exempt certain products from patenting.[406] The principle of international exhaustion will also improve people's access to cheaper medicines if employed by Zimbabwe. As it is, Zimbabwe's Patents legislation has no provision for the principle of exhaustion and it is highly recommended that the Patents Act be amended to include more flexibilities such as the principle of exhaustion and probably grey marketing until such a time the country is economically, politically and socially stable to sustain its people and realise their rights to health and development.

Zimbabwe could also borrow a leaf from South Africa's model of competition law as well as price control mechanisms and utilise them to prevent excessive pricing of medicines as recommended by Azam.[407] Competition is a natural remedy of eradicating the problem of monopoly and has the ripple effect of lowering the price of medicines hence improving the general populace access to medicines. The overpricing of medicines or rather the demand of inflated amounts of the bond note currency being used in the country could be avoided through such mechanisms.

The flourishing of local pharmaceutical companies depends highly on the funding that is channelled towards research and development (R&D) by the government; hence it is recommended that the Zimbabwean government abides by the Abuja Protocol and issue at least a minimum of 10% budget towards health. By doing so, the country can also reach targets set under the SDG, in particular developmental goals discussed in Chapter 3. A particular interest by the Zimbabwe government in research and development will serve the country a lot of money in medicines and result in the realisation of the right to health and development in the long run.

In accordance with Chapter 4, which highlights Zimbabwe's political, economic and social status, Herzenberg's suggestion of introduction of measures and policies as well as the political will to bring to an end systemic political malpractice which results in the misallocation of resources is very relevant.[408] The political will of African governments to encourage meaningful public involvement and access to data on legislation and policies will be of paramount importance in

[406] M Khor, 'Implications of some WTO rules on the realisation of MDGs' 16.
[407] M. Monirul Azam 'The Experiences of TRIPS-Compliant Patent Law Reforms in Brazil, India, and South Africa and Lessons for Bangladesh', (2014) 7:2 *Akron Intellectual Property Journal* 61,94.
[408]C Herzenberg 'The World Summit on Sustainable DevelopmentImplications forsocio-economic rights in South Africa' (2002)Vol 3 No 3 *ESR Review* 10, 11.

ending such alpractice.[409] However, Zimbabwe also needs to introduce suitable governance instruments to hold decision-makers accountable for sustainable socio-economic delivery at the local and national levels.[410]

5.3 How can Zimbabwe improve its Patent law by learning from India and South Africa?

Although Zimbabwe has managed to domesticate the TRIPS Agreement, the country can utilise India's Patent rules designed to favour domestic industries over foreign companies[411] whereby any new form of a known substance or a new property or a new use for a known substance is not legible to be patented.[412] The prohibition of patenting of new forms or use of an already patented product is a useful means to preventing the occurrence of 'ever-greening' which promotes monopoly by recycling of a product's patent life through unlimited modifications.[413]

The provision mentioned above ensures that inventions essential to the development of the country and with a technological advance in Patents are patented, thereby protecting against evergreening. Furthermore, parallel importation is also permitted in India, where a person can import a patented product from another person authorised to sell and distribute the product by the patent holder.[414] This provision allows the country to source for and acquires cheaper drugs, thereby expanding its ability to realise its peoples right to health and development.

Currently, India has some of the best compulsory licensing provisions captured under Sections 84, 91 and 92 of the country's Patents Act which are discussed further below in this paragraph. Any interested person[415] or holder of a voluntary license can file, three years after the grant of a patent, a compulsory licence request with the Controller of Patents.[416] There are three possible grounds upon which a non-voluntary licence might be sought, and these are: that the reasonable

[409] Ibid.
[410] I A Ardigo, 'Local government accountability mechanisms' available at www.u4 no/publications/local-government-accountability-mechanisms accessed on 8 July 2021.
[411] Le, Vu Van, 'Compulsory Licensing of Patented Pharmaceuticals in the Developing World. A Legitimate or Illegitimate Way to Enhance the Access to Medicines?' (2018)145-146.
[412] Section 3 (b) of Patents Act 1970.
[413] R. F. Beall, J W. Nickerson, W A. Kaplan and A Attaran, 'Is Patent "Evergreening" Restricting Access to Medicine/Device Combination Products?' *PLoS ONE* 11(2) (2016) 2.
According to the article, "the term "evergreening" has been coined to disparage the practice of making incremental, patentable innovations for medicines without corresponding benefit, particularly if patients are aggressively or forcibly transitioned to the new product".
[414] Section 107 A (b) of Patent Act 1979.
[415] Section 2(t) explains that an 'interested person' is anyone who has engaged in, or promoted research in the same field as that to which the invention relates.
[416] Section 84 of the Patent Act 1979.

requirements of the public have not been satisfied (unavailability),[417] or that the invention is not available at a reasonably affordable price (unaffordability),[418] or that the invention is not worked in India (lack of local working).[419] An example of the use of a compulsory license in India is when Natco Company applied for a compulsory license against Bayer to produce a liver and kidney cancer drug known as Naxavar and it was granted under the condition that Natco pays 7% royalties to Bayer from the total sales it makes.[420] In this current economic and political era, Zimbabwe would do well in terms of realising the right to health and people's access to medicines if it utilises the flexibility of compulsory license to the extent that India has.

