

**A CRITICAL DISCUSSION ON BOTSWANA'S ACCESS TO MEDICINE
AND TRIPS FLEXIBILITIES**

By

Tamanda Agatha Kamwendo

216071885

**A dissertation submitted in partial fulfilment of the requirements for
the degree of**

MASTERS OF LAWS

At the

UNIVERSITY OF KWAZULU-NATAL

COLLEGE OF LAW AND MANAGEMENT STUDIES

SCHOOL OF LAW

SUPERVISOR: MRS C STEVENS

DECEMBER 2016

DECLARATION

This research has not been previously accepted for any degree and is not being currently considered for any other degree at any other university.

I declare that this Dissertation contains my own work except where specifically acknowledged.

Tamanda Agatha Kamwendo (216071885)

Signed:

A handwritten signature in black ink, appearing to read 'Agatha', with a horizontal line drawn through it.

Date: 22 December 2016.

ACKNOWLEDGMENTS

First and above all, I am grateful to God for the good health and wellbeing that were necessary for the completion of this thesis. I wish to express my sincere thanks to my parents for their financial support and encouragement throughout the study. I would also like to thank my brothers Martin, Titus and Edward for their technical support. I warmly thank Noor Saidi, Samke Cwele, Shikara Singh for their inspiring guidance and invaluable friendly advice. Lastly, special thanks should be given to my lovely supervisor, Mrs Stevens for her professional guidance and valuable support. I really appreciate it all.

KEY TERMS

Access to medicine; Compulsory licenses; Developing countries; Doha Declaration; Ever greening; Free Trade Agreements; GATT; Generic drugs; Government use; Health care; HIV/AIDS; Intellectual Property rights; Least Developed Countries; Millennium Development Goals; Paragraph six system; Parallel importation; Patent rights; Patentability; Public health, SADC; TRIPS flexibilities; WTO.

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CHAPTER 1:

INTRODUCTION

1.1 BACKGROUND OF THE STUDY

Access to medicine has two dimensions, that is; medicines need to be accessible as well as be affordable. Financial accessibility of medicines is one of the ongoing challenges faced by most developing countries.¹ As such, access to medicine remains a challenge in the Southern African Development Community (SADC) region as most of these countries battle with three common killer diseases; Tuberculosis, Human Immunodeficiency Virus and Acquired Immune Deficiency Syndrome (HIV/AIDS), and Malaria. Most of the countries in this region depend on imported medicaments² and although pharmaceutical companies attempt to make drugs affordable, most patented drugs are very pricy which often leads to affordability barriers.

Since the 1980s, Intellectual Property Rights (IPRs) have been protected through a series of international conventions, namely; the Paris Convention for the Protection of Industrial Property (1883), the Berne Convention for the Protection of Literary and Artistic Works (1886) and the Washington Treaty on Intellectual Property on Integrated Circuits. It was only in 1995 that the World Trade Organisation (WTO) Agreement on the Trade Related Aspects of Intellectual Property (TRIPS)³ was formulated as a result of the Uruguay Round of negotiations. It is as a result of this Agreement that intellectual property rules that seek to inforce and protect IPRs especially patent rights were for the first time introduced into the multilateral trading system. Prior to the TRIPS there were

¹ Lee, J & Hunt, P ~~Human~~ Rights Responsibilities of Pharmaceutical Companies in Relation to Access to Medicines(2012) *Journal of Law, Medicine & Ethics* 225-226.

² These are substances used for medical treatment. See www.oxforddictionaries.com, accessed on 15 April 2016.

³ TRIPS: Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, THE LEGAL TEXTS: THE RESULTS OF THE URUGUAY ROUND OF MULTILATERAL TRADE NEGOTIATIONS 320 (1999), 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994) [hereinafter TRIPS Agreement].

no international conventions that set out the minimum standards of patent protection.⁴ This places a duty on WTO Members to modify their national legislation so as to conform to the minimum standards of intellectual property rights protection as set out by the TRIPS Agreement.⁵ Therefore, since ratification of the TRIPS is a compulsory prerequisite of WTO membership, any state seeking to access international markets governed by the WTO must incorporate the intellectual property rules mandated by TRIPS into their national legislation.⁶ It is for this reason that the TRIPS is considered the most important WTO Agreement that seeks to foster protection of IPRs.

As such, the TRIPS Agreement increased patent protection at the expense of the States' discretion to determine the duration of patent protection. It is undoubting that the patent system has advanced innovativeness and resulted in the development of medicines used to treat diseases that were once considered incurable. However, due to the TRIPS, states that did not allow patent protection for pharmaceuticals or had limited protection to pharmaceuticals had to amend their legislation in order to become "TRIPS compliant".⁷

The pharmaceutical industry has exploited the patent system in a way to inhibit access to medicine by poorer countries by making these patented drugs unaffordable to them. For instance, it has been noted that the notorious practice by pharmaceutical companies of extending patent life spans past the compulsory 20 year time frame⁸ by filing for secondary patents is the leading cause of exorbitant drug prices.⁹ This practice elongates the exhaustion period of these patents therefore making it impossible for other pharmaceuticals to produce generic versions of the patented drugs. These current events highlight the need to prevent excessive intellectual property rights standards that

⁴ WTO and the TRIPS Agreement available at http://www.who.int/medicines/areas/policy/wto_trips/en/, accessed on 20 April 2016.

⁵ Article 1.1 of the TRIPS Agreement.

⁶ Article 65 *ibid*.

⁷ Article 65(1) and (2) *ibid*.

⁸ Article 33 *ibid*.

⁹ These are subsequent patent rights based on modified compounds, dosages, formulations, medical uses of existing patented drugs.

may ultimately delay access to generic drugs.¹⁰ Countries such as India and Brazil have modified their patent laws to exclude from patentability new forms and uses of existing drugs so as to allow timely entrance of generic drugs in the market.¹¹

Secondly, the absence of the definition of 'invention' under the TRIPS Agreement has affected access to medicine. This is so because pharmaceutical companies may acquire new licenses to drugs whose patent rights were almost exhausted by minimally improving the use of the drug and terming it as an inventive step. Drug patents are therefore extended without a clear improvement in their efficacy.¹² These patents are usually known as 'evergreen' patents and are permissible under the TRIPS Agreement.¹³

As an outcry to the over pricing of patented drugs, TRIPS flexibilities were included in the Agreement. These are provisions in the Agreement that permit governments to disregard in the enforcement of the Agreement for national concerns such as, but not limited to, health emergencies.¹⁴ Thus, developing countries may make use of TRIPS flexibilities to avoid patent protections and have access to generic drugs. It is on this basis that this thesis seeks to establish whether TRIPS ' flexibilities provide a legal basis for developing countries to evade the consequences of the patent system thus enabling them to have access to essential medicines.¹⁵

¹⁰ Amin, T & Kesselheim, AS Secondary Patenting of Branded Pharmaceuticals: A Case Study of How Patents on two HIV Drugs could be Extended for Decades (2012) 31(10) *Health Affairs* 2287.

¹¹ Committee on Development and Intellectual Property (CDIP) *Study on Pharmaceutical Patents in Chile* available at www.wipo.int/edocs/mdocs/mdocs/en/cdip_15/cdip_15_inf_2.docx, accessed on 20 November 2016.

¹² Ndlovu, L Lessons for the SADC from the Indian case of Novartis AG v Union of India (2015) 18(4) *Potchefstroom Electronic Law Journal* 785.

¹³ Article 1 TRIPS Agreement.

¹⁴ Sacco, SF *A Comparative Study Of The Implementation In Zimbabwe And South Africa Of The International Law Rules That Allow Compulsory Licensing And Parallel Importation For HIV/AIDS Drugs* (Unpublished LLM thesis, American University in Cairo, 2004) 21.

¹⁵ Marks, SP Access to Essential Medicines as a Component of the Right to Health (2009) *Health: A Human Rights Perspective* 85-88.

The TRIPS Agreement contains a number of flexibilities such as parallel importing¹⁶, government use,¹⁷ compulsory licensing,¹⁸ exhaustion of patent rights,¹⁹ exclusions from patentability,²⁰ limitations on data protection²¹ and exceptions to patentability²² designed to permit countries to access cheaper medicines. While the Agreement leaves the issue of interpretation and implementation at the statesqdiscretion, differentials in power and resources place limitations on how the TRIPS flexibilities can be utilized by developing countries.²³

The Doha Declaration on TRIPS and Public Health reaffirms IPRs but most importantly clarifies the scope of TRIPS and the position of developing countries. This was after developing countries raised concerns over developed countries using a narrow approach towards the TRIPS. The Doha Declaration therefore established that the TRIPS ought to be interpreted in a way that promotes access to medicine for all.²⁴ It acknowledged the magnitude of health care problems faced by developing countries and as such exempted the Least Developed Countries (LDCs) from complying with the TRIPS until 1 January 2016.²⁵

There is an emerging phenomenon that the issue of access to medicine ought to be tackled from a human rights perspective. Access to medicine is a facet of the right to health and therefore countries need to deal away with existing obstacles in promoting access to medicines as a way of protecting the greater right to health.²⁶ It has been

¹⁶ Article 6 of the TRIPS Agreement.

¹⁷ Article 31(b) *Ibid.*

¹⁸ Article 31 *Ibid.*

¹⁹ Article 28 *Ibid.*

²⁰ Article 27 *Ibid.*

²¹ Article 39.3 *Ibid.*

²² Article 30 *Ibid.*

²³ Musungu, SF *The Right to Health in the Global Economy: Reading Human Rights Obligations into the Patent Regime of the WTO-TRIPS Agreement* (unpublished LLM thesis, Makerere University, (2001)10.

²⁴ Declaration on the TRIPS Agreement and Public Health, WTO Ministerial Conference, Fourth Session, Doha, adopted on 14 November 2001, WT/MIN(01)/DEC/2, at par 4.

²⁵ WTO document IP/C/25, available at http://www.wto.org/english/tratop_e/trips_e/art66_1_e.htm, accessed on 21 November 2016.

²⁶ Hestermeyer, H *Human Rights and the WTO: The Case of Patents and Access to Medicines* Oxford: Oxford University Press, (2007). Also read with Article 12 of the International Covenant on Economic, Social and Cultural Rights.

argued that the inability to access cheaper medicine is a threat to the right to health as drugs and therapies are an integral part of the realization of the right. The right to good health is a precondition to the enjoyment of all other rights²⁷ and hence states are obligated to avert unreasonably high costs of medicines.²⁸

Access to medicine is not only based on the right to health but also the right to share in scientific advancements and its benefits.²⁹ This entails that medical test data needs to be shared to enable production of generic drugs. This right based approach has been commended as it is founded on principles enshrined in human rights treaties which WTO Members are parties to and under which they voluntarily undertake to enforce trade rules and to respect and fulfil human rights.³⁰ This presupposes that the right to health is a greater right compared to intellectual property rights which are merely temporary rights established to promote scientific inventions hence IPRs should never override the right to health.

This position was re-affirmed in 2006 by General Comment No 17 in which the Committee affirmed the following;

In contrast with human rights, intellectual property rights are generally of a temporary nature, and can be revoked, licensed or assigned to someone else. While under most intellectual property systems, intellectual property rights, with the exception of moral rights, may be allocated, limited in time and scope, traded, amended and even forfeited, human rights are timeless expressions of fundamental entitlements of the human person.³¹

²⁷ Socio economic rights such as the right to housing and the right to education cannot be enjoyed in the absence of good health.

²⁸ Chirwa, DM 'The Right to Health in International Law: Its Implications for the Obligations of State and Non-State Actors in Ensuring Access to Essential Medicines' (2003) 19 *SAJHR* 545-547.

²⁹ Article 15 (1) (b) International Covenant on Economic, Social and Cultural Rights (ICESCR).

³⁰ Benatar S, Brock G *Global Health and Global Health Issues* Cambridge: Cambridge University Press, (2011) 124-126.

³¹ CESCR, *General Comment No. 17 on the right of everyone to benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he or she is the author*, (2006) at para. 2.

However, the full enjoyment of the right to health remains indistinct due to obstacles in accessing cheaper medicines by most developing countries. The United Nations Millennium Development Goals (MDGs)³² emphasize the need to cooperate with pharmaceutical companies in order to improve availability of affordable essential medicines in developing countries.³³ Goals number 4, 5 and 6 relate to health care in poor countries as they aim to reduce child mortality, improve maternal health and combat HIV/AIDS, malaria and other diseases respectively. According to the MDG reports, improved access to medicines in poor countries has led to the decline of most avoidable deaths.³⁴ For instance deaths of children under 5 years of age as a result of measles has declined rapidly since 2000, from 544,200 deaths to 145,700 deaths in 2013.³⁵ Furthermore, despite that the rate of new HIV infections still remains high, more HIV positive people are able to live longer due to the increased use of antiretroviral therapy (ART).³⁶ Since the introduction of ART in 1995, an estimate of 7.6 million deaths have been averted.³⁷ It is therefore evident that poor access to medicines continues to be the leading cause of deaths in most developing countries. This is because if essential medicines are not available in the public sector which usually provides medicines at a very low charge or no charge at all, patients will have to purchase medicines from the higher-priced private pharmacies, or forgo treatment altogether.

³² These are the world's 8 time-bound and quantified targets set at the UN Millennium Summit in 2000 for addressing extreme poverty in its many dimensions such as income poverty, lack of adequate healthcare, disease, lack of adequate shelter, education and environmental sustainability. See <http://www.unmillenniumproject.org/goals/>, accessed on 20 April 2016.

³³ Target 8e of the Millennium Development Goals available at <https://www.oecd.org/dac>, accessed on 20 December 2016.

³⁴ Jamison, DT et al. *Disease Control Priorities in Developing Countries* 2 ed New York: Oxford University Press, (2006) 40.

³⁵ The Millennium Development Goals Report of 2015, available at www.un.org/2015_MDG_Report.pdf, accessed on 20 December 2016.

³⁶ *Ibid.*

³⁷ *Ibid* at 45-47.

1.2 PROBLEM STATEMENT

Botswana is a landlocked country located in the South Western part of Africa bordering with Namibia, South Africa, Zambia and Zimbabwe. Due to its landlocked nature, it is highly reliant on alien commodities.³⁸

Due to Botswana's small market size, its pharmaceutical industry till date does not manufacture pharmaceutical drugs and has a small number of registered pharmaceutical manufacturers.³⁹ As a developing country, Botswana's infant pharmaceutical industry is mostly involved in repackaging medicaments and distributing of the drugs.⁴⁰ The government of Botswana therefore imports pharmaceutical medicaments and raw materials which are distributed to pharmacies for private consumption or for commercial repackaging and institutional uses.⁴¹ The country therefore remains reliant on importing pharmaceutical drugs in order to meet the needs of its people.

Trade related IPRs may be the stepping stone in helping Botswana access cheaper generic drugs. In 2001, Botswana notified the WTO TRIPS Council of its intention to implement the minimum standards of IP protection according to the WTO TRIPS Agreement.⁴² Botswana as a developing country took advantage of these international trade law provisions and reviewed its IP laws to include these TRIPS flexibilities.⁴³ Botswana's current legal and policy environment therefore makes it conducive to access cheaper medicines in the form of generics.

Apart from other non-communicable diseases that the nation has to deal with, Botswana has one of the highest HIV infection rates in the world. As of 2014, Botswana had about

³⁸ These are products imported from other countries.

³⁹ See <https://www.frost.com/prod/servlet/report-brochure.pag?id=M438-01-00-00-00>, accessed on 21 November 2016.

⁴⁰ *Ibid.*

⁴¹ See http://www.pharmexcil.com/v1/docs/Pharma_Industry_in_Botswana.pdf accessed on 24 April 2016.

⁴² WTO, Council for Trade-Related Aspects of Intellectual Property Rights *Notification of Laws and Regulations under Article 63.2 TRIPS* (2002).

⁴³ Guzik, B. Botswana's Success in Balancing the Economics of HIV/AIDS with TRIPS Obligations and Human Rights (2006-2007) 4(2) *Loyola University Chicago International Law Review* 259.

390 000 people living with AIDS out of a total population of 1.2 million.⁴⁴ In 2008 the government introduced a policy known as Botswana's National Operational Plan for HIV and AIDS which was aimed at achieving Zero HIV infections in the years to come. This plan entails procuring and distributing critical medicines across all districts of Botswana.⁴⁵ Botswana being a developing country, this policy has weighed heavily on the state's finances. The HIV pandemic has had adverse impacts on the economy of Botswana. More so, due to lack of access to proper and adequate health care, the country's mortality rate has sky rocketed leading to about 67 000 orphans due to AIDS related deaths.⁴⁶ This creates an extra burden on the government to see to the needs of these orphaned children.

As a result, in 2015, the Botswana government increased its state budget share to the pharmaceuticals sector with an allocation of BWP1.99billion as opposed to BWP1.82billion as was in the previous year.⁴⁷ The Ministry of Health continues to receive the second largest state budget share.⁴⁸ This goes to show the increasing need of the government to inject more money into the health sector in order to continue meeting the health needs of its people. Botswana currently uses patented drugs such as the Anti-Retro Viral (ARVs) and these patented drugs are becoming more expensive. It is therefore evident that the government needs to devise means of ensuring that it continues to scale up treatment and prevention within its financial capabilities. The use of generic drugs that are equivalent and interchangeable with the patented ones would be an important step to cutting the cost of drugs and therefore allowing the treatment of more people.⁴⁹

⁴⁴ UNAIDS available at <http://www.unaids.org/en/regionscountries/countries/botswana>, Accessed on 16 March 2016.

⁴⁵ National Operational Plan for Scaling Up HIV Prevention in Botswana: 2008 . 2010 available at http://hivhealthclearinghouse.unesco.org/sites/default/files/resources/iiep_hiv_prevention_operational_plan_botswana_april_2008.pdf, accessed on 21 November 2016.

⁴⁶ UNAIDS available at <http://www.unaids.org/en/regionscountries/countries/botswana>, Accessed on 18 March 2016.

⁴⁷ Matambo, OK *2015 Budget Speech* available at <http://www.gov.bw/global/portal%20team/2015%20budget%20speech%20by%20honourable%20o.pdf>, accessed on 9 March 2016.

⁴⁸ *Ibid.*

⁴⁹ Generic drugs are copies of brand-name (patented) drugs that have exactly the same dosage, intended use, effects, side effects, route of administration, risks, safety, and strength as the original drug.

Accordingly, this study seeks to establish the extent to which TRIPS flexibilities have been incorporated in Botswana's national legislation. The study will further seek to examine the technical barriers in trade that are preventing Botswana from fully utilizing these TRIPS flexibilities in order to promote access to cheaper medicines.

1.3 PRELIMINARY LITERATURE REVIEW

In recent years, the increased protection of IPRs has become a controversial topic especially in developing countries as countries are aiming to intensify ways of promoting access to medicine but due to the monopoly pharmaceutical prices associated with these rights, treatment of diseases has become very expensive. There is an ongoing debate as to whether the right to health care and intellectual property rights conflict or coexist. Further, in the presence of a conflict which of the two rights should be given preference over the other.

