

**UNIVERSITY OF THE WESTERN CAPE
FACULTY OF LAW**

**TOWARDS THE EFFECTIVE UTILISATION OF TRADE-RELATED ASPECTS OF
INTELLECTUAL PROPERTY RIGHTS FLEXIBILITIES TO IMPROVE ACCESS
TO ESSENTIAL MEDICINES IN GHANA**

Barbara Bangfudem Kuudogrme

Student Number: 3868835

Supervisor: Prof P Lenaghan

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DECLARATION

I declare that,

‘Towards the Effective Utilisation of Trade-Related Aspects of Intellectual Property Rights Flexibilities to Improve Access to Essential Medicines in Ghana’

is my own work and that this work has not been submitted before for any degree or currently being considered for a degree at any other institution and all the sources I have used or quoted have been duly acknowledged as complete references.



Barbara Bangfudem Kuudogrme

3868835



Prof Patricia Lenaghan

Supervisor

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DEDICATION

I dedicate this work to my uncle Mr Patrick Kubayanda, a cancer survivor and all patients who have challenges accessing essential medicines in Ghana.

Uncle, anytime medicines were prescribed for you, it was a headache for the family not just because they were expensive but also because, they were scarce on the market. In all these challenges, we managed to purchase some of these medicines from South Africa which has sustained you till date.

Getting involved in purchasing medicines for you amidst all the challenges motivated this research. It is my prayer that you never relapse and that all patients will be able to access the essential medicines needed for their medical conditions.



LIST OF ACRONYMS AND ABBREVIATIONS

ACHPR	African Charter on Humans and Peoples Right
AG	Attorney-General
AIDS	Acquired Immune Deficiency Syndrome
API	Active Pharmaceutical Ingredients
ARIPO	African Regional Intellectual Property Organisation
BIRPI	United International Bureau for the Protection of Intellectual Property
DCs	Developing Countries
EC	European Commission
ECOWAS	Economic Community of West African States
EPA	Economic Partnership Agreement
EPRC	Entrance Pharmaceuticals and Research Centre
FDA	Food and Drug Authority
FTA	Free Trade Agreements
GATT	General Agreement on Tariffs and Trade
GMP	Good Manufacturing Practice
GSK	GlaxoSmithKline
HIV	Human Immune deficiency Virus
ICCPR	International Covenant on Civil and Political Rights
ICESCR	International Covenant on Economic, Social and Cultural Rights
IPRs	Intellectual Property Rights
LDCs	Less Developed Countries
MFN	Most Favoured Nation
MOH	Ministry of Health
MRSCA	Medicines and Related Substances Control Amendment
NMIMR	Noguchi Memorial Institute for Medical Research
PCT	Patent Cooperation Treaty
PUC	Protection against Unfair Competition
R&D	Research and Development
RSCA	Medicines and Related Substances Control Amendment



SDG	Sustainable Development Goals
TRIPS	Trade-Related Aspects of Intellectual Property Rights
UDHR	Universal Declaration for Human Rights
UN	United Nations
US	United States
VAT	Value Added Tax
WHO	World Health Organisation
WIPO	World Intellectual Property Organisation
WTO	World Trade Organisation



ABSTRACT

Access to medicines is an essential component of the basic human right to health and a key determinant of the importance attached to the health care system of a country. It essentially entails the availability and acceptability of the essential medicines on the market and the ability of patients to afford such medicines when needed. Globally, countries face access to medicine challenges partly because of patents which undoubtedly accounts for excessive pricing of medicine. As such, efforts have been made to ensure the accessibility of medicines through the Trade-Related Aspects of Intellectual Property Rights (TRIPS) flexibilities of the World Trade Organisation (WTO). Beyond these interventions, it is incumbent on Members of the WTO to domesticate the flexibilities of the TRIPS Agreement before their utilisation because by their very nature, they cannot be self-executed.

With an estimated population of 29.6 million, about 310 000 people in Ghana are living with HIV. The country's health facilities record 40 per cent of outpatient visits each year and about 14 550 per 100 000 of the population are infected with tuberculosis with cancer on the rise. These diseases require medicines which are mostly patented yet Ghana has access to medicine problems despite the existence of a national health insurance system. Ghana has however not fully incorporated the TRIPS flexibilities in its national legislations and therefore unable to fully utilise the flexibilities as an option to access essential medicines. Questions therefore remain as to why and how Ghana can utilise the flexibilities to improve access to medicines.

Based on an examination of the WTO's patent system and legislations of Ghana, this mini-thesis contends that, the extent of incorporation of the flexibilities are inadequate due to the existence of lacunas in the Ghanaian legislations. Furthermore, a comparative assessment with South Africa supports an understanding that conditions are not ripe for full utilisation of all the flexibilities. It further argues that the utilisation of the TRIPS flexibilities by Ghana has been rendered ineffective due to administrative, political, economic and social challenges which adversely affects the full utilisation of the flexibilities incorporated and those yet to be incorporated. It is therefore important that Ghana adopts a holistic approach taking into consideration international best practices if the TRIPS flexibilities must be effectively utilised.

This mini-thesis concludes that, the TRIPS flexibilities are necessary for accessing essential medicines in Ghana to promote the right to health and that a review of Ghana's current legislations to fully incorporate the TRIPS flexibilities and addressing other non-legal challenges are the required linchpin for effective utilisation of the TRIPS flexibilities.

KEYWORDS

Access to medicines, Trade-Related Aspects of Intellectual Property Rights (TRIPS), TRIPS flexibilities, patents, compulsory licensing, parallel importation, bolar exception, evergreening, generic medicines, test data protection



“People can be killed by biological weapons and can be killed by no access to medicines; the results are the same.”

Aaron Motsoaledi

Minister of Health of South Africa

UNIVERSITY OF THE
WESTERN CAPE

CHAPTER ONE

INTRODUCTON

1.1 Research Background:

The right to health is a basic human right which is fundamental to the physical and mental health of all individuals and aids in the realisation of other basic human rights.¹ Recognising this right as vital to human existence, countries including Ghana, have commitments at the international, regional and national levels to ensure its attainment. At the international level, this right is recognised by treaties such as the Universal Declaration for Human Rights (UDHR),² the International Covenant on Civil and Political Rights (ICCPR)³ and the International Covenant on Economic, Social and Cultural Rights (ICESCR).⁴ These treaties set out measures which governments must adopt in order to provide good standards of living and progressively realise the health needs of their people. At the regional level, the African Charter on Humans and Peoples' Rights (ACHPR)⁵ recognises the right to health. In addition to the ACHPR, the Economic Community of West African States (ECOWAS), of which Ghana is a member, admonishes its members to attach importance to this right recognised under the Treaty of ECOWAS.⁶ Ghana, a signatory to the above treaties also imposes an obligation on the President, under the Directive Principles of State Policy,⁷ to report to Parliament on the steps taken to realise the basic right to health.⁸

A key component of evaluating the basic right to health is, access to medicines. Access to medicines refers to the continuous availability and affordability of medicines within the shortest possible time.⁹ This essential component of health is therefore shaped by both supply and demand factors such as distributing existing drugs, effectiveness of incentives to develop

¹ United Nations Committee on Economic, Social and Cultural Rights, *General Comment No. 14: The Right to the Highest Attainable Standard of Health* 11 August 2000 E/C.12/2000/4 paragraph 1 available at <https://www.refworld.org/docid/4538838d0.html> (accessed 8 August 2018).

²Article 25 UDHR (1948) G.A. Res. 217A (III), U.N. Doc. A/810 at 71 available at https://www.ohchr.org/EN/UDHR/Documents/UDHR_Translations/eng.pdf (accessed 18 October 2018).

³ Article 3 ICCPR (1967) 6 ILM 368.

⁴ Article 12 ICESCR (1967) 6 ILM 368.

⁵ Article 16 ACHPR (1982) 21 ILM 58.

⁶ Article 61(2) (d) Treaty of ECOWAS (1993) 35 ILM 660.

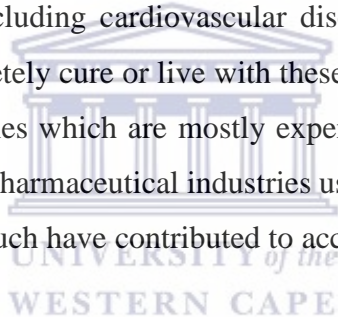
⁷ The Directive Principles of State Policy urges the entire nation from the President to the citizens to make conscious efforts to ensure the realisation of the basic human rights enshrined in the constitution. See Constitution of the Republic of Ghana, 1992 chapter 6.

⁸ Article 25 Constitution of the Republic of Ghana, 1992.

⁹ United Nations Development Group *Indicators for Monitoring the Millennium Development Goals* (2003) 89.

new drugs, income levels, financing and prices.¹⁰ Thus to enjoy the basic right to health, factors such as receiving appropriate medications, the ability to afford these medications, the ability to pay for treatment when needed as well as an effective and efficient system to supply health needs are essential. In the case of *Minister for Health and others v Treatment Action Campaign*,¹¹ where the government failed to make the medicine ‘Nevirapine’ accessible to all pregnant women, the Constitutional Court of South Africa held that, the right to health entails making provisions to progressively realise this basic right and includes making ‘Nevirapine’ accessible to everyone. This case is of persuasive effect to other countries within the African sub-region as it imposes an obligation on governments to attach importance to the basic right to health and its components.

Despite it being an essential component of the right to health, access to essential medicines¹² has been a matter of concern as it remains a challenge in most developing countries (DCs), including Ghana.¹³ The people of these countries suffer from diseases such as tuberculosis, malaria, human immune deficiency virus/acquired immune deficiency syndrome (HIV/AIDS) and other terminal diseases including cardiovascular disease, cancer, diabetes or chronic respiratory disease.¹⁴ To completely cure or live with these diseases require effective health-care delivery including medicines which are mostly expensive and may not be covered by medical aid. Unfortunately the pharmaceutical industries use patents¹⁵ which tend to increase the prices of medicines and as such have contributed to access to medicines challenges.¹⁶



¹⁰ Maskus KE ‘Ensuring Access to Essential Medicines: Some Economic Considerations’ (2001-2002) 20(3) *Wisconsin International Law Journal* 565.

¹¹ 2002 (5) SA 721 para 94 & 95.

¹² Essential medicines are medicines that satisfy the health care needs of the majority of the population. See WHO ‘Essential Medicines’ available at https://www.who.int/topics/essential_medicines/en/ (accessed 15 October 2018).

¹³ Lee J & Hunt P ‘Human Rights Responsibilities of Pharmaceutical Companies in Relation to Access to Medicines’ 2012 *Journal of Law, Medicine & Ethics* 220.

¹⁴ United Nations *Sustainable Development Goals Report* (2017) available at <https://unstats.un.org/sdgs/files/report/2017/the-sustainable-development-goals-report-2017.pdf> (accessed 29 August 2018) (hereinafter *SDG Report 2017*).

¹⁵ A patent is an exclusive right granted for an invention after the technical information of it has been disclosed which provides a new way of doing something or offers a new technical solution to a problem. See WIPO ‘Patents’ available at <http://www.wipo.int/patents/en/> (accessed 29 August 2018).

¹⁶ Saxlin-Hautamaki E ‘Establishing Coherence: The Right to Access to Medicines, Pharmaceutical Patents and the WTO Medicines Decision’ 2010 *Nordic Journal of Commercial Law* 2.

The United Nations (UN), recognising the challenges associated with accessing essential medicines, places emphasis in its Sustainable Development Goals (SDGs),¹⁷ on the need to ensure universal access to ‘safe, effective, quality and affordable medicines and vaccines’.¹⁸ Goal number three of the 2017 SDG Report, particularly aims at providing health-care in poor countries to reduce child mortality, improve maternal health and fight HIV/AIDS, tuberculosis, malaria and other diseases.¹⁹ According to the Report, between the year 2000 and 2015, the global maternal mortality rate declined by 37 per cent and the under-five mortality rate declined by 44 per cent. The same period saw a 46 per cent reduction in HIV/AIDS, 17 per cent in tuberculosis and 41 per cent decrease in incidence of malaria.²⁰ More HIV positive people are able to live longer due to the increased use of antiretroviral drugs and between the year 2000 and 2015, the prevalence of HIV among children under 18 declined by 72 per cent due to the rapid expansion in access to the aforementioned medicines which prevented mother-to-child transfers.²¹ Undoubtedly, access to medicines from the above statistics, has been a key factor contributing to the reduction in the mortality rates of various countries. Despite this realisation, access to medicines still remains a problem in most countries with its attendant social costs.

Access to medicines concerns have therefore received much attention worldwide over the years and since the year 1995, the multilateral Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)²² has been instrumental in addressing intellectual property rights (IPRs) issues including those related to patents. The TRIPS Agreement, as part of its objectives aims at finding an optimal balance between the right to health on the one hand, and the right to protect patentees²³ and innovation on the other hand.²⁴ In order to find this balance, the Agreement has gone through several phases and has been amended to reflect

¹⁷ The Sustainable Development Goals are schemes or guidelines geared towards achieving a better and more sustainable future for all by addressing the global challenges relating to social, economic and environmental aspect of development. See Szpak A ‘International Solidarity as the Basis for Millennium/Sustainable Development Goals’ (2017) 26 *Polish Quarterly of International Affairs* 120.

¹⁸ SDG Report (2017) 4.

¹⁹ SDG Report (2017) 4.

²⁰ SDG Report (2017) 4.

²¹ SDG Report (2017) 21.

²² (1994) 33 ILM 1197 as amended (hereinafter TRIPS Agreement).

²³ A person to whom a patent has been granted; who appears on the official government registry as the patent owner See Duhaime's Law Dictionary available at <http://www.duhaime.org/LegalDictionary/P/Patentee.aspx> (accessed 16 August 2018).

²⁴ World Intellectual Property Organization (WIPO) ‘Public health and Patents’ available at <http://www.wipo.int/patent-law/en/developments/publichealth.html> (accessed 16 August 2018).

the competing interests so as to improve access to medicines challenges which countries may face.

As a result of complaints to medicine access issues, such as the excessive pricing of essential medicines, flexibilities including compulsory license and parallel importation were included in the TRIPS Agreement as safeguards pursuant to which Members of the World Trade Organisation (WTO) (hereinafter Members), can employ to improve their access challenges. The use of these flexibilities is however not a carte blanche but subject to Members incorporating or domesticating the flexibilities in their national legislations before their utilisation can be triggered.²⁵ This requirement is in accordance with the single undertaken²⁶ practice of the WTO which makes it mandatory for its Members to incorporate the IPRs rules into their national legislations with some special and differential treatment for DCs and least-developed countries (LDCs).²⁷ Thus Members are given the opportunity to legislate in a manner which aids in accessing affordable essential medicines while complying with the TRIPS Agreement and fostering innovation. Notwithstanding the deference of the implementation of the TRIPS Agreement to Member states, disparities in resources, however, places limitations on how the TRIPS flexibilities can be utilised by DCs and LDCs.²⁸

Owing to the disparities in resources, the WTO adopted the joint Declaration on the Agreement on TRIPS and Public Health (Doha Declaration)²⁹ on 14 November 2001 at a Ministerial Conference in Doha. This was due to complaints by DCs that developed countries were using narrow approaches to interpreting the TRIPS Agreement. To resolve this, the Declaration affirmed the right of Members to interpret and implement the Agreement to protect public health and in particular, access to medicines.³⁰ Although the Declaration broke

²⁵ Article 1(1) TRIPS Agreement.

²⁶ By this concept virtually every item agreed as part of the WTO negotiation is part of a whole and indivisible package and cannot be agreed separately and for that reason all countries are bound by it. See Wolfe R 'The WTO Single Undertaking as Negotiating Technique and Constitutive Metaphor' (2009) 12(4) *Journal of International Economic Law* available at <https://academic-oup-com.ezproxy.uwc.ac.za/jiel/article/12/4/835/2193545> (accessed 13 October 2018).

²⁷ Article 65 TRIPS Agreement.

²⁸ Musungu SF *The Right to Health in the Global Economy: Reading Human Rights Obligations in to the Patent Regime of the WTO - TRIPS Agreement* (unpublished LLM thesis, Makerere University, 2001) 10 available at https://repository.up.ac.za/bitstream/handle/2263/931/musungu_sf_1.pdf;sequence=1 (accessed 5 August 2018).

²⁹ WTO Ministerial Declaration of 14 November 2001 WTO Doc. WT/MIN (01)/DEC/1 (2002) 41 ILM 746 available at https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm (accessed 16 July 2018) (hereinafter Doha Declaration).

³⁰ Paragraph 4 Doha Declaration.

new grounds in guaranteeing access to medicines, it did not resolve all the challenges allied with public health.³¹ This led to further debates to address the major health problems facing DCs and LDCs such as insufficient manufacturing capacities. The Ministerial Council was therefore charged with finding a solution to the challenges of countries with insufficient manufacturing capacities or no manufacturing capacities at all before the end of 2002.³²

On 30 August 2003 a temporal decision was reached to enable countries with production capacities to export to LDCs and for countries to import subject to certain conditions especially for DCs.³³ A permanent amendment was subsequently made in 2005 to implement the August 2003 Decision (2005 Amendment).³⁴ The 2005 Amendment however entered into force on 23 January 2017 after two-thirds of Members deposited their instruments of ratification, paving the way for the export and import of medicines to countries unable to manufacture them as well as those with insufficient manufacturing capacities. Members yet to sign the Amendment have up to December 2019 to do so, and as such, the August 2003 Decision can still be invoked to export or import patented medicines.³⁵

It is obvious that countries including Ghana have numerous right-to-health obligations at the national, regional and international levels to ensure the right to health, thereby justifying the utilisation of the TRIPS Agreement flexibilities as an option to improve access to medicines. The patent system undoubtedly has advanced innovativeness and resulted in the development of essential medicines for treatment of emerging diseases through research and development. The WTO patent system, despite existing challenges strives to find a balance between the patentees and users through its flexibilities in the TRIPS Agreement. Unfortunately, despite the reduction of incidents pertaining to the availability of medications, the rate of new infection remains high, with emerging diseases and outbreaks, which require essential medicines, on the rise.

The full enjoyment of the right to health still remains a problem as many DCs do not meet the requirements for using the flexibilities. As such, the flexibilities cannot be utilised without

³¹ Hoen E 'TRIPS, Pharmaceutical Patents, and Access to Essential Medicines: A Long Way from Seattle to Doha' (2002) 3(1) *Chicago Journal of International Law* 28.

³² Paragraph 6 Doha Declaration.

³³ WTO Decision of the General Council of 30 August 2003 WT/L/540 available at https://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm (accessed 17 July 2018).

³⁴ WTO Protocol Amending the TRIPS Agreement WT/L/641 available at https://www.wto.org/english/tratop_e/trips_e/wt641_e.htm (accessed 17 July 2018).

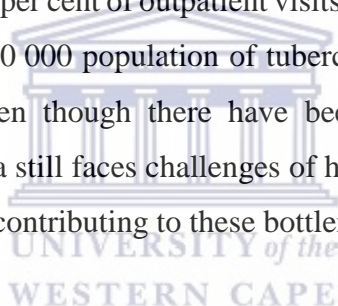
³⁵ WTO 'How to accept the Protocol Amending the TRIPS Agreement' available at https://www.wto.org/english/tratop_e/trips_e/accept_e.htm (accessed 16 June 2018).

facing challenges from patentees. Members of the WTO which have legislated the flexibilities also do not utilise them and questions remains as to why this is so. This may serve as a disincentive for countries yet to legislate and apply such legislation to actually do so.

1.2 Problem Statement

Ghana is a country located in the western part of Africa with a population estimated at 29.6 million people.³⁶ As a DC,³⁷ it has been a member of the WTO since 1 January 1995 and a member of the General Agreement on Trade and Tariffs (GATT) since 17 October 1957.³⁸ By virtue of the single undertaken practice of the WTO, Ghana has obligations to use the TRIPS flexibilities to address its public health needs.