In South Africa, the Patents Act 57 of 1978 (Patents Act 1987) subsections 56 (2) (a), (c) and (e) allow 'compulsory licenses where the patented product is not manufactured in South Africa and the South African market is being serviced by expensive imports'. It allows the government to issue compulsory licences when the use of patents is abused through such action including:

> failure to manufacture in South Africa: nonworking, prevention of local manufacture because of importation, failure to meet demand on reasonable terms, refusal to grant licences where this causes stagnation of the industry in South Africa, and where the market is being met by imported goods whose prices are excessive.[421]

According to the Act, the holder of a compulsory licence is allowed to import the patented goods on the condition that the Commissioner *may* restrict such importation.[422]

South Africa also employs the Medicines and Related Substances Control Act (MRSCA) to explore use of TRIPS flexibilities fully.[423] The Act is a paradigm for the parallel importation of patent-protected medicines. This provision makes it legal for the South African government to import medicines from other countries at lower prices without having to revoke compulsory licensing. In addition to that, the flexibility of international exhaustion is also used in South Africa whereby the country can legally import drugs manufactured in a third country even though the

[417] Section 84 (1) (a) of Patents Act 1987.
[418] Section 84 (1) (b) of Patents Act 1987.
[419] Section 84 (1) (c) of Patents Act 1987.
[420] *Natco v. Bayer* (Controller of Patents, 2012).
[421] There are a few cases whereby compulsory licensing was granted, *Syntheta (Pty) Ltd (formerly Delta G Scientific (Pty) Ltd v. Janssen Pharmaceutica NV and Another* 1999 (1) SA 85 (SCA) at 88I (S. Afr.); *Sanachem (Pty) Ltd v. British Tech. Grp. plc 1992 BP 276, and Afitra (Pty) Ltd and Another v. Carlton Paper of SA (Pty) Ltd* 1992 BP 331
[422] Section 56 (4) (a) of Patents Act 1987.
[423] Section 15 C of Medicines and Related Substances Control Act.

products are under patent in South Africa as long as the products were originally sold for or by the patent owner in the county.[424]

Besides the Patents Act, South Africa also uses the Competition Act of 1998 to enforce flexibilities provided for under TRIPS. An example is the case of *Hazel Tau and Others vs GlaxoSmithKline and Boehringer Ingelheim*,[425] in which the prices set by the GlaxoSmithKline and Boehringer Ingelheim were challenged and considered an obstacle to accessing ARV medicines.[426] The Competition Commission ruled that the companies had violated the Competition Act of 1998 by refusing to license their patents to generic manufacturers in return for a reasonable royalty, which would support competition between patent holders and their generic competitors.[427] In essence, this would.

5.4 Conclusion

From the previous chapters, the argument that has been preferred is that TRIPS favours the already developed countries as it fails to adequately balance market interests and human rights to health and ultimately development as these rights are interlinked. It is therefore of paramount importance that the exchange between IP laws and different needs of countries be remodelled to accommodate all the WTO members according to their capacity and developmental status. Large pharmaceutical companies who are mainly focused on royalties even where compulsory licenses are granted should be regularised through policy, making it mandatory for such companies to sell drugs in DCs at cost price and issue licenses without demanding royalty payments. Overally, the process of acquiring waivers to relevant TRIPS provisions during pandemics such as COVID 19 should be simplified; for example only a certain number of member states should support the application for a waiver before it is granted and a short time frame should be allocated from the date of application to date of finalisation.

[424] S McKeith 'Pharmaceutical Patents in Developing Nations: Parallel Importation and the Doctrine of Exhaustion' (2014) 6:2 *African Journal of Legal Studies* 287,300.
[425] *Competition Commission of South Africa. Hazel Tau and others v GlaxoSmithKline and others* – Statement of Complaint (2002) available at http://www.section27.org.za/wpcontent/uploads/2010/TauvGSKevidenceAndLegaaclSubmissions.pdf. Accessed on 11 December 2020.
[426] Ibid.
[427] *Hazel Tau* (note 425 above).

Finally; Zimbabwe as a developing country has to build an independent judiciary and a state that is sensitive to and respects the rule of law and promote alignment of laws with the current Constitution to ensure the progressive realisation of the rights to health and development.

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UNIVERSITY OF KWAZULU-NATAL
INYUVESI YAKWAZULU-NATALI

Miss Ropafadzo Blessing Munemo (209531877)
School Of Law
Howard College

Dear Miss Ropafadzo Blessing Munemo,

Protocol reference number: 00012477
Project title: The impact of the Trade Related Aspects of Intellectual Property Rights (TRIPS) on the right to health and the right to development: A study of the implementation of TRIPS in Zimbabwe

Exemption from Ethics Review

In response to your application received on 17 June 2021, , your school has indicated that the protocol has been granted **EXEMPTION FROM ETHICS REVIEW.**

Any alteration/s to the exempted research protocol, e.g., Title of the Project, Location of the Study,Research Approach and Methods must be reviewed and approved through an amendment/modification prior to its implementation. The original exemption number must be cited.

For any changes that could result in potential risk, an ethics application including the proposed amendments must be submitted to the relevant UKZN Research Ethics Committee. The original exemption number must be cited.

In case you have further queries, please quote the above reference number.

PLEASE NOTE:
Research data should be securely stored in the discipline/department for a period of 5 years.

I take this opportunity of wishing you everything of the best with your study.

Yours sincerely,

[redacted]

Mr Simphiwe Peaceful Phungula
obo Academic Leader Research
School Of Law

UKZN