With the ongoing battle, Velasquez is of the opinion that developing countries are becoming victorious towards promoting access to medicine.⁵⁰ He supports his argument by stating that the 2001 Doha Declaration was a stepping stone in dealing away with the misinterpretation of the TRIPS by most developed countries.⁵¹ He further argues that most developing countries can now import essential medicine from other Member States through the Paragraph 6 system.⁵² Velasquez is therefore of the view that even though the battle in promoting access to medicine is far from over, it is moving in the right direction.⁵³

The predicament of a country's use of TRIPS flexibilities to access cheaper medicine is generally two-fold as it revolves around a country's ability to acquire compulsory

Available at <http://www.medicinenet.com/script/main/art.asp?articlekey=46204>, accessed on 25 April 2016.

⁵⁰ Velasquez, German Bilateral Trade Agreements and Access to Essential Drugs, Bermudez Jorge, AZ and Oliveira-Auxiliadora, M, Intellectual Property in the Context of the WTO TRIPS Agreements: Challenges for Public Health, ENSP/ WHO . Oswaldo Cruz Foundation, 63 (2004).

⁵¹ *Ibid.*

⁵² *Ibid.*

⁵³ WIPO, *Promoting Access to Medical Technologies and Innovation; Intersections between Public Health, Intellectual Property and Trade* London: Book Now Ltd, (2013) 185.

licenses and to manufacture and export generic versions of patented drugs.⁵⁴ The existence of IPRs has been the barrier of most developing countries to access cheaper generic drugs. As already discussed, most developing countries have infant pharmaceutical industries that make them unable to manufacture these generic drugs on their own. However, it is as a result of the increased patent protection offered by the TRIPS that pharmaceutical companies have become politically powerful as they consider the TRIPS as a launching pad for their ever expanding patents based on the argument that pharmaceuticals promote innovation. Ellen Hoen strongly points out that due to their exclusive nature, patent rights undoubtedly restrict access to medicines.⁵⁵ She argues that competition is the most proven effective way to bring drug prices down and this cannot be achieved where there is monopoly of positions in the pharmaceutical industry.⁵⁶

Most African countries believe that the standards set out in the TRIPS Agreement are the ceiling and not the floor of intellectual property rights protection.⁵⁷ However as argued by Ellen Hoen, the TRIPS merely serve as a launching pad and there is nothing that prevents States from imposing stricter intellectual property protection in their national laws.⁵⁸ The TRIPS merely sets out the minimum standards of protection that Member states are not to contravene.⁵⁹

Scholars such as Watal argue that TRIPS promotes the interests of global pharmaceutical companies by allowing them extend their control over their intellectual

⁵⁴ Ndlovu, L *Access to Medicines under the World Trade Organization TRIPS Agreement: A Comparative Study of Select SADC Countries* (unpublished LLD thesis, University of South Africa, 2014) 12.

⁵⁵ Hoen, E *TRIPS, Pharmaceutical Patents and Access to Essential Medicines: Seattle, Doha and Beyond* Paris: National Agency for AIDS Research, (2003) 41.

⁵⁶ Hoen, E *TRIPS, Pharmaceutical Patents, and Access to Essential Medicines: A Long Way from Seattle to Doha*(2002) 3 *Chicago Journal of International Law* 27-29.

⁵⁷ Mgbefi, I *TRIPS and TRIPS Plus Impacts in Africa*in *Intellectual Property, Trade and Development: Strategies to Optimize Economic Development in a TRIPS-Plus Era* Oxford: Oxford University Press, (2007) 269.

⁵⁸ Hoen, E *TRIPS, Pharmaceutical Patents, and Access to Essential Medicines: A Long Way from Seattle to Doha*(2002) 3 *Chicago Journal of International Law* 32.

⁵⁹ Article 1 of the TRIPS Agreement states that Members are not obliged implement in their law more extensive protection than is required by the Agreement.

property.⁶⁰ Grabowski emphasizes that increased patent protection is justifiable because the costs of innovation in the pharmaceutical industry are relatively high as compared to the costs of imitation so they ought to be patent protected.⁶¹ On the contrary, there is little evidence to prove that increased intellectual property protection incentivizes pharmaceutical innovation within developing countries. This may be supported by the CIPIH report which stated the following;

It is also assumed that society at large will be able to benefit from present and future innovation. But where most consumers of health products are poor, as are the great majority in developing countries, the monopoly costs associated with patents can limit the affordability of patented health-care products required by poor people in the absence of other measures to reduce prices or increase funding. Thus the overall effect of intellectual property regimes is context-specific. The impact in a country such as India may differ from that in Thailand or in Ghana.⁶²

Furthermore, pharmaceutical companies that own these patent rights are also resistant in permitting importation of these generic drugs.⁶³ Pharmaceutical companies tend to abuse intellectual property rights in trade agreements thus undermining the very existence of patent flexibilities.⁶⁴ Adusei further argues that one of the reasons most developing countries are unable to fully utilize TRIPS flexibilities is due to a poorly executed patent systems within these countries.⁶⁵ He alludes to the fact that the same

⁶⁰ Watal, J. (2000). Access to Essential Medicines in Developing Countries: Does the WTO TRIPS Agreement Hinder It? Science, Technology and Innovation Discussion Paper No. 8, Center for International Development, Harvard University, Cambridge, MA, USA.

⁶¹ Grabowski, H. Patents, Innovation and Access to New Pharmaceuticals (2002) 5(4) *Journal of International Economic Law* 849.

⁶² See Report of the Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH), World Health Organization, Geneva, available at: <http://www.who.int/intellectualproperty/documents/thereport/ENPublicHealthReport.pdf> accessed on 21 April 2016.

⁶³ Greene, W. *The Emergence of India's Pharmaceutical Industry and Implications for the U.S Generic Drug Market* Washington D.C: US International Trade Commission, (2007).

⁶⁴ Adusei, P. Exploiting Patent Regulatory Flexibilities to Promote Access to Antiretroviral Drugs in Sub-Saharan Africa (2009) 9 *University of Botswana Law Journal* 3.

⁶⁵ *Ibid* at 4.

TRIPS Agreement that seems to promote access to medicine permits states to grant protection for medicinal test data.⁶⁶ This is problematic as the TRIPS already grants a lengthy 20 year patent protection to pharmaceutical processes and products and therefore protecting medical test data creates some form of monopoly on the data which could have been utilized in the production of generic drugs. It could therefore be deduced that incorporating TRIPS flexibilities in a country's intellectual property legislation cannot in itself promote access to medicine if the patent system itself is faulty. It is therefore clear that the battle of promoting access to medicine requires a balance of rights between the rights of the developing countries to access cheaper medicine and the protection of the pharmaceutical companies' patent rights.⁶⁷ Striking the balance between patent rights and promotion of public health requires a more comprehensive approach than merely having numerous flexibilities in the TRIPS Agreement promoting access to medicines.

Pfumorodze also argues that most developing countries fail to fully utilize these flexibilities and this has been attributed to the social, economic and political status of the economy.⁶⁸ He further argues that a country can only fully utilize TRIPS flexibilities if it has a relatively stable political and economic environment which is not the case for most developing countries.⁶⁹ Pfumorodze made reference to Zimbabwe being the first developing country to issue a compulsory license in the post Doha period for manufacturing generic HIV/AIDS drugs by one of its pharmaceutical companies.⁷⁰

Furthermore, Sell identifies Free Trade Agreements (FTAs) as one of the barriers to access to medicine. She argues that these FTAs promote a strict standard of IPRs protection which denies developing countries the opportunity to pursue certain public

⁶⁶ Article 39.3 of the TRIPS Agreement.

⁶⁷ Hanefeld, J. *Patent Rights v Patient Rights: Intellectual Property, Pharmaceutical Companies and Access to Treatment for People Living with HIV/AIDS in Sub-Saharan Africa* (2002) 72 *Feminist Review* 84-92.

⁶⁸ Pfumorodze, J. *WTO TRIPS Agreement and Access to Medicines in Southern Africa* (2011) 13 *University of Botswana Law Journal* 99.

⁶⁹ *Ibid* at 102.

⁷⁰ *Ibid* at 101.

policy goals in the health sector.⁷¹ Sell argues that IP rights have been elevated to the status of master as opposed to servant when dealing with public policy matters.⁷² Roffe and Spennemann further substantiate this argument by stating that the growth of TRIPS-plus FTAs puts developing countries at risk of being unable to utilize the flexibilities granted to them through the TRIPS Agreement.⁷³ This is so because most TRIPS-plus obligations aim at strengthening the position of pharmaceutical companies and are less geared towards promoting public health.⁷⁴ This is worrisome as patent rights in their very own nature restrict developing countries' access to medicine and therefore entering into FTAs may further jeopardize actual usage of TRIPS flexibilities.

The above discussed literature therefore points to the fact that patent system is necessary and beneficial to promote innovation in the pharmaceutical industry. However, the very same patent system has proven to be a barrier in promoting access to medicine by poorer countries. Present literature has sought to identify the various reasons why developing countries are having challenges in fully utilizing the TRIPS flexibilities. However, the literature seems to analyze the position of developing countries as a whole without narrowing it down to country by country basis. This study therefore attempts to focus on Botswana specifically and then carry out a comparative analysis with other SADC countries.

1.4 RESEARCH OBJECTIVES

This study evaluated the extent to which SADC countries utilize TRIPS flexibilities in promoting access to medicine. The study attempted to answer the following specific research questions

1. How did intellectual property come to be on the trade agenda?

⁷¹ Sell, SK 'Trips-Plus Free Trade Agreements and Access to Medicines' (2007) 28 *Liverpool Law Review* 57-58.

⁷² *Ibid* at 58.

⁷³ Roffe, P & Spennemann, C 'The impact of FTAs on public health policies and TRIPS flexibilities' (2006) 1 (Nos. 1/2) *International Journal of Intellectual Property Management* 77.

⁷⁴ *Ibid* at 86.

2. How is the right to access to health care and intellectual property rights protected in Botswana?
3. To what extent have TRIPS flexibilities been incorporated in SADC countriesq domestic legislations particularly Botswana to advance access to medicine?
4. How do we ensure that developing countries make full use of the TRIPS flexibilities without falling foul of the basic tenets of intellectual property law?
5. What legal and policy interventions need to be implemented to ensure that developing countries fully utilize TRIPS flexibilities?

1.5 RESEARCH DESIGN

This study was a qualitative non-empirical study. A qualitative study explores the richness and complexity inherent in a given research area rather than numbers and is most appropriate for exploratory studies.⁷⁵ A qualitative study usually involves analysing information in an organized way which leads to the emergence of themes which helps the researcher unravel various aims and objectives of the research.⁷⁶ This was suitable for this study as the researcher intended to delve into the complexities of the TRIPS flexibilities in promoting access to medicine in great depth so as to form a proper analysis. The research also involved constant comparison between the positions in the various SADC countries.

In conducting the study, the researcher utilised both exploratory and analytical research methods. An exploratory study is mostly utilized where the researcher seeks to uncover information whose scope is unclear. It therefore seeks to reveals the dimensions of a particular phenomenon. In this study, the researcher attempted to establish the extent to which TRIPS flexibilities have been utilized by Botswana and other SADC countries.

⁷⁵ Burns, N & Grove, SK *Understanding Nursing Research* Philadelphia: WB Saunders, (1999) 339.

⁷⁶ Polit, PD & Hungler, BP *Essentials of nursing research. Methods, appraisal and utilization* 4thed Philadelphia: Lippincott (1997) 239.

An analytical research method was used to identify any causal links between the factors that pertain to the research problem. In this study philosophical analysis was used to examine a proposition from various perspectives through the extensive exploration of literature. The study explored possible reasons why TRIPS flexibilities have not been fully utilized in Botswana and other SADC countries. This was so because from the existing literature it was observed that most developing countries have not fully utilized TRIPS flexibilities and hence the present study sought to discern the possible reasons for such.

1.6 RESEARCH METHODOLOGY

The study was an outright desk-top literature study. The researcher relied on primary and secondary sources of data. The study involved perusal of legislations of some SADC countries with particular emphasis on the laws of Botswana as well as International Treaties and Conventions that speak to human rights law and the right to health. The analysis of the intellectual Property Act of Botswana formed the bedrock of this research.

The researcher made use of reliable internet sources in particular, the researcher consulted websites of International Organizations such as the World Health Organization (WTO) for purposes of accurate health related statistics needed for this research. The study to a large extent referred to textbooks and journal articles relating to the TRIPS Agreement and access to medicine particularly in the context of African developing countries. Such journal articles and textbooks were either be accessed from internet sources or from the library.

1.7 STRUCTURE OF THESIS

This study was organized into 5 chapters and is outlined as follows;

Chapter One: Introduction. This chapter sets out the background of the research and a detailed outline of the research problem. This chapter also sets out the aims of the

study together with the objectives the researcher sought to achieve by the end of this research.

Chapter Two: History of the development of Intellectual Property in International Trade. This chapter discusses the founding history of the General Agreement on Tariffs and Trade (GATT) and the World Trade Organisation (WTO). The TRIPS Agreements, Paris Convention together with the Berne Convention were discussed in great details together with their relevance to this study.

Chapter Three: The human rights and intellectual property framework of Botswana. The aim was to identify how intellectual property laws and human rights are protected in the country. The chapter evaluated how national regulatory bodies in Botswana protect the right to health care and intellectual property rights. The chapter also assessed the level of protection that is afforded to non-governmental organizations (NGOs) as well as government authorities that deal with the issue of access to medicine and the right to health in general.

Chapter Four: Comparison of Botswana's intellectual property legislation with other SADC countries such as South Africa and Zimbabwe. The aim was to discern the extent to which these other SADC countries have incorporated TRIPS flexibilities in their national legislation. Relevant case law was discussed under this chapter.

The final chapter, Chapter Five comprised of the recommendations and conclusion of the study.

CHAPTER 2:

HISTORY OF THE DEVELOPMENT OF INTELLECTUAL PROPERTY IN INTERNATIONAL TRADE

2.1 INTRODUCTION

Intellectual property rights (IPRs) have always existed but resided primarily within the domestic sphere.⁷⁷ The protection of IPRs at an international level has been characterised with different phases of development. The initial phase is characterised with the absence of the international protection of IPRs. As such, it was only towards the end of the 19th century that states began to demonstrate more prominent enthusiasm towards the likelihood of worldwide co-operation on intellectual property matters. This was mostly portrayed through the formation of unions by European countries for the protection of literary and artistic works and industrial property.⁷⁸ Formerly, international protection of intellectual property was only found in bilateral commercial agreements involving mainly European countries.

Over the years there has been a remarkable creation of different international instruments that deal with intellectual property. These instruments were dissimilar in as far as the extent of protection of IPRs that was afforded. This eventually led to the formation of the Paris Convention for the Protection of Industrial Property, 1883⁷⁹ and the Berne Convention for the Protection of Literary and Artistic Works, 1886.⁸⁰ These

⁷⁷ Tully, LD *Prospects for Progress: The TRIPS Agreement and Developing Countries after the DOHA Conference* (2003) 26(1) *B.C. Int'l & Comp.L.Rev* 131.

⁷⁸ Onguglo, BF *Developing Countries and Unilateral Trade Preferences in the New International Trading System* available at https://www.wto.org/english/tratop_e/devel_e/sem01_e/ongugl_e.doc, accessed on 15 August 2016.

⁷⁹ Paris Convention for the Protection of Industrial Property of March 20, 1883 as revised at Brussels on December 14, 1900, at Washington on June 2, 1911, at The Hague on November 6, 1925, at London on June 2, 1934, at Lisbon on October 31, 1958, and at Stockholm on July 14, 1967, and as amended on October 2, 1979 [hereinafter Paris Convention].

⁸⁰ Berne Convention for the Protection of Literary and Artistic Works of September 9, 1886, completed at Paris on May 4, 1896, revised at Berlin on November 12, 1908, completed at Berne on March 20,

are the oldest agreements in as far as international protection of intellectual property rights is concerned. The final development phase was the formation of the Agreement on Trade-Related Aspects of Intellectual Property Rights, 1994 (the TRIPS Agreement).⁸¹

This chapter seeks to discuss the history of IPRs in international trade. The chapter will therefore include a detailed discussion of various international agreements and the level of intellectual property rights protection that is accorded by each of the agreements. The chapter will also identify the possible setbacks of these agreements as far as protection of intellectual property rights is concerned.

2.2 THE PARIS CONVENTION FOR THE PROTECTION OF INDUSTRIAL PROPERTY 1883

This was the first and most important international instrument that dealt with protection of intellectual property, particularly, the protection of patents on industrial innovations. Its main aim was to harmonize patent laws and regulations as stipulated by various countries.⁸² The adoption of the Paris Convention was preceded by the International Conference on patent rights held in Vienna, Austria in 1873.⁸³ The Congress of Vienna led in turn to an International Congress on Industrial Property, convened at Paris in 1878.⁸⁴ At the latter Congress, States sought to establish an international uniform patent application process. Prior to the Paris Convention, individuals wanting to protect their inventions in several countries needed to simultaneously file patent applications in all

1914, revised at Rome on June 2, 1928, at Brussels on June 26, 1948, at Stockholm on July 14, 1967, and at Paris on July 24, 1971, and amended on September 28, 1979 [hereinafter Berne Convention].

⁸¹ Drahos, P. 'The Universality of Intellectual Property Rights: Origins and Development' available at http://www.wipo.int/edocs/mdocs/tk/en/wipo_unhchr_ip_pnl_98/wipo_unhchr_ip_pnl_98_1.pdf, accessed on 29 June 2016.

⁸² Correa, CM. 'An Agenda for Patent Reform and Harmonization for Developing Countries' A Paper prepared for the Bellagio Dialogue on Intellectual Property and Sustainable Development: Revising the agenda in a new context+, International Center for Trade and Sustainable Development (ICTSD), 24 - 28 September 2005, Bellagio, Italy.

⁸³ Reiss, SM. 'Commentary on the Paris Convention for the Protection of Industrial Property' *Lex- IP* available at <http://www.lex-ip.com/Paris.pdf>, accessed on 3 August 2016.

⁸⁴ WIPO, *Introduction to Intellectual Property, Theory and Practice* Kluwer Academy: Kluwer Law International, (1997) 359.

such countries in order to avoid the loss of eligibility of patent protection in such countries.⁸⁵ It is for this reason that the French Government circulated a draft convention setting out an international unification for the protection of industrial property. The 1880 International Conference in Paris adopted this draft convention of which many of its provisions underlie the current Paris Convention.⁸⁶

The Paris Convention therefore deals with cross boarder patenting and simplifies the patent application process. Developing countries have always been reluctant to ratify patent treaties particularly the Paris Convention due to the fear that no technical assistance would be afforded to developing countries in as far as implementing treaty obligations is concerned.⁸⁷ However, States that are not members to the Paris Convention but are signatories to the WTO are obliged to comply with the provisions of the Paris Convention from the date of their application to the WTO.⁸⁸ This is also stipulated under Article 2 of the TRIPS Agreement which requires all WTO members to comply with Articles 1 through 12 and 19 of the Paris Convention. The above stated Articles state as follows;

Industrial property shall be understood in the broadest sense and shall apply not only to industry and commerce proper, but likewise to agricultural and extractive industries and to all manufactured or natural products⁸⁹ patents shall include the various kinds of industrial patents recognized by the laws of the countries of the Union, such as patents of importation, patents of improvement, patents and certificates of addition, etc.⁸⁹

⁸⁵ See <http://www.adamsadams.com/wp-content/uploads/2015/12/Patent-Brochure.pdf>, accessed on 21 December 2016.