The last three decades (1990-present) have however witnessed unprecedented sufferings and deaths as a result of diseases such as tuberculosis, malaria and HIV/AIDS in Ghana with terminal diseases such as cancer on the rise. An estimated 310 000 (260 000 - 370 000) people in Ghana are living with HIV.³⁹ With the whole population susceptible to malaria, this endemic disease accounts for 40 per cent of outpatient visits in the country's health facilities.⁴⁰ In the year 2017, 14 550 per 100 000 population of tuberculosis infection were detected by Ghana's health facilities.⁴¹ Even though there have been a significant improvement in healthcare over the years, Ghana still faces challenges of high mortality rate with low access to essential patented medicines contributing to these bottlenecks.⁴²



³⁶ Citifmonline Ghana 'Ghana's population hits 29.6m – Statistical Service' <http://citifmonline.com/2018/03/12/ghanas-population-hits-29-6m-statistical-service/> (accessed 16 June 2018).

³⁷ Following the discovery and subsequent exploration of petroleum oil, 'Ghana experienced impressive economic growth and social development which succeeded in halving the level of extreme poverty and placing Ghana in the group of medium income developing countries'. See WTO 'Trade Policy Review: Ghana' available at https://www.wto.org/english/tratop_e/tpr_e/tp398_crc_e.htm (accessed 16 June 2018).

³⁸ WTO 'Ghana and the WTO' available at https://www.wto.org/english/thewto_e/countries_e/ghana_e.htm (accessed 28 June 2018).

³⁹ UNAIDS 'Country Fact Sheet 2017' available at <http://www.unaids.org/en/regionscountries/countries/ghana> (accessed 28 June 2018).

⁴⁰ Ameme DK, Afari EA & Nyarko KM et al 'Direct observation of outpatient management of malaria in a rural Ghanaian district' (2014) *Pan Afr Medical Journal* 1 available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4407949/> (accessed 28 June 18).

⁴¹ WHO 'Tuberculosis country profile Ghana' available at https://extranet.who.int/sree/Reports?op=Replet&name=/WHO_HQ_Reports/G2/PROD/EXT/TBCountryProfile&ISO2=GH&outtype=pdf (accessed 28 June 18).

⁴² Cohen JC, Gyansa-Lutterodt M & Torpey K et al 'TRIPS, the Doha Declaration and increasing access to medicines: policy options for Ghana' (2005) 1:17 *Globalization and Health* available at <https://doi.org/10.1186/1744-8603-1-17> (accessed 28 June 18).

Ghana's pharmaceutical policy, therefore aims at ensuring that, there are high quality medicines on the market, that there is in existence an efficient supply chain and that there is rational use of medicines by professionals and patients.⁴³ For this reason, pharmaceuticals are available in many health facilities across the country, however, access is largely limited.

The role of adequate legislation in resolving challenges such as access to medicines cannot be underestimated, especially with the WTO's patent regime, which provides an option to access patented medicines through its flexibilities. The burden, to some extent now lies with Ghana to ensure that adequate legislations incorporating the flexibilities are put in place. This, however, seems not to be the case as less impact has been made at the national level because of challenges including limitation on domestic legislations and other challenges such as TRIPS-plus provisions.⁴⁴ Thus the limitations of domestic legislations and other challenges such as infrastructural capacities have contributed to most DCs including Ghana either not utilising the flexibilities allowed by the TRIPS Agreement or partially utilising them.⁴⁵

Ghana, as part of its efforts to improve access to essential patented medicines and recognising the role of law in this, amended its patents legislation in 2003 to incorporate some flexibilities such as compulsory license and parallel importation.⁴⁶ This notwithstanding, other flexibilities such as the bolar exception are yet to be incorporated. Thus Ghana is not eligible to fully tap into these flexibilities as a means of solving its access to medicines challenges. Ghana has also not signed the Protocol amending the TRIPS Agreement though it has only up to the year 2019 to do so.

From the above, it can be argued that, the complaints of patents as a barrier to improving access to medicines, to some extent, has been resolved by the international patent regime through the flexibilities provided. The incorporation of these flexibilities into the legislative framework of Ghana has only been partially done which may have short-changed the options that could be explored by the country to improve its access to medicines challenges.

⁴³ Seiter A & Martha Gyansa-Lutterodt M 'Policy Note: The Pharmaceutical Sector in Ghana' (2009) 2 available at https://www.researchgate.net/publication/242688773_Policy_Note_The_Pharmaceutical_Sector_in_Ghana (accessed 28 June 2018).

⁴⁴ Baker B 'Processes and issues for improving access to medicines: Willingness and ability to utilise TRIPS flexibilities in non-producing countries' (2004) 19 available at https://www.iprsonline.org/resources/docs/Baker_TRIPS_Flex.pdf (accessed 2 July 2018).

⁴⁵ Correa CM 'Implication of the Doha Declaration on the TRIPS Agreement and Public Health' (2002) 12 *Health Economic and Drugs EDM 18* available at <http://apps.who.int/medicinedocs/pdf/s2301e/s2301e.pdf> (accessed 2 July 2012).

⁴⁶ Patents Act 657 of 2003.

Furthermore, the flexibilities incorporated into the legislations are impeded by challenges which hinder their effective utilisation. Ghana, therefore, denies itself the opportunity to use the flexibilities as an option to help address its access to medicines challenges. The result is that, the same channels will be relied on to access medicines and mortality rates may remain the same.

1.3 Research questions

The main research question to be answered against the background and problem statement set out above is: how can Ghana effectively utilise the TRIPS flexibilities to help improve access to essential patented medicines?

In addressing the main research question, the following sub questions will be answered:

- 1.1.1 What are the flexibilities provided under the WTO's patent regime which can be used to improve access to essential patented medicines?
- 1.1.2 What are the current national legislative frameworks put in place by Ghana to help utilise the flexibilities and what is the extent of incorporation and utilisation of these flexibilities by Ghana in comparison with that of South Africa?
- 1.1.3 What challenges does Ghana face in utilising the flexibilities incorporated in its current national legislations and what challenges does it face in incorporating other flexibilities provided by the TRIPS Agreement?
- 1.1.4 What recommendations can be made to ensure that Ghana fully utilise the TRIPS flexibilities to improve access to medicines?

1.4 Significance of the Research

Once there is life, human beings will always be susceptible to diseases which will require access to medicines for cure or sustenance. The issue of access to medicines, therefore should be of much importance to Ghana. As was succinctly put by Nnamuchi:

‘to contend that an individual possesses the right to life in the absence of the ingredients necessary for its sustenance (such as health care) is, on many levels, vacuous. Enjoyment of the right to health is not only vital to all aspects of a person's life and well-being, it is also crucial to the actualization of all the other fundamental rights and freedoms.’⁴⁷

⁴⁷ Nnamuchi O ‘Kleptocracy and Its Many Faces: The Challenges of Justiciability of the Right to Health Care in Nigeria’ 2008 *Journal of African Law* 10.

As such, placing priority on the mechanisms for facilitating access to medicines to improve health can help improve the productive capacity of countries including Ghana as mortality rates will be reduced.⁴⁸

This research is also significant in the sense that, as by examining the WTO's patent regime, it will enlighten Ghana's authorities and pharmaceutical industries about the options available to them in terms of mitigating the access to medicine challenges the country faces. This will help Ghana comply with its international obligations within the WTO to avoid any protracted legal battles in utilising the flexibilities. Examining the flexibilities will thus provide an understanding of which flexibility can be best utilised and at what point in time with the necessary justifications and the medicines that are involved. This is particularly important as there has been a general misconception which seems to suggest that the flexibilities are only for certain patented medicines and diseases.⁴⁹

A focus on and examination of the current legislative framework of Ghana and that of South Africa will help determine whether the extent of incorporation of the TRIPS flexibilities is adequate. Considering the role that laws play in addressing challenges in a country, an examination of the legislations will help unravel the limitations, gaps and implications with respect to the flexibilities that are yet to be domesticated. This will help inform appropriate reforms in the future. Though addressing the gaps and implementing the laws does not absolutely solve the problem, they are stepping stones toward facilitating access to help reduce mortality rates. Additionally, the identification of challenges which goes beyond the legal gaps and impede the utilisation of the flexibilities will help to improve access to medicines.

Lastly, this research hopes to influence stakeholders on effectively finding ways of increasing access to essential medicines by the use of the TRIPS flexibilities as options to promote the right to health in Ghana by the recommendations which will be made following the discovery of the existing legal gaps coupled with the challenges that we now face.

1.5 Methodology

The research questions have been answered through a desktop-based research conducted mainly through a review of the available literature related to the topic. The internet was of

⁴⁸ Sen A *Development as Freedom* (1999) 3.

⁴⁹ Outterson K 'Should Access to Medicines and TRIPS Flexibilities Be Limited to Specific Diseases?' 2008 *American Journal of Law & medicine* 280-1.

much use as a source, especially websites of international organisations for purposes of accurate statistics that were necessary for this research.

Both primary and secondary sources, therefore were used. Primary resources included legal instruments, such as international legal instruments that speak to patents and access to medicine especially the TRIPS Agreement. A comparative analysis was done between Ghana and South Africa on the extent of incorporation of the flexibilities and therefore, the domestic legislations of both countries were resorted to. South Africa was selected for this research considering the fact that it has been the pacesetter concerning access to medicines in Africa exposing the treachery of pharmaceutical industries. The judicial decisions of some countries and cases of the WTO were also used. Secondary sources included books, journal articles, papers, reports and other scholarly materials relating to the TRIPS Agreement and access to medicine particularly in the context of DCs.

The reliance on primary and secondary sources was informed by the nature of the research and the vast literature available in relation to the research topic.

1.6 Chapter outline

The research is divided into five chapters with each chapter focusing on a specific portion of the research topic.

Chapter One

Chapter one introduces the research with a discussion of the background and the research problem. It further formulates research questions needed to answer the problem statement. The significance of the research and methodology adopted for this research are also discussed.

Chapter Two

This chapter examines the WTO's patent regime and access to medicines. It further discusses the historical antecedents to the TRIPS Agreement, the TRIPS Agreement and its key principles as well as an analysis of patents and access to medicines. The chapter identifies and examines the flexibilities under the TRIPS Agreement which seek to promote access to medicines.

Chapter Three

Chapter three examines Ghana's current legislative framework for patent protection and the extent of incorporation of the TRIPS flexibilities in the legislations in comparison with that of South Africa. This unravels whether or not conditions are ripe for the effective utilisation of the flexibilities in Ghana.

Chapter Four

This chapter focuses on the challenges faced by Ghana in utilising the WTO flexibilities already incorporated into its legislation and the reasons and challenges in incorporating the others and utilising them. Also discussed are the possible reasons and implications, for Ghana, of not signing and ratifying the TRIPS Amendment.

Chapter Five

This chapter concludes the research and makes recommendations based on the findings of the research.



CHAPTER TWO

THE WORLD TRADE ORGANISATION'S PATENT REGIME AND ACCESS TO MEDICINES

2.1 Introduction

Patent protection has become the spotlight of conflict between the 'private interests and profit motives of pharmaceutical companies' and 'public health and social impact concerns of governments'.⁵⁰ Some argue⁵¹ that patents foster innovation because, if considerable resources are spent on inventing new medicines without reimbursement, patentees will not be motivated to innovate.⁵² Others counter that, pharmaceuticals use patents to protect minor improvement which impedes access to medicines with much public funds accruing to their benefit.⁵³ Be that as it may, the World Trade Organisation's (WTO's) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)⁵⁴ is a global nexus for medicine access issues and aims at balancing these competing interest for sustainable development.⁵⁵

This chapter therefore examines the WTO's patent regime and access to medicines. It focuses on the historical antecedents to the TRIPS Agreement, its key principles and the relationship between access to medicines and intellectual property rights (IPRs). Also to be examined are the flexibilities in the TRIPS Agreement which seek to promote access to medicines, their legal basis as well as their conditions for utilisation. This is aimed at answering the question, 'What are the flexibilities provided under the WTO's patent regime which can be used to improve access to essential patented medicines?'⁵⁶

2.2 The Trade-Related Aspects of Intellectual Property Agreement

The TRIPS Agreement is the main international legal instrument currently governing IPRs under which patents fall. In discussing the patent regime of the WTO, it is important

⁵⁰ Opati LM 'Intellectual property rights in health-Impact on access to drugs' in Wekesa M and Sihanya B (eds) *Intellectual property rights in Kenya* (2009) 13- 38 21.

⁵¹ Opati LM in Wekesa M and Sihanya B (2009) 21.

⁵² Trebilcock MJ 'Economic Analysis of Law' in Devlin RF (ed) *Canadian Perspectives on Legal Theory* (1991) 111.

⁵³ Opati LM in Wekesa M and Sihanya B (2009) 22.

⁵⁴ (1994) 33 ILM 1197 (hereinafter TRIPS Agreement).

⁵⁵ Outterson K 'Pharmaceutical Arbitrage: Balancing Access and Innovation in International Prescription Drug Markets' (2005) 5 *Yale Journal of Health Policy Law and Ethics* 193.

⁵⁶ See Section 1.3 above.

understand the historical antecedents of the TRIPS Agreement, its key principles and features and how far the Agreement has come to support access to medicines issues.

2.2.1 The historical antecedents

The development of a system for IPRs protection dates back to the 19th century following the surge in globalisation leading to the emergence of bilateral and multilateral treaties.⁵⁷ This period saw the emergence of treaties, notable among them, the Paris Convention for the Protection of Industrial Property⁵⁸ and the Berne Convention for the Protection of Literary and Artistic Works.⁵⁹ The Paris convention in its article 2(1) defines its scope to apply among others, to inventions, trademarks and industrial designs.⁶⁰ The Berne Convention on the other hand, deals with copyright protection.⁶¹ The United International Bureau for the Protection of Intellectual Property (BIRPI) was subsequently created to administer the aforementioned treaties.⁶² The administrative work was however handed over to the World Intellectual Property Organisation (WIPO), a United Nations (UN) agency established in 1970.⁶³

The countries in the global north, during the cold war era, however faced problems of trade distortions in the IPRs field. They were frustrated by the fact that most developing countries (DCs) had failed to join WIPO and therefore had no obligation to incorporate IPRs in their legislation.⁶⁴ In addition, they complained that WIPO was not ideal to protect their interest due to the lack of effective protection for IPRs in new fields, the lack of substantive standards and an effective enforcement mechanism.⁶⁵

To address these problems, developed countries considered a change in IPRs negotiations from WIPO to multilateral trade negotiation. The United States (US) and the European Commission (EC) responded by recommending that IPRs be made a topic under the General

⁵⁷ Aplin T & Davies J *Intellectual Property: text, cases and materials* 2 ed (2013) 24.

⁵⁸ (1883) 828 UNTS 305.

⁵⁹ (1886) 1161 UNTS 3.

⁶⁰ A trademark is a symbol, word, device, name, design or combination of any of these which distinguishes the goods and services of the owner from others. See Bird RC & Jain SC *The Global Challenge of Intellectual Property Rights* (2008) 5. An industrial design constitutes the ornamental or aesthetic aspect of an article. See WIPO 'Industrial Designs' available at <http://www.wipo.int/designs/en/> (accessed 15 August 2018).

⁶¹ A copyright is a legal right over a material which guarantees its creator to use it to the exclusion of all others. See Darkey EM & Akussah H 'Academic Libraries and Copyright Issues in Ghana: University of Ghana in Focus' (2009) 36 *International Journal of Legal Information* 434.

⁶² Aplin T & Davies J (2013) 25.

⁶³ Aplin T & Davies J (2013) 25.

⁶⁴ Brewster R 'The Surprising Benefits to Developing Countries of Linking International Trade and Intellectual Property' (2011) 12(1) *Chicago Journal of International Law* 9.

⁶⁵ Brewster R (2011) 10.

Agreement on Tariffs and Trade (GATT) which was aimed at establishing a post-cold war world system for trading through rounds of negotiations.⁶⁶ The GATT platform gave greater leverage for the US and EC to negotiate because of their large domestic markets and the outcome of the negotiations was preferred to WIPO's protection due to the GATT's ability to create a nexus between IPRs and other issues within the GATT, in addition to a more effective way of settling disputes.⁶⁷ At the Uruguay round of negotiations, the WTO was established and the TRIPS Agreement was adopted as a multilateral agreement to deal with IPRs.⁶⁸

2.2.2 Key principles and features

The TRIPS Agreement came into force on 1 January 1995 and it is to date known to be the most 'comprehensive multilateral agreement' on IPRs because it covers most types of IPRs including patents.⁶⁹ It also incorporates its predecessor treaties⁷⁰ and imposes an obligation on WTO Members (hereinafter Members) to comply with existing obligations provided under these predecessor treaties.⁷¹ Thus the Agreement does not operate in isolation but complements the existing treaties on IPRs.

The protection of IPRs has been established with definite principles reinforced by the TRIPS Agreement. The main principles and features of the Agreement for the purpose of this research are minimum standards, rights conferred, non-discrimination principles, enforcement and dispute settlement. These key principles and features discussed below, are necessary for this research because they generally serve as a guide to Members in the application of the IPRs provided under the TRIPS Agreement and more importantly in the application of patents to help improve access to medicines.

i. Standards

The TRIPS Agreement sets minimum standards for IPRs protection otherwise referred to as the '*substantive minima*'.⁷² In accordance with article 1 of the Agreement, all Members are obliged to give effect to its provisions by enacting appropriate legislations. As such it is

⁶⁶ Gunaratne C *Genetic resources, Equity and International Law* (2012) 142.

⁶⁷ Helfer LR 'Regime Shifting: The TRIPs Agreement and New Dynamics of International Intellectual Property Law making' (2004) 29 *Yale Journal of International Law* 21-22.

⁶⁸ Final Act embodying the results of the Uruguay round of Multilateral Trade Negotiations (1994) 33 ILM 1125.

⁶⁹ Correa CM *Intellectual Property Rights, the WTO and Developing Countries: The TRIPS Agreement and Policy Options* (2000)1.

⁷⁰ See 2.2.1 above.

⁷¹ Article 2 TRIPS Agreement.

⁷² Dinwoodie GB 'The Architecture of the International Intellectual Property System' (2002) 77 *Chicago Kent law Review* 994.

binding on Members to ensure that their legislations meet the minimum threshold required by the TRIPS Agreement. Thus Members have the freedom to confer protection beyond the minimum standard while respecting the principles of the Agreement. The minimum standard is necessary to help improve access to medicines because, it ensures certainty and predictability and enables Members to legislate in a broader manner and take advantage to access medicines without any legal ramification.

ii. Rights conferred

The Agreement prescribes exclusive rights which Members are obliged to confer unto patentees with regard to their products and processes qualifying for patent protection.⁷³ This is important because an exclusive right enables pharmaceutical industries recuperate the cost involved in inventing, further research on the invention and to make profits. This right is however not absolute as it is, subject to exhaustion of IPRs.⁷⁴ The exclusive right however cannot end before 20 years from the date of filing of the patent.⁷⁵

This conferred right is important because, it helps in determining when a patent exploitation to improve access to medicine can be dubbed an infringement.

iii. Non-discrimination principles

The TRIPS Agreement also recognises the principles of national treatment and most favoured nation (MFN) with some differences due to the intangible and territorial nature of IPRs.⁷⁶

The national treatment principle, imposes an obligation on each Member in protecting IPRs, to accord equal treatment to its nationals and nationals of other Member states subject to the Paris and Berne Conventions.⁷⁷ This principle under article 3 of the Agreement has been recognised by the Appellate body in *US –Section 211 Appropriation Act*⁷⁸ as not only a foundation to the development of the Paris and Berne Convention but also a keystone to the global trading system.⁷⁹

⁷³ Article 28 TRIPS Agreement.

⁷⁴ Article 6 TRIPS Agreement.

⁷⁵ Article 33 TRIPS Agreement.

⁷⁶ Van der Bossche P & Werner Z *The Law and Policy of the World Trade Organization; Text, cases and Materials* 4 ed (2017) 1003.

⁷⁷ Article 3 TRIPS Agreement.

⁷⁸ WT/DS176/AB/R (2002).

⁷⁹ WT/DS176/AB/R (2002) para 241-2.

The MFN principle on the other hand, require Members to extend equal advantage or favour granted any state ‘immediately and unconditionally’ to all Member states.⁸⁰ This implies equal treatment ‘but to that *other* party which is most favoured’.⁸¹ The TRIPS Agreement was the first IPRs treaty to introduce this principle and its importance was emphasised by the Appellate body of the WTO in *US –Section 211 Appropriation Act* as not just new, but fundamental to the IPRs system.⁸²

The above principles give hope to especially foreign pharmaceutical companies operating in other Member states because, there is an assurance of fair treatment of all pharmaceutical companies. Guided by this principle, the fair treatment may attract more foreign pharmaceutical investors to support the local producers and help advance access to essential medicines especially for countries with little or no manufacturing capacities.

iv. Enforcement

The enforcement procedures under the Agreement seek to contribute to technological advancement and balancing rights and obligations.⁸³ The panel report in *China-Intellectual Property Rights*⁸⁴ observed that the concept of enforcement procedures used in the TRIPS Agreement is wide.⁸⁵ This is because it contains provisions on civil and criminal procedures, and remedies among others, enabling right holders to effectively enforce their rights.⁸⁶ The enforcement mechanisms ensures adherence to conditions governing the use of the WTO’s patent regime to access medicines and serves as a deterrent to Members.

v. Dispute settlement

The seeming significance of IPRs in trade and the obscurity of balancing interests makes conflict over IPRs protection practically inevitable.⁸⁷ The interpretation and implementation of the TRIPS Agreement therefore requires clear provisions on dispute resolution. As such the TRIPS Agreement subjects disputes to the WTO's dispute settlement procedure.⁸⁸ The

⁸⁰ Article 4 TRIPS Agreement.

⁸¹ Jackson J *The World Trading System, Law and Policy of International Economic Relations* (1997) 133.

⁸² WT/DS176/AB/R (2002) para 297.

⁸³ Article 7 TRIPS Agreement.

⁸⁴ WT/DS362/15 (2010)

⁸⁵ WT/DS362/15 (2010) para 7.

⁸⁶ Part 3 TRIPS Agreement.

⁸⁷ Taubman A ‘Rethinking TRIPS: ‘Adequate Remuneration’ for Non-voluntary Patent Licensing’ (2014) 11(4) *Journal of International Economic Law* 929.

⁸⁸ India - Patent Protection for Pharmaceutical and Agricultural Chemical Products WT/DS50/AB/R (1997) para 29.

procedure adopted by the Dispute Settlement Body of the WTO instils confidence in its Members and ensures that, the exploitation of patents without adhering to the conditions, will be fairly resolved by the WTO to protect both patentees and users.

From the above, it can be observed that the TRIPS Agreement and its guiding principles shape the IPRs system and more importantly patents. Having discussed the historical antecedent of the TRIPS Agreement and its guiding principles, the next section will examine the TRIPS Agreement and Public health with specific reference to the relationship between access to medicines as a human right and IPRs.

2.3 Intellectual property rights and Public health

The TRIPS Agreement as indicated above does not only protect right holders but carefully strikes a balance between the patentees and users of the right. For the WTO's patent system to be finding an optimal balance between patentees and the users with regards to public health, there must exist a relation between access to medicines and IPRs. Therefore the relationship between access to medicines and IPRs will be examined in the next section to determine IPRs' impact on access to medicines.

2.3.1 Relationship between access to medicines and intellectual property rights

Human rights and IPRs are often considered as two distinct areas of law. The latter seeks to incentivise the creativeness of people and as such the right is not permanent but temporal which can be 'revoked, licensed or assigned' to another person while human rights are permanent and inherent and therefore 'fundamental, inalienable and universal entitlements' to individuals or groups.⁸⁹

Despite the differences in the nature, basis and operation of these two rights, the two rights have successfully coexisted culminating into the emergence of two approaches as to how a good interface can be created between them.⁹⁰ The first approach sees the interface created by human rights and IPRs as conflicting because strong IPR protection undermines and impedes the enjoyment of human rights while the second approach sees the two rights as

⁸⁹ UN Committee on Economic, Social and Cultural Rights (CESCR) *General Comment No. 17: 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* (12 January 2006) E/C.12/GC/17 Para 1 available at: <https://www.refworld.org/docid/441543594.html> (accessed 9 July 2018).

⁹⁰ Helfer LR 'Human rights and intellectual property: conflict or co-existence?' (2003) 5 *Minnesota Intellectual Property Review* 47.

compatible as the rights encourage inventions and incentivise inventors.⁹¹ It is important to note that striking the balance between inventors and users has always been difficult.

One area of connection between human rights and IPRs relates to the TRIPS Agreement.⁹² Attention was given to the TRIPS Agreement by the UN Human Rights Systems which then adopted Resolution 2000/7 in the year 2000 when the transition period of DCs was expiring.⁹³ The Resolution identified the existence of ‘actual or potential conflicts’ between TRIPS and the realisation of human rights in a wide spectrum of factors.⁹⁴ With regard to the right to health, this relationship is seen between patents and access to medicines, especially HIV/AIDS medicines which are mostly patented.⁹⁵

To address these conflicts, the Sub-Commission on Protection and Promotion of Human Rights of the UN which was tasked to set out a new agenda to review IPRs and to give it primacy delivered its task through resolutions and reports. The UN special rapporteur, argued that IPR protection has undermined human rights objectives and in establishing a relationship between the two rights under consideration, observed as follows:

‘a product patent enables a patentee to set high prices. Higher standard of patent protection, which can reduce the number of easily granted patents, can facilitate competition and lower the prices of medicines. Lower standards of patent protection, however, which can increase the number of easily granted patents can lead to higher prices. Generic competition in the field of pharmaceuticals therefore has the potential to significantly lower prices and increase access.’⁹⁶

From the above, patents have direct impacts on access to medicines because they have the potential to improve access by providing incentives for creativity especially for novel diseases as well as restrict access because of higher prices. This confirms a relationship between the two rights and the fact that patents are real barriers to access medicines, the

⁹¹ Helfer LR (2003) 48.

⁹² Helfer LR (2003) 54.

⁹³ Reichman JH ‘The TRIPS Agreement Comes of Age: Conflict or Cooperation with the Developing Countries?’ (2000)32 *Case Western Reserve J Int’l L* 441.

⁹⁴ The Sub-Commission on the Promotion and Protection of Human Rights 52nd Session *Intellectual Property Rights and Human Rights*, Res. 2000/7 Doc. E/CN.4/Sub.2/RES/2000/7 preamble 11 available at http://ap.ohchr.org/documents/alldocs.aspx?doc_id=8200 (accessed 17 September).

⁹⁵ Yamin AE ‘Not Just a Tragedy: Access to Medications as a Right under International Law’ (2003) 21(2) *Boston University International Law Journal* 325.

⁹⁶ United Nations *Report of the Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health* (2009) UN DOC. A/HRC/11/12 para 19 available at https://www2.ohchr.org/english/bodies/hrcouncil/docs/11session/a.hrc.11.12_en.pdf (accessed 17 September).

absence or relaxation, and use of such a relaxation can improve access to medicines. In addition, the Human Rights Council recognising the nexus between patents and access to medicines called on countries to utilise fully the TRIPS flexibilities as an option to improve access to medicines.⁹⁷

Having established the relationship between patents and access to medicines and its impact, with the Human Rights Council calling for the utilisation of the TRIPS flexibilities, it is important to know what these flexibilities within the WTO patent system are.

2.4 Patent-related flexibilities within the Trade-Related Aspects of intellectual Property Rights Agreement and access to medicines

This part discusses what the flexibilities within the TRIPS Agreement are and how they promote access to medicines while still respecting the rights of patentees.

2.4.1 Meaning of flexibilities

The flexibilities refers to the options by which TRIPS obligations can be incorporated into national laws so that WTO Members can exploit it to suit their national interest without having to breach the principles in the TRIPS Agreement.⁹⁸

Ghanotakis describes TRIPS patent-related flexibilities, in the context of health, as follows:

‘WTO Member countries were giving some room to manoeuvre and customize their patent laws in accordance with their unique legal systems, public-health situations and development needs. In particular, Members were given the ability to adopt certain measures that neutralise the impact of exclusive rights, promote competition and facilitate access to medicines. There were several “flexibilities” inherent in the TRIPS Agreement. All of those measures, consistent with the TRIPS Agreement, reduce prices and increase the affordability of medicines, without negatively affecting future R&D’.⁹⁹

From the above definition, the flexibilities are safeguards aimed at helping governments resolve challenges in accessing patented medicines for all diseases without any implications.

⁹⁷ UN Human Rights Council *Resolution on access to medicines in the context of the right to health* UN Doc A/HRC/23/L.10/Rev.1 available at

http://ap.ohchr.org/documents/E/HRC/d_res_dec/A_HRC_23_L10_Rev1.doc (accessed 18 September 2018).

⁹⁸ WIPO, Patent Related Flexibilities in the Multilateral Legal Framework and their Legislative Implementation at the National and Regional Levels(2010) CDIP/7/REF/CDIP/5/4REV available at http://www.wipo.int/meetings/en/doc_details.jsp?doc_id=153559 (accessed 22 July 2018) 11.

⁹⁹ Ghanotakis E ‘How the U.S. Interpretation of Flexibilities Inherent in Trips affects Access to Medicines for Developing Countries’ 7(14) *Journal of World IP* (2004) 566-7.

The nature of the flexibilities are such that they must be first incorporated into the legislative framework of Members before they can be utilised. Thus, even though the flexibilities give room for countries to manoeuvre, it cannot be used to breach or neglect obligations under the TRIPS Agreement.

The flexibilities identified in the TRIPS Agreement which aims at ensuring access to medicines are compulsory licensing and government use, parallel importation, exemption from patentability, patentability criteria, test data protection, transition period and competition laws. These flexibilities will be examined in details in subsequent sections. Before examining the flexibilities, their general legal basis will be discussed in the next section.

2.4.2 Legal basis for flexibilities

The TRIPS Agreement is the main legal instrument from which the flexibilities derive their legality. The Doha Declaration also supplements the TRIPS Agreement to give legality to the use of the flexibilities. This section therefore discusses the TRIPS Agreement and the Doha Declaration as the general legal basis for the flexibilities.

a) Provisions in the TRIPS Agreement

The term ‘flexibility’ is first used in paragraph 6 of the preamble of the TRIPS Agreement to recognise the different levels of development of countries and the need to allow some level of special and differential treatment in the form of bespoke arrangements to meet the needs of Members as outlined in articles 65 and 66 of the TRIPS Agreement. This flexibility can also be gleaned from the language of article 1(1) which sets a minimum threshold enabling Members to legislate in a manner that promote access to medicines without any legal implications.

The flexibilities also result from the objectives and principles enumerated in article 7 of the TRIPS Agreement which refers respectively to IPRs being enforced in a manner that contributes to ‘social and economic welfare, and to a balance of rights and obligations’.¹⁰⁰ Article 8 of the TRIPS Agreement also encourages Members to give much attention to vital areas like health especially in the implementation of their laws and indirectly seems to reiterate the need for the domestication of the flexibilities. Thus this provisions guarantee the use of the flexibilities in a manner which ensures an optimal balance between right holders and the users.

¹⁰⁰Article 7 TRIPS Agreement.

b) The Doha Declaration

In addition to the TRIPS Agreement, the Doha declaration was dictated by different interpretations given by developed countries and DCs to the applicability of the TRIPS provisions. DCs in seeking to clarify whether the TRIPS flexibilities provided sufficient grounds to access medicines argued that, the TRIPS Agreement permitted them to take measures to address their public health concerns and needs.¹⁰¹ In advancing their argument, DCs sent a strong signal to developed countries that, they will take steps to advance their essential needs.¹⁰² Developed Countries on the other hand argued that, the Agreement already strikes a balance by accommodating DCs and LDCs through the use of transition period flexibility which gives them time to implement the Agreement and as such the only flexibility they recognise.¹⁰³

As a result of these divergent views, there was a ministerial meeting in Doha, the capital of Qatar in 2001 which adopted the Doha Declaration.¹⁰⁴ The Declaration affirmed that, the provisions in the Agreement should not prevent Members from taking measures to solve their public health needs.¹⁰⁵ It urged Members to interpret the TRIPS Agreement in a manner which supports public health needs of countries and in particular access to medicines.¹⁰⁶ Thus the Declaration basically reaffirmed the existence of numerous flexibilities and not just transition period as was argued by developed countries.

Further, it recognised the needs of especially LDCs in accessing medicines and urged the committee to find a more sustainable solution to insufficient or no manufacturing capacity challenges facing Members by the end of the year 2002.¹⁰⁷ In the year 2003, a decision was reached which culminated into an amendment in the year 2005 and entered into force in the

¹⁰¹ Ghathii JT 'The legal Status of the Doha Declaration on TRIPS and Public health under the Vienna Convention on the Laws on Treaties' (2002) 15 *Harvard Journal of Law and Technology* 292.

¹⁰² Abbott FM 'The Doha Declaration on the TRIPS Agreement and Public Health: Lighting a Dark Corner at the WTO' (2002) *J Int Economic Law* 469.

¹⁰³ Ghathi JT (2002) 292.

¹⁰⁴ WTO Ministerial Declaration of 14 November 2001 WTO Doc WT/MIN (01)/DEC/1, 41 ILM 746 available at https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm (accessed 16 July 2018) (hereinafter Doha Declaration).

¹⁰⁵ Paragraph 5 Doha Declaration.

¹⁰⁶ Paragraph 5 Doha Declaration.

¹⁰⁷ Paragraph 6 Doha Declaration.

year 2017.¹⁰⁸ The details of the Declaration, Decision and Amendment will be discussed in the flexibilities in subsequent sections.

From the above discussions, the Declaration is a separate document which has led to several decisions and outcomes now incorporated into the TRIPS Agreement. It gives context to the interpretation of the TRIPS Agreement and according to the rules of treaty interpretation, the Declaration needs to be taken into account when interpreting the TRIPS Agreement.¹⁰⁹ It can also be regarded as a ‘subsequent agreement’ between the parties regarding the interpretation of the TRIPS Agreement and the application of its provisions.¹¹⁰ The Declaration also evidences the budding stages of subsequent practice that can be used in interpreting the TRIPS Agreement.¹¹¹ In *Japan-Taxes on Alcoholic Beverage*¹¹² the Appellate body held that a subsequent practises between parties to a WTO treaty may have the same legal status as a WTO treaty.

From the above, the Doha Declaration has been very instrumental in clarifying and reaffirming the obligations under the TRIPS Agreement and therefore it is right to regard it as a legal basis for the utilisation of flexibilities.

2.4.3 The flexibilities promoting access to medicines

The flexibilities create an equilibrium between the exclusive rights conferred under the TRIPS Agreement and the interests of the public. The flexibilities identified in the TRIPS Agreement promoting access to medicines and to be discussed are:

- compulsory license and government use
- parallel importation
- exemption from patentability
- patentability criteria
- transition periods
- test data protection and

¹⁰⁸ WTO Decision of the General Council of 30 August 2003 WT/L/540 available at https://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm (accessed 17 August 2018) (hereinafter August 2003 Decision).

¹⁰⁹ Vienna Convention on the Law of the Treaties (1969) ILM 679 (hereinafter VCLT).

¹¹⁰ Article 31(3) (a) VCLT.

¹¹¹ Ghathi JT (2002) 310 and VCLT art 31(3) (b).

¹¹² WT/DS10/AB/R (1996) 24.

- competition laws

These flexibilities with the exception of transition periods which has lapsed will be discussed in subsequent sections to understand what they mean, the conditions for their use and how they can be used by Members to help improve access to medicines.

2.4.3.1 Compulsory license and government use

A compulsory license is the authorisation by the state to a third party (generic manufacturer) to exploit a patented invention without permission from the patentees.¹¹³ A government use also referred to as ‘crown use’, is the right exercised by government itself or agents of the government to exploit a patent without the consent of a patentee.¹¹⁴ This flexibility derives its source from article 31 of the TRIPS Agreement.

The provision does not expressly provide exhaustive grounds upon which a compulsory license may be issued and thus leave it to Members to determine their own grounds for its grant.¹¹⁵ As such, Member states authorise compulsory license mostly on grounds of public interest, public health and nutrition, national emergency, anti-competitive behaviours, dependant patents and failure to exploit.¹¹⁶ This provision enables countries to legislate in a broader manner to import, manufacture and exports medicines.

Notwithstanding the fact that article 31 of the TRIPS Agreement does not limit the grounds for compulsory license, its utilisation is however premised on some procedures and conditions summarised below.¹¹⁷

1. The Agreement requires the grant of a license to be considered on its individual merits with express authorisation from a patentee on reasonable commercial terms.
2. There must be an establishment of prior but futile negotiations with the patentee for a voluntary license.

¹¹³ Murthy D ‘The Future of Compulsory Licensing: Deciphering the Doha Declaration on the TRIPs Agreement and Public Health’ 2002 *American University International Law Review* 1307.

¹¹⁴ Correa CM *Guide for the Application and Granting of Compulsory Licencing and Authorization of Government Use of Pharmaceutical Patents* (2009) 11 available at <http://apps.who.int/medicinedocs/documents/s19902en/s19902en.pdf> (accessed 20 September 2018).

¹¹⁵ Paragraph 5 Doha Declaration.

¹¹⁶ Musungu SF& Oh C *The Use of Flexibilities in TRIPS: Can they Promote Access to Medicines?* (2006) 15-7.

¹¹⁷ Article 31 TRIPS Agreement.

3. The license granted must define the purpose and timeline for its use since it is not granted in perpetuity and can only be terminated if upon assessment, the condition is not likely to return.
4. It must be made available for everyone with capacity to exploit, however, it must not be assigned by any other enterprises unless it receives a grant from the State or enjoys similar goodwill.
5. It must consider the commercial interest of patentees and its use must be limited to the domestic market.
6. Adequate remuneration must be paid to the patentee taking into account the economic value of the license. Conflicts on remuneration can be challenged in a court or reviewed by a higher authority.
7. Where the license is issued for second use, the invention must involve an important technical advancement of considerable economic significance in relation to the invention claimed in the first patent.

The conditions summarised above ensures that, inasmuch as Members are exploiting compulsory license to advance access to medicines, a patentee is also protected to encourage innovation. In the case of government use order, the above conditions apply however, prior negotiations are waived because the 'government acts ex officio' to address public health concerns of the country but adequate compensation must be paid.¹¹⁸ This waiver helps avoid any delay strategies and accelerates the process especially where there is an outbreak of diseases requiring lifesaving medicines. It also enables the government to limit remedies against itself in respect of remuneration.¹¹⁹

Compulsory license as discussed above thus enable countries to produce generic versions of any drug or import them despite its procedural requirements to improve access challenges of medicines which otherwise would not have been available because of patents.

Despite it being flexible, some problems arise from a provision of the TRIPS Agreement which requires the production of medicines under compulsory license, to be supplied only to the domestic market.¹²⁰ This provision limits the utilisation of compulsory license to Member states with manufacturing capacities and deprives others having challenges from exploiting

¹¹⁸ Correa CM (2009) 21.

¹¹⁹ Article 44(2) TRIPS Agreement.