⁸⁶ Reiss, SM *Commentary on the Paris Convention for the Protection of Industrial Property* *Lex- IP* available at <http://www.lex-ip.com/Paris.pdf>, accessed on 3 August 2016.

⁸⁷ Correa, CM & Yusuf AA (ed) *Intellectual Property and International Trade: The TRIPS Agreement* Amsterdam: Kluwer Law International, (2008) at 36.

⁸⁸ Reiss, SM *Commentary on the Paris Convention for the Protection of Industrial Property* *Lex- IP* available at <http://www.lex-ip.com/Paris.pdf>, accessed on 4 August 2016.

⁸⁹ Article 1 of the Paris Convention.

Each country of the Union undertakes to establish a special industrial property service and a central office for the communication to the public of patents, utility models, industrial designs, and trademarks.⁹⁰

It is understood that the countries of the Union reserve the right to make separately between themselves special agreements for the protection of industrial property, in so far as these agreements do not contravene the provisions of this Convention.⁹¹

One of the setbacks of this Convention was its failure to outline minimum standards for patent protection to which its Members must adhere.⁹² The scope and level of the intellectual property rights protection Member States were expected to implement under the Convention were left to domestic legislation and courts to develop. This therefore did not in any way harmonize the standards of intellectual property protection in international trade as standards were subject to states' discretion.⁹³ The lack of provisions setting out the minimum standards of IPRs and mandating the enforcement of those rights has been argued to be the basis for the establishment of the TRIPS Agreement which will be discussed later.⁹⁴

2.3 BERNE CONVENTION FOR THE PROTECTION OF LITERARY AND ARTISTIC WORKS 1886

The Berne Convention was the oldest international convention in the area of copyright and still forms the cornerstone of international copyright law. The Agreement was prompted by the need to bring uniformity to the number of bilateral agreements that existed at that time. Interestingly, the Berne Convention was successful in outlining the minimum standards of copyright protection. For example, Article 2(7) of the Convention

⁹⁰ Article 12 of the Paris Convention.

⁹¹ Article 19 of the Paris Convention.

⁹² Tully, LD *Prospects for Progress: The TRIPS Agreement and Developing Countries after the DOHA Conference* (2003) 26(1) *B.C. Int'l & Comp.L.Rev* 132.

⁹³ Article 19 of the Paris Convention.

⁹⁴ Reiss, SM *Commentary on the Paris Convention for the Protection of Industrial Property* *Lex- IP* available at <http://www.lex-ip.com/Paris.pdf>, accessed on 3 August 2016.

provides that Member States are free to decide the extent and conditions under which works of applied art and industrial designs are protected in their national laws. According to Article 20 of the Convention, %States are permitted to enter into special agreements, among themselves, which grant authors more protection than those granted by the Convention or other provisions which do not contradict the provisions of the Convention.+However, the Convention failed to establish extensive legal remedies which could be enforced by the copyright holders against the copyright infringers.

Conclusively, the Paris and Berne Conventions steered in harmonizing international cooperation in intellectual property. In 1893, the Paris and Berne Conventions became part of the United International Bureaux for the Protection of Intellectual Property also known as *Bureaux Internationaux Réunis pour la Protection de la Propriété Intellectuelle* (BIRPI) which later evolved into the World Intellectual Property Organisation (WIPO) which will be discussed later.⁹⁵

Linked to the developments in IP was the idea to revive the world economy, thus in the wake of the World War II an organisation called the International Trade Organization (ITO) was formed whose mandate was to regulate international trade.⁹⁶ The ITO was thus intended to perform the role of a global trade ministry. This organisation was championed by the United States together with its allies but became a %still born+due to the US Congress withholding its ratification of the Havana Charter. The Havana Charter was the agreement that provided for the establishment of the ITO.⁹⁷ The failure of the ITO marked the first casualty of the post-war international political environment.

2.4 THE GENERAL AGREEMENT ON TARIFFS AND TRADE (GATT) 1947

In 1947, after the failure of the ITO, about 23 negotiating states led primarily by the United Kingdom, United States (US) and Canada converged in Geneva, Switzerland in

⁹⁵ Curtis, JM ~~Intellectual Property Rights and International Trade: An Overview~~(No.3 May 2012),*CIGI papers* available at <https://www.cigionline.org/sites/default/files/no.3.pdf>, accessed on 17 June 2016.

⁹⁶ *Ibid.*

⁹⁷ Bossche, P *The Origins of the WTO. The Law and Policy of the World Trade Organization: Text, Cases and Materials* Cambridge: Cambridge University Press, (2005) 14.

order to establish a post war world trading system.⁹⁸ The General Agreement on Tariffs and Trade (GATT) came about at the end of World War II. After World War I & II, the international trading system was in shambles. The goal therefore was to create an agreement that would ensure postwar stability and avoid a repeat of the mistakes of the past. States had begun to conclude unfair trade arrangements for their own political agendas. This led to the destruction of the multilateral trading system that existed prior to World War I.⁹⁹ The GATT was therefore established as the custodian and enforcer of free trade in the multilateral trading system. As such, the GATT was more of a contract to which states were Contracting Parties rather than an organization in which they were Member States.

The GATT was characterized by 8 rounds of negotiations addressing various trade issues starting with the Geneva Round in 1947 ending with the Uruguay round which ran from 1986-1994.¹⁰⁰ The first rounds of GATT negotiations mostly dealt with tariff reductions. Countries participating in these negotiations were primarily focused on reducing tariff trade barriers across the board which they succeeded in substantially. The Uruguay Round was responsible for ending the GATT era in 1994 by ushering in the WTO. Similarly, it was only during the Uruguay round of negotiations that intellectual property matters were tabled for discussion under the GATT.¹⁰¹

Intellectual property rights were not completely foreign to the GATT before they were tabled for negotiation during the Uruguay Round. However, the GATT did not expressly oblige States to accord any level of protection towards intellectual property rights.¹⁰² The founding Agreement under Article XX(d) allowed Contracting States to enforce intellectual property rights in a manner that would normally be inconsistent with the

⁹⁸ Irwin, DA et al. *The Genesis of the GATT* Cambridge: Cambridge University Press, (2009)1.

⁹⁹ *Ibid* at 7-9.

¹⁰⁰ GATT rounds; Geneva Round 1947, Annecy Round 1949, Torquay Round 1951, Geneva Round 1955-56, Dillon Round 1960-62, Kennedy Round 1964-67, Tokyo Round 1973-79, Uruguay Round 1986-94.

¹⁰¹ WTO website *The GATT Years: From Havana to Marrakesh* available at www.wto.org/english/thewto_e/whatis_e/tif_e/fact4_e.htm, accessed on 17 August 2016.

¹⁰² Chung-Lui, K & Sun, H *A Universal Copyright Fund: A New Way to Bridge the Copyright Divide* (2006) 1(2) *National Taiwan University Law Review* 38-40.

GATT provided such measures are not used as a disguised barrier to trade. The Article stipulates that:

Subject to the requirement that such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade, nothing in this Agreement shall be construed to prevent the adoption or enforcement by any contracting party of measures

ō

(d) necessary to secure compliance with laws or regulations which are not inconsistent with the provisions of this Agreement, including those relating to ō the protection of patents, trademarks and copyrights, and the prevention of deceptive practicesō q¹⁰³

The Agreement does not make any special dispensation for the protection of intellectual property rights. Article XX(d) of the GATT therefore did not compel Contracting States to adopt such measures but rather gave a leeway when the need to enforce intellectual property rights arose.¹⁰⁴

Furthermore, in 1967, a diplomatic conference was held in Stockholm at which all the clauses of all existing multilateral treaties administered by BIRPI were revised and the Convention Establishing the World Intellectual Property Organization (WIPO) was signed.¹⁰⁵ The Convention came into effect in 1970. WIPO as a specialized agency of the United Nations is responsible for the protection of intellectual property rights across the globe by ensuring statesq cooperation of treaties administered under this organization. However the formation of a new organisation was looming which was envisioned to govern all aspects of Trade, including IP.¹⁰⁶

¹⁰³ General Agreement on Tariffs and Trade 1947 (GATT 1947), 55 U.N.T.S. 194.

¹⁰⁴ Hartridge, D & Subramanian A Intellectual Property Rights: The Issues in GATTq(1989) 22 *Vanderbilt Journal of Transitional Law* 901.

¹⁰⁵ Bogsch, A *Brief History of the First 25 Years of the World Intellectual Property Organization* Geneva: World Intellectual Property Organization, (1992) 7.

¹⁰⁶ *Ibid* at 8.

2.5 THE WORLD TRADE ORGANISATION (WTO)

Upon the failure of the ITO, countries fell back on the GATT which became the centre-piece of the multilateral trading system. Consequently, this led to the number of GATT contracting parties multiplying. The WTO came into force on 1 January 1995 as a result of the eight rounds of multilateral trade negotiations that were hosted by the GATT. The Uruguay round which marked the final GATT round marked the birth of the WTO. The formation of the WTO coincided with the end of the Cold War.¹⁰⁷

The WTO is founded on very important principles that govern the multilateral trading system such as that of non-discrimination, open and predictable trade by reducing trade barriers, transparency and providing special treatment for less-developed Members. Due to stunted economic growth, most developing countries cannot fully enjoy the benefits of trade liberalization. There is need for the WTO to make efforts aimed at ensuring that less-developed countries equally participate in the multilateral trading system as developed countries. Also, the principle of transparency as provided for under Article X of the GATT requires Member States to make publicly available all relevant trade regulations before application and to notify the WTO and other Members of its actions.¹⁰⁸ The principle of non-discrimination has two facets; Most Favoured Nation (MFN) principle and the principle of National Treatment. The MFN principle subject to exceptions prohibits Member States from discriminating between their trading partners whereas the National Treatment principle dictates that locally-produced goods and imported goods should be treated equally.¹⁰⁹

¹⁰⁷ VanGrasstek, C *The History and Future of the World Trade Organization* Geneva: Atar Roto Presse SA, (2013) 10-15.

¹⁰⁸ Matsushita, M *Basic Principles of the WTO and the Role of Competition Policy* (2004) 3(2) *Washington University Global Studies Law Review* 366-368.

¹⁰⁹ Ya Qin, J *Defining Non Discrimination under the Law of the World Trade Organization* (2005) 23 *Boston University International Law Journal* 216-222.

2.5.1 Organizational Structure of the WTO

The Ministerial Conference is the highest decision making body of the WTO.¹¹⁰ It is usually composed of Ministers of Trade of the Members of the WTO. Below the Ministerial Conference lies the General Council. The General Council is considered as the engine of the WTO as it responsible for the day to day running of the WTO. It also sometimes assumes the powers of the Ministerial Council when latter is not in operation.¹¹¹ The General Council also acts as the Trade Policy Review Body and the Dispute Settlement Body (DSB).¹¹² At the next level is the Council for Trade in Goods, the Council for Trade in Services and the Council for Trade-Related Aspects of Intellectual Property Rights (TRIPS). The Council for TRIPS is an important body for purposes of this research as it is charged with the monitoring of WTO Members' compliance with their obligations under TRIPS Agreement.¹¹³ It therefore serves as a forum for consultation between Member States regarding the interpretation of TRIPS provisions. Consequently the Council for TRIPS may in advance resolve impending disputes between States without the need to seek recourse from the DSB.¹¹⁴ At the bottom of the organizational structure lies specialized committees such as the Committee on Balance-of-Payments, the Committee on Trade and Development, Restrictions and the Committee on Budget, Finance and Administration¹¹⁵ followed by the Director-General and the Secretariat which operate on a purely administrative basis.

2.6 THE TRIPS AGREEMENT

Prior to the Uruguay Round of negotiations, there was little protection of intellectual property rights in the international realm. The GATT considered intellectual property matters to be internal matters that resonated between States in their private dealings.

¹¹⁰ WTO, Understanding the WTO-Organization Chart, available at https://www.wto.org/tif_e/org2_e, accessed on 21 December 2016.

¹¹¹ *Ibid.*

¹¹² Article IV:(2)-(4) of the WTO Agreement.

¹¹³ Article IV:(5) of the WTO Agreement.

¹¹⁴ Malbon, J & Lawson, C *Interpreting and Implementing the TRIPS Agreement: Is it fair?* Edward Elgar Publishing, (2008) 53.

¹¹⁵ Article IV:(7) of the WTO Agreement.

The primary thrust of GATT rules of relevance was to ensure that intellectual property laws do not discriminate against or between imported goods.¹¹⁶ For this reason, the TRIPS Agreement has been a major step in international trade as far as the protection of IPRs is concerned. It sets the minimum standards for the protection of IPRs relating to patents, copyright and trade secrets particularly those related to innovation and technology transfer, and public health issues.¹¹⁷ As noted earlier, these standards mostly emanate from obligations emanating from the Berne, Paris, Rome and Washington Conventions.

The genesis of the TRIPS Agreement can be traced as far as the case of Punta del Este mandate in September 1986.¹¹⁸ This Ministerial Meeting formed the genesis of the Uruguay Round of trade talks. Its main aim was to clarify the GATT provisions and to develop a multilateral framework of rules and principles dealing with international trade in counterfeit goods. The TRIPS was therefore not the main focus of attention in Punta del Este but the US was the driver behind intellectual property being included as a negotiating issue.¹¹⁹ This is so because at the end of the Tokyo Round of negotiations, the US became concerned at the level at which there was inadequate and ineffective protection of intellectual property abroad thus discouraging innovativeness and damaging the US industry at large.¹²⁰ These sentiments were also shared by other industrialized countries who were of the opinion that increased intellectual property rights protection would lead to greater economic gains as it would drastically reduce piracy.¹²¹

¹¹⁶ Otten, A "The TRIPS Negotiations: An Overview" available at https://www.wto.org/english/res_e/booksp_e/trips_agree_e/chapter_3_e.pdf, accessed on 1 July 2016 at 55. See also Article III:4 of the GATT.

¹¹⁷ Intellectual Property in the World Trade Organization: Turning it Into Developing Countries' Real Property: United Nations Conference on Trade and Development (or UNCTAD), (2010) at p3.

¹¹⁸ See Ministerial Declaration of the GATT contracting parties launching the Uruguay Round in Punta del Este in 1986.

¹¹⁹ Drahos, P "Expanding Intellectual Property's Empire: the Role of FTAs" available at <http://www.ictsd.org/downloads/2008/08/drahos-fta-2003-en.pdf>, accessed on 17 August 2016.

¹²⁰ Otten, A "The TRIPS Negotiations: An Overview" available at https://www.wto.org/english/res_e/booksp_e/trips_agree_e/chapter_3_e.pdf, accessed on 2 July 2016 at 58.

¹²¹ Tully, LD "Prospects for Progress: The TRIPS Agreement and Developing Countries after the DOHA Conference" (2003) 26(1) *B.C. Int'l & Comp.L.Rev* 137.

Then again, developing countries were of the view that IPR protection campaign by the US government was solely for the benefit of its industries and the international IPR regime was intended to promote the interests of Western businesses and not those of developing countries.¹²² Furthermore, developing countries were of the view that IPRs would restrict free flow of information which was responsible for facilitating development in the pharmaceutical sector. These developing countries were also enjoying unprecedented freedom to exploit intellectual property for their own economic development.¹²³ Increased intellectual property protection would therefore hamper the economic development of these countries as they freely use such information. As such, developing countries vehemently resisted the idea of including IPR protection as a topic of discussion under the multilateral trade negotiations.¹²⁴

There are several other issues that led to the issue of IPRs being tabled during the Uruguay round of negotiations. The formation of WIPO whose mandate was to coordinate intellectual property rights laws across the multilateral system led to developed countries becoming frustrated at the progress of intellectual property rights protection under the WIPO. One of the issues of concern was the fact that many developing countries had not joined the WIPO and therefore such countries did not have any obligations under international law to implement IPRs in their domestic laws.¹²⁵

Secondly, developed countries were dissatisfied with the level of protection that was afforded to intellectual property rights under the WIPO as the level of intellectual property rights protection under the WIPO was weaker than what most developed countries had established domestically.¹²⁶ The rules under WIPO also did not cover a wide range of intellectual property areas such as software which developed countries

¹²² Doubt, K *Sociology after Bosnia and Kosovo: Recovery Justice* USA: Rowman & Littlefield Publishers, (2000) 155-156.

¹²³ Harris, DP 'TRIPS' Rebound: An Historical Analysis of How the TRIPS Agreement Can Ricochet back against the United States (2004) 25(1) *Northwestern Journal of International Law & Business* 101.

¹²⁴ Bellmann, C & Melendez-Ortiz, R *Trading in Knowledge: Development Perspectives on TRIPS, Trade and Sustainability* United Kingdom: ICTSD-Earthscan, (2003) 24-25.

¹²⁵ Brewster, R 'The Surprising Benefits to Developing Countries of Linking International Trade and Intellectual Property' (2011) 12(1) *Chicago Journal of International Law* 8-10.

¹²⁶ *Ibid* at 10.

sought to protect.¹²⁷ The Uruguay round of negotiations therefore gave developed countries an opportunity to negotiate higher levels of intellectual property rights protection in the international realm. Hence, since developing countries did not join WIPO due to their lack of interest in implementing intellectual property rights in their domestic laws, it would have also naturally followed that developing countries would be reluctant in joining the WTO's intellectual property agreement (TRIPS Agreement).

It was only in December 1988 at a mid-term review meeting held in Montreal where some developing countries, especially those considered to be market based economies and export-oriented began to move their positions in TRIPS matters. At the time of its conclusion, the WTO TRIPS Agreement was the most far-reaching international treaty ever negotiated in the area of intellectual property rights.¹²⁸ The Agreement identifies and defines seven categories of intellectual property and sets out the international minimum standards of protection they ought to be accorded. It identifies the main elements of protection for each category, the rights to be conferred and permissible exceptions to those rights. These categories include; patents, copyright, industrial designs, trade secrets, integrated circuit designs, trademarks and geographical indications.¹²⁹ The TRIPS Agreement therefore not only ensures intellectual property rights are protected but also ensures that legal remedies are available for rights holders.

It further effectively linked intellectual property rights with international trade whilst at the same time balancing between the need to promote and protect innovations with the need to other promote socio-economic rights.¹³⁰ Article 7 of the Agreement stipulates that;

the protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination

¹²⁷ Helfer, LR *Regime Shifting: The TRIPS Agreement and New Dynamics of International Intellectual Property Lawmaking*(2004) 29(1) *Yale Journal of International Law* 20-23.

¹²⁸ Harris, DP *'TRIPS' Rebound: An Historical Analysis of How the TRIPS Agreement Can Ricochet back against the United States*(2004) 25(1) *Northwestern Journal of International Law & Business* 104.

¹²⁹ Fink, C *Intellectual Property and the WTO* (November 2004), available at http://siteresources.worldbank.org/INTRANETTRADE/Resources/.../IPR-WTO_Fink.doc, accessed on 2 August 2016.

¹³⁰ Tully, LD *Prospects for Progress: The TRIPS Agreement and Developing Countries after the DOHA Conference*(2003) 26(1) *B.C. Int'l & Comp.L.Rev* 134.

of technology ... and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.¹³¹

Unlike the shortfalls outlined in the Paris and Berne Convention, the TRIPS Agreement therefore addressed problems of inadequate international protection of intellectual property rights which often resulted in disparities in the levels of protection of intellectual property across the world. Furthermore, the TRIPS Agreement provided effective enforcement of the various intellectual property rights and acceding to submit such disputes to the WTO Dispute Settlement Understanding (DSU).¹³²

2.6.1 Post TRIPS

The TRIPS Agreement being an agreement administered under the WTO marked the beginning of an evolution in as far as globalizing of intellectual property rights is concerned.¹³³ Article 1.1 of the TRIPS Agreement places a *duty on WTO Members to modify their national legislation so as to conform to the minimum standards of intellectual property rights protection as set out by the TRIPS Agreement*. Consequently, ratification of TRIPS is a compulsory pre-requisite of WTO membership and it is for this reason that the TRIPS is considered the most important WTO Agreement that seeks to foster protection of IPRs. This therefore has a harmonizing effect on IPRs in the international realm by setting out the detailed minimum standards IPRs.

The post-TRIPS era has been a period in which states have engaged in the task of national implementation of their obligations under the TRIPS Agreement. Furthermore, the monitoring by the Council for TRIPS through the enforcement of intellectual property obligations has fostered the protection of these rights particularly patent rights. More so,

¹³¹ Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), 1869 U.N.T.S. 299.

¹³² Ndlovu, L *Access to Medicines under the World Trade Organization TRIPS Agreement: A Comparative Study of Select SADC Countries* (unpublished LLD thesis, University of South Africa, 2014) at 51.

¹³³ Drahos, P & Braithwaite, J *The Corner House Who Owns the Knowledge Economy? Political Organizing Behind TRIPS* available at <http://www.thecornerhouse.org.uk/sites/thecornerhouse.org.uk/files/32trips.pdf>, accessed on 25 July 2016.

the TRIPS Agreement brought diverse impacts on developing countries based on the extent to which these countries domestically championed for IPRs protection prior to becoming WTO Members. To most developing countries, the establishment of the TRIPS Agreement entailed a great deal of reform to their domestic legislation in as far as intellectual property was concerned. However, developing countries were granted up to 5 years of transitional period to implement TRIPS obligations while Least Developed Countries (LDCs) were granted a 10 year transitional period which could be extended upon request.¹³⁴

As earlier discussed in this chapter, developing countries were reluctant to sign the TRIPS Agreement due to fear of the economic implications as the Agreement would forestall access to new technologies leading to higher prices especially in pharmaceuticals. In order to address these concerns, the TRIPS gives Member States flexibilities in implanting their domestic intellectual property regimes. These flexibilities allow states to disregard TRIPS obligations for national concerns such as health issues.

2.7 DEVELOPMENT OF INTELLECTUAL PROPERTY IN FREE TRADE AGREEMENTS (FTAs)¹³⁵

While many believed that the introduction of the TRIPS Agreement sufficiently placated intellectual property rights, the Agreement could be said to have become a stepladder in achieving stronger IPRs. Over the years, the world has witnessed an increase in the formation of FTAs which address a variety of matters but at the same time contain intellectual property provisions which are agreed on between Member States in exchange for trade preferences and other advantages. These FTAs which at times involve agriculture seek to implement intellectual property standards set out in the TRIPS Agreement. These agreements are known as TRIPS- plus FTAs.

¹³⁴ Fink, C. Intellectual Property and the WTO (November 2004), available at http://siteresources.worldbank.org/INTRANETTRADE/Resources/.../IPR-WTO_Fink.doc, accessed on 2 August 2016.

¹³⁵ These are agreements between states whose aim is to liberalize the trade of goods and services and access to investment between member states.

Member States are then required by these agreements to implement the bare minimum standards of the TRIPS which signify a growing trend in the inclusion of intellectual property matters in FTAs.¹³⁶ This often results in domestic laws that exceed the minimum standards outlined by the TRIPS Agreement.¹³⁷ Consequently, while developing countries are still struggling to conform to the standards set out by the TRIPS, developed countries continue to strengthen intellectual property rights through FTAs. This is a challenge to most developing countries as higher standards of intellectual property protection may restrict their access to cheaper medicines.

There has been a significant broadening of patentability in FTAs. These agreements introduce provisions that allow patenting of new forms and new uses of known substances, which create the threat of 'ever-greening' of pharmaceutical patents.¹³⁸ Ever greening in the pharmaceutical industry is described as instances where a pharmaceutical company patents a new invention which is merely a slight modification of an old drug.¹³⁹ However, even though the pharmaceutical companies aver that the generic versions of the old version can still be produced, the creation of the new version counteracts and disrepute the effectiveness of the old version thereby compelling doctors to prescribe the improved version.¹⁴⁰

Extension of patent duration is also a TRIPS plus provision that prolongs the patent monopoly and further restrains the entrance of generic competitors to the markets. These FTAs are usually drafted in ways that ensure swift integration of developing countries into multilateral IP regimes. Thus, developing countries are being obliged to

¹³⁶ Drahos, P. *Expanding Intellectual Property's Empire: The Role of FTAs* (2003), available at www.ictsd.org/drahos-fta-2003-en, accessed on 19 December 2016.

¹³⁷ Lindstrom, B. *Scaling Back Trips-Plus: An Analysis of Intellectual Property Provisions in Trade Agreements and Implications for Asia and the Pacific* available at <http://nyujilp.org/wp-content/uploads/2012/04/42.3-Lindstrom.pdf>, accessed on 5 August 2016.

¹³⁸ Trans-Pacific Partnership: Threats to Affordable Medicines, available at <https://www.citizen.org/documents/TPP-IP-Factsheet-December-2015.pdf>, accessed on 21 December 2016.

¹³⁹ Collier, R. *Drug Patents: The Ever-greening Problem* 2013 June 11 185(9) *Canadian Medical Association Journal* 385.

¹⁴⁰ *Ibid* at 385- 386.

conform to multilateral standards in Conventions to which they are not a party to and/or to ratify multilateral treaties.¹⁴¹

However, due to the increased preference of free trade agreements over multilateral agreements, developing countries are not hesitant to trade off intellectual property rights in order to gain market access in these free trade agreements. This is so because developing countries perceive free trade agreements to be more beneficial compared to the pyrrhic victories of multilateralism.¹⁴² TRIPS- plus provisions therefore have the potential of limiting the flexibilities available to mostly developing countries. Under normal circumstances free trade agreements should not compromise on the core TRIPS flexibilities. This is so because such derogation may be construed to be incompatible with the object and purpose of the TRIPS Agreement. The Preamble encourages the need for Member States to

to take into account the need to promote effective and adequate protection of intellectual property rights, while recognizing the underlying public policy objectives of national systems for the protection of intellectual property, including developmental and technological objectives.

Conclusively, there is growing evidence that TRIPS-plus provisions may adversely limit the use of the flexibilities which impacts medicine prices and consequently, access to medicine.

2.8 CONCLUSION

The negotiation and development of intellectual property rights has always existed in the international realm but existed independent to international trade negotiations. The development of intellectual property rights in international trade has become

¹⁴¹ Drahos, P. *Expanding Intellectual Property's Empire: the Role of FTAs* available at <http://www.ictsd.org/downloads/2008/08/drahos-fta-2003-en.pdf>, accessed on 17 August 2016.

¹⁴² Mercurio, B. *TRIPS-Plus Provisions in FTAs: Recent Trends* (November 2006), *Research Gate* available at https://www.researchgate.net/publication/228154939_TRIPS-Plus_Provisions_in_FTAs_Recent_Trends, accessed on 5 August 2016.

increasingly a multidimensional process as it entails harmonizing a diversity of international organizations, free trade agreements, national laws and most importantly international agreements such as the TRIPS Agreement. The TRIPS agreement is the major highlight as far as the protection of intellectual property rights is concerned. Issues of intellectual property rights went from being issues of national consideration to having a status of a core obligation in the international trading system. The integration between intellectual property rights and international trade has called for a solid and harmonized intellectual property rights framework in order to ensure adequate protection of these rights and effective remedies internationally.

Thus, chapter three will address how these intellectual property rights are protected in Botswana. The chapter will begin off with a discussion on the existence of the right to health care in Botswana's Bill of Rights. Furthermore, the chapter will include an analysis on how Botswana's IP legislations seek to protect IP rights. The chapter will conclude with a discussion on the various Non- Governmental Organizations that seek to foster IP rights protection in Botswana.

CHAPTER 3:

THE HUMAN RIGHTS AND INTELLECTUAL PROPERTY FRAMEWORK OF BOTSWANA

3.1 INTRODUCTION

The crux to protecting health rights such as access to medicine is the incorporation of the right to health care in the Bill of Rights or national legislation of a given country. Where countries have such national legal frameworks where the Constitution is the supreme law of the land like Botswana, then any subsidiary laws that seek to violate such constitutional rights would be unconstitutional and unenforceable. This creates an obligation on the state to ensure that the right to health care is upheld and protected at all times. The state is also expected to take reasonable steps in developing an administrative and legal framework that is conducive for the actualization of the right.¹⁴³

In general, the realization of socio-economic rights has been cumbersome particularly their inclusion as justiciable rights in the Constitution. These groups of rights are subject to state resources due to the fact that they are usually classified as rights granting %access+ to certain social benefits, rather than as direct rights to the social benefits in question.¹⁴⁴ Socio- economic rights can be classified into two categories; qualified and unqualified rights. Qualified socio-economic rights are those rights that are inherently limited due to the availability of state resources whereas unqualified rights do not make reference to available state resources reasonable measures and progressive realization. The right to health care is classified as an unqualified socio-economic right.¹⁴⁵ However, due to limited state resources, unqualified rights may also be

¹⁴³ Ndlovu, L. The WTO TRIPS Agreement and Access to Medicines in South Africa Twenty Years into Democracyqa paper presented at the conference on Twenty years of Constitutionalism, Democracy and the Bill of Rights in South Africa held at the University of Fort Hare, East London, South Africa, October 2013.

¹⁴⁴ Heyns, C & Brand, D Introduction to Socio-Economic Rights in the South African Constitutionq(1998) 2 *Law, Development & Democracy* 185-187.

¹⁴⁵ Coomans, F Reviewing Implementation of Social and Economic Rights: An Assessment of the %Reasonableness+ Test as Developed by the South African Constitutional Courtq(2005) 65 *Heidelberg Journal of International Law* 170.

limited.¹⁴⁶ This position was reinforced by the South African courts in the case of *Soobramoney*¹⁴⁷ where it was stated that;

Given this lack of resources and the significant demands on them ..., an unqualified obligation to meet these needs would not presently be capable of being fulfilled.¹⁴⁸

This chapter therefore seeks to determine whether the right to access to health care is protected in Botswana. Further, the chapter also seeks to establish the extent to which intellectual property rights are protected in Botswana. Thus, the chapter will firstly review Botswana's position on the right to health care before addressing the protection of intellectual property rights.

3.2 THE RIGHT TO HEALTH CARE AND ACCESS TO MEDICINE IN BOTSWANA

Unlike South Africa which will be discussed later, the Constitution of Botswana has no express provision to the right to health care. However, Section 4 of the Constitution¹⁴⁹ provides for the right to life. It stipulates that;

No person shall be deprived of their life intentionally unless done in execution of a sentence of a Court in respect of an offence under the law in force in Botswana of which they have been convicted.

The Constitution however allows for other rights to be disregarded for the protection of public health. Section 8(1)(a)(i) of the Constitution permits one's property to be compulsorily taken possession of where the acquisition is necessary for the protection of public health. Similarly, Section 9 justifies searching of another's property or entering on such premises without the owner's consent where it is reasonably required in the

¹⁴⁶ *Ibid* at 192.

¹⁴⁷ *Soobramoney v Minister of Health, KwaZulu-Natal* 1997 (12) BCLR 1696.

¹⁴⁸ *Ibid* at par 11.

¹⁴⁹ CAP 00:01 of the Laws of Botswana.

interest of public health.¹⁵⁰ Botswana therefore has a very conservative Constitution in as far as promoting the right to health care is concerned. The Constitution of Botswana does make specific reference to access to medicines. It does not expressly provide for the right to health care but however contains provisions that limit other rights such as the right to protection from deprivation of property and the right to privacy of one's property in the interest of public health.

3.3 PUBLIC HEALTH: INTERNATIONAL REGIONAL AND NATIONAL LEGAL FRAMEWORKS

It is worthwhile considering whether the protection of public health is a facet of the greater right to health care under international instruments protecting the right to health. It is worth noting that International human rights instruments have not been consistent in the formulation of this right to health. For example, the Constitution of the World Health Organization (WHO) defines health as a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity.¹⁵¹

On the other hand, Article 25 of the United Nations' Universal Declaration of Human Rights (UDHR)¹⁵² states that Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services. Article 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR)¹⁵³ considers the right to adequate standards of living as a component of the right to health. This is in line with the definition of health under the WHO which includes social well-being as an aspect of health. It states as follows;

Everyone has the right to a standard of living adequate for the health and wellbeing of himself and of his family, including food, clothing, housing and

¹⁵⁰ Mulumba, M, Kabanda, D & Nassuna, V Constitutional Provisions for the Right to Health in East and Southern Africa EQUINET Discussion Paper 81, (April 2010) 6.

¹⁵¹ See Preamble to the WHO Constitution.

¹⁵² UN General Assembly, *Universal Declaration of Human Rights*, Adopted and proclaimed by General Assembly resolution 217 A (III) of 10 December 1948.

¹⁵³ UN General Assembly, *International Covenant on Economic, Social and Cultural Rights*, Adopted and proclaimed by the General Assembly resolution 2200A (XXI) of 16 December 1966.

medical care and necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control (emphasis added).q

This entails that under Article 12 of the ICESCR, the right to health is not confined to health care alone but extends to conditions pertinent to good health such as housing, a healthy environment and access to safe and potable water. This is important bearing in mind that promoting the right to health through ensuring access to medicine cannot be achieved in isolation to all other underlying conditions.¹⁵⁴ The Constitution of Botswana can therefore be said to be more focused on the social well-being aspect of the right to health as compared to the others.

Notably, the right to health as outlined under Article 25 of the UDHR entails that people should have access to medical care. Access to essential medicine is a pre-requisite to proper medical care in any given country.

3.3.1 South Africa

In comparison to the South African position, the starting point would be Section 11 of the Constitution¹⁵⁵ which guarantees everyone the right to life. Not only is the right to life protected under the Constitution, the right to health care is also provided for under Sections 27, 28 and 35 of the Constitution. Section 27(1)(a) states that;

Everyone has the right to have access to health care services, including reproductive health care... and no one can be denied emergency medical treatment.d¹⁵⁶

¹⁵⁴ Chirwa, DM 'The Right to Health in International Law: Its Implications for the Obligations of State and Non-State Actors in Ensuring Access to Essential Medicine' (2003) 19 *SAJHR* 545-547.

¹⁵⁵ The Constitution of the Republic of South Africa, 1997.

¹⁵⁶ Section 27(3) of the Constitution of the Republic of South Africa, 1997.

Section 28(1)(c) grants every child the right to basic health care services, while section 35(2)(e) provides for ~~a~~adequate medical treatment~~q~~for detainees and prisoners at the State's expense.

Not only does the South African Constitution guarantee the right to health care, the Medicines and Related Substances Act¹⁵⁷ under Section 22F also promotes the substitution of patented drugs for generic medicines as a way of promoting access to cheaper essential medicines. It creates a duty on the dispensing pharmacist ~~to~~ *inform the person visiting the pharmacy of the benefits of the substitution of a branded medicine for an “interchangeable multi-source medicine” and shall in the case of a substitution...dispense an interchangeable multi-source medicine instead of the medicine prescribed by a medical practitioner...unless expressly forbidden to do so.*¹⁵⁸

Section 22F describes generic medicines as *“interchangeable multi-source medicines”*. The term *“interchangeable multi-source medicines”* has been defined as ~~a~~medicines that contain the same active substances which are identical in strength or concentration, dosage form and route of administration and meet the same or comparable standards, which comply with the requirements for therapeutic equivalence as prescribed.¹⁵⁹

The above Section further prohibits such substitution where the ~~re~~tail price of the interchangeable multi-source medicine is higher than that of the prescribed branded medicine.¹⁶⁰ This is so because the purpose of the Section is to afford cheaper alternative drugs to patients where the branded medicine is costly. Having more expensive generic drugs forgoes the true purpose of their creation which is to help alleviate the strain of expensive drugs on the consumer. Other countries like Zimbabwe (as discussed below) and Botswana have similar pieces of legislation neither of the two pieces of legislation make reference to the use of generic drugs as in the South African Act.

¹⁵⁷ Act 101 of 1965

¹⁵⁸ Section 22F (1) (a)-(b)

¹⁵⁹ Section 1 of the Medicines and Related Substances Act

¹⁶⁰ Section 22F(4)(b)

3.3.2 Zimbabwe

In Zimbabwe, the right to health-care is provided for under Section 76 of the Constitution of Zimbabwe¹⁶¹. It states that;

Every citizen and permanent resident of Zimbabwe has the right to have access to basic health-care services—no person may be refused emergency medical treatment in any health-care institution—and the state must take reasonable legislative and other measures to achieve the realization of this right.

The absence of the right to health care under Botswana's Bill of Rights is very flawed. This is so because General Comment 14 of the ESCR (Economic, Social and Cultural Rights) Committee¹⁶² illuminates that health is a fundamental human right indispensable for the exercise of other human rights. Although these comments are not legally binding on states, they serve as authoritative expert advice on the interpretation of the rights enshrined in the ICESCR. This essentially entails that a state should first guarantee its citizens the right to health care as the bedrock right before other subsidiary rights could be achieved.¹⁶³

Human rights are an important empowering tool as they enable vulnerable individuals to assert themselves against powerful entities such as the government. The absence of the right to health care in the Constitution of Botswana strips off its citizens with the most important fighting tool in advocating for better health care services. Furthermore, the provision of the right to health care also serves as a yardstick that social delivery structures use in achieving the desired goal and measuring its outcome. That being the case, what criteria does the government of Botswana use in assessing whether adequate health care services are being rendered to its citizens.¹⁶⁴

¹⁶¹ Constitution of Zimbabwe Amendment (No.20) Act, 2013.