¹²⁰ Article 31(f) TRIPS Agreement.

it.¹²¹ This limitation necessitated the Doha Declaration to instruct the Council of Ministers to find a solution to the problem and the outcome of the Council's meeting was the August 30 2003 Decision discussed below.¹²²

a. The August 2003 Decision

The August 30th 2003 Decision attempted to address the problem of no or insufficient manufacturing capacity by waiving some of the requirements for compulsory license. The Decision waves the 'predominantly for the domestic market' limitation requirement for exporting Members¹²³ and the adequate remuneration requirement for importing Members.¹²⁴ Finally several importing members who are parties to a Regional Trade Agreement (RTA) and sharing a health problem can pool as importers.¹²⁵ This decision helps especially DCs and LDCs to improve their access to medicine needs as they benefit from countries which produce in excess but hitherto could not export because of the aforementioned limitation.

The use of the waivers were however temporal and subject to both importing and exporting Members putting the mechanism in place. With regards to the obligation of an importing Member, there must be prior notification to the TRIPS council as an eligible member (LDC or Member with no or insufficient manufacturing capacity).¹²⁶ In addition, the notification must specify the names and expected quantity of the product(s) needed. Furthermore, a confirmation is required to establish that the product is patented in the importing Member's territory which the importing Member has granted or intends to grant a compulsory license in accordance with article 31 of the TRIPS Agreement with an undertaking to avoid re-exporting imported products.¹²⁷

The exporting Member on the other hand is obliged to ensure that the country has issued a license in accordance with article 31 of the TRIPS Agreement indicating that, the products are produced under such a system and an assurance that, only the amount needed will be manufactured and all exported to Members who have notified the Council.¹²⁸ The exporting Member must also ensure special packaging of the products to distinguish the products and a

¹²¹ Abbott FM 'The TRIPS Agreement, Access to Medicines and the WTO Doha Ministerial Conference' (2002) 5(1) *Journal of World Intellectual Property* 28.

¹²² Paragraph 6 Doha Declaration.

¹²³ August 2003 Decision.

¹²⁴ Paragraph 3 August 2003 Decision.

¹²⁵ Paragraph 6 August 2003 Decision.

¹²⁶ Paragraph 2 (a) (ii) August 2003 Decision.

¹²⁷ Paragraph 2 (a) (i) & (iii) August 2003 Decision.

¹²⁸ Paragraph 2(b) (i) August 2003 Decision.

post on the licensee's website indicating 'the quantities being supplied to each destination'.¹²⁹ Finally the exporting Member has an obligation to notify the TRIPS Council with the above information and pay adequate remuneration to the patentee.¹³⁰

The pharmaceutical industry contends that the Decision increases competition amongst pharmaceutical companies in the introduction and development of new patented medicines which will not necessary solve the problems of DCs.¹³¹ On the other hand DCs shared interest in the fact that it provide other options for medicines not under the control of patentees.¹³² Developed countries with concentration of big pharmaceutical industries including the US shared interest in the Decision based on the fact that they generate revenue from patent exploitation which encourages research and development (R&D).¹³³ Be that as it may, the Decision was a relief of a temporal nature despite its cumbersome procedures to most countries. It widened the scope of compulsory license and enabled DCs to use it however, simplifying it for LDCs. It also reduces cost with bulk procurement by RTAs. This decision subsequently led to the first permanent amendment to the TRIPS Agreement in the year 2005.

b. The December 2005 Amendment

The Amendment¹³⁴ came to force on 23 January 2017 after two thirds of Members ratified it. The Amended is incorporated into the TRIPS Agreement as article 31 *bis*. In accordance with WTO Jurisprudence, the Amendment will only apply to the Members which have ratified it.¹³⁵ Members which have not ratified it, can still rely on the August 2003 Decision to import patented medicines until the December 2019.

From the above, the compulsory license flexibility despite its procedural problems is an indispensable mechanism not only to improve access to essential medicines but to encourage R&D. The opportunity given to generic manufacturers ensures availability and affordability of essential medicines which is a necessary component of access to medicines.

¹²⁹ Paragraph 2(b) (ii) and (iii) August 2003 Decision.

¹³⁰ Paragraphs 2(c) & 3 August 2003 Decision.

¹³¹ Abbott FM The WTO 'Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health' (2005) 99 *The American Journal of International Law* 324.

¹³² Abbott FM (2005) 324-5.

¹³³ Abbott FM (2005) 325.

¹³⁴ Protocol Amending the TRIPS Agreement WT/L/641 available at https://www.wto.org/english/tratop_e/trips_e/wt641_e.htm (accessed 17 July 2018).

¹³⁵ Article X Paragraph 3 WTO Agreement: Marrakesh Agreement Establishing the World Trade Organization (1994) 33 ILM 1144.

Having examined the compulsory license flexibility, the flexibility of parallel importation will be examined in the next section.

2.4.3.2 Parallel importation

The limited resources of countries account for differentials in pricing of medicines by pharmaceutical companies thereby making some medicines, cheaper in some countries than others.¹³⁶ Countries limited by resources, are hence inclined to purchasing and importing patented medicines from other countries at a relatively cheap price rather than buying them from their local markets. The act of importing and reselling a relatively cheap medicine legitimately put on the market by the patentee or with the consent of the patentee is known as parallel importation.¹³⁷ Thus, parallel importation concerns the distribution process for medicines in the market without direct authorisation of the patentee and not the attributes of the medicines.¹³⁸

The TRIPS Agreement however confers a right under its article 28(1) (a) on patentees to prevent third parties from importing patented products without right owners consent. This conferred right as held in the case of *Kodak SA v Jumbo-Market AG*¹³⁹ is not a ban on parallel importation but a mere right conferred on patentees to stop imports that infringe their rights. The TRIPS Agreement therefore imposes an obligation on states, to adopt an exhaustion regime as a pre requisite to import.¹⁴⁰ Thus the conferred right is not absolute as it is limited by the doctrine of exhaustion upon which parallel importation is premised.

The doctrine of exhaustion in the context of public health is to the effect that, once a patentee is compensated by the first sale of medicines, the patentee is not entitled to further control any use or resale of medicines placed on the market because the rights are exhausted by the act of

¹³⁶Avafia T & Savita MN *The TRIPS Agreement and Access to ARVs* (2006)15 available at <http://www.undp.org/content/dam/aplaws/publication/en/publications/hiv-aids/the-trips-agreement-and-access-to-arvs/5.pdf> (accessed 23 September 2018).

¹³⁷ Abbott F *Parallel Importation: Economic and social welfare dimensions* (2007) 4 available at https://www.iisd.org/pdf/2007/parallel_importation.pdf (accessed 23 September 2018).

¹³⁸ MacGillivray RA *Parallel importation* (2010) 7.

¹³⁹4C. 24/1999/.

¹⁴⁰ Article 28 TRIPS Agreement and Paragraph 5(d) Doha Declaration.

selling.¹⁴¹ Thus the ability of the patentee to exercise his rights depends largely on the importing country's treatment of exhaustion of rights.¹⁴²

As such the exhaustion regime strikes and maintains a balance between free movement of innovative goods and remuneration for innovation.¹⁴³ Article 6 of the TRIPS Agreement grants Members the freedom to determine their own regime, which could be national, regional or international subject to the non-discriminatory principles as reaffirmed in paragraph 5(d) of the Doha Declaration. In jurisdictions which adopt national exhaustion, the right of patentees are exhausted only in respect of the first sale of products put on the market in which the patent is protected.¹⁴⁴ With the regional exhaustion, the patentee's rights are not exhausted until the first sale of the product within a demarcated region.¹⁴⁵ Under the international regime, a patentee's rights are exhausted upon the first sale of the medicine anywhere in the world by or with the consent of the patent owner.¹⁴⁶

While some are of the view that this flexibility controls competition and the progress of R&D with a resultant higher price fluctuation of medicines, others believe that parallel importation boosts competition, improves effectiveness and benefits consumers in importing countries.¹⁴⁷ Members however, seem to resort to a particular exhaustion regime based on the needs of their country and the objective the country wants to achieve. Thus a DC which wants to obtain relatively cheap but quality medicines will resort to the international regime.¹⁴⁸ Further, developed countries which are more interested in protecting their IPRs are more likely to adopt either the national or the regional exhaustion just to restrict its circulation without their consent.

Despite the dissenting views, parallel importation must be utilised by Members to improve their essential medicines challenges because importing relatively cheap medicines from other

¹⁴¹Vélasquez G & Boulet P 'Essential drugs in the new international economic environment' (1999) 77(3) *Bulletin of the World Health Organization* 290.

¹⁴² Zappalaglio A 'International exhaustion of trademarks and parallel imports in the US and the EU: How to achieve symmetry?' 5(1) *Queen Mary Journal of Intellectual Property* 69.

¹⁴³ Sloboom M 'The Exhaustion of Intellectual Property Rights - Different Approaches in EC and WTO Law' (2003) 6 *Journal of World Intellectual Property* 422.

¹⁴⁴ Bonadio E 'Parallel Imports in a Global Market: Should a Generalised International Exhaustion be the Next Step?' (2011) *European Intellectual Property Review* 33(3) 153.

¹⁴⁵ Karjiker S 'The firstsale doctrine: Parallel importation and beyond' 2015 *Stellenbosch LR* 642.

¹⁴⁶ Pires De Carvalho N *The TRIPS Regime of Patent Rights* (2002) 103.

¹⁴⁷ Matsushita M, Schoenbaum TJ & Mavroidis PC *The World Trade Organization: Law, Practice and Policy* 2ed (2006) 734

¹⁴⁸ Matsushita et al (2006) 735.

markets tends to force domestic distributors to reduce prices of medicines and also increases competition.¹⁴⁹ Members especially DCs should therefore make use of the international regime since by its description, it provides the best option while ensuring that the right of a patentee is respected.

Having examined the flexibility of parallel importation, I will proceed to examine the flexibility of exemption from patentability in the next section.

2.4.3.3 Exemption from patentability

The TRIPS Agreement allows for some limited exceptions to rights conferred on patentees. The scope of these exceptions are not defined but precedent on conditions which must not conflict with the legitimate exploitation, interest of patentee and interest of a third party.¹⁵⁰ These conditions are cumulative and failure to comply with any one of the three, may result in the article 30 exception being disallowed.¹⁵¹ Even though Members have considerable freedom to determine their own exceptions, they do not operate automatically but require legislating the specific exceptions before exploitation.¹⁵² The exceptions considered by most countries to advance access to medicines are, research exception and early working exception, details of which are discussed hereunder.¹⁵³

a. Research exception

The Panel in *Canada-Patent Protection of Pharmaceutical Product*,¹⁵⁴ defined this exception as ‘the exception under which use of the patented product for scientific experimentation, during the term of the patent and without consent, is not an infringement’. Thus during the subsistence of a patent, this exemption can be used for all experimental purposes without having to go through the burden of obtaining any license from the patentee. On the other hand it impacts negatively on innovation because innovators do not receive any compensation for the use of the patent for experiments.¹⁵⁵

¹⁴⁹ Kuanpoth J ‘Patents and Access to Antiretroviral Medicines in Vietnam after World Trade Organization Accession’ (2007)10 *Journal of World Intellectual Property* 204.

¹⁵⁰ Article 30 TRIPS Agreement.

¹⁵¹ *Canada-Patent Protection of Pharmaceutical Products* WT/DS114/R paragraph 7.20.

¹⁵² *Musungu SF& Oh C (2006)* 55.

¹⁵³ *Musungu SF& Oh C (2006)*55.

¹⁵⁴ WT/DS114(2000) paragraph 7.69

¹⁵⁵ Rowe EA ‘The Experimental Use Exception to Patent Infringement: Do Universities Deserve Special treatment?’(2005) 57 *Hasting Law Journal* 921-954.

b. Early working exception

This exception enables the use of patented medicines without the consent of a patentee in order to obtain a regulatory approval of a generic product and facilitate marketing of the generic product right after a patent protected expires.¹⁵⁶ This practice is allowed because, once patents expire, they fall back into the public domain and opens up an avenue for anyone to exploit.¹⁵⁷ The exception prevents delay in entry of generic medicines and also patentees whose patent have expired from enjoying any form of monopoly.¹⁵⁸

This exception otherwise known as the bolar exception originates from the case of *Roche Products v Bolar Pharmaceuticals*.¹⁵⁹ In this case, Bolar lost against Roche for using its patented active ingredient to experiment. The decision of the Court, was reversed by the US government by the enactment of the Hatch-Waxman Act¹⁶⁰ which permitted generic manufacturers to experiment with patented drugs, obtain regulatory approvals and launch such medicines when the original patent expires. This act of conducting an experiment for regulatory approval, without stockpiling has been affirmed by the WTO Panel as consistent with article 30 of the TRIPS Agreement.¹⁶¹

The above exceptions promote access to essential patented medicines especially in DCs where certain diseases are peculiar to it through the launch of medicines that suit these conditions immediately the patent expires. It thus prevent delays, monopolies, unfair competition and promotes further R&D. The early entry therefore reduce prices of medicines and improves access to medicines.

Another flexibility which is crucial to helping address access to medicine challenges is the patentability subject matter which is examined in the next section.

2.4.3.4 Patentable subject matter

The scope of patentable subject matter and the term of patent provisions in the TRIPS Agreement were directed towards raising the standard for countries that were deemed by DCs

¹⁵⁶ Musungu SF& Oh C (2006)55.

¹⁵⁷ Ho CM *Access to Medicine in the Global Economy: International Agreements on Patents and Related Rights* (2011) 92.

¹⁵⁸ Correa CM *The Bolar Exception: Legislative Models and Drafting Options* (2016) 1 available at https://www.southcentre.int/wp-content/uploads/2016/03/RP66_The-Bolar-Exception_EN1.pdf (accessed 30 September 2018).

¹⁵⁹ US Federal Circuit, no. 733 F2d 858, 1984.

¹⁶⁰ Drug Price Competition and Patent Restoration Act (1984)

¹⁶¹ WT/DS114(2000) paragraph 7.69

to fall short of a ‘minimum level’.¹⁶² According to the TRIPS Agreement, patents must be granted to all inventions provided that they are new, they involve an inventive step, and they are capable of industrial application subject to some exceptions.¹⁶³ A patent can thus be excluded in the context of public health if it is for a method of treatment being it therapeutic or diagnostic.¹⁶⁴

There is however an inherent flexibility in the footnote of article 27 of the TRIPS Agreement which gives Members the freedom to determine what constitutes an invention, when an invention is new and when an invention is capable of industrial application. Arguably, this is a flexible provision as there is recognition of different shared and ethical values of societies. However some have argued that, the lack of definition may result in the likelihood of shifting away from the principle of absolute originality to exploitation of existing inventions.¹⁶⁵ Others argue that, the lack of a definition may lead to the possibility of Members excluding new uses of medicines from patentability under their national laws.¹⁶⁶ Be that as it may, countries can use this flexibility to improve access to medicines by making use of the freedom granted, to set strict criteria for patents and exempt the grant of patents to known inventions to support their right to health needs.

Guided by this inherent freedom under article 27 of the TRIPS Agreement, India has used this flexibility to improve access to medicines by raising the criteria to prevent patenting known inventions.¹⁶⁷ This is illustrated by the case of *Novartis AG v Union of India*.¹⁶⁸ The pitch of this case was whether the Appellant was entitled for patent protection of a compound ‘Imatinib Mesylate’, marketed under the name ‘Glivec’ or ‘Gleevec’.¹⁶⁹ The court ruled that ‘Imatinib’ failed the test of invention provided for under the Patents Act because it did not improve therapeutic efficacy.¹⁷⁰ This decision is of persuasive effect and as such countries

¹⁶² Chisum DS ‘Patentability under TRIPS: The Need for Uniformity’ (20006) 2 *Indian Journal of Law and Technology* 2.

¹⁶³ Article 27 TRIPS Agreement.

¹⁶⁴ Article 27(2) (3) TRIPS Agreement.

¹⁶⁵ Ndlovu L ‘Lessons for the SADC from the Indian Case of Novartis Ag V Union of India’ 18(4) *Per / Pelj* 2015(18) 785.

¹⁶⁶ Musungu SF, Villanueva S & Blasetti R *Utilizing TRIPS Flexibilities for Public Health Protection through South-South Regional Frameworks* (2004) 15.

¹⁶⁷ See s 3(d) of the Indian Patent (Amendment) Act 2005.

¹⁶⁸ *Novartis AG v India* (Supreme Court of India) Civil Appeal No 2706-2716 of 1 April 2013 (*Novartis* case).

¹⁶⁹ *Novartis* case para 3.

¹⁷⁰ *Novartis* case para 195.

can rely on it to set stringent patentability criteria for pharmaceuticals in order to facilitate the early entry of relatively cheaper generics.

Having discussed the flexibility of patentability subject matter above, the next section will be an examination of the flexibility of test data protection.

2.4.3.5 Test data Protection

This flexibility requires Members to protect the secret test data submitted by pharmaceutical companies for regulatory approval against ‘disclosure’ and ‘unfair commercial use’.¹⁷¹ There seems to be an inherent flexibility in the language of the provision because there is no definition of the terms used in the provision and therefore leaves it for countries to determine what constitutes disclosure and unfair commercial use taking into account their policy objectives. This inherent freedom language in article 39(3) therefore permits the authorisation by government of a generic product as a result of an earlier grant of regulatory approval for the original product without breaching the article’s prohibition on disclosing test data submitted by the original pharmaceutical company.¹⁷²

The flexibility enables the early entry of medicines which reduces monopoly and encourage competition. Some however argue that, data protection is one incentive that can be offered DCs to treat their conditions since the markets in developed countries alone would not always justify the expenses associated with research and testing.¹⁷³ To facilitate access to medicines especially in DCs, the protection of data is necessary to incentivise the pharmaceutical industries especially for countries which rely heavily on imports.

Having examined the flexibility of test data protection, I shall proceed to examine the last flexibility, competition laws in the next section.

2.4.3.6 Competition laws

The TRIPS Agreement allow Members to adopt appropriate measures to prevent or control anti-competitive behaviours in contractual licenses.¹⁷⁴ Such anti-competitive behaviours includes but not limited to, conditions preventing challenges to the validity and coercive

¹⁷¹ Article 39(3) TRIPS Agreement.

¹⁷² Junod V ‘Drug Marketing Exclusivity under United States and European Union Law’ (2004) 59 Food & Drug LJ 479-80.

¹⁷³ Skillington GL & Solovy EM ‘The Protection of Test and Other Data Required by Article 39.3 of the TRIPS Agreement’ (2003-2004) 24 *North-western Journal of International Law & Business* 13.

¹⁷⁴ Article 40 TRIPS Agreement.

package licensing.¹⁷⁵ As such a Member having cause to believe that, another Member is engaged in an anti-competitive behaviour may enter into consultation with that Member to reach a mutually satisfactory agreement.¹⁷⁶ This flexibility when used ensures price control and unnecessary monopolies within the pharmaceutical industry.

2.5 Chapter conclusion

This chapter has demonstrated that the flexibilities of compulsory licensing and government use, parallel importation, exemption from patentability, patentability criteria, test data protection and competition laws inherent in the TRIPS Agreement can be used to advance access to medicines. The chapter has also established that, these flexibilities contribute to addressing access to essential medicines challenges while ensuring that patentees are protected. They are important and therefore countries must take advantage by incorporating them in their national legislations to enable their use without any consequences. As such, the next chapter will focus on the legislative framework of Ghana and its incorporation of these flexibilities in comparison with that of South Africa to ascertain whether the extent of incorporation is enough to enable their utilisation to improve access to medicines.



¹⁷⁵ Article 40(2) TRIPS Agreement.

¹⁷⁶ Article 40(3) TRIPS Agreement.

CHAPTER THREE

THE LEGAL FRAMEWORK OF GHANA AND THE EXTENT OF INCORPORATION OF THE TRIPS FLEXIBILITIES INTO GHANA'S LEGISLATIONS IN COMPARISON WITH THAT OF SOUTH AFRICA

3.1 Introduction

In the previous chapter, the World Trade Organisation's (WTO's) patent regime and the health related flexibilities under the Trade Related-Aspects of Intellectual Property (TRIPS) Agreement were examined. The chapter established that the flexibilities, if utilised can help improve access to medicines. Some have however argued¹⁷⁷ that developing countries (DCs) within Sub-Saharan Africa are unable to fully utilise the TRIPS flexibilities due to 'poorly executed patent systems' within these countries. The first point of call to utilising the flexibilities nonetheless, is the domestication of the flexibilities.

This chapter therefore examines Ghana's incorporation of the TRIPS flexibilities into its legislative framework in comparison with that of South Africa. The first part of this chapter focuses on Ghana's general legal framework and its current laws which promote the TRIPS flexibilities. The second part examines the extent of incorporation of the flexibilities in identified legislations while comparing with South Africa's extent of incorporation to determine whether conditions are ripe for their utilisation in Ghana. This is aimed at answering the question, 'What are the current national legislative frameworks put in place by Ghana to help utilise the flexibilities and what is the extent of incorporation and utilisation of these flexibilities by Ghana in comparison with that of South Africa?'¹⁷⁸

3.2 The General Legal Framework of Ghana

The legal history of Ghana dates back to Britain's colonisation of Ghana and the introduction of the first legislation based on English law on 24 July 1946 which shaped the drafting of subsequent Ghanaian legislations.¹⁷⁹ On 6 March 1947, Ghana gained independence from Britain and became a republic in 1960.¹⁸⁰ After several military interventions, the Constitution

¹⁷⁷ Adusei P 'Exploiting Patent Regulatory "Flexibilities" to Promote Access to Antiretroviral Medicines in Sub-Saharan Africa' (2009) 9 *University of Botswana Law Journal* 4.

¹⁷⁸ See Section 1.3 above.

¹⁷⁹ Amankwah HA 'Ghanaian Law: Its Evolution and Interaction with English Law (1970)' 4(1) *Cornell International Law Journal* 38.

¹⁸⁰ Amankwah HA (1970) 50.

of 1992 was adopted and has since been in force.¹⁸¹ Ghana has a pluralistic legal system because it derives its laws from sources including, the Constitution, Acts of Parliament, orders, rules and regulations, the customary law of Ghana, as well as the doctrines of common law and equity.¹⁸² The Constitution of 1992 is thus the supreme law of Ghana.

Having discussed the history and the sources of law in Ghana, it is important to determine the place of international law within the legal framework of Ghana since the TRIPS Agreement is an international Agreement.

3.2.1 Relationship between Domestic laws of Ghana and International Law

Ghana as a sovereign state has the the power to do everything necessary to govern itself. As an autonomous state which has relations with other countries, the laws governing this relationship must be clearly defined. Ghana joined the WTO in the year 1995 and automatically became a signatory to the TRIPS Agreement.¹⁸³

In accordance with the jurisprudence of Ghana, the accession of an international agreement or obligation requires subsequent ratification by an Act or a simple majority vote of Parliament.¹⁸⁴ Thus in terms of the relationship between domestic and international law, the Constitution of Ghana adopts a dualist stance to the recognition of international law. As such an international treaty does not have automatic and immediate effect. This position has been affirmed by the Supreme Court of Ghana in the case of *Republic v High Court Accra Ex Parte; Attorney General (Interested Parties NML Capital Ltd & the Republic of Argentina)*.¹⁸⁵

In this case, the Court held as follows:

‘The mere fact that a treaty has been ratified by Parliament through one of the two modes indicated above does not, of itself, indicate that it has been incorporated into the laws of Ghana. A treaty may come into force and regulate the rights and obligations of the state on the international plane, without changing rights and obligations under municipal law. Where the mode of ratification is through an Act of Parliament, that Act may incorporate the treaty by appropriate legislations into the municipal law of Ghana’.¹⁸⁶

¹⁸¹ Amankwah HA (1970) 50.

¹⁸² Article 11 Constitution of the Republic of Ghana, 1992 (hereinafter Constitution of Ghana).

¹⁸³ WTO ‘Membership Information’ available at https://www.wto.org/english/thewto_e/countries_e/ghana_e.htm (accessed 10 August 2018).

¹⁸⁴ Article 75 (2) Constitution of Ghana.

¹⁸⁵ [2013- 2014] 2 SCGLR.

¹⁸⁶ [2013- 2014] 2 SCGLR 1000

Thus the above case affirms that, an international treaty cannot be relied upon by Ghana without making the international obligation a part of the domestic laws. This judgement and the Constitution are therefore in line with WTO jurisprudence which requires that the TRIPS flexibilities be first incorporated into the laws of WTO Members (hereinafter Members) before their utilisation.

Prior to the judgement in *Republic v High Court Accra*, Ghana had shown some interest in the monist system¹⁸⁷ contrary to dualist requirement that an international treaty be incorporated into the domestic legal system to be enforceable in Ghana. This was demonstrated in the case of *New Patriotic Party v. Inspector General of Police*,¹⁸⁸ where the High Court of Ghana held that since Ghana was a signatory to the African Charter, effect could be given to the obligations which the state had signed onto even though no specific legislation had been passed to give effect to the Charter. This judgement was handed down by the Court around the same period that Ghana became a member of the WTO.

The monist system however is in conflict with the constitution of Ghana and therefore the decision in *Republic v High Court Accra Ex Parte; Attorney General* is void. This is because of the supremacy of the Constitution which makes any other law found to be inconsistent with any of its provisions to the 'extent of the inconsistency', null and void.¹⁸⁹ Additionally the decision of the Supreme Court being, the highest Court of Ghana overrules that of the High Court.

Thus from the above discussions, Ghana cannot rely on the judgement in *New Patriotic Party v. Inspector General of Police* to utilise the TRIPS flexibilities without taking steps to first incorporating the flexibilities into a national legislation.

Having stated the relationship between domestic laws and international law, this research will now proceed to identify the specific laws in Ghana which incorporates the TRIPS flexibilities. This will enable a proper examination of the extent of incorporation of the flexibilities.

¹⁸⁷ According to the monist, there is no need for incorporation of international laws into national legislation before they can binding because, international and municipal law are aspects of the same juridical reality. See Starke JG 'Monism and Dualism in the Theory of International Law' (1963) 17 *British Year Book of International Law* 67.

¹⁸⁸ (1993-94) 2 GLR 459- 466.

¹⁸⁹ Article 1(2) Constitution of Ghana.

3.2.2 The Laws in Ghana promoting the flexibilities

The main legislation governing patents in Ghana is the Patents Act which is complemented by the Patent Regulations. The other legislations promoting the flexibilities are, the Public Health Act, the Protection against Unfair Competition Act and the Trademarks Act. The details of aforementioned laws will be discussed below to determine generally how they promote access medicines in the era of patents.

a. The Patent Act of Ghana¹⁹⁰

The protection of patents in Ghana dates back to the colonial era when its colonial masters, the United Kingdom (UK) decided to extend its patent system to all its colonies.¹⁹¹ The UK's patent system was introduced into Ghana through the Patents Ordinance of 1899 which enabled patents to be registered under the control of a registrar.¹⁹² The ordinance was however repealed by Patents Registration Ordinance (Cap 179) in 1925 which made Ghana a part of the UK system to serve as a re-registration point.¹⁹³

Due to the tedious nature of the registration process which caused problems such as Ghana's inability to grant compulsory license, Cap 179 was repealed by the Patents Registration (Amendment) Decree 1972 which exempted pharmaceutical products from patentability and granted the Ghanaian government the right to grant compulsory license.¹⁹⁴ A new patents law¹⁹⁵ was enacted in 1992 to enable local inventors directly register patents in Ghana. This law solved the problem of double registration as local inventors in Ghana could obtain patents directly or through the Patent Cooperation Treaty (PCT) under World Intellectual Property Organisation (WIPO) or the African Regional Intellectual Property Organisation (ARIPO).¹⁹⁶

¹⁹⁰ Patent Act 657 of 2003 (hereinafter Patent Act of 2003).

¹⁹¹ Penrose E *The Economics of the International Patent System* (1951) 220 - 33.

¹⁹² Manteaw SO 'Patents and Development in Ghana: Proposals for Change' (2008-2010) 24 *University of Ghana Law Journal* 115.

¹⁹³ Sikoyo GM, Nyukuri E & Wakhungu JW *Intellectual Property Protection in Africa; Status of Laws, Research and Policy Analysis in Ghana, Kenya, Nigeria, South Africa and Uganda* (2006)15.

¹⁹⁴ Sikoyo GM, Nyukuri E & Wakhungu JW (2006) 16.

¹⁹⁵ Patent Law PNDCL 305A of 1992.

¹⁹⁶ Sikoyo GM, Nyukuri E & Wakhungu JW (2016) 16. The PCT consist of 150 countries and makes it possible for any national or resident of a contracting state to file for patent protection for an invention simultaneously in each country by an international patent application instead of filing several separate patent applications. The granting of patents however remains under the control of the national or regional patent Offices. See WIPO 'PCT FAQs' available at <https://www.wipo.int/pct/en/faqs/faqs.html> (accessed 15 September 2018); ARIPO is an inter-governmental organization with the objective of pooling financial, human resources and seeking technological advancement to that facilitates cooperation among member states in intellectual property matters. See ARIPO 'About ARIPO' available at <http://www.aripo.org/about-aripo> (accessed 15 September 2018).

The Patents Law of 1992 thus made all inventions which involved an inventive step patentable including pharmaceuticals which were hitherto exempted.¹⁹⁷ It also widened the grounds for the grant of a compulsory license and made provision for parallel importation of medicines which was however limited to national exhaustion.¹⁹⁸

The 1992 Patents Act was however considered as falling below the standards of the TRIPS Agreement after Ghana joined the WTO. To bring Ghana into compliance with the TRIPS Agreement the Ghanaian government repealed the Patents Law of 1992 culminating into the Patents Act of 2003.¹⁹⁹ This Act is the main legislative instrument currently governing patent protection in Ghana and predominantly the law which incorporates most of flexibilities such as compulsory license, parallel importation and other flexibilities.

b. Patent Regulations²⁰⁰

The Regulations supplement the Patent Act and addresses matters relating to the application of patents, the cost of patent applications, examination of patents, the maintenance of patents when granted and other ancillary matters relating to patents. Thus it serves generally as a guide to prospective patentees.

c. Public Health Act²⁰¹

This Act aims at preventing diseases and protecting the health of both humans and animals.²⁰² It governs the importation, distribution, sale and advertising of medicines in Ghana. The Act incorporates the flexibility of parallel importation by ensuring that medicines imported into Ghana, are accessible and affordable through guidelines on importation, distribution and sales. This Act thus ensures that, quality products are imported into the country while ensuring that they are in accord with the TRIPS Agreement.

d. Protection against Unfair Competition Act²⁰³

This Act aims at protecting consumers from practices which seek to cause confusion, damage another person's goodwill, mislead the public, secret information and unfair competition.²⁰⁴

¹⁹⁷Section 2 Patent Law of 1992.

¹⁹⁸Section 45-8 Patent Law of 1992.

¹⁹⁹ Patent Act of 2003.

²⁰⁰ L.I. 1616 of 1996.

²⁰¹ Public Health Act 851 of 2012.

²⁰² Preamble Public Health Act of 2012.

²⁰³ Act 589 of 2000 (hereinafter PUC Act of 2000).

²⁰⁴ Section 1-6 PUC Act of 2000.

This Act seeks to prevent unfair competition and in the context of medicines, unfair competition among pharmaceutical companies.

e. Trademarks Act ²⁰⁵

The Trademarks Act is important in the distribution of medicines to distinguish one from the other on the market. This law promotes importation of generic versions of medicines which require special packaging, colouring and shaping of the products to distinguish the products. The Trademarks Act therefore comes in to facilitate these requirements.

From the above, Ghana has promulgated adequate legislations to promote the TRIPS flexibilities hence the second part of this chapter will examine the extent of incorporation of the flexibilities discussed in chapter two in the above legislations. This will be compared with the extent of incorporation of the flexibilities by South Africa.

3.3 Incorporation of flexibilities into Ghana's legislation and usage in comparison with that of South Africa

The flexibilities to be discussed are compulsory licensing and government use, parallel importation, exemption from patentability, patentability criteria, test data protection and competition laws in Ghana and South Africa.²⁰⁶ South Africa is selected for this comparison because it is a DC just like Ghana and was the first country to raise awareness about access to medicines issues from a DCs viewpoint and uncovered the treachery of the pharmaceutical industry and also a pacer of compulsory licenses and parallel imports.²⁰⁷

3.3.1 Compulsory licensing and government use in Ghana and South Africa

a. Ghana

Compulsory license and government use are covered under section 13 the Patents Act of Ghana (hereinafter the Act).²⁰⁸ The TRIPS Agreement gives freedom to determine the grounds for the grant of this flexibility, therefore, the starting point for examining the Act is section 13(1) which allows for the grant of compulsory licensing on two main grounds:

²⁰⁵ Trade Marks Act 664 of 2000.

²⁰⁶ See Section 2.4.3 above for discussion of the flexibilities.

²⁰⁷ Ndlovu L 'The WTO TRIPS Agreement and Access to Medicines in South Africa Twenty Years into Democracy' 90 available at <http://specjuris.uvh.ac.za/sites/default/files/SJ2314FPLonias%20%281%29.pdf> (accessed 17 November 2018).

²⁰⁸ Patents Act of 2003

- i. Public interest such as national security, nutrition, health or development of other vital sectors of the national economy and
- ii. To remedy anti-competitive practices declared by a judicial or administrative process

Ghana obviously has taken advantage of the freedom to determine the grounds for the grant of compulsory license and legislated broadly in that regard, taking into account its national needs.²⁰⁹ The above provision provides Ghana with a wide range of grounds to take advantage of the flexibilities because public interest ground is not defined and therefore not exhaustive. In this regard, the Interpretation Act of Ghana²¹⁰ states:

‘in an enactment, the expression public interest includes a right or advantage which enures or is intended to enure for the benefit generally of the whole of the people of the Republic.’²¹¹

The constitution of the Republic of Ghana²¹² also defines public interest as:

‘[i]ncludes any right or advantage which enures or is intended to enure to the benefit generally of the whole of the people of Ghana’.²¹³

These two definitions are not exhaustive because the word ‘includes’ and not ‘means or denote or connote’ is used in the definition under both the Interpretation Act and the Constitution. Public interest in the context of access to medicines can thus be interpreted as, any act which enures to the benefit of everyone in the country to have access to medicines when needed.

The flexibility is granted by the Attorney-General (AG) upon recommendation by the Minister of Health.²¹⁴ This provision may encourage especially generic drug pharmaceutical companies to pursue compulsory licensing since it is not granted by the courts which are sometimes undesirable in terms of cost and delay in procedures.²¹⁵

The license granted by the AG must specify the scope of exploitation, the time period and the payment of adequate remuneration to the patentee taking into account the economic value and

²⁰⁹ See Section 2.4.3.1 above.

²¹⁰ Interpretation Act 792 of 2009.

²¹¹Section 46 Interpretation Act of 2009.

²¹² Constitution of Ghana.

²¹³ Article 295 Constitution of Ghana.

²¹⁴ Section 13(1) Patent Act of 2003.

²¹⁵ Amankwah AS, Bonsu GA & White P ‘Media Exposé of Judicial Corruption in Ghana: Ethical and Theological Perspectives’ 2017 *Legon Journal of the Humanities* 4.

the need to remedy anti-competitive practises if that was the ground for the grant.²¹⁶ The AG however has a discretion to maintain the authorisation if there is evidence that such authorisation is necessary for exploitation after the duration stated on the license.²¹⁷ The authorisation can only be transferred with the enterprise or business of that person.²¹⁸ The Act does not define what ‘adequate remuneration’ is just like the TRIPS Agreement.²¹⁹ The above conditions are in accord with the TRIPS Agreement and cannot be dispensed with if compulsory license must be utilised.

The authorisation is however subject to conclusion of license contracts with the patentee.²²⁰ Therefore the request must prove that, the patentee has received from the person seeking the authorisation a request for a contractual license which has been unsuccessful. The requirement is waived in cases of national emergency or extreme urgency and as such the AG can proceed to authorise and thereafter notify the patentee as soon as it can.²²¹ This waiver helps avoid any delays associated with the conditions especially when there are outbreaks of diseases which require lifesaving medicines.

The decision of the AG with regards to granting of a license is however not final because aggrieved persons on matters relating to compulsory license may appeal to the Court.²²² This provision ensures that the AG, as a public officer, acts fairly.²²³

The exploitation of the invention is however predominantly for the supply of the domestic market.²²⁴ This controversial requirement in the TRIPS Agreement has been resolved to some extent by article 31 *bis* of the TRIPS Agreement. In this regard, the current legislation of Ghana does not make provision to enable the use of article 31 *bis* because Ghana has not signed the Amendment nor notified the TRIPS Council of its intention to use it.²²⁵

²¹⁶ Section 13(2) Patents Act of 2003.

²¹⁷ Section 3(5) and (6) Patents Act of 2003.

²¹⁸ Section 13(7) Patents Act of 2003.

²¹⁹ See Section 2.4.3.1 above.

²²⁰ Section 11(2) Patents Act of 2003.

²²¹ Section 13(10) Patents Act of 2003.

²²² Section 13(13) Patents Act of 2003.

²²³ Articles 23 and 296 Constitution of Ghana.

²²⁴ Section 13(11) Patents Act of 2003.

²²⁵ WTO Council for TRIPS ‘Annual Review of the Special Compulsory Licensing System Report to the General council’ (25 October 2017) 3 available at https://docs.wto.org/dol2fe/Pages/FE_Search/ExportFile.aspx?id=239708&filename=q/IP/C/79.pdf (accessed 25 October 2018).

In addition, the Act provides for another form of license known as non-voluntary license granted by the Court on grounds of ‘non exploitation’ or ‘insufficient exploitation of patents’.²²⁶ The first ground is invoked if after four years of filing a patent or three years after a patent has been granted there are no supplies in the market on reasonable terms without any justification, another person may apply for a non-voluntary license in Ghana to exploit it.²²⁷ The second ground is triggered where there are supplies in the market but such supplies are unable to meet the demands of the market. This therefore provides Ghana with additional grounds to justify the utilisation of the flexibility to advance access to medicines. The license granted must specify the scope of exploitation, the time period and the payment of adequate remuneration to the patentee.²²⁸ An obligation is therefore bestowed on the person to whom the license is granted to exploit it within the scope, time limit and sufficiently.²²⁹ This invariable will motivate patentees or workers of the patent to constantly supply the market to prevent their patents being exploited.

A license may also be granted where there are interdependent patents. In this case, an owner of a subsequent patent may apply to the Court for a non-voluntary license for an earlier patent. However, the precondition is that the invention must constitute a more ‘important technical advance of considerable economic significance’ in relation to the invention claimed under earlier patent.²³⁰ If the first patentee so desires, he may also request and obtain a cross-license on the earlier patent.²³¹ Unlike compulsory license under section 13, section 14 of the Act makes provision for exploitation of second patents.

Based on the incorporation of compulsory license and government use flexibility into Ghana’s legislation, a government use order was issued for public health reasons on 26 October 2005 after a state of emergency was declared within the national human immune deficiency virus/acquired immune deficiency syndrome (HIV/AIDS) program.²³² The notification was for the importation of generic antiretroviral (ARVs) from India which were patented by GlaxoSmithKline (GSK). The duration of license was for 3 years without the payment of royalties which dropped the cost of the ARVs by almost 50 per cent and government made

²²⁶ Section 14(1) Patents Act of 2003.