¹⁶² This committee is responsible for the implementing, monitoring and enforcing economic, social and cultural rights under the International Covenant on Economic, Social and Cultural Rights (ICESCR).

¹⁶³ Vawda, YA & Baker, BK *Achieving Social Justice in the Human Rights/Intellectual Property Debate: Realising the Goal of Access to Medicines*(2013) 13 *African Human Rights Law Journal* 61-62.

¹⁶⁴ Pieterse, M *Can Rights Cure?* Pretoria: Pretoria University Law Press (PULP), (2014) 1-2.

Others may argue that since the Constitution of Botswana does not expressly provide for the right to health care particularly access to medicine, then the right in question is not justiciable.¹⁶⁵ It has however been counter argued that absence of codification of the right in a country's national law does not bar its adjudication and enforcement by the domestic courts of law. Lack of constitutional protection therefore burdens the courts and other non-state actors with the onerous task of enforcing these indistinct rights.¹⁶⁶ The right to life as guaranteed by Section 4 of the Constitution has corollaries on the right to health care if interpreted extensively. Courts and other bodies may simply argue that the state therefore has a duty to take provide adequate health care services so as to prevent death as a means of protecting the greater right to life.

3.4 NON-GOVERNMENTAL ORGANIZATIONS' INTERVENTION IN PROMOTING PROPER HEALTH CARE

The protection of health care rights by legislation alone is insufficient. There is need for non-state actors to ensure such legislation is respected. Despite the absence of the right to health care in Botswana, it has quite a number of non-governmental organizations (NGOs) that aim at protecting and promoting health interests of the citizens particularly the vulnerable ones. These NGOs do exist to provide health and social services to the community as a way of promoting proper health care as provided for in international charters to which Botswana is a signatory of. NGOs may therefore be regarded as valuable partners in promoting better health care services. Discussed below are some of the NGOs that seek to promote better health care and human rights in general;

¹⁶⁵ Twinomugisha, BK *Implications of the Trips Agreement for the Protection of the Right of Access to Medicines in Uganda*(2008) 2(2) *MLJ* 259.

¹⁶⁶ Byrne, I *Making the right to health a reality: Legal strategies for effective implementation*, a paper presented at the Commonwealth Conference, London, September 2005.

3.4.1 Ditshwanelo

Ditshwanelo (established in 1993) also known as the Botswana Centre for Human Rights is the most prominent and only non-governmental organization (NGO) that is aimed at promoting and protecting all aspects of human rights in Botswana. There exist other NGOs dealing with human rights but such organizations are rights-focused for instance dealing with children's rights. The Organization is tasked with raising public awareness of the various human rights that are provided for in the Constitution of Botswana.¹⁶⁷ They also advocate for reforms in governmental policies, practices and laws that are a threat to human rights. In pursuit of protecting human rights, the organization provides paralegal services to aggrieved citizens who cannot afford legal representation. The Organization also works in partnership with other rights-focused organizations in Botswana to educate, mediate on issues of human rights especially to the marginalized and disempowered population.¹⁶⁸

Ditshwanelo could therefore be described as the voice of the nation when dealing with matters of human rights infringement. Its existence as a non-governmental organization makes it independent and not subject to manipulation by governmental bodies or sectors.

3.4.2 BONASO

The Botswana Network of AIDS Services Organization (BONASO) is yet another organization that seeks to facilitate the environment for HIV/AIDS NGOs. It therefore serves as the umbrella body that coordinates all other NGOs that deal with HIV/AIDS issues. This in turn strengthens the capacity of these NGOs in Botswana as it serves as a mouth piece for all its members.¹⁶⁹

¹⁶⁷ Ditshwanelo available at <http://www.ditshwanelo.org.bw/>, accessed on 21 August 2016.

¹⁶⁸ *Ibid.*

¹⁶⁹ BONASO available at <http://www.bonaso.org.bw/>, accessed on 22 August 2016.

3.4.3 The Botswana Network on Ethics, Law and HIV/AIDS (BONELA)¹⁷⁰

This is a non-governmental organization that seeks to integrate a human rights approach to the fight against HIV/AIDS as way of promoting the greater right to health. The organization is vested with a human rights monitoring (HRM) unit whose responsibility is to investigate human rights violations and to develop strategies in addressing HIV/AIDS human rights violation. The HRM also probes into all unprogressive and oppressive laws and policies.¹⁷¹ Although the organization seeks to monitor all types of human rights violation such as the right to education and personal liberty (gay rights), its main focus is on the right to health particularly in relation to HIV/AIDS.¹⁷²

3.4.4 BONEPWA (BOTSWANA NETWORK OF PEOPLE LIVING WITH HIV/AIDS)

BONEPWA is an organization of people living with HIV/AIDS in Botswana. Its main objective is to facilitate the formation of support groups for people living with HIV/AIDS in Botswana. This includes the formation of projects that seek to ensure that people living with HIV/AIDS have access to proper health care and other needs peculiar to their condition.¹⁷³

3.4.5 The Holy Cross Hospice

This is a non-governmental organization that seeks to provide additional palliative care to persons suffering from life threatening illnesses especially those coming from poor communities of the country. Their palliative services are meant to improve the quality of life and well-being of the patients by providing better medical care as they are mostly unable to afford proper medical care on their own. This has been achieved by their

¹⁷⁰ The organization was launched in September 1995 and registered under the Societies Act in early 2002.

¹⁷¹ http://www.bonela.org/index.php?option=com_content&view=article&id=99&Itemid=226, accessed on 22 August 2016.

¹⁷² *Ibid.*

¹⁷³ BONEPWA available at [http://www.bonepwa.org.bw/content/id/2/About-BONEPWA+/,](http://www.bonepwa.org.bw/content/id/2/About-BONEPWA+/) accessed on 25 August 2016.

hospice facilities which are sustained by raising funds in various ways so as to remunerate personnel that are responsible for carrying out the objectives. Furthermore, in order to ensure that the hospice program of care is living up to its objectives, the organization also provides essential medicines to the patients.¹⁷⁴ This is an important milestone in ensuring people living with life threatening diseases have access to proper medical care. The organization works very closely with the Ministry of Health of Botswana and health training institutions such as the medical and nursing schools for additional technical assistance.¹⁷⁵

3.5 PROTECTION OF INTELLECTUAL PROPERTY RIGHTS IN BOTSWANA

Botswana is a signatory to a number of international agreements that deal with intellectual property rights such as Paris Convention of 1998.¹⁷⁶ Botswana has only two pieces of legislation that deal with intellectual property rights, that is; the Copyright and Neighbouring Rights Act¹⁷⁷ and the Industrial Property Act.¹⁷⁸ According to the Industrial Property Act, the provisions of any international agreement dealing with intellectual property rights to which Botswana is a party of shall be applicable under the Act in the absence of any reservations made in relation to those treaties.¹⁷⁹ Botswana is also a Member of the ARIPO (African Regional Intellectual Property Organization) which is an inter-governmental organization that deals with intellectual property matters in Africa. The ARIPO which is also a signatory to the Patent Cooperation Treaty was established in 1976 by the Lusaka Agreement as result of a diplomatic conference held in Zambia championed by the World Intellectual Property Organisation (WIPO) and the UN Economic Commission for Africa (UNECA). The Harare Protocol which was subsequently adopted by the Administrative Council of the ARIPO in December 1982 entrusted ARIPO with the task of granting and registering of patents on behalf of

¹⁷⁴ See <http://www.holycrosshospice.org/>, accessed on 1 September 2016.

¹⁷⁵ *Ibid.*

¹⁷⁶ Adams & Adams, *Practical Guide to Intellectual Property in Africa* Cape Town: ABC Press, (2012) at 64.

¹⁷⁷ CAP 68:02 of the Laws of Botswana.

¹⁷⁸ CAP 68:03 of the Laws of Botswana.

¹⁷⁹ Section 136 of the Industrial Property Act.

Member States.¹⁸⁰ Botswana only became a member of the ARIPO on 6 February 1985. The above treaties assist Botswana in constructing a framework for the protecting of intellectual property rights in the country. This is so because the treaties acceded to require Botswana to implement the minimum set out intellectual property standards in their national legislation. This is important particularly in the era where there is an increase in innovativeness in the pharmaceutical industry and hence the need to protect such inventions.¹⁸¹

The Copyright and Neighbouring Rights Act deals with the protection of the rights of artists, authors and creators, as well as the protection of their literary and artistic work such as musical works, drawings, poems and films.¹⁸² The most relevant piece of legislation for the purposes of this research is the Industrial Property Act. The classifications of intellectual property rights protected under this Act are trademarks,¹⁸³ industrial designs,¹⁸⁴ utility models¹⁸⁵ and patents¹⁸⁶.

The Industrial Property Act provides for the registration of trademarks and patents. Botswana has domesticated in its national laws the Harare Protocol which regulates patent filings in ARIPO. This is an intellectual property protective mode as it gives valid patent protection to applicants seeking to obtain a patent via an ARIPO application. Patent protection in Botswana is therefore available by way of a national filing (in Botswana) or via an ARIPO application designating Botswana.¹⁸⁷

Under the national filing system, a patent application is filed with the Registrar of Marks, Patents and Designs accompanied with a petition that a patent be granted.¹⁸⁸ The Registrar then examines the application to determine if such application complies with

¹⁸⁰ Section 1 of the Harare Protocol on Patents and Industrial Designs within the framework of the African Regional Intellectual Property Organization (ARIPO)(1982)hereinafter referred as Harare Protocol

¹⁸¹ International Bureau of WIPO *The Advantages Of Adherence To The WIPO Copyright Treaty (WCT) And The WIPO Performances And Phonograms Treaty (WPPT)*: International Bureau of WIPO.

¹⁸² Section 3 of the Copyright and Neighbouring Rights Act.

¹⁸³ Part VIII of the Industrial Property Act.

¹⁸⁴ Part V *ibid.*

¹⁸⁵ Part IV *ibid.*

¹⁸⁶ Part II *ibid.*

¹⁸⁷ Section 29 *ibid.*

¹⁸⁸ Section 12(1)-(2) *ibid.*

the requirements of the Act.¹⁸⁹ According to Section 8 of the Act, ~~an~~ invention is patentable if it is new, involves an inventive step and is capable of industrial application.¹⁹⁰ Where the Registrar is satisfied that these requirements have been fulfilled, a patent is to be granted to the applicant and a patent certificate is issued.¹⁹⁰

Under the Harare protocol, the applicant designates all other ARIPO member states to which the application applies.¹⁹¹ The applicant therefore need not make subsequent duplicate applications in all other countries. Only one application is sufficient by designating the Member states where protection is required.¹⁹² Upon receipt of the patent application, the ARIPO office examines whether the object of the application is patentable.¹⁹³ According to Section 10(a) of the Harare Protocol, ~~a~~ patent shall be granted if its new, involves an inventive step and capable of industrial application.¹⁹⁴ Once all the requirements for patentability have been satisfied copies of the application are sent to all designated member states. The designated states are to respond to the notification within six months and inform the ARIPO office if the patent if granted will have effect in its territory.¹⁹⁴ Upon the expiration of the six months period, the Office shall grant the patent which shall have effect even in designated States which did not respond to the notification.¹⁹⁵ Furthermore, Section 29 of the Industrial Property Act makes specific reference to patents granted under the Harare protocol. It states that;

~~a~~ patent granted by ARIPO by virtue of the Harare Protocol under which Botswana was designated, shall have the same effect and enjoy the same protection in Botswana as a patent granted under this Act unless the Registrar communicates to ARIPO to state that patent shall have no effect in Botswana.¹⁹⁵

¹⁸⁹ Section 22 *ibid.*

¹⁹⁰ Section 23 *ibid.*

¹⁹¹ Section 1*bis* of the Harare Protocol on Patents and Industrial Designs

¹⁹² Section 3 (1)(iii) *ibid.*

¹⁹³ Section 3 (2)-(3) *ibid.*

¹⁹⁴ <http://www.aripo.org/about-aripo/legal-framework>, accessed on 6 September 2016. See also Section 3(6)(b) Harare Protocol.

¹⁹⁵ Section 3(7) of the Harare Protocol.

It is also worth noting that Botswana is also a member of the Patent Cooperation Treaty (PCT).¹⁹⁶ ARIPO Member states automatically become members of the PCT. The PCT patent application process comprises of two phases which are the international and the regional phase. Under the international phase, the applicant files an application with the Receiving Office (RO). Once the PCT application has been filed, all contracting states of the PCT are automatically designated. According to Article 11(3) of the PCT treaty, any international application accorded an international filing date shall have the effect of a regular national application in each designated State as of the international filing date, which date shall be considered to be the actual filing date in each designated State.^q

Since Botswana is a member of the PCT and ARIPO which is also party to the PCT, once a PCT application is filed, Botswana may be designated when the application reaches the ARIPO regional phase of the PCT application and such patent if granted is known as a regional patent.¹⁹⁷ Members may however file for reservation to be excluded from the automatic designation. It is worth highlighting that the PCT does not grant patents. The PCT procedure merely simplifies the procedure of filing patent applications in multiple PCT Member states. The PCT application may therefore be granted or rejected based on the applicable national law of each designated state.

Before the Industrial Property Act of 2010 came into effect, Botswana had not domesticated any Patent Cooperation Treaty provisions into its national intellectual property laws. Therefore, although it was possible for a pharmaceutical company to file a PCT application designating Botswana, it was not clear whether enforceable rights could be obtained by such patent being granted on PCT national phase filing in Botswana. The Industrial Property Act under Part III now provides for PCT applications.¹⁹⁸ Section 37 of the Act seeks to establish the effects of designating Botswana in an international application. It stipulates that;

¹⁹⁶ Patent Cooperation Treaty, done at Washington on June 19, 1970, amended on September 28, 1979, modified on February 3, 1984 and on October 3, 2001.

¹⁹⁷ A regional patent is granted by an intergovernmental body mandated to grant patents in more than one state. This is in contrast to a national patent which is granted by the national authority of a given country. See Article 2 (iii)- (iv) of the Patent Cooperation Treaty.

¹⁹⁸ <http://www.adamsadams.com/africa/country-guide/countries/botswana/>, accessed on 2 September 2016.

An international application designating Botswana shall be treated as an application for a patent filed under this Act and shall have as its filing date the international filing date accorded under the Patent Cooperation Treaty.^q

The Act under Section 41 further provides that ~~when~~ processing an international application the Patent Cooperation Treaty, its Regulations and the administrative instructions issued under it shall, in the event of any conflict, prevail over this Act and its regulations.^q

3.6 THE COMPANIES AND INTELLECTUAL PROPERTY AUTHORITY

The Companies and Intellectual Property Authority (CIPA) is the formal tool for intellectual property rights management in Botswana. The CIPA Botswana is a parastatal under the Ministry of Trade and Industry established by the Companies and Intellectual Property Authority Act.¹⁹⁹ This body was formerly a governmental department and was known as the Registrar of Companies and Intellectual Property (ROCIP). The body is tasked with the registration of trade marks, industrial designs and the granting of patent certificates.²⁰⁰ Most importantly, the body is responsible for the protection of intellectual property rights by administering the Industrial Property Act²⁰¹ and the Copyright and Neighboring Rights Act.²⁰² CIPA may therefore be regarded as the custodian of intellectual property rights in Botswana as one of its responsibilities save for the registration of patents is combating copyright infringement and piracy in Botswana.

Furthermore, the transition of this body from a governmental body to a parastatal was an important step in ensuring its independence thus improving its efficiency. Such privatization has reduced the possible threat of government manipulation in carrying out its task of protecting intellectual property rights. Protection of intellectual property rights particularly patent rights encourages innovation in the pharmaceutical industry. This

¹⁹⁹ CAP 42:13 of the Laws of Botswana.

²⁰⁰ <http://www.cipa.co.bw/about-us>, accessed on 23 August 2016.

²⁰¹ CAP 68:03 of the Laws of Botswana.

²⁰² CAP 68:02 of the Laws of Botswana.

eventually leads to an increase in the discovery and development of medicines to cure various diseases. The patent system has therefore worked well for pharmaceutical companies as they are enthused to discover new medicines since they are guaranteed protection of their inventions.²⁰³

3.7 CONCLUSION

The Constitution of Botswana has no express provision on the right to health care. However, other rights enshrined in its Bill of Rights may be disregarded for the protection of public health. The absence of the right to health care under Botswana's Bill of Rights is very flawed as good health forms the bedrock of the enjoyment of all other subsidiary rights. This has created an onerous task on NGOs in Botswana in enforcing and protecting this indistinct right. Botswana could therefore learn from South Africa and Zimbabwe by amending its Constitution to include the right to health care particularly access to medicine. More so, Botswana could amend its Drugs and Related Substances Act to include provisions similar to those under South Africa's Medicines and Related Substances Act encouraging the substitution of patented drugs for generic versions as a way of promoting access to cheaper medicine. Conclusively, there is inadequate protection of these rights in Botswana. The government needs to do more in protecting both the right to health care and intellectual property rights thus ultimately making them more justiciable.

²⁰³ Ndlovu, L *Access to Medicines under the World Trade Organization TRIPS Agreement: A Comparative Study of Select SADC Countries* (unpublished LLD thesis, University of South Africa, 2014) 12-14.

CHAPTER 4:

BOTSWANA'S ACTUAL USAGE OF TRIPS FLEXIBILITIES IN COMPARISON TO SOUTH AFRICA AND ZIMBABWE

4.1 INTRODUCTION

In the year 2000, it was reported that over 2 million people in sub-Saharan Africa died of AIDS.²⁰⁴ AIDS therefore is the leading threat to human security in the region and this is mostly attributed to the lack of or shortage of Antiretroviral drugs (ARVs) supply in these countries.²⁰⁵ Thus, improving access to medicines particularly ARVs in this region would drastically reduce the death toll. The Trade-Related Aspects of Intellectual Property Rights Agreement (TRIPS)²⁰⁶ contains a number of flexibilities aimed at promoting and improving access to medicines. Khor argues that the adoption of the Doha Declaration on the TRIPS Agreement and Public Health at the Doha Ministerial Conference in 2001, emphasized that developing countries should make full use of the flexibilities to take public health measures, including compulsory licensing and parallel importation, which can make medicines more accessible and affordable.²⁰⁷ More so the author argues that least developed countries should also make use of the extra flexibilities afforded to them under the same Declaration.²⁰⁸ However, despite the appeals of Doha, developing countries have been lackluster in taking advantage of this call.

Thus, this chapter seeks to discuss the extent to which the flexibilities contained in the TRIPS have been incorporated in Botswana's domestic intellectual property legislation and the extent of the actual usage of each of the flexibilities in promoting access to essential medicines. This chapter shall further explore the reasons for Botswana's

²⁰⁴ UNAIDS, *Report on the Global HIV/AIDS epidemic*, (June 2000) available at http://data.unaids.org/pub/Report/2000/2000_gr_en.pdf, accessed on 9 December 2016.