²²⁷ Section 14(1) Patents Act of 2003.

²²⁸ Section 14(3) Patents Act of 2003.

²²⁹ Section 14(4) Patents Act of 2003.

²³⁰ Section 14(5) Patents Act of 2003.

²³¹ Section 14(6) Patents Act of 2003.

²³² See Notification available at <http://www.cptech.org/ip/health/cl/Ghana.png> (accessed 25 September 2018).

savings and since then, no government use license has been issued.²³³ This was a few months after the December 2005 Amendment.

Around the same period, Danadams, a local pharmaceutical company was contracted to supplement the ARVS imported from India and the procurement from the company had to be paid for with resources from the government of Ghana.²³⁴ The ARVS were thus made available and affordable to people who needed them.

From the above discussions, the current legislation partially incorporates compulsory license because article 31 *bis* has not been signed and ratified. Also, some of the conditions and terms such as adequate remuneration are not defined. Undoubtedly, these gaps would limit the full utilisation of compulsory licensing in Ghana and actual usage of the flexibility.

b. South Africa

South Africa's Patents Act²³⁵ and Medicines and Related Substances Control Amendment (MRSCA) Act²³⁶ provides for compulsory license. Generally, South Africa grants compulsory license on grounds of dependent patents or where there is abuse of patent rights.

Accordingly, compulsory license on grounds of dependant patent is granted wherein the working of a patent is dependent on another patent and the patentee and prospective licensee cannot agree on the terms of licensing.²³⁷ In the case of *Atomic Energy Corporation of SA Ltd v The Du Pont Merck Pharmaceutical*,²³⁸ it was held that, the applicant for a license must show that the dependent patent is valid, and that the royalty he suggests is reasonable.

An abuse of power on the other hand occurs where a patent is not being worked in South Africa or demands are not met on reasonable commercial terms.²³⁹ In addition it occurs where there is refusal to grant a license which prejudices the establishment of a new industry in the interest of the public or where demand is met but prices charged by importers are more than

²³³WIPO 'Regional Seminar for Certain African Countries on the Implementation and Use of Several Patent-Related Flexibilities' available at http://www.wipo.int/edocs/mdocs/patent_policy/en/wipo_ip_dur_13/wipo_ip_dur_13_ref_t10b.pdf (accessed 5 October 2018) .

²³⁴ Osewe PL, Nkruma KY & Sackey EK *Access to HIV Medicines in Africa, Trade Related Aspects of Intellectual Property Rights Flexibilities* (2008) 40.

²³⁵ Sections 52-59 Act 57 of 1978 As Amended (hereinafter Patent Act of 1978).

²³⁶ Section 5(c) Act 90 of 1997 (hereinafter MRSCA Act of 1997).

²³⁷ Section 55 Patents Act of 1978.

²³⁸ Co 1997 BIP 90 (CP) at 93H.

²³⁹ Section 56 (2) (a) & (b) Patents Act of 1978.

the prices in the country of manufacture.²⁴⁰ These grounds legislated by South Africa are elaborate as they give more room to grant licenses to ensure access to medicines. The definition of what constitutes an abuse will thus ensure constant supply to meet the demand for medicines at reasonable prices.

Compulsory licenses are granted by the Courts however, products considered to be of vital importance may be put under compulsory license by an order from the Minister with equitable remuneration to the patentee.²⁴¹ The problem with the grant by the Courts is that, it is susceptible to all the challenges of procedure associated with the process but one may argue that, this is cured with the possibility of a minister having the power to issue compulsory license when a product is of vital importance.

The procedural requirements follows that of the TRIPS Agreement and as such section 56(2) (d) of the Patents Act provides for equitable remuneration for the patentee just like the TRIPS Agreement without defining what equitable remuneration is.

In addition to incorporating compulsory license in its legislation, South Africa has ratified the TRIPS Amendment to allow the grant of compulsory licenses to its generic suppliers to manufacture for domestic use and exports.²⁴² This is a step in the right direction because it narrows the gap for access to medicines challenges.

Comparing the extent of incorporation of the two legislative frameworks, South Africa seems to have taken a dynamic position in ensuring that patents do not overly impede its means of acquiring essential medicines than Ghana. With the exception of the imprecise facet around the determination of compensation, its compulsory license provisions cater for any contingency that may act as a stumbling block in ensuring that South Africa has access to adequate medicine for its inhabitants as compared to Ghana.²⁴³

Having examined the extent of incorporation of compulsory license in the legislations of Ghana and South Africa, I shall proceed to examine the extent of incorporation of parallel importation in the legislations of both countries.

²⁴⁰ Section 56 (2) (c) & (d) Patents Act of 1978.

²⁴¹ Section 54 & 56 (2) (d) Patents Act of 1978.

²⁴² WTO 'South Africa accepts protocol amending the TRIPS Agreement' available at https://www.wto.org/english/news_e/news16_e/trip_23feb16_e.htm (accessed 17 November 2018).

²⁴³ Ndlovu L 'The WTO TRIPS Agreement and Access to Medicines in South Africa Twenty Years into Democracy' 86.

3.3.2 Parallel importation in Ghana and South Africa

a. Ghana

Parallel importation is incorporated under the Patents Act (the Act),²⁴⁴ and the Public Health Act of Ghana.²⁴⁵ The Act, under its section 11(1) encourages the exploitation of patents while imposing an obligation on exploiters to seek the consent of the patentees. This is in accordance with article 28 of the TRIPS Agreement which protect patentees by conferring some rights on them. A reading of section 11(1) of the Act alone may seem to pose a limitation on parallel importation. This is however not the case because the Act incorporates article 6 of the TRIPS Agreement on rights of exhaustion, making parallel importation possible in Ghana.²⁴⁶ In this regard, the Act provides as follows;

‘The rights under the patent shall not extend to acts in respect of articles which have been put on the market in any country by the owner of the patent or with the owner’s consent.’²⁴⁷

The above provision’s use of the word ‘any’ makes parallel importation possible so far as a product which enjoys protection in Ghana is put on a market by a patentee or by a third party authorised by the patentee. The provision implores the utmost flexibility which is the international exhaustion regime.

In the case of *Rhone-Poulence SA & anor v Ghana National trading Corporation*,²⁴⁸ the Plaintiffs had a patent that covered a drug called metronidazole manufactured and sold by the second Plaintiff under the trade name Flagyl. The Defendant who was not a licensee of the patentee imported generic version of the drug for sale in Ghana. The Plaintiffs sought an injunction to restrain sale of the drug in Ghana. The court held that a product which is made in accordance with a patented process and imported for sale by a third person is an infringement. It further held that, the exclusive rights of the plaintiffs was violated by the importation of the drug into Ghana. This case was however decided at the time when Ghana had not adopted the international system of exhaustion. Thus, should this case be brought before the Ghanaian Courts today, judgement will be given in favour of the Defendants because of the adoption of the international exhaustion regime.

²⁴⁴ Patents Act of 2003

²⁴⁵ See Section 3.2.2 above

²⁴⁶ Section 11 (4) (a) Patents Act of 2003.

²⁴⁷ Section 11(4) (a) Patents Act of 2003

²⁴⁸ [1972] 2 GLR 109.

Another legislation incorporating this flexibility is the Public Health Act.²⁴⁹ Unlike the Patent Act, the Public Health Act specifically defines parallel importation to mean ‘importing a drug without authorisation of the drug registration holder from another country where it is legitimately placed’.²⁵⁰ The Public Health Act only requires that a product is legitimately placed without defining what legitimately placed and public interest are. This opens up for different interpretations as to the phrase ‘legitimately placed’ which could mean anyone other than the patentee or his agent.

Ghana in accordance with the incorporation, used this flexibility in the year 2000 to import generic medicines from India for HIV treatment manufactured by GSK who owned the patents that covered ‘Lamivudine’ and ‘Zidovudine’ formulations in Ghana. In the year 1998, CIPLA offered zidovudine to home and foreign markets at less than half the prevailing global price. CIPLA’s version of the drug was priced at US\$ 1.16 per tablet as against the international prices ranging between US\$ 2.90 and US\$ 5.90 per tablet. In the year 2000, CIPLA made shipments of a combination drug Duovir (Zidovudine plus Lamivudine) to customers in Ghana. GSK subsequently issued a warning to prevent the sale of Duovir in Ghana.²⁵¹ This led to a ban and affected the Ghanaian populace since the price of brand-name drugs was beyond the means of most Ghanaians. This ban however was not in accordance with the principles of parallel importation.

From the above, the current legislations meets the minimum standards of the TRIPS Agreement with the adoption of the most flexible regime and the use of this has enabled importation of relatively cheap medicines. Ghana has fully incorporated parallel and therefore eligible to utilise it to advance access to medicines in Ghana.

b. South Africa

South Africa’s Patent Act gives the impression of a national system of exhaustion for parallel importation.²⁵² The passage of the MRSCA Act²⁵³ in 1977 clarified that, South Africa has an

²⁴⁹ Public Health Act of 2012

²⁵⁰ Section 122(4) Public Health Act of 2012.

²⁵¹ CIPLA Ltd. And the Provision of Anti-AIDS Pharmaceuticals available at http://pconway.web.unc.edu/files/2016/01/cipla_aids.pdf (accessed 17 November 2018).

²⁵² Section 45 (2) of Patent Act of 1978 provides that, ‘The disposal of a patented article by or on behalf of a patentee or his licensee shall, subject to other patent rights, give the purchaser the right to use, offer to dispose of and dispose of that article’. This seems to suggest a national exhaustion regime.

²⁵³ MSRCA Act of 1997.

International exhaustion regime. The MRSCA Act enables the Minister to safeguard access while ensuring that, such safeguard does not contravene with the rights of the medicines already marketed in the country legally.²⁵⁴ Thus there is some protection of commercial interests in the country.²⁵⁵

To protect consumers and patentees with regards to parallel imported medicines, the Consumer Protection Act²⁵⁶ provides that;

‘a person who markets any goods that bear a trade mark, but have been imported without the approval or license of the registered owner of that trade mark, must apply a conspicuous notice to those goods in the prescribed manner and form’.²⁵⁷

The above section ensures that, consumers make informed choices since parallel imported products are not covered by any guarantee of the authorised distributor.

Arguable and from the above, both countries have adopted the best regime, however south Africa, in addition to the provisions to import relatively cheaper medicines and protect consumers, has the Consumer Protection Act while Ghana’s consumer protection regulations is still at the bill stage waiting to be passed into a substantive law.

In the next section, the research will discuss the extent of incorporation of the exemption from patentability flexibility in both countries’ legislations.

3.3.3 Exemption from patentability

a. Ghana

Under the Patent Act of Ghana (the Act), the right to exploit an invention extend to acts done only for ‘experimental purposes’ relating to a patent invention.²⁵⁸ It is however unclear whether the experimental purpose contemplated is in respect of the common exceptions of research and bolar exception when the scope has not been clearly defined.

The Panel in *Canada-Patent Protection of Pharmaceutical Product* defined the research exception as ‘the exception under which use of the patented product for scientific

²⁵⁴ Section 15(c) MSRCA Act of 1997.

²⁵⁵ CIPC Submission by South Africa (2017) available at http://www.wipo.int/export/sites/www/scp/en/meetings/session_27/3rdparty_comments/south_africa.pdf (accessed 17 November 2018).

²⁵⁶ Consumer Protection Act 68 of 2008.

²⁵⁷ Section 25 (2) Consumer Protection Act 68 of 2008.

²⁵⁸Section 11(4) Patents Act of 2003.

experimentation, during the term of the patent and without consent, is not an infringement'.²⁵⁹ The Act states that, acts done only for experimental purposes may be exempted. It does not indicate which type of experiment and the use of the word 'only' seems to suggest that any type of experiment is permitted and after the experiment the findings cannot be used for any other purpose. The provision seems to restrict itself in terms of the type of experiment to advance access to medicines. As such the closest exception that can be used is the research exception but not the bolar exception because of the specific requirement for naming the exception before it can be deemed incorporated.²⁶⁰ The failure to specifically name the exceptions undoubtedly will have a negative effect on access to medicines.

In this regard, the Clinical Pathology Department of the Noguchi Memorial Institute for Medical Research conducts research that contributes to intervention strategies and safeguards of public health in Ghana.²⁶¹ Entrance Pharmaceuticals and Research Centre also exploits resources to produce standardised medicines through research and development in collaboration with University of Ghana School to help advance studies in Pharmaceutics and product development.²⁶²

b. South Africa

This exception is provided under section 69A of its Patents Act.²⁶³ This is however limited to the bolar exception. This allows for introduction of generic medicines on the market by using the patented invention other than for the purposes of obtaining regulatory approval. Further, the Patents Act prohibits manufacturing and hoarding a product prior to the expiry date of the relevant patent with a view to lunch commercial sales immediately the patent expires.²⁶⁴ This provision thus protects patentees to enjoy the term of their exclusive rights.

Unlike Ghana which provides for experimental purpose exception, South Africa's Patents Act does not make provision for research exception. The bolar exemption thus enable generic manufacturers in South Africa take advantage to avoid monopoly in the system. Ghana unfortunately does not incorporate the bolar exception.

²⁵⁹ WT/DS114 (2000) paragraph 7.69.

²⁶⁰ See Section 2.4.3.3 above.

²⁶¹ Noguchi Memorial Institute for Medical Research available at <https://www.noguchimedres.org/index.php/clinical-pathology> (accessed on 18 November 2018).

²⁶² Entrance Research Centre available at <http://entrancepharmaceuticals.com/research-centre.html> (accessed on 18 November 2018).

²⁶³ Patents Act of 1978.

²⁶⁴ Section 69 A Patents Act of 1978.

Having examined the flexibility of exemption from patentability in both countries, the next section will examine the extent of incorporation of the patentability subject matter flexibility.

3.3.4 Patentability subject matter

a. Ghana

The Patent Act (the Act)²⁶⁵ of Ghana incorporates this flexibility by adopting the wording used by the TRIPS Agreement. Section 3(1) of the Act stipulates that ‘an invention is patentable if it is new, involves an inventive step and is industrially applicable’. Section 12(1) of Act incorporated Article 33 of TRIPS, doubling the period of patent protection to 20 years. This delays the entry of generic competition, and since generic competition tends to lower drug prices, a reduction in overall cost-savings is likely.²⁶⁶

The Act further defines the aforementioned terms unlike the TRIPS Agreement which does not define ‘new’ and only equate ‘inventive step’ and ‘capable of industrial application’ to ‘non-obvious’ and ‘useful’ respectfully.²⁶⁷ Under the Act, an invention is new if it is not anticipated by a prior Act.²⁶⁸ The Act further elaborate on prior act as everything disclosed to the public, anywhere in the world prior to the filing or, where appropriate, the priority date, of the application claiming the invention.²⁶⁹

Aside the procedural requirements necessary for application for a patent substantive examinations are also required to determine whether or not they are new and involve an inventive step.²⁷⁰

From the above if an act has been done before then it cannot be termed as new. The Act also defines the term inventive step and capable of industrial application which is synonymous to the definition provided in the TRIPS Agreement.²⁷¹

The Act under its section 2 provides an elaborate list of exemptions which includes discovery, scientific theory or mathematical method, rules for doing business and methods used for the treatment of the human body by therapy or surgery.

²⁶⁵ Patents Act of 2003.

²⁶⁶ Cohen JC, Gyansa-Lutterodt M, Torpey K et al, TRIPS, the Doha Declaration and increasing access to medicines: policy options for Ghana (2005) in 1(17) *Globalization and Health online Journal* 5.

²⁶⁷ Article 27 TRIPS Agreement.

²⁶⁸ Section 3(2) Patents Act of 2003.

²⁶⁹ Section 3(3) & 4 Patents Act of 2003.

²⁷⁰ Section 9 Patents Act of Ghana.

²⁷¹ Sections 3(4) and (6) Patents Act of 2003.

A review of this flexibility shows that Ghana has fully incorporated this flexibility into its current legislation with elaborate provisions explaining all the terms. Conditions are therefore ripe for Ghana to fully utilise it to advance access to medicines especially that it provides exemption for public health matters.

b. South Africa

South Africa adopts the same definition under the TRIPS Agreement and thus define patentable inventions as ‘any new invention which involves an inventive step and which is capable of being used or applied in trade or industry or agriculture’.²⁷²

With specific reference to pharmaceuticals, the Patents Act gives the impression that patenting of new uses of known substances may be allowed.²⁷³ The TRIPS Agreement does not expressly refer to the patenting of new uses of known substances. South Africa also makes provision for patent examinations, however the depository system for the registration of patents skips this substantive requirement.²⁷⁴

In comparison, both countries have provisions for the utilisation of the flexibility.

The next section will examine the flexibility of test data protection and the extent of incorporation by both countries.

3.3.5 Test data protection

a. Ghana

This flexibility under article 39 of the TRIPS Agreement aims at effective protection of data against unfair competition. In this regard, Ghana’s PUC Act²⁷⁵ aims at preventing unfair competition among products and services.²⁷⁶ Unfair competition according to the PUC Act includes acts in the course of industry or commercial activity that results in a breach in a manner contrary to honest business practices.²⁷⁷

²⁷² Section 25(1) Patent Act of 1978.

²⁷³ Section 25 (9) of the Patents Act of 1978 provides that ‘the fact that the substance or composition forms part of the state of the art immediately before the priority date of the invention shall not prevent a patent being granted for the invention if the use of the substance or composition in any such method does not form part of the state of the art at that date.’

²⁷⁴ CIPC Submission by South Africa (2017) available at http://www.wipo.int/export/sites/www/scp/en/meetings/session_27/3rdparty_comments/south_africa.pdf (accessed 17 November 2018).

²⁷⁵ PUC Act of 2000.

²⁷⁶ Preamble PUC Act of 2000.

²⁷⁷ Section 6 (2) (a) Unfair Competition Act of 2000.

The TRIPS Agreement imposes an obligation on Members to protect data against disclosure and against unfair commercial use when data is submitted for obtaining marketing approval.²⁷⁸ The PUC Act provides protection for undisclosed information or secret information which it defines as that which is not readily available in the circles, has commercial value and subjected to reasonable steps by the person lawfully in control of the secret.²⁷⁹ The act adopts the language of Article 39(2) in providing this protection in this regard.

The PUC Act however defines ‘industrial or commercial activities’ to include the activities of an enterprise providing a product or service.²⁸⁰ Thus the protection is in relation to products and services contrary to the protection of data as contemplated under Article 39.3 of the TRIPS Agreement. As such obtaining marketing authorisation from the Food and Drugs Authority (FDA) does not involve provision of a product or service and the submission of undisclosed data to obtaining marketing authorisation, is also not contemplated by this Act and for that reason issues of making commercial use of the data or otherwise do not arise.²⁸¹

Considering the requirement that the flexibilities be domesticated, it can be argued that the provisions under article 39 has been introduced into the Ghanaian legislation to protect unfair competition but not to protect data as envisaged by the TRIPS Agreement.

The obligations under TRIPS cannot therefore be enforced based on this Act and this may lead to relatively higher prices of medicines in the absence of product substitutes.

b. South Africa

There is a general protection of information submitted in respect of the regulation of medicines against unfair commercial use.²⁸² In this regard, the Director General of Health has the discretion to disclose information in respect of medicines deemed ‘expedient and in the public interest’.²⁸³ There is however no specific mention of this flexibility in South African legislations.

²⁷⁸ Section 39(3) TRIPS Agreement.

²⁷⁹ Section 5 PUC of 2000.

²⁸⁰ Section 2 PUC of 2000.

²⁸¹ Kunku I *The Regulation of the Distribution of Pharmaceuticals and its Impact on Access to Medicines in Ghana* (Unpublished LLM thesis Munich Intellectual Property Law Center 2014/2015) 12-13 available at <http://www.miplc.de/research> (accessed 5 September 2018).

²⁸² Section 34B MRSCA Act of 1997.

²⁸³ Section 24B MRSCA Act of 1997.

In comparison, both Ghana and South Africa even though have provisions to protect unfair competition, the provisions do not fully support the protection of data as required by the TRIPS Agreement.

Having discussed the flexibility of test data protection, the final section will discuss competition laws in both countries.

3.3.6 Competition Laws in Ghana and South Africa

a. Ghana

Ghana currently does not have a competition law. A draft bill²⁸⁴ however, has been in existence since the year 2004 awaiting parliamentary approval to be passed. Currently, the only legislation which makes express reference to ‘competition’ in Ghana is the PUC Act.²⁸⁵ Unfortunately, the PUC Act does not create any regulatory body or administrative process for the purpose of enforcement and as such aggrieved persons may seek common law remedies in a competent court.²⁸⁶ This PUC Act does not address issues of restrictive business practises, abuse of dominant positions and mergers which are required to check monopoly and indirectly reduce prices of product. The absence of such a law and a regulatory body can therefore be used as a leverage by big pharmaceutical industries to impede access to medicines through higher prices.

b. South Africa

South Africa has a competition law²⁸⁷ and a competition commission which investigates and prosecutes restrictive business practises, abuse of dominant positions and decide on mergers and acquisitions applications.²⁸⁸ The Commission therefore aims at achieving equity and efficiency in the South African economy.²⁸⁹ In the context of pharmaceuticals, the commission ensures that, there is adequate and healthy competition to regulate prices of medicines.

The competition Act in its section 8 seeks to prevent excessive pricing of medicines and acts which prevents competitors to access an essential facility. In the case of *Hazel Tau and Others*

²⁸⁴ Competition and Fair Trade Practices Bill (the Competition Bill).

²⁸⁵ PUC Act of 2000

²⁸⁶ Section 8 Unfair Competition Act of 2000.

²⁸⁷ Competition Act 89 of 1998.

²⁸⁸ Section 21 Competition Act 89 of 1998.

²⁸⁹ Competition Commission available at <http://www.compcom.co.za/> (accessed 20 November 2018).

v GlaxoSmithKline and Boehringer Ingelheim,²⁹⁰ the Applicants, Treatment Action Campaign²⁹¹ and other non-governmental organisations filed a complaint to the Competition Commission against Boehringer Ingelheim and GlaxoSmithKline, the Respondents. The Applicants alleged that the Respondents had charged excessive prices for ARVs which according to them violated section 8(a) of the Competition Act.²⁹² In addition, the Applicants averred that the exorbitant prices led to deaths of people living with HIV/AIDS as people could not afford them.²⁹³

The commission extended its investigations to include allegations that, the Respondent had further violated sections 8(b) and (c) of the Act by refusing to give competitors access to an essential facility. The Commission then held that, the Respondents had abused their dominant position by charging exorbitant prices for their drugs thereby denying other pharmaceutical companies the right to manufacture generic versions of their patented drugs.²⁹⁴ The Respondents subsequently agreed to allow the manufacture of generic versions of their drugs by selected pharmaceutical companies and export to the African sub region. In addition, the Respondent agreed to allow importation of the ARVS for distribution in South Africa with royalties not exceeding 5 per cent of the net sales of the relevant ARV's.

This was a ground breaking ruling for South Africa because it paved way to make generic drugs commercially available in South Africa.²⁹⁵ This ruling led to significant price decrease, increased competition and cumulative cost saving and lowered tender prices.²⁹⁶ This ruling supports the flexibilities of compulsory license and parallel importation to help improve access to medicines.

²⁹⁰ Case No 2002 Sep226.

²⁹¹ Treatment Action Campaign is a South African Non-Governmental Organisation which seeks to protect and advocates the s rights of persons living with HIV.

²⁹² Case No 2002 Sep226 para 2.

²⁹³ Case No 2002 Sep226 para 3.

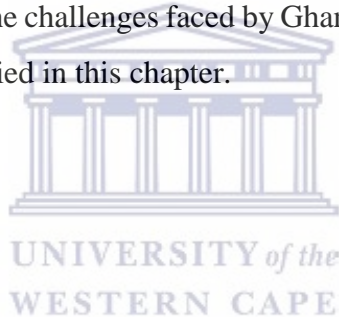
²⁹⁴ Case No 2002 Sep226 para 4.

²⁹⁵ Avafia T Berger J & Hartzenberg T 'The Ability of Select Sub-Saharan African Countries to utilise TRIPS Flexibilities and Competition Law to Ensure a Sustainable Supply of Essential Medicines: A study of Producing and Importing Countries' (2006) TRALAC available at <http://www.section27.org.za/wp-content/uploads/2010/10/Avafia-Berger-and-Hartzenberg.pdf> (accessed 17 November 2018).

²⁹⁶ International Working Group for Research of Competition Issues in the Pharmaceutical Market 'South Africa's Experience in Pharmaceuticals Industry: The case of antiretroviral drugs' available at [https://en.fas.gov.ru/upload/other/South%20Africa%E2%80%99s%20experience%20in%20pharmaceuticals%20industry%20\(H.%20Ratshisusu\).pdf](https://en.fas.gov.ru/upload/other/South%20Africa%E2%80%99s%20experience%20in%20pharmaceuticals%20industry%20(H.%20Ratshisusu).pdf) (accessed 18 November 2018).

3.4 Chapter conclusion

It has been shown that the TRIPS flexibilities reduces the effect of patents thereby promoting access to relatively cheap medicines. It is noteworthy that the legal framework and the extent of incorporation of the flexibilities in Ghana and South Africa are to some extent similar with some difference such as no provision for bolar exception, competition laws and non-ratification of the TRIPS Amendment on the part of Ghana. Ghana's legislative framework incorporates flexibilities such as compulsory license, parallel importation and research exception with some lacunas in these flexibilities incorporated. South Africa as the pacers in access to medicines even though has not incorporated all the flexibilities, has made significant advancement in terms of the flexibilities incorporated such as compulsory licencing, parallel importation, bolar exception and a functional competition law to help improve access to medicines. As such, Ghana's extent of incorporation of the flexibilities is not enough to help improve access to medicines. There is the need to review and fix the lacunas identified in the legislations if the flexibilities are to be utilised as options to accessing essential medicines. The next chapter will examine the challenges faced by Ghana in utilising the flexibilities apart from the legislative gaps identified in this chapter.



CHAPTER FOUR

CHALLENGES AND REASONS IMPEDING THE INCORPORATION AND UTILISATION OF THE TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS FLEXIBILITIES IN GHANA

4.1 Introduction

The preceding chapter established that, incorporating the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement flexibilities into the legislations of WTO Members is a prerequisite for the utilisation of the flexibilities. Some have however argued that, elaborate provisions in the statute books in itself does not guarantee promoting access to essential medicine and therefore requires addressing other non-legal issues.²⁹⁷

This chapter therefore explores the challenges and reasons impeding the incorporation and full utilisation of TRIPS flexibilities discussed under chapters two and three above. This is aimed at answering the question, ‘What challenges does Ghana face in utilising the flexibilities incorporated in its current national legislations and what challenges does it face in incorporating other flexibilities provided by the TRIPS Agreement?’²⁹⁸

To begin with, the next section will discuss the challenges impeding the successful utilisation of compulsory license and government use in Ghana.

4.2 Challenges impeding the utilisation of compulsory license and government use under article 31 of the TRIPS Agreement in Ghana

Compulsory license has been incorporated under sections 13 and 14 of the Patent Act of Ghana.²⁹⁹ Despite the domestication of this flexibility, the actual usage of it has been limited as much licenses have not being granted.³⁰⁰ This section identifies the challenges faced by Ghana in utilising compulsory license as follows:

- Administrative and infrastructure barriers
- Size of local pharmaceutical market
- World Health Organisation’s prequalification requirements

²⁹⁷ Adusei P ‘Exploiting Patent Regulatory “Flexibilities” to Promote Access to Antiretroviral Medicines in Sub-Saharan Africa’ (2009) 9 *University of Botswana Law Journal* 22.

²⁹⁸ See Section 1.3 above.

²⁹⁹ See Section 3.3.1 above

³⁰⁰ See Section 3.3.1 above.

- Viability of Ghana's local pharmaceutical industries questionable
- Cost of raw materials
- Lack of a substantive definition or guidelines for adequate remuneration
- TRIPS-plus requirements

These aforementioned challenges discussed below are not exhaustive but generally the major problems affecting the utilisation of the flexibility in Ghana.

4.2.1 Administrative and infrastructure barriers

The effective implementation of compulsory license requires a functional system with adequate know-how and administrative infrastructure.³⁰¹ The barriers created by the administrative infrastructure however hinder the effective utilisation of the compulsory license in Ghana.³⁰²

Issues of patents in Ghana are handled by the patent office of the Registrar General's Department. The Department started the transformation of its manual registry into a digital format in the 2017 to create a timely and accurate online filing system. Prior to the start of this transformation, the manual system of filing and registering patents created problems of uncertainty and delay in patent searches and the determination of patent status.³⁰³ The challenge of uncertainties and delays however still exist as the migration unto the digital system is still in process. The delays therefore serve as a disincentive to prospective patentees who then opt to file their patent applications and searches either through the Patent Cooperation Treaty (PCT) or the African Regional Intellectual Property Organisation (ARIPO).³⁰⁴ A patent search at ARIPO however has been discouraging because, the results sometimes fails to clarify the patent status of some products. In a response to a search to determine the status of some products, ARIPO used an ambiguous wording: 'It would appear that those products were patented in Ghana'.³⁰⁵

³⁰¹ Skees S Thi-ing up the TRIPS Agreement: Are Compulsory Licenses the Answer to Thailand's AIDS Epidemic? (2007) 19 *Pace International LR* 271.

³⁰² Cohen JC, Gyansa-Lutterodt M, Torpey K et al TRIPS, the Doha Declaration and increasing access to medicines: policy options for Ghana' (2005) 1:17 *Globalization and Health* 6 available at <https://doi.org/10.1186/1744-8603-1-17> (accessed 28 June 18) .

³⁰³ Registrar General Department available at <http://rgd.gov.gh/> (accessed 12 November 2018).

³⁰⁴ See Section 3.1.2 (a) above.

³⁰⁵ Osewe PL, Nkruma KY & Sackey EK *Improving Access to HIV Medicines in Africa, Trade Related Aspects of Intellectual Property Rights Flexibilities* (2008) 24.

These barriers created by patent infrastructure in both national and regional systems make it difficult to determine the status of a patent in Ghana which is necessary for the issuance of a compulsory license. The challenge, delays the entry of essential generic medicines because generic producers will want to avoid any protracted legal battles when the status of product is ambiguous.

4.2.2 Size of local pharmaceutical market

The issue of market size has an effect on the effective utilisation of compulsory license because a small market size may not justify investments in manufacturing generic version of medicines and payment of adequate remuneration to a patentee.³⁰⁶ Thus, where medicines are manufactured with potential off takers, it has an effect on its prices as a result of passionate savings in cost gained by an increased level of production. Most pharmaceuticals in Ghana however manufacture predominantly for the domestic market.³⁰⁷ The result is that more money is spent manufacturing for the local market which serves as a disincentive to pharmaceutical companies manufacturing generic medicines.

4.2.3 World Health Organisation's prequalification requirements

The World Health Organisation (WHO) prequalification of medicines programme was initiated in 2001 in response to the lack of harmonised system for regulating drugs in developing countries (DC).³⁰⁸ The requirement was to ensure that, medicines procured by governments meet the standards of 'quality, safety and efficacy' of medicinal products by manufacturers worldwide.³⁰⁹ Prequalification consist of five components including prospective manufacturers providing comprehensive data for evaluating the purity of all ingredients used in manufacturing finished pharmaceutical product and results of bioequivalence tests.³¹⁰

³⁰⁶ Stirner B & Thangaraj H 'Learning from practice: compulsory licensing cases and access to medicines' 2013 *Pharm. Pat. Analyst* 195.

³⁰⁷ Cohen JC, Gyansa-Lutterodt M & Torpey K et al (2005) 7.

³⁰⁸ Ra'go L & Santoso B 'Drug regulation: history, present and future' in Van Boxtel CJ, Santoso B and Edwards IR (eds) *Drug benefits and risks: International textbook of clinical pharmacology* (2008) 65–77.

³⁰⁹ Worku WZ, Gordon J and, Stahl MMS et al 'Deficiencies in generic product dossiers as submitted to the WHO Prequalification of Medicines Programme' (2012) *Journal of Generic Medicines* 9(2) 63.

³¹⁰ WHO 'Prequalification Fact sheet' (2010).

Going through the prequalification process however requires huge finances for conducting tests which are prohibitive to manufacturing companies.³¹¹ The inability to pay these huge finances result in delays in acquiring documentations. This leaves the government of Ghana with no other option than to contract pharmaceutical companies and purchase the medicines without the WHO prequalification. The option of government purchasing medicines without prequalification requirements is however unsustainable because a huge chunk of money is spent by the government instead of the process being donor-funded.³¹²

A case in point is when Danadams Pharmaceutical Company which had no WHO prequalification requirements had to supply Antiretroviral (ARVs) although the company had modern manufacturing equipment.³¹³ The government of Ghana contracted the company for a year to supplement ARVS and thus the procurement from the company had to be paid for with resources of the government and not with funds from the Global Fund.³¹⁴

4.2.4 Viability of domestic pharmaceutical companies

Insufficient manufacturing capacities constrain licensing activities in Ghana thus making the viability of Ghana's pharmaceutical companies questionable.³¹⁵ Ghana has about 38 licensed pharmaceutical manufacturers which are good manufacturing practices (GMP) certified.³¹⁶ Of this number, about 22 are active with 17 to 18 producing throughout the entire year.³¹⁷ This number may be enough to produce medicines if all are producing at the same time. However if only 17 are producing then, it goes to confirm that most of the generic manufacturers in the country do not either have the necessary technology or market to engage in manufacturing for local and external consumption. In the absence of a viable market, the option of importing medicines becomes economically viable.

³¹¹ Huang Y, Pan K, Peng D et al 'A qualitative assessment of the challenges of WHO prequalification for anti-malarial drugs in China' (2018) *Malaria J* 17:149.

³¹² Osewe PL, Nkruma KY & Sackey EK (2008) 39.

³¹³ Osewe PL, Nkruma KY & Sackey EK (2008) 39.

³¹⁴ Osewe PL, Nkruma KY & Sackey EK (2008). The Global Fund is a 21st-century partnership organization between governments, civil society, the private sector and people affected by the diseases founded in 2002 designed to accelerate the end of AIDS, tuberculosis and malaria as epidemics. The Global Fund has been supporting health programs in Ghana since 2002. See The Global Fund available at <https://www.theglobalfund.org/en/overview/> (accessed 25 October 2018).

³¹⁵ Cohen JC, Gyansa-Lutterodt M, Torpey K et al (2005) 7.

³¹⁶ The draft Ghana strategy document 'The Future of Ghana's Pharmaceutical Industry – Building a Centre of Excellence in Africa' (2010).

³¹⁷ Cohen JC, Gyansa-Lutterodt M & Torpey K et al (2005) 7.

Ghana's pharmaceutical industry is more focused on the final formulation and packaging stages. They source their raw materials from international suppliers with Active Pharmaceutical Ingredients (APIs) mostly imported from India and China.³¹⁸ The inability to produce raw materials affects the utilisation of compulsory license because, even if a license is issued for production in Ghana, it will not be viable for the local pharmaceutical companies due to the cost of the APIs.

4.2.5 Cost of raw materials

Most raw materials in the form of APIs needed for manufacturing pharmaceutical products are imported and subject to duties, taxes and tariffs.³¹⁹ The taxes on these APIs imported are high which serve as a disincentive to pursuing compulsory license locally. In this regard, the government of Ghana provides exemptions in instances of public procurement to reduce the cost of manufacturing.³²⁰ These exemptions includes bottles, caps, drug information leaflets and other inputs but does not cover all active ingredients.³²¹ The exemptions erode the potential cost advantage that local manufacturing can provide. This is because, the cost of raw materials including APIs coupled with the tax on them despite the tax exemptions may still be prohibitive inhibiting the use of compulsory license locally.

4.2.6 Lack of a substantive definition or guidelines for adequate remuneration

The TRIPS Agreement defers what constitute adequate remuneration to the discretion of countries.³²² Unlike Japan and Canada³²³ which have strict guidelines on adequate remuneration, Ghana has not yet established a concrete policy for determining what an adequate remuneration should be. The result is that, if royalties are exorbitant, it will serve as a disincentive to private investors especially generic manufacturers due to the unattractive

³¹⁸ The draft Ghana strategy document (2010).

³¹⁹ The draft Ghana strategy document (2010).

³²⁰ The Value Added Tax (VAT) (Exemption of Active Ingredients, Selected Inputs and Selected Drugs or Pharmaceuticals) (Amendment) Regulations of 2017.

³²¹ Valued Added Tax Amendment (2017).

³²² Article 31(h) TRIPS Agreement.

³²³ 'Royalty guidelines proposed by the Japanese Patent Office (1998) and UNDP (2001) set royalties from 0 to 6% of the price charged by the generic competitor. The 2005 Canadian royalty guidelines for the export of medicines to countries that lack manufacturing capacity set royalties at 0 to 4% of the generic price, depending upon the level of development of the importing county'. See UNDP Remuneration guidelines for non-voluntary use of a patent on medical technologies available at http://www.who.int/hiv/amds/WHOTCM2005.1_OMS.pdf (accessed 21 November 2018).

profits. This situation inevitably makes government investment the only safe net especially in times of national emergencies.³²⁴

4.2.7 TRIPS-plus requirements

Ghana is regarded as having a TRIPS ‘plus’ status in terms of its intellectual property rights (IPRs) laws.³²⁵ This is because unlike the TRIPS flexibilities which aims at balancing the interest of patentees and users, most TRIPS-plus obligations aims at protecting pharmaceutical companies and are less geared towards promoting public health.³²⁶ The TRIPS-plus obligations are normally strict obligations incorporated into Free Trade Agreements (FTAs).³²⁷ These FTAs set standards beyond those provided by the TRIPS Agreement which imposes strict obligation on countries.³²⁸ Most investment agreements apply to rights not covered by the TRIPS Agreement and incorporate the national treatment principle clause without the exceptions provided for under IPRs treaties.³²⁹ The TRIPS-plus provisions therefore puts countries like Ghana at risk of being unable to utilise the TRIPS flexibilities.³³⁰

Ghana has a bilateral FTA with the European Union with coverage in goods.³³¹ This FTA is linked to the European Partnership Agreement (EPA) with the African Caribbean Pacific Countries³³² which Ghana is also a signatory to. All European FTA’s tend confirm their

³²⁴ Ley B ‘Patent rights and access to medicines: Are patents really the only barrier for good health care in developing countries?’ in Sinjela M (ed) *Human Rights and intellectual property rights: Tensions and convergences* (2007) 114-117.

³²⁵ Harper J and Gyansa-Lutterodt M (2007) 65.

³²⁶ Roffe P & Spennemann C ‘The impact of FTAs on public health policies and TRIPS flexibilities’ (2006) 1 *International Journal of Intellectual Property Management* 86.

³²⁷ A free trade agreement (FTA) is a trade treaty between two or designated group of countries that have agreed to eliminate tariffs, quotas and preferences on most (if not all) goods and services traded between them. Usually these agreements aim to give each other access to markets by lowering or removing border protection measures such as border taxes on exports and imports, and other barriers such as standards, processes. See IMC- Economic Research & Training Foundation Paper on Free Trade Agreement available at http://www.imcnet.org/cms/public/content/ertf_thoughtpaper/2.%20Free%20Trade%20Agreement.pdf (accessed on 20 November 2018).