²⁰⁵ *Ibid.*

²⁰⁶ This is an international agreement administered by the World Trade Organization and is encapsulated under Annex 1C of the *Marrakesh Agreement*.

²⁰⁷ Khor, M *Implications of some WTO rules on the realization of the MDGs* Third World Network August 2005 www.twn.my/title2/par/mk004.doc, at 16.

²⁰⁸ *Ibid.*

failure to make full use of the TRIPS flexibilities to promote access to medicine in comparison to Zimbabwe and South Africa.

4.2 INCORPORATION OF TRIPS FLEXIBILITIES IN BOTSWANA'S IP LEGISLATION

4.2.1 Introduction

In light of the controversy surrounding access to medicines and patents the following exceptions will be explored; exceptions to patent rights, compulsory licensing, limitations on data protection, the Paragraph 6 system, parallel importing, exclusions from patentability and public non-commercial use of patents.

i. Exclusions from Patentability

The TRIPS Agreement under Article 27.1 provides for the basic test of patentability. It provides that patents shall be available for any inventions provided they are new, involve an inventive step and are capable of industrial application.²⁰⁹ More so, Article 27 thereon goes to provide for exceptions to patentability²⁰⁹ which is an important flexibility in promoting access to medicine as they facilitate the dissemination of technology in the pharmaceutical sector. The aforementioned Article stipulates that;

Members may exclude from patentability *inter alia* one which is necessary to protect human life and diagnostic, therapeutic and surgical methods for the treatment of humans²¹⁰

This is a mostly forgotten TRIPS flexibility as emphasis is placed on the flexibilities that are acceptable under the TRIPS Agreement and not the issue of the grant of the pharmaceutical patent itself.²¹⁰ The Industrial Property Act²¹¹ of Botswana has similar

²⁰⁹ Article 27.2 and 27.3 of the TRIPS Agreement.

²¹⁰ Masungu, F & Oh, C *The Use of Flexibilities in TRIPS by Developing Countries: Can they promote access to medicines?*: Commission on Intellectual Property Rights, Innovation and Public Health (CIPRH), (August 2005).

²¹¹ CAP 68:02 of the Laws of Botswana.

provisions dealing with exclusions from patentability. Particularly, Section 8 of the Act provides that;

an invention shall be patentable if it is new, involves an inventive step and is capable of industrial application.^q

The wording of Section 8 of the Industrial Property Act is similar to that of Article 27.1 of the TRIPS Agreement. Furthermore, Section 9 of the Act²¹² provides for matters that are excluded from patent protection even if they may be regarded as inventions. The relevant exclusion for purposes of this discussion is the exclusion of methods used for the treatment of the human body by therapy or surgery as well as all diagnostic methods except products used in any such methods.²¹³

ii. Compulsory Licensing

A compulsory license may be defined as a license issued by a government authority to a pharmaceutical company which is not the patent owner authorizing the use or manufacturing of a patent-protected drug without the consent of the right holder.²¹⁴ Patent rights enable a patentee to prevent third parties from exploiting his intervention. Under compulsory licensing, reasons such as that of public health enable a third party to exploit such a patent without prior authorization from the patentee.²¹⁵ Under the TRIPS Agreement, compulsory licenses are worded differently. The Agreement uses the wording '*use without authorization of the right holder*'²¹⁶ when referring to compulsory licensing.

More so, Article 31 of the TRIPS Agreement deals with the granting of a compulsory license to a third party. It provides that compulsory licensing may only be issued after the person seeking to acquire it had tried to negotiate with the right holder to obtain a

²¹² Industrial Property Act.

²¹³ Section 9(2)(a) *ibid*.

²¹⁴ Taubman, A & Wager, H & Watal, J A *Handbook on the WTO TRIPS Agreement* Cambridge: University Press, (2012) 109.

²¹⁵ DeRoo, P 'Public Non-Commercial Use' Compulsory Licensing for Pharmaceutical Drugs in Government Health Care Programs (2011) 32(2) *Michigan Journal of International Law* 382.

²¹⁶ Article 31 of the TRIPS Agreement.

voluntary license.²¹⁷ The right holder is entitled to adequate remuneration upon granting of the compulsory license.²¹⁸ Compulsory licensing may therefore be utilized by local pharmaceutical companies to manufacture generic versions of patented drugs where the patented drugs are costly. The granting of compulsory licenses in Botswana is provided for under Section 31 of the Industrial Property Act. It stipulates that;

A Minister may without the consent of the patentee authorize a Government agency, or other person to exploit the patented invention on the payment of adequate remuneration to the patentee where it is in the public interest to do so for purposes of nutrition and health.²¹⁹

Despite the fact that compulsory licensing may seem to be an effective way to ensure access to medicine by enabling generic production of drugs, there are limitations to its effectiveness in Botswana. It should be noted that the TRIPS Agreement under Article 31(f) provides that drugs manufactured under a compulsory license shall be predominantly for use in the domestic market of the country granting the license and not for export. Botswana has no domestic pharmaceutical manufacturing capacity and therefore cannot use this flexibility to avoid the costs associated with patent recognition of pharmaceuticals. The requirement of Article 31(f) is what led to the developing world pressuring other WTO Members to devise a solution to this barrier.²²⁰

As such, in 2001, the Doha Ministerial Conference as a way of solving this problem suggested a waiver of this export restriction to allow developing countries unable to manufacture the pharmaceuticals to manufacture generic drugs from a foreign pharmaceutical company.²²¹ This waiver was approved in 2003 by the decision of the WTO General Council and led to the establishment of the Paragraph 6 system.²²² Of interest, compulsory licensing on its own did little to increase access to medicines in

²¹⁷ Article 31(b) of the TRIPS Agreement.

²¹⁸ Article 31(h) of the TRIPS Agreement.

²¹⁹ Section 31(1)(a) of the Industrial Property Act.

²²⁰ Gumbel, M *Is Article 31Bis Enough? The Need to Promote Economics of Scale in the International Compulsory Licensing System*(2008) *Temple Int'l Comp. Law Journal* 162-163.

²²¹ Niesporek, A *Compulsory Licensing of Pharmaceutical Products & Access to Essential Medicines in Developing Countries* (unpublished thesis, Linköping University, 2005) 24.

²²² See https://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm, accessed on 10 October 2016.

countries with little or no pharmaceutical manufacturing capacity and the Paragraph 6 system therefore provided for derogations from obligations set out under Article 31 of the TRIPS Agreement.²²³ It waived under certain circumstances the requirements that;

- 1) compulsory licenses are only to be granted for the purposes of predominantly supplying the domestic market²²⁴ and
- 2) Members are to pay adequate remuneration to the right holder once is compulsory license is granted.²²⁵

The Paragraph 6 system enables a WTO Member to import or export drugs manufactured under compulsory licensing amongst other Members of a Regional Trade Agreement (RTA) on condition that at least half the membership of consists of LDCs.²²⁶ LDCs are automatically eligible to import under the Paragraph 6 system while the declaration also lists 23 developed countries that may not make use of this waiver to import generic drugs.²²⁷ Consequently, Member countries such as Botswana that do not have their own pharmaceutical manufacturing capability can issue a compulsory license so that another country manufactures generic drugs on their behalf.

This waiver was incorporated in the TRIPS Agreement under Article 31*bis*. Article 31*bis* therefore amends Article 31(f) of the TRIPS Agreement by permitting foreign pharmaceutical manufacturers to export drugs to developing countries under compulsory licensing. The Paragraph 6 system allows for compulsory licenses to be issued in countries for the manufacture of generic drugs provided they are exported to principally LDCs.²²⁸ The purpose of this derogation was to address the concerns of developing countries that due to their small markets they are unable to effectively attract

²²³ Owoeye, OA *Compulsory Patent Licensing and Local Drug Manufacturing Capacity in Africa*(2014) (92) *Bull World Health Organ* 214.

²²⁴ Article 31(f) of the TRIPS Agreement

²²⁵ Article 31(h) of the TRIPS Agreement

²²⁶ World Trade Organisation *Model Notifications for use of the Paragraph 6 System*, available at https://www.wto.org/english/tratop_e/trips_e/par6_modelnotifs_e.pdf, accessed on 17 October 2016.

²²⁷ *Ibid.*

²²⁸ *Ibid.*

generic suppliers to produce medicines for their countries and this made it mandatory for other WTO members to export to LDCs.²²⁹

Furthermore, the Paragraph 6 system sought to avoid double remuneration to the patentee when a compulsory license is granted.²³⁰ Where a patented drug exists in both the importing and exporting countries, Article 31(h) of the TRIPS Agreement requires that adequate remuneration be paid in both countries to the patentee. Paragraph 6 system derogates from this obligation and provides for payment of remuneration only by the exporting Member.²³¹ Developing countries already lack financial resources to acquire most medicines and therefore it was rather punitive to require them to also pay the patentee remuneration when importing such medicines.

In order for a country to rely on the Paragraph 6 system, the potential exporting country must amend its domestic legislation to enable the production and export of generic medicines under compulsory licenses.²³² This can create a potential barrier for some developing countries to make use of this waiver under Article 31*bis* of the TRIPS Agreement. This is because this may be a difficult task to implement on the part of the potential exporting country. Furthermore, Paragraph 6 system dictates that for a country to import such drugs, they must be an illegible importing Member.²³³ An importing illegible Member has been defined as;

any LDC member or any member that has notified the TRIPS council of its intention to use the system set out in Article 31*bis*...as an importer.²³⁴

Such notice must also set out the names of the drugs and quantity needed.²³⁵ This creates a burdensome expectation on a developing country like Botswana that is already facing a health crisis.

²²⁹ Thapa, R *Waiver Solution in Public Health and Pharmaceutical Domain under TRIPS Agreement* (2011) 16 *Journal of Intellectual Property Rights* 473-474.

²³⁰ Taubman, A & Wager, H & Watal, J *A Handbook on the WTO TRIPS Agreement* Cambridge: University Press, (2012)189.

²³¹ *Ibid* at 184-194.

²³² Thapa, R *Waiver Solution in Public Health and Pharmaceutical Domain under TRIPS Agreement* (2011) 16 *Journal of Intellectual Property Rights* 472.

²³³ Ho, CM *Comment: Access to Essential Medicines: A New World Order for Addressing Patent Rights and Public Health* (2007) 82(3) *Chicago-Kent Law Review* 1472.

²³⁴ Paragraph 1(b) of the Annex to the TRIPS Agreement.

Botswana's Industrial Property Act²³⁶ provides that exploitation of patented invention for compulsory licensing purposes shall be for the supply of domestic market in Botswana except where Article 31***bis*** applies. Furthermore, Section 32(4) also provides that;

where a compulsory license is granted, and remuneration has been paid in the exporting country, the obligation to pay remuneration to import that product into Botswana shall not apply.^q

Thus, as argued above, since Botswana is a developing country that has no pharmaceutical manufacturing capacity and has incorporated the provision of the Paragraph 6 system, it may make use of this waiver to import generic drugs from other countries under compulsory licensing.

iii. Public non Commercial Use of Patents (Government Use)

This is the right conferred on a government to use a patented product without the consent of the patentee.²³⁷ Article 31 of the TRIPS Agreement covers both non voluntary use of patents by compulsory licensing and government use. Article 31(b) of the TRIPS therefore recognizes non-commercial use of patented products by the government without the consent of the patentee. It does not define what amounts to non-commercial use but it should be understood to mean for non-profit purposes. The distinction between government use and compulsory licensing lies in the use of the patent.²³⁸ Under government use, the use of the patent is limited to non-commercial purposes whereas compulsory licensing may cover private and commercial use.²³⁹

In respect of this, Section 32 of the Industrial Property Act of Botswana provides for

the importation of patented products such as generic pharmaceutical products from any legitimate alternative foreign source without the approval of the

²³⁵ Paragraph 2(a) of the Annex to the TRIPS Agreement.

²³⁶ Section 31(3) of the Industrial Property Act.

²³⁷ DeRoo, P 'Public Non-Commercial Use' Compulsory Licensing for Pharmaceutical Drugs in Government Health Care Programs (2011) 32(2) *Michigan Journal of International Law* 386.

²³⁸ DeRoo, P 'Public Non-Commercial Use' Compulsory Licensing for Pharmaceutical Drugs in Government Health Care Programs (2011) 32(2) *Michigan Journal of International Law* 386-387.

²³⁹ *Ibid* at 387-389.

patentee where it is in the public interest to do so for purposes of nutrition and health²⁴⁰ or the market for the patented product is not being supplied in sufficient quantities or on reasonable terms in relation to market demand as long as it is done solely for non-commercial purposes.²⁴¹

Under this flexibility, the government needs to inform the patentee of the intention to override the patent. This makes it easier to utilize because the procedure involved is not as cumbersome as that of compulsory licensing.²⁴²

iv. Parallel Importing

Parallel importing is the import and resale in a country without the consent of the patent holder of a patented product that has been legitimately put on the market of the exporting country.²⁴³ The disparity between market prices of pharmaceuticals in various countries is the economic driver of parallel importing. Parallel importing expands the competition faced by the manufacturers and benefits consumers through lower prices of drugs.²⁴⁴ In reference to access to medicine, this essentially means that medicines may be imported from countries where they are sold at a lower price if the same medicine is available in the importing country but at a higher price.

Article 28 of the TRIPS Agreement confers certain rights on the patentee, one of which is the right preventing third parties from importing patented products without the patentee's consent.²⁴⁵ However, patent rights are not absolute and may be limited by the exhaustion doctrine. Parallel importing arises as a consequence of the doctrine of exhaustion of rights. The doctrine of exhaustion stipulates that once a patented product has been marketed either by the patentee or by other with his/her consent the patent

²⁴⁰ Pfumorodze, J. 'The WTO TRIPS Agreement and Access to Medicines in Southern Africa' (December 2011) 13 *University of Botswana Law Journal* 97.

²⁴¹ Masungu, F & Oh, C. *The Use of Flexibilities in TRIPS by Developing Countries: Can they promote access to medicines?*: Commission on Intellectual Property Rights, Innovation and Public Health (CIPRH), (August 2005).

²⁴² Maskus, KE. *Parallel Imports in Pharmaceuticals: Implications for Competition and Prices in Developing Countries*: Final Report to World Intellectual Property Organization (April 2001) 25.

²⁴³ Article 28(1)(a) of the TRIPS Agreement.

rights of commercial exploitation over this given product can no longer be exercised.²⁴⁴ This means that once the patented drug is launched into the market, the patent holder has no right to control its subsequent circulation.

There are three types of exhaustions; national, regional and international exhaustion.²⁴⁵ Article 6 of the TRIPS Agreement states that practices relating to exhaustion cannot be challenged under the WTO dispute settlement system. The Doha Declaration has reaffirmed that Members do have the right to establish their own regime for such exhaustion without challenge. The TRIPS Agreement therefore renders parallel importing as an issue for domestic consideration and a country has a choice to opt for any of the three systems of exhaustion.²⁴⁶

A system of national exhaustion provides that patent right owner's distribution rights are only considered exhausted until they put the patented item on the market in that country.²⁴⁷ Under international exhaustion, a patentee is barred from exercising rights over products that have already been put anywhere in the international market. This limitation therefore allows countries to import the patented drugs where such drugs have already been placed on the market by the patentee anywhere in the world.²⁴⁸ A developing country like Botswana is mostly likely to opt for international exhaustion to enable it import drugs across the world where they are offered at a cheaper price therefore increasing its access to medicine.

Thus, Section 24 of the Industrial Property Act provides for rights conferred by a patent to the patentee. It states that a patent confers the right to prevent third parties from exploiting a patent in Botswana without his/her consent and such exploitation includes importing the product for purposes of offering it for sell or using it.²⁴⁹ This section may

²⁴⁴ Adusei, P *Patenting of Pharmaceuticals and Development in Sub-Saharan Africa: Laws, Institutions, Practices and Politics* New York: Springer, (2013)186.

²⁴⁵ Bonadio, E *Parallel Imports in a Global Market: Should a Generalised International Exhaustion be the Next Step?* (2011) 33(3) *European Intellectual Property Review* 154-157.

²⁴⁶ Sun, H *The Road to Doha and Beyond: Some Reflections on the TRIPS Agreement and Public Health* (2004) 15(1) *European Journal of International Law* 128-129.

²⁴⁷ Taubman, A & Wager, H & Watal, J *A Handbook on the WTO TRIPS Agreement* Cambridge: University Press, (2012) 19.

²⁴⁸ Clugston, CJ *International Exhaustion, Parallel Imports, and the Conflict between the Patent and Copyright Laws of the United States* (2013) 4(3) *Beijing Law Review* 96-98.

²⁴⁹ See Section 24(1) and (2)(a)(ii)

seem to restrict parallel importing in its entirety. However Section 25 of the Act provides for exceptions to rights conferred by a patent. It stipulates that;

this right shall not extend to articles which have been put on the market in Botswana or abroad by the patentee or any other person acting with the patentee's consent.²⁵⁰

Section 25(1)(a) therefore seeks to override Section 24(2)(a)(ii) and thus suggesting that parallel importing is permissible in Botswana and the government can 'shop around' and get better prices for pharmaceutical products. Botswana seems to follow the international exhaustion doctrine as it permits access to the importation of drugs available on the international market without the patent holder's consent provided the drugs have been placed on the international market by the patent holder or a person acting under the authority of the patent holder.²⁵¹

v. Exceptions to Patent Rights

Member States are permitted under Article 30 of the TRIPS Agreement to implement limited exceptions to the exclusive rights conferred by a patent. These exceptions are based on the ground patent rights are not absolute and may be waived where a greater public interest arises. Article 30 provides for a three-fold test to be satisfied. It states that '*patent rights must not unreasonably conflict with a normal exploitation of the patent and not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.*'

Section 25 of the Industrial Property Act provides for a list of exceptions to patent rights. One which is of relevance is that patent rights shall not extend to articles which have been put on the market in Botswana or abroad by the patentee or any other patentee's consent.²⁵² One advantage of using this flexibility as a tool to access medicine is that

²⁵⁰ Subsection 1 paragraph (a)

²⁵¹ Ndlovu, L *Access to Medicines under the World Trade Organization TRIPS Agreement: A Comparative Study of Select SADC Countries* (unpublished LLD thesis, University of South Africa, 2014) 178.

²⁵² See Section 25(1)(a)

they apply automatically and therefore do not need prior consent of the patent holder or other authority. It also does not require that the patent holder be compensated. This is one of the flexibility that~~s~~ been mostly utilized by the government of Botswana to acquire medicines elsewhere once the needed medicine has been already introduced in the international market.

vi. Limitations on Data Protection

Article 39.3 of the TRIPS Agreement provides for data protection of test data against unfair commercial use. This right may be flexed to allow the timely entrance of generic drugs into the market. If the law is to grant exclusive data rights to the patent holder then generic companies cannot use such data submitted to produce generic drugs until the data exclusivity period ends. Usually, manufacturers of generic drugs rely on the use of originator~~s~~ test data as it is cumbersome and costly for generic industry to repeat the testing process.²⁵³ Interestingly, Section 114(4) of the Industrial Property Act prohibits the act of unfair competition. It provides that;

~~u~~hen, as a condition of approving the marketing of a pharmaceutical chemical product that utilizes new chemical substances requires the submission of undisclosed tests or other data, the origination of which involves a considerable effort, such data shall be protected against unfair commercial use and disclosure and where it is necessary to protect the public, such data shall be disclosed on condition that steps are taken to protect it from unfair commercial use.q

It further provides that;

~~h~~ test data shall be considered undisclosed if it is not generally known or readily accessible to persons within the circles which it is normally dealt with; it has been

²⁵³ Generic Drugs: Overview of ANDA Review Process, available at <http://www.fda.gov/downloads/Drugs/NewsEvents/UCM167310.pdf>, accessed on 21 December 2016.

subjected to reasonable steps under the circumstances to preserve it from disclosure; and it has commercial value because it is secret.²⁵⁴

As already stated, Botswana has pharmaceutical manufacturing capability and therefore it is difficult for the government to implement this flexibility to enable local manufacturers to use the test data in producing generic drugs.

4.3 ACTUAL USAGE OF THE TRIPS FLEXIBILITIES

i. Exclusion from Patentability

On the issue of patentable subject matter, Section 9 of the Industrial Property Act excludes from patentability all methods used for treatment of the human body as well as diagnostic methods practiced in relation thereto. There has been actual implementation of this flexibility in Botswana. For instance, the Botswana Harvard AIDS Institute Partnership (BHP) carries out clinical and laboratory researches dealing with HIV infections. All diagnostic methods conducted by the Botswana-Harvard HIV Reference laboratory cannot be patented and as such HIV/AIDS diagnostic kits cannot be patented in Botswana.²⁵⁵

ii. Parallel importing

In the year 2000, the Botswana government declared HIV/AIDS a national emergency and launched the Botswana Antiretroviral Therapy (ART) Programme. As such, the Government of Botswana went into partnership with pharmaceutical companies and began importing generic ARVs from pharmaceuticals companies in India that offered discounted pricing despite the existence of the same generic ARVS in the Botswana market so as to ensure greater coverage of the ART Programme.²⁵⁶ Recently, the

²⁵⁴ Section 114(5) of the Industrial Property Act.

²⁵⁵ Available at <https://aids.harvard.edu/research/bhp/>, accessed on 27 September 2016.

²⁵⁶ See Regional Seminar for Certain African Countries on the Implementation and Use of Several Patent-Related Flexibilities- Overview of the Use of Patent-Related Flexibilities and the Main

Ministry of Health of Botswana launched the 'Treat All' HIV/AIDS strategy campaign which aims to ensure that persons that test positive to HIV must receive treatment immediately despite their CD4 count as opposed to the old method of reserving treatment for those with lower CD4 counts.²⁵⁷

The Ministry has since then entered into agreement with one of the leading pharmaceutical companies ViiV Healthcare for the supply of the dolutegravir drug used as a first line treatment in HIV infected persons. The company offers lower prices to lower middle income countries like Botswana.²⁵⁸ Consequently, Botswana became the first Sub Saharan country to use this drug as part of a national health programme since its recommendation by the WHO in the year 2015.²⁵⁹ As such, parallel importing of this drug has therefore allowed more HIV infected to have access to the drug which would have otherwise been very costly to acquire.

Zimbabwe on the other hand also follows the international exhaustion of patent rights regime and has made actual use of parallel importing. This is permitted under Section 24A of its Patent Act²⁶⁰. One of the local pharmaceutical companies called Datlabs imports cheaper drugs from a pharmaceutical company in India called Ranbaxy.²⁶¹

iii. Exceptions to patent rights

Section 25 of the Industrial Property Act deals with the exhaustion of patent rights once the patented drug has been placed in Botswana's local or international market by the

Constraints thereon within the Region, available at http://www.wipo.int/edocs/mdocs/patent_policy/en/wipo_ip_dur_13/wipo_ip_dur_13_ref_t5a.pdf (accessed on 08 October 2016).

²⁵⁷ World Health Organisation Regional Office for Africa: available at <http://www.afro.who.int/en/botswana/press-materials/item/8739-botswana-launches-treat-all-strategy.html>, accessed on 10 October 2016. A CD4 count is a laboratory test that measures how well one's immune system is working and the rate of HIV progression (<https://www.aids.gov/hiv-aids-basics/just-diagnosed-with-hiv-aids/.../cd4-count/>).

²⁵⁸ See <http://www.gsk.com/en-gb/media/press-releases/2016/viiv-healthcare-announces-public-tender-agreement-with-botswana-ministry-of-health-for-dolutegravir/>, accessed on 10 October 2016.

²⁵⁹ WHO Policy brief: Consolidated Guidelines on the Use of Antiretroviral Drugs for Treating and Preventing HIV Infection. Published Nov 2015. Available at <http://www.who.int/hiv/pub/arv/policy-brief-arv-2015/en/>, accessed on 10 October 2016.

²⁶⁰ Chapter 26:03, Laws of Zimbabwe.

²⁶¹ Pfumrodze, J 'The WTO TRIPS Agreement and Access to Medicines in Southern Africa' (December 2011) 13 *University of Botswana Law Journal* 98-99.

patent holder or any other person duly authorized. This allows the government of Botswana to import drugs without the patent holder's consent once they have been introduced into the market. This is the most utilized flexibility to acquire medicines in Botswana since the sale of patented drugs in any part of the world causes exhaustion of such rights in Botswana as well. Botswana can therefore freely import such drugs without prior consent of the patent holder. Below is a table showing some of the drugs imported to Botswana from India in the year 2016.²⁶²

DATE	PRODUCT DESCRIPTION	VALUE (USD)	QTY
21-Oct-2016	Drugs & Pharma, Medicines Coxerin (Cycloserine 250mg Caps)	573.94	1200
2-Sep-2016	Drugs & Pharma, Medicines Rifa60/Iso30mg(2-Fdc) Paediatric Dispersible Tabs	1023.47	84000
16-Jul-2016	Medicines Rifampicin 60/Isoniazid 30/ Pyrazinamide 150mg Paediatric Dispersible Tabs	3164.75	64400
21-Jun-2016	Medicines Rifampicin 150 Mg /Isoniazid 75 Mg Pyrazinamide 400 Mg /Ethambutol Hcl275 Mg Tabs	171201.25	3033000
21-Jun-2016	Drugs & Pharma, Medicines Rifampicin 150mg Isoniazid 75 Mg / Ethambutol 275 Mg Tablets	287709.36	6150000
14-Jun-2016	Drugs & Pharma, Medicines Rifampicin 150mg /Isoniazid 75 Mg Pyrazinamide 400 Mg/Ethambutol Hcl 275 Mg Tabs	190115.48	3367000
14-Jun-2016	Drugs & Pharma, Medicines Rifa 60/Iso 30/Pyra 150mg Paediatric Dispersible Tabs	1314.10	25200
7-May-2016	Drugs & Pharma, Medicines Rifampicin 150/ Isoniazid 75/ Ethambutol 275 Mg Tablets	38183.46	833000

In comparison, Zimbabwe's provision on exceptions to patent rights has gone further to also incorporate the flexibility on limitation of data protection by providing for early working exceptions. Section 24B of the Patent Act provides that *'test batches of a patented product may be produced without the consent of the patentee six months*

²⁶² Available at <http://www.infodriveindia.com/india-export-data/medicine-export/fc-botswana/fp-tartous/hscod-30049057-report.aspx>, accessed on 25 October 2016.

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.' Consequently, once the test batches have been produced, the original term of the patent may not be extended. This has assisted its local pharmaceutical companies such as Varichem and Datlabs to use such test data prematurely in manufacturing generic versions of drugs.²⁶³

iv. Compulsory licensing

Till date no compulsory licenses have been issued by Botswana.²⁶⁴ The government of Botswana has not yet made use of the notification by submitting its intention to the TRIPS council to import drugs under the Paragraph 6 system.²⁶⁵

Under the South African Patents Act,²⁶⁶ compulsory licenses are allowed where there is an abuse of patent rights. According to Section 56 of the Act, abuse of patent rights may occur in four scenarios. Namely where;

- the invention is not being worked in South Africa on a commercial scale²⁶⁷
- the demand for the patented drug is not being met adequately and on reasonable terms²⁶⁸
- the patentee has refused to grant a license on reasonable terms and such refusal prejudices the establishment of a new industry or that it is in the public interest that a license should be granted²⁶⁹ and
- the demand for the patented drug is being met by importation and the price charged for the patented drug by the patent holder is excessive in relation to the price charged in the country of manufacture.²⁷⁰

²⁶³ Pfumorodze, J 'The WTO TRIPS Agreement and Access to Medicines in Southern Africa'(December 2011) 13 *University of Botswana Law Journal* 99.

²⁶⁴ Botswana Investment and Business Guide Volume 1 Strategic and Practical at 59 available at <https://books.google.co.za/books?isbn=1514528797>, accessed on 10 October 2016.

²⁶⁵ Munyuki, E & Machemedze, R Implementation of the TRIPS flexibilities by East and Southern African countries: Status of patent law reforms by 2010: *EQUINET Discussion paper 80*, (2010) 16.

²⁶⁶ Act No 57 of 1978.

²⁶⁷ Section 56(2)(a)

²⁶⁸ Section 56(2)(b)

²⁶⁹ Section 56(2)(c)

South Africa therefore seems to have taken a robust position in ensuring that patent rights do not unjustifiably inhibit its means of acquiring essential medicines. Its compulsory license provisions cater for any eventuality that may act as a stumbling block in ensuring South Africa has access to adequate medicine for its citizens.²⁷¹ In 2001 South Africa announced that compulsory licenses would be issued on ARVs manufactured by GlaxoSmithKline (GSK) and Boehringer Ingelheim (BI).²⁷² On the contrary, Prof. Yousuf Vawda in his recent article avers that since 1978, South Africa has never issued a compulsory license.²⁷³

Similarly, Zimbabwe has also incorporated TRIPS flexibilities in its Patent Act²⁷⁴ to promote access to medicine and has made actual use of the compulsory licensing flexibility. Section 35 of Zimbabwe's Patent Act allows for issuance of compulsory licenses by the government during periods of public health emergencies. The government of Zimbabwe in May 2002 declared a six months period of public health emergency on HIV/AIDS and began to locally manufacture ARVs by issuing a compulsory license to a company called Varichem Pharmaceuticals (Private) Limited.²⁷⁵ The company later began manufacturing generic versions which lowered the price of ARVs from US\$1,168 to US\$412 per patient per year.²⁷⁶

Till date several local manufacturing pharmaceutical companies in Zimbabwe have been granted compulsory licenses by the government to manufacture and or import HIV/AIDS generic drugs.²⁷⁷ Furthermore, the World Health Organisation (WHO) in 2010 certified that Varichem Pharmaceuticals conforms to international standards and may

²⁷⁰ Section 56(2)(d)

²⁷¹ Ndlovu, L *Access to Medicines under the World Trade Organization TRIPS Agreement: A Comparative Study of Select SADC Countries* (unpublished LLD thesis, University of South Africa, 2014) 199-201.

²⁷² See Knowledge Ecology International's brief, available at http://keionline.org/misc-docs/recent_cls_8mar07.Pdf, accessed on 14 October 2016.

²⁷³ Regering hou jou medikasie duurq *Netwerk24*, 30 October 2016 available at <http://www.netwerk24.com/Nuus/Gesondheid/regering-hou-iou-medikasie-duur-20161029>, accessed on 23 November 2016.

²⁷⁴ Chapter 26:03, Laws of Zimbabwe.

²⁷⁵ Ndlovu, L *Access to Medicines under the World Trade Organization TRIPS Agreement: A Comparative Study of Select SADC Countries* (unpublished LLD thesis, University of South Africa, 2014) 195.

²⁷⁶ *Ibid* at 195.

²⁷⁷ Pfumrodze, J 'The WTO TRIPS Agreement and Access to Medicines in Southern Africa' (December 2011) 13 *University of Botswana Law Journal* 97.

export its drugs to other countries in the region.²⁷⁸ This has helped promote the availability of ARVs in Zimbabwe and ensuring its citizens are afforded proper health care. Other countries in the region may also benefit from this by importing cheaper ARVs from Zimbabwe.

v. Government Use of Patents

In 2000 the Government of Botswana went into agreement with the Bill & Melinda Gates Foundation and Merck & Co. Inc to establish the African Comprehensive HIV/AIDS Partnerships (ACHAP). Under the agreement, Merck & Co. continuously donates two anti-retroviral drugs namely Crixivan (Indinavir) and Stocrin (Efavirenz) to Botswana to be used in public hospitals. This could be Botswana's answer in ensuring that its needy citizens have access to essential medicines.²⁷⁹

4.4 CONCLUSION

The flexibilities enshrined in the TRIPS Agreement seek to diminish the adverse effects of intellectual property rights on the cost of medicines and thereby promoting access to cheaper medicines. Botswana being a signatory of the TRIPS Agreement has domesticated and implemented the TRIPS Agreement in a manner that does not completely hinder the right of the country to protect public health and to promote access to medicines. It is evident that Botswana has incorporated all the above discussed TRIPS flexibilities in its current Industrial Property Act. However, Botswana has up to this point not fully utilized most of these flexibilities as a mechanism for ensuring adequate access to essential medicines due to its market size and lack of pharmaceutical manufacturing companies. Botswana could learn from countries like Zimbabwe and make use of the compulsory licensing flexibility to access cheaper ARVs for its people.

²⁷⁸ Pfumrodze, J. "The WTO TRIPS Agreement and Access to Medicines in Southern Africa" (December 2011) 13 *University of Botswana Law Journal* 97.

²⁷⁹ Guzik, B. "Botswana's Success in Balancing the Economics of HIV/AIDS with TRIPS Obligations and Human Rights" (2007) 4(2) *Loyola University Chicago International Law Review* 266-267.

CHAPTER 5:

CONCLUSION AND RECOMMENDATIONS

5.1 INTRODUCTION

Access to medicine in Botswana is cumbersome. The research has highlighted a number of concerning matters in respect of access to medicine in Botswana and the TRIPS agreement. The study was guided by the following pertinent objectives;

- To determine how intellectual property came to be on the trade agenda;
- To determine how the right to access to health care and intellectual property rights are protected in Botswana;
- To determine the extent to which TRIPS flexibilities been incorporated in SADC countriesq domestic legislations particularly Botswana to advance access to medicine;
- To determine how developing countries can make full use of the TRIPS flexibilities without falling foul of the basic tenets of intellectual property law; and lastly
- To determine what the legal and policy interventions need to be implemented to ensure that developing countries fully utilize TRIPS flexibilities.

Now, it is incumbent on this chapter to succinctly discuss these problem areas highlighted in the preceding chapters. Thereafter, the chapter will propose recommendations that may be useful in resolving the problem of access to medicine in Botswana.

5.2 ISSUES IDENTIFIED

It was established in chapter one that financial accessibility of medicines is one of the ongoing challenges faced by most developing countries.²⁸⁰ Most of the SADC countries depend on imported drugs and although pharmaceutical companies attempt to make drugs affordable, most patented drugs are very pricy which often lead to affordability barriers. Prior to the TRIPS Agreement²⁸¹ there were no international conventions that set out the minimum standards of patent protection but WTO Members are now expected to modify their national legislation so as to conform to the minimum standards of intellectual property rights protection as set out by the TRIPS Agreement.²⁸² It was further established that the pharmaceutical industry has exploited the patent system in a way to inhibit access to medicine by poorer countries by making these patented drugs unaffordable to them. As discussed, the notorious practice by pharmaceutical companies of extending patent life spans beyond the mandatory 20 year period by filing for secondary patents is the leading cause of exorbitant drug prices.²⁸³ This practice elongates the exhaustion period of these patents therefore making it impossible for other pharmaceuticals to produce generic versions of the patented drugs.²⁸⁴

As an outcry to the over pricing of patented drugs, TRIPS flexibilities were included in the Agreement. Thus, developing countries may avail themselves to TRIPS flexibilities to avoid patent protections and have access to generic drugs.²⁸⁵ According to the MDG reports, improved access to medicines in poor countries has led to the decline of most avoidable deaths.²⁸⁶ For instance deaths of children under 5 years of age as a result of measles has declined rapidly since 2000, from 544,200 deaths to 145,700 deaths in 2013.²⁸⁷ It is therefore evident that poor access to medicines continues to be the leading

²⁸⁰ Par 1 of page 1.

²⁸¹ TRIPS: Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, THE LEGAL TEXTS: THE RESULTS OF THE URUGUAY ROUND OF MULTILATERAL TRADE NEGOTIATIONS 320 (1999), 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994) [hereinafter TRIPS Agreement].

²⁸² Par 2 of page 2.

²⁸³ Par 3 of page 2.

²⁸⁴ Par 3 of page 2.

²⁸⁵ Par 3 of page 3.

²⁸⁶ Page 6.

²⁸⁷ Page 6.

cause of deaths in most developing countries. Botswana, for example being a landlocked country and having limited market size does not have any pharmaceutical manufacturing capacity. Despite the continued injection of more money into the health sector to continue meeting the health needs of its people, the country is still reliant on imported drugs which are mostly patented drugs in order to meet the needs of its people.²⁸⁸ Thus, it reviewed its IP laws to include the TRIPS flexibilities. As such, the study sought to establish the extent to which TRIPS flexibilities have been incorporated in Botswana's national legislation and found that Botswana has incorporated most of the TRIPS flexibilities in its Industrial Property Act.²⁸⁹ The study also sought to examine the technical barriers in trade that are preventing Botswana from fully utilizing these TRIPS flexibilities in order to promote access to cheaper medicines and found lack of pharmaceutical manufacturing capacity to be the leading setback.²⁹⁰

Further, the discussion regarding the historical development of intellectual property in international trade (in chapter 2), the protection of intellectual property rights in international trade has been characterised with different phases of development. The initial phase is characterised with the absence of the international protection of intellectual property rights.²⁹¹ It was only towards the end of the 19th century that states began to take a greater interest in the possibility of international co-operation on intellectual property matters.²⁹² It was established that despite the Paris Convention for the protection of Industrial Property (1883) whose aim was to harmonize patent laws and regulations as stipulated by various countries, developing countries were reluctant to ratify the Paris Convention due to the fear that no technical assistance would be afforded to them in as far as implementing treaty obligations are concerned.²⁹³ One of the setbacks of the Convention was its failure to outline minimum standards for patent protection to which its Members must adhere.²⁹⁴ The level of intellectual property rights

²⁸⁸ Par 2 of page 7.

²⁸⁹ Par 3 of Page 7.

²⁹⁰ Par 1 of page 9.