³²⁸ Sell SK ‘Trips-Plus Free Trade Agreements and Access to Medicines’ (2007) 28 *Liverpool Law Review* 57-8.

³²⁹ Correa CM ‘Investment Protection in Bilateral and Free Trade Agreements: Implications for the Granting of Compulsory Licenses’ (2004) 26 *Michigan Journal of Int’l L* 352.

³³⁰ Roffe P & Spennemann C (2006) 77.

³³¹ WTO ‘Ghana’ available at <http://rtais.wto.org/UI/PublicSearchByMemberResult.aspx?MemberCode=288&lang=1&redirect=1> (accessed 11 November 2018).

³³² The EPA negotiations result from the interaction of the Lome Conventions and the Cotonou Agreement with the WTO Agreement. The Conventions, of which Cotonou was the last iteration, set up a system of non-

adherence to the Doha Declaration in their preamble yet the substantive provisions of the agreements include TRIPS-plus provisions which impacts negatively on access to medicines.³³³ In addition, the Commission of the European Union uses trade policies such as placing countries on a trade watch list to pressure countries to refrain from making full and legitimate use of TRIPS flexibilities.³³⁴ Ghana and other countries therefore rather adhere to the strict obligations in order not to be put on such trade watch lists.

Having identified the challenges which hinders the effective use of compulsory licenses under article 31 of the TRIPS flexibilities, this research proceeds to identify the possible reasons accounting for Ghana not signing and ratifying Article 31 *bis* (Amendment) of the TRIPS Agreement.

4.3 Possible challenges or reasons for Ghana not signing and ratifying the TRIPS Amendment

The Amendment to the TRIPS Agreement came to force on 23 January 2017 after two thirds of WTO Members ratified it. In accordance with WTO Jurisprudence, the Amendment will only apply to the countries that have ratified it.³³⁵ As indicated in chapter 2, there is still a leeway for countries like Ghana to rely on the August 2003 Decision to import patented medicines until December 2019.

The challenges discussed below have been identified as the possible reasons accounting for Ghana not signing and ratifying the Amendment.

4.3.1 Status of the country

The uncertainty of the use of article 31 *bis* seems to have contributed to Ghana not signing the Amendment which undoubtedly will have an impact on access to medicines in Ghana. The use of article 31 *bis* of the TRIPS Agreement is limited to Least developed countries

reciprocal preferences between the EU and the ACP. This system of preferences was established in part to enable the economic development of the ACP countries by providing preferential access for their products to European markets as compared to other countries. See 'The European Approach to Intellectual Property in European Partnership Agreements with the African, Caribbean And Pacific Group of Countries, Discussion Paper, April 2007 available at http://www.ciel.org/Publications/EU_EPAs_Draft_18Apr07.pdf (accessed 28 November 2018).

³³⁴ Health Action International 'Empty Gestures: The EU's Commitments to Safeguard Access to Medicines Review of the European Union's Trade & Investment Policy' (2015) 3 available at http://trade.ec.europa.eu/doclib/docs/2015/october/tradoc_153873.pdf (accessed 28 November 2018).

³³⁵ Article X paragraph 3 WTO Agreement: Marrakesh Agreement Establishing the World Trade Organization (1994) 33 I.L.M.

(LDCs) and DCs which have demonstrated that, they have no or insufficient manufacturing capacities.³³⁶ It is however unclear whether a DC like Ghana with about 38 local pharmaceutical industries can use the amendment and if so, under what circumstances.³³⁷

4.3.2 Manufacturing capacity of Ghana

Ghana has limited industries which can produce APIs. With manufacturing companies such as Danadams, Ernest Chemist and Tobinco pharmaceutical companies, the country has been classified as being able to reproduce drugs as long as APIs are imported.³³⁸ To facilitate local production, the government of Ghana has exempted some pharmaceutical products from tax and tariffs. If Ghana is able to exempt taxes for importing APIs, then there will be no motivation for signing the Amendment or notifying the council for its use once Ghana can import the APIs and produce for its domestic market.

4.3.3 Administrative complexities and ambiguities concerning remuneration

The application for the use of compulsory license comes with its administrative complexities such as prior notification to the TRIPS Council and both the exporting and importing countries obtaining compulsory licenses.³³⁹ The Amendment also limits the exporting country's compulsory license to a 'single-supply basis', implying that the entire complex process must repeat for each new request.³⁴⁰ This administrative complexities increases transaction costs and possibilities for delay as every license has to go through the whole process.³⁴¹

Also the ambiguity surrounding adequate remuneration may result in 'exporting countries paying prices that are either too high, thereby negating the potential gains they receive as a result of producing low cost medicine or too low, in which case the patentee would not receive adequate compensation for use of his patent'.³⁴² These administrative complexities may make article 31 *bis* unappealing to Ghana.

³³⁶ See Section 2.4.3.1(a) above.

³³⁷ Cohen JC, Gyansa-Lutterodt M, Torpey K et al (2005) 7.

³³⁸ Cohen JC, Gyansa-Lutterodt M, Torpey K et al (2005) 7.

³³⁹ See Section 2.4.3.1 above.

³⁴⁰ Cohen JC, Gyansa-Lutterodt M, Torpey K et al (2005) 7.

³⁴¹ Lang MC 'Note, What a Long, Strange "TRIPS" It's Been: Compulsory Licensing from the Adoption of TRIPS to the Agreement on Implementation of the Doha Declaration' (2004) 3 *J Marshall Rev Intell Prop L* 343.

³⁴² Anderson B 'Better Access to Medicines: Why Countries Are Getting —Tripped Up and Not Ratifying Article 31-Bis' (201) 1 (2) *Case Western Reserve Journal of Law, Technology & the Internet* 176.

4.3.4 Political challenges of ECOWAS and pressures from developed countries

One of the waivers in the Amendment was to enable exports to markets of other DCs or LDC who are parties to an RTA sharing the health problem in question.³⁴³ The waiver may however pose a number of administrative and technical difficulties. This is because the ECOWAS trade bloc to which Ghana belongs, has sixteen countries with only five anglophone countries of which Ghana is one.³⁴⁴ These countries have different legislations and more importantly the procurement laws are not the same. The difference in legislation may act as a barrier to procuring medicines or producing to export to the countries within the region. The political instability of most of the countries may also affect the bulk procurement and without a sufficient political will, the ECOWAS will find it difficult sustaining this system for the benefit of its member states.³⁴⁵

Also, developed countries are known for pressurising DCs to refrain from using compulsory licenses even as they invoke compulsory licenses on their own behalf.³⁴⁶ Article 31 *bis* attempted to rectify this situation by including a provision preventing Members from challenging any measures taken in conformity with the provisions of the TRIPS Agreement.³⁴⁷ However, a persistent fear of sanctions resulting from the year 2001 Brazil litigation along with consternation over angering pharmaceutical companies arguably deters DCs like Ghana from ratifying the amendment.³⁴⁸

The above discussion has established that the flexibility is saddled with challenges which makes it difficult to utilise especially when issued for local production. The Amendment came as a relief to resolve some of the challenges but came with it us own challenges. This challenges may be disincentives to Ghana not signing the Amendment. However, do the above reasons and challenges for not signing the Amendment outweigh the implications? The next section discusses the implications of Ghana not signing and ratifying the Amendment.

³⁴³ See Section 2.4.3.1 above.

³⁴⁴ ECOWAS available at <http://www.ecowas.int/member-states/> (accessed 10 October 2018).

³⁴⁵ Osewe PL, Nkruma KY & Sackey EK (2008) 24.

³⁴⁶ Dutfield G 'Delivering Drugs to the Poor: Will the TRIPS Amendment Help?' (2008) *34 American JL & Med* 115-6.

³⁴⁷ Article 31 bis (4) TRIPS Agreement.

³⁴⁸ Weissman R 'A Long, Strange TRIPS: The Pharmaceutical Industry Drive to Harmonise Global Intellectual Property Rules, and the Remaining WTO Legal Alternatives Available to Third World Countries' (1996) *17 UPA JINT' L ECON L* 1079.

4.4 Implications for Ghana not signing the Amendment

As already indicated, there is still a leeway for Countries like Ghana to rely on the August 6 Decision to import patented medicines up until the December 2019. This however has three major implications for Ghana in accessing essential medicines taking into consideration the WTO's jurisprudence.

1. The first implication is that, Ghana after December 2019 cannot rely on the August 2003 Decision to import medicines even in situations of emergency where the manufacturing capacity is unable to produce. This therefore might lead to shortage of medicines in extreme emergencies.
2. Secondly, the local pharmaceutical industries, if they are able to produce generic versions in large quantities cannot expand their market size to LDCs by producing generic versions of medicines for exports. In the absence of potential off takers from other countries and any financial injections from the government to support the high cost of production in Ghana, this may push some pharmaceutical industries out of the market. The consequence is that, access to medicines may be limited.
3. Finally, pharmaceutical industries contribute to the economy of Ghana through the payment of import and export taxes. If Ghana ratifies the Amendment, it may increase the foreign exchange of the country through exports of medicines. Ghana however cannot do so after the year 2019 if the Amendment is not signed. The consequence is that government aside ensuring access for its citizens, losses some form of revenue from imports and exports.

Based on the implications identified above, Ghana stands a better chance of signing and ratifying the Amendment to shield it in times of emergency when its pharmaceutical industry cannot support the country other than not doing so now.

Having discussed the challenges in utilising compulsory licencing, it is important to note that the flexibility of parallel importation is also not without challenges. The next section will therefore discuss the challenges impeding the utilisation of parallel importation.

4.5 Challenges impeding the utilisation of parallel importation in Ghana

Ghana has incorporated parallel importation into its current legislations and adopted the most flexible regime of exhaustion which enables importation of essential medicines.³⁴⁹ Despite the adoption of the most flexible regime, the following major challenges have been identified as impeding its effective utilisation:

- Administrative barriers
- Influx of counterfeit or substandard products
- Prohibited and restricted imports
- Pharmaceutical mark-ups

The aforementioned challenges to be discussed hereunder if addressed will to a large extent incentivise pharmaceutical industries to import quality but less expensive medicines to improve access to essential medicines in Ghana.

4.5.1 Administrative barriers

In Ghana, one can only parallel import products when the requisite import permits are granted by the designated authorities. The import permits are however difficult to obtain in Ghana.³⁵⁰ Ghana has a set of guidelines administered by the Food and Drug Authority (FDA) detailing the procedures and conditions to be met for the issuance of an import permit for the importation of products. These guidelines are intended to ensure that parallel imported medicines are duly approved and registered by the FDA of Ghana.³⁵¹

The procedures involved in obtaining these import permits are however cumbersome. This places more burden on the importers and in the event of the importers not meeting the requirements, the licenses are not granted. These procedures and requirements include the importer ensuring that, the medicine intended to be imported is registered in Ghana. In the absence of such registration, it is incumbent on the importer to import some samples for prior registration with the FDA. The importer also has the duty to notify the holder of the registered

³⁴⁹ See Section 3.3.2 above.

³⁵⁰ Cohen JC, Gyansa-Lutterodt M, Torpey K et al (2005) 6.

³⁵¹ FDA 'Guidelines For The Registration Of Parallel Imported Drugs Or Herbal Medicinal Products' DOC NO: FDA/MDD/GL-04 (2013).

license of his intention to import such products. The FDA further requires an application to be submitted for registration of parallel import from each individual exporting country.³⁵²

In addition, the FDA has no discretion to waive licensing requirements for medicines imported into the country even in times of emergency. It can however process applications limited to paediatric formulation, Ministry of Health (MOH) tender purposes or certain public health programmes but not for private pharmaceutical industries.³⁵³

Even though the procedures are to ensure that quality products are imported, they delay the grant of the import license which may serve as a disincentive to parallel import. This challenge undeniably limits the utilisation of the flexibility and affects access to essential medicines in Ghana.

4.5.2 Influx of counterfeit medicines

In Ghana, parallel importation has led to the increase in importation of counterfeit medicines sourced and imported into the country which reaches the end user before undergoing the stringent procedures required by the FDA.³⁵⁴ The counterfeit medicines are easily imported into the country through the loose and porous borders of Ghana.³⁵⁵ These medicines are often less expensive and more accessible than the original drugs because they do not undergo any examinations and no taxes are paid on them.

Due to the less expensive nature of counterfeit medicines, people patronise them more than the original ones imported by licensed pharmaceutical industries. Coupled with the stringent procedures for importation, the influx of counterfeit medicines serves as a disincentive for registered pharmaceutical companies to utilise parallel importation.

4.5.3 Prohibited and restricted imports

The government of Ghana in 2017 banned the importation drugs deferring their production to local manufacturers with the aim boosting local production to encourage innovation.³⁵⁶ The ban is in relation to 49 medicines which includes aluminium hydroxide or magnesium

³⁵² FDA (2013) 3.

³⁵³ Kunku I *The Regulation of the Distribution of Pharmaceuticals and its Impact on Access to Medicines in Ghana* (Unpublished LLM thesis Munich Intellectual Property Law Center 2014/2015) 17.

³⁵⁴ Cohen JC, Gyansa-Lutterodt M, Torpey K et al (2005) 6.

³⁵⁵ Oneko S 'Fighting the spread of fake drugs in Africa' (11 January 2018) available at <https://mg.co.za/article/2018-01-11-fighting-the-spread-of-fake-drugs-in-africa> (accessed on 25 November 2018).

³⁵⁶ Gazette Executive Instrument 181 (E.I. 181) (2017).

trisilicate suspension, amoxicillin capsules and suspension, aspirin or caffeine tablet, folic acid tablet, and cetirizine tablet.³⁵⁷

The ban may encourage local pharmaceutical companies to innovate but at the same time a restriction on the flexibility of parallel importing these 49 banned medicines. The result is that, even if it is not viable for pharmaceutical companies to produce these banned medicines locally because the ingredients to be used are expensive, parallel importation cannot be resorted to.

4.5.4 Pharmaceutical mark-ups and uncontrolled distribution system

Ghana receives discounted medicines from generic pharmaceutical industries however, mark-ups³⁵⁸ between 11 to 275 percent contrary to the approved 10 per cent margin by the Ministry of Health wipes out many price advantages once they get into the country.³⁵⁹ The weaknesses in drug pricing controls due to an uncontrolled distribution system and absence of an enforceable drug price mark-up therefore makes it possible for drugs to receive several mark-ups to cover the tariffs and duties paid.³⁶⁰

The private sector pharmaceutical distribution system in Ghana has also been described as chaotic because of the number of intermediaries involved in pharmaceutical distribution which is difficult to determine.³⁶¹ This chaotic system impacts adversely on the availability, product security and the final price of pharmaceutical products and undermines the possibility of consumers to obtain medicines.³⁶² As such the FDA has adopted guidelines for good distribution practices aimed at ensuring quality assurance of medicines. The FDA guidelines unfortunately do not regulate the activities of wholesalers and retailers leaving the distribution system still chaotic.³⁶³

³⁵⁷ Gazette Executive Instrument 181 (E.I. 181) (2017).

³⁵⁸ A mark-up is the difference between the cost price of a drug and the selling price See Ball D WHO/HAI Project on Medicine Prices and Availability 'Pharmaceutical Pricing Policies and Interventions: The Regulation of Mark-ups in the Pharmaceutical Supply Chain' (Working Paper 3, May 2011) 1 available at <http://www.haiweb.org/medicineprices/05062011/Mark-ups%20final%20May2011.pdf>. (accessed 28 August 2018).

³⁵⁹ Cohen JC, Gyansa-Lutterodt M, Torpey K et al, (2005) 7.

³⁶⁰ Harper J and Gyansa-Lutterodt M (2007) 30.

³⁶¹ Harper J and Gyansa-Lutterodt M (2007) 30.

³⁶² Harper J and Gyansa-Lutterodt M (2007) 30.

³⁶³ FDA Guidelines For Good Distribution Practices For Drugs, Cosmetics, Medical Devices And Household Chemical Substances (FDA/DRI/DED/GL-GDP/2013/06) available at <http://www.fdaghana.gov.gh/images/stories/pdfs/downloads/drugs%20guidelines/GUIDELINES%20FOR%20GOOD%20DISTRIBUTION%20PRACTICES%20FOR%20DRUGS.COSMETICS.MEDICAL%20DEVICE%20AND%20HOUSEHOLD%20CHEMICAL%20SUBSTANCES.pdf> (accessed 12 October 2018).

Given this chaotic situation of distribution, even if medicines are imported at low prices, they do not translate into actual benefits for the locals.³⁶⁴ In the absence of a competition law mark-ups defeat the whole purpose of parallel importing. This is made worse as Ghana does not regulate the prices of medicines.³⁶⁵ The absence of price regulations can therefore lead to the formation of cartels fixing prices.

The challenges discussed above have impacted negatively on utilising parallel importation and the next section will discuss the challenges impeding the utilisation of the exemption from patentability flexibility.

4.6 Challenges impeding the utilisation of exemption from patentability in Ghana

Exemption from patentability has been partially introduced into the legislation of Ghana.³⁶⁶ In addition to the undefined scope in the legislation, this section identifies the following major challenges hindering the effective utilisation of this flexibility:

- Extension of life of patents
- Test data and market authorisation laws

4.6.1 Extension of life of patents.

In Ghana, patents are granted for a period of 20 years.³⁶⁷ However, a problem always arise where big pharmaceutical companies in their bid to maintain monopoly attempt to extend patent life by refusing to grant licenses to generic companies.³⁶⁸ The process of extending the life of patents is known as ‘evergreening’, which is a tactic used to apply for ‘secondary patents over related or derivative technologies’.³⁶⁹ The Patents Act of Ghana does not address evergreening and there has not been any decisions but generics manufacturing companies do

³⁶⁴ Ley B in M Sinjela (eds) (2007) 114-17.

³⁶⁵ McCabe and others, ‘Private Sector Pharmaceutical Supply and Distribution Channels in Africa: A Focus on Ghana, Malawi and Mali’ [August 2011 Health, Nutrition and Population (HNP)] Discussion Paper, 15 available at <http://siteresources.worldbank.org/HEALTHNUTRITIONANDPOPULATION/Resources/281627-1095698140167/PvtSectorPharma0811.pdf> (accessed 21 November 2018).

³⁶⁶ See Section 3.3.3.

³⁶⁷ Section 12 (1) Patent Act of 2003.

³⁶⁸ Chalmers R ‘Evergreen or Deciduous? Australian Trends in Relation to the ‘Evergreening’ of Patents’ (2006) 30 *Melbourne University Law Review* 29.

³⁶⁹ Chalmers R (2006) 29. Also see WIPO, Primary and Secondary Patents available at www.wipo.int/edocs/mdocs/en/cdip_15/cdip_15_inf_2.docx (accessed 29 November 2018) Patents on active ingredients are referred to as primary patents. In later phases of the drug development, patents are filed on other aspects of active ingredients such as different dosage forms, formulations, production methods etc. These patents are referred to as secondary patents.

however, complain that the system works against them.³⁷⁰ Even though there are patentability requirements provided under the Patent Act of Ghana, patenting of new uses of known substances by adding minor changes of existing drugs still persist in Ghana. Innovator companies also use ‘brand migration’ as a substitute in order to extend product life cycles.³⁷¹

The result is that, the practise of extending patent life acts as a disincentive for continued research and development in the pharmaceutical industry because the research conducted by prospective manufactures may become obsolete and not serve its intended purpose.

4.6.2 Test data and market authorisation laws

Pharmaceutical companies rely on the use of the originators’ test data or submit data for market authorisation.³⁷² This process involved in submitting data for marketing authorisation is time-consuming and expensive for the generic industries because it require the repetition of safety and efficacy testing. The process also requires finance which may discourage generic manufacturers from experimenting and coming out with new drugs.

Having discussed the challenging in utilising exception from patentability, the next section will be a discussion of challenges in effectively utilising