²⁹¹ Par 1 of page 17.

²⁹² Par 1 of page 17.

²⁹³ Par 2 of page 19.

²⁹⁴ Par 3 of page 20.

protection to be implemented was left to domestic legislation and courts to develop.²⁹⁵

The Berne Convention of 1886 was the cornerstone of international copyright law. The Convention miserably failed to establish extensive legal remedies which could be enforced by the copyright holders against the copyright infringers.²⁹⁶ It was further established in the chapter that the General Agreement on Tariffs and Trade (GATT 1947) came about at the end of World War II. After World War I, states had begun to conclude unfair trade arrangements for their own political agendas which led to the destruction of the multilateral trading system that existed prior to the war. The GATT was therefore established as the custodian and enforcer of free trade in the multilateral trading system.²⁹⁷ Despite the fact that the first seven rounds of GATT negotiations mostly dealt with tariff reductions, intellectual property rights were not completely foreign to the GATT before they were tabled for negotiation during the Uruguay Round.²⁹⁸ Ultimately, this final GATT round marked the birth of the World Trade Organisation (WTO). In contrast, to the WTO, the GATT considered intellectual property matters to be internal matters that resonated between States in their private dealings.²⁹⁹

The advent of the TRIPS Agreement (an agreement administered under the WTO) marked the beginning of an evolution in as far as globalizing of intellectual property rights is concerned.³⁰⁰ To most developing countries, the establishment of the TRIPS Agreement entailed a great deal of reform to their domestic legislation in as far as intellectual property rights were concerned thus they were reluctant to sign the TRIPS Agreement due to fear of the economic implications as the Agreement would forestall access to new technologies leading to higher prices especially in pharmaceuticals.³⁰¹ It was discussed that in order to address these concerns, the TRIPS gave Member States flexibilities which allowed states for example to disregard TRIPS obligations for national

²⁹⁵ Par 3 of page 20.

²⁹⁶ Par 4 of page 20.

²⁹⁷ Par 1 of page 22.

²⁹⁸ Par 3 of page 22.

²⁹⁹ Par 2 of page 25.

³⁰⁰ Par 3 of page 29.

³⁰¹ Par 2 of page 30.

concerns such as health issues in implanting their domestic intellectual property regimes. Despite this, the TRIPS Agreement has led to an increase in the formation of free trade agreements that seek to implement intellectual property standards set out in the TRIPS Agreement.³⁰² Consequently, while developing countries are still struggling to conform to the standards set out by the TRIPS, developed countries continue to strengthen intellectual property rights through free trade agreements. However, due to the increased preference of free trade agreements over multilateral agreements, developing countries are not hesitant to trade off intellectual property rights in order to gain market access for agricultural goods in these free trade agreements.³⁰³ Issues of intellectual property rights have therefore transitioned from being issues of national consideration to having a status of a core obligation in the international trading system.

Having established the effect of TRIPS on developing countries, chapter three assessed the legal framework of Botswana particularly how human rights and intellectual property rights are protected and found that the Constitution of Botswana has no express provision to the right to health. The Constitution only allows for other rights to be disregarded for the protection of public health.³⁰⁴ Due to this finding, the chapter examined international instruments such as the Universal Declaration of Human Rights (UDHR) and the International Covenant on Economic, Social and Cultural Rights (ICESCR) to establish whether public health was a facet to the right to health.³⁰⁵ It was established that the right to health is not confined to health care alone but extends to conditions pertinent to good health such as housing, a healthy environment and access to safe and potable water. Therefore, the Constitution of Botswana does not address the issue of health care through ensuring access to medicine but is rather more focused on the social well-being aspect of the right to health.³⁰⁶ In comparison to Botswana, South Africa and Zimbabwe have incorporated health care provisions in their

³⁰² Par 6 of page 35.

³⁰³ Khor, M. Bilateral and Regional Free Trade Agreements: Some Critical Elements and Development Implications (September 2008), available at <http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.370.7928&rep=rep1&type=pdf>, accessed on 23 November 2016, 7-10.

³⁰⁴ Par 1 of page 36.

³⁰⁵ Par 2 of page 36.

³⁰⁶ Par 2 of page 37.

Constitutions.³⁰⁷ Lack of constitutional protection of the right to health care in Botswana therefore burdens the courts and other non-state actors with the onerous task of enforcing this indistinct right.³⁰⁸

The chapter also explored the various Non-governmental Organizations (NGOs) in Botswana that seek to protect and promote human rights and intellectual property rights and identified them to be the key players in raising public awareness of the various human rights that are provided for in the Constitution of Botswana. These NGOs also exist to provide health and social services to the community as a way of promoting proper health care.³⁰⁹

Further, the research found that Botswana has only two pieces of legislation that deal with intellectual property rights, that is; the Copyright and Neighbouring Rights Act and the Industrial Property Act and found that the Copyright and Neighbouring Rights Act deals with the protection of the rights of artists, authors and creators, as well as the protection of their literary and artistic work whereas the Industrial Property Act deals with trademarks, industrial designs, utility models and patents.³¹⁰ It was also found that the Companies and Intellectual Property Authority is a parastatal which is regarded as the formal tool for intellectual property rights management in Botswana. The body is tasked with the registration of trade marks, industrial designs and the granting of patent certificates. The body is also responsible for combating copyright infringement and piracy in Botswana.³¹¹

As such, chapter four explored the various TRIPS flexibilities that have been domesticated into Botswana's Industrial Property Act and discussed the extent to which such flexibilities have actually been utilized by the government of Botswana in order to

³⁰⁷ Pages 37-39.

³⁰⁸ Par 1 of page 40.

³⁰⁹ Par 2 of page 40.

³¹⁰ Par 2 of page 44.

³¹¹ Par 3 of page 47.

improve access to medicine.³¹² The findings of this chapter may be summarized as follows;

- Botswana being a signatory of the TRIPS Agreement has domesticated and implemented the TRIPS Agreement in a manner that does not completely hinder the right of the country to protect public health and to promote access to medicines; and
- Botswana has incorporated various TRIPS flexibilities in its current Industrial Property Act namely; exception to patent rights, exclusion from patentability, compulsory licensing, paragraph 6 system, parallel importing, public non-commercial use of patents (government use) and limitations on data protection.³¹³

However, Botswana has up to this point not fully utilized most of these flexibilities as a mechanism for ensuring adequate access to essential medicines due to its market size and lack of pharmaceutical manufacturing companies. It has also been established that Botswana has not yet submitted its intention to the TRIPS Council to make use of the Paragraph 6 system which could be its gateway to improving its access to cheaper medicines.³¹⁴ The introduction of the waiver under the TRIPS Agreement allowing the importation and exportation of drugs manufactured under compulsory licensing should have been Botswana's loophole to allow foreign pharmaceutical companies to manufacture drugs on behalf of Botswana. This has been noted as Botswana's major weakness in as far as promoting access to medicine is concerned. However, the chapter noted in contrast that Zimbabwe has utilized the compulsory licensing flexibility in the production of ARVs which has consequently been beneficial to the SADC region at large.³¹⁵ The position of South Africa regarding actual issuance of compulsory licenses is unclear. However, South Africa awards a higher percentage of pharmaceutical patents than western countries, even USA and European states, due to

³¹² Par 2 of page 49.

³¹³ Pages 50-60.

³¹⁴ Par 2 of page 63.

³¹⁵ Pages 63-65.

it not having a patent inspection system which consequently results in numerous patents being awarded on the same product.³¹⁶

5.3 RECOMMENDATIONS

Having identified the above issues, this chapter will now make particular recommendations on how Botswana can make full use of the TRIPS flexibilities incorporated in the Industrial Property Act thereby further promoting access to medicine. These recommendations are made upon a critical analysis on how its neighboring countries such as South Africa and Zimbabwe have taken advantage of these flexibilities to promote local production of medicines and improving access to medicine in general.

5.3.1 Establishing local pharmaceutical manufacturing companies

One of the main reasons why Botswana has not fully utilized the TRIPS flexibilities is due to lack of pharmaceutical manufacturing capacity. Encouraging local production of drugs will massively lower the cost of importing drugs from countries such as India and South Africa. This is because it is cheaper to import raw materials used in manufacturing drugs than the finished drugs themselves. Locally manufacturing drugs will not only improve access to medicine in Botswana alone as this will also stimulate export to other countries in the region.³¹⁷

Furthermore, establishing local pharmaceutical companies will enable Botswana to make full use of other flexibilities such as limitation on test data. Section 114(4) of the Industrial Property Act provides that test data of a new drug may be disclosed where such data is in the public health interest. The use of such test data will allow for timely manufacturing of generic drugs in Botswana. This is because manufacturers of generic

³¹⁶ Page 64.

³¹⁷ Kaplan, W & Laing, R *Local Production of Pharmaceuticals: Industrial Policy and Access to Medicines: An Overview of Key Concepts, Issues and Opportunities for Future Research*: HNP Discussion paper, (January 2005) 8-10.

drugs rely on the use of originator's test data as it is cumbersome for the generic industry to repeat the testing process.³¹⁸

5.3.2 Submit intention to make use of Paragraph 6 system under Article 31*bis* of the TRIPS Agreement

In order to import drugs under the Paragraph 6 system, Paragraph 1(b) of the Annex to the TRIPS Agreement requires Member States to notify the TRIPS Council of its intention to use the system. Previously, drugs manufactured under compulsory licensing were to be predominantly for the supply of the domestic market.³¹⁹ This created a barrier for developing countries with no pharmaceutical manufacturing capacity. With the introduction of the Paragraph 6 system, developing countries may issue compulsory licenses to foreign pharmaceutical companies to manufacture drugs on their behalf. As noted above, Botswana is a qualifying member but has however not utilized this waiver in order to have access to cheaper drugs. Consequently, unlike Zimbabwe, Botswana cannot take advantage of the compulsory licensing flexibility to use foreign pharmaceutical companies to manufacture the ARVs that it undeniably needs.

5.3.3 Amendment of Botswana's competition laws to extend to intellectual property rights

The TRIPS Agreement permits countries to implement competition-based exceptions to patent rights. Botswana's competition laws do not address the issue of intellectual property rights particularly patent rights. Such competition laws would serve as a deterrent to abuse of patent rights in Botswana. Therefore Botswana's Competition Act of 2009³²⁰ would be the ideal piece of legislation to address the issue of abuse of patent rights. A lesson could be drawn from South Africa's inclusion of competition law as a TRIPS flexibility to facilitate access to medicine. Section 8(a) of the South African

³¹⁸ Generic Drugs: Overview of ANDA Review Process, available at <http://www.fda.gov/downloads/Drugs/NewsEvents/UCM167310.pdf>, accessed on 21 December 2016.

³¹⁹ https://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm, accessed on 21 December 2016.

³²⁰ CAP 46:09, Laws of Botswana.

Competition Act³²¹ prohibits the abuse of dominance by stipulating that a dominant firm shall not charge excessive prices to the detriment of consumers. As demonstrated by case law, the aforementioned provision has positively advanced access to medicine by ensuring that pharmaceutical companies do not unreasonably charge high prices for drugs.

In the case of *Hazel Tau and Others v GlaxoSmithKline and Boehringer Ingelheim*,³²² the applicants, Treatment Action Campaign (TAC)³²³ acting on behalf of HIV patients and medical professionals filed a complaint to the Competition Commission alleging that Boehringer Ingelheim and GlaxoSmithKline charged excessive prices for ARVs which is in contravention of Section 8(a) of the Competition Act.³²⁴ The Applicant further alleged that the exorbitant prices of ARVs led to deaths of people living with HIV/AIDS due to being unable to afford the drugs. The allegations were investigated by the Competition Commission and it was subsequently held that the two pharmaceutical companies had abused their dominant position in the market by charging exorbitant prices for their drugs and denying other pharmaceutical companies to manufacture generic versions of their patented drugs for a reasonable royalty.³²⁵ Consequently, the two companies agreed to allow the manufacture of generic versions of their drugs by selected pharmaceutical companies. For the first time, generic drugs were now commercially available in South Africa.³²⁶

Further, in *Treatment Action Campaign v Bristol-Myers Squibb*³²⁷, the AIDS Law Project (ALP) in 2005 acting on behalf of Treatment Action Campaign lodged a complaint that Bristol-Myers was over pricing an anti-fungal medicine which was mostly used to treat HIV/AIDS related fungal infections. The patent rights of the drug in question had expired but the company still enjoyed monopoly over the drug and generic versions of it were

³²¹ Act No 89 of 1998.

³²² Case No 2002Sep226.

³²³ This is a South African NGO that advocates rights of persons living with HIV.

³²⁴ At Par 2.

³²⁵ At Par 4.

³²⁶ Avafia, T & Berger, J & Hartzenberg, T *The Ability of Select Sub-Saharan African Countries to Utilize TRIPS Flexibilities and Competition Law to Ensure a Sustainable Supply of Essential Medicines: A study of Producing and Importing Countries*: TRALAC,(2006) 40.

³²⁷ Case No 4138/98.

not available in South Africa.³²⁸ According to the complainants, a generic version of the drug was available in Brazil and was being sold at a fraction of the price of the drug in South Africa. Consequently, Bristol-Myers agreed to lower the price of its anti-fungal medicine.³²⁹

Based on the example of South African case law, it can be argued that competition laws may be the best watchdog against abuse of patent rights in developing countries particularly where the government is unwilling to act.³³⁰ The Botswana government could therefore amend its competition laws to extend to patent rights so as to ensure prices of drugs in its local market are not exorbitant.

5.3.4 Judicial strategy

Due to the absence of an express provision promoting access to medicine in Botswana, the courts should step in and clarify the nature and scope of ~~public health~~. Public health cannot be achieved where access to essential medicine is not protected by the law. Having the right to access to medicine as a facet of the greater right to health will ensure that the government accords utmost attention to implementing health policies that address the health needs of the people in Botswana. This is because any omissions in protecting the right may be challenged in the courts of law. Non-Governmental Organizations (NGOs) or private individuals may therefore bring actions to the courts of Botswana challenging violation of their right to access to medicine.³³¹

For instance, Section 27 of the South African Constitution entitles citizens to challenge their right to have access to health care services as was illustrated in the case of *Soobramoney v Minister of Health (KwaZulu-Natal)*.³³² In this case, Mr Soobramoney who was suffering from a chronic kidney failure was denied access to dialysis machine

³²⁸ At par 9.

³²⁹ Melendez-Ortiz, R *Intellectual Property and Sustainable Development: Development Agendas in a changing world* United Kingdom: Edward Elgar Publishing,(2009)190-195.

³³⁰ Melendez-Ortiz, R *Intellectual Property and Sustainable Development: Development Agendas in a changing world* United Kingdom: Edward Elgar Publishing,(2009)193.

³³¹ Twinomugisha, BK *Implications of the TRIPS Agreement for the Protection of the Right of Access to Medicines in Uganda*(2008) 2(2) *Makerere Law Journal* 272-273.

³³² 1998 (1) SA 765 (CC)

for not satisfying the medical criteria that he was illegible for a kidney transplant.³³³ He applied to the Court challenging the infringement of two of his basic Constitutional rights being the right to life³³⁴ and the right not to be denied of emergency medical treatment.³³⁵ The Constitutional Court dismissed the claim on the ground that his failure to meet the criteria did not constitute a violation of his rights as the state's limited resources could not cater for everyone.³³⁶ The Constitutional Court further held that his condition was not a medical emergency as it was an ongoing state of affairs.³³⁷ Although the case was dismissed, the court rose to the occasion to elucidate on what emergency medical treatment in terms of Section 27(3) of the Constitution entails.³³⁸ It held that the right to emergency medical treatment meant that an individual who suffers a sudden catastrophe that necessitates speedy medical attention should not be denied such treatment from a hospital equipped to administer the necessary treatment.

Similarly, in the case of *Minister of Health and others v Treatment Action Campaign*,³³⁹ Treatment Action Campaign brought an action against the Minister of Health for not ensuring that drugs that prevent mother-to-child transmission of HIV called Nevirapine are widely available to the population.³⁴⁰ In light of Section 27 of the Constitution, the court found that the government had infringed Section 27 since doctors at public hospitals and clinics were not allowed to prescribe the drug even where it was medically indicated. Furthermore, only medical practitioners at research and training sites could make use of the drug as a mode of preventing mother-to-child transmission of HIV.³⁴¹

5.4 CONCLUSION

From the findings of this study, it is clear that incorporating TRIPS flexibilities into the national legislation does not automatically yield better access to medicine. As already

³³³ *Supra* at 769 par D-H.

³³⁴ Section 11

³³⁵ Section 27(3)

³³⁶ At 777 par 20.

³³⁷ At 774 par 21.

³³⁸ At 774 par 20.

³³⁹ 2002 (5) SA 721 (CC).

³⁴⁰ *Supra* at 731 par F-H.

³⁴¹ *Supra* at 765 par C-D.

discussed, there is need to change economic and political framework of the country in order for a country to fully utilize these flexibilities. The government of Botswana took a step in the right direction by incorporating the TRIPS flexibilities in its Industrial Property Act. However, it is clear from the findings of this study that despite having incorporated these flexibilities, Botswana has up to date been unable to fully utilize them. This has mostly been attributed to economic factors such as Botswana's small market size and the lack of pharmaceutical manufacturing capacity. Therefore, the recommendations suggested can only be effective in improving access to cheaper medicine if Botswana amends its laws and policies relating to access to medicine and implements all other necessary changes to Botswana's political and economic framework that favour access to medicine.

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02 June 2016

Ms Tamanda Agatha Kamwendo (216071885)
School of Law
Howard College Campus

Dear Ms Kamwendo,

Protocol reference number: HSS/0691/016M

Project title: A critical discussion on Botswana's access to medicine and trips flexibilities

Full Approval – No Risk / Exempt Application

In response to your application received on 01 June 2016, the Humanities & Social Sciences Research Ethics Committee has considered the abovementioned application and the protocol have been granted **FULL APPROVAL**.

Any alteration/s to the approved research protocol i.e. Questionnaire/Interview Schedule, Informed Consent Form, Title of the Project, Location of the Study, Research Approach and Methods must be reviewed and approved through the amendment/modification prior to its implementation. 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.

The ethical clearance certificate is only valid for a period of 3 years from the date of issue. Thereafter Recertification must be applied for on an annual basis.

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

Yours faithfully

.....
Dr Shenuka Singh (Chair)

/ms

Cc Supervisor: Clydenia Stevens
Cc Academic Leader Research: Dr Shannon Bosch
Cc School Administrator: Mr Pradeep Ramsewak / Ms Robynne Louw

Humanities & Social Sciences Research Ethics Committee

Dr Shenuka Singh (Chair)

Westville Campus, Govan Mbeki Building

Postal Address: Private Bag X54001, Durban 4000

Telephone: +27 (0) 31 260 3587/8350/4557 **Facsimile:** +27 (0) 31 260 4609 **Email:** ximbap@ukzn.ac.za / snymann@ukzn.ac.za / mohun@ukzn.ac.za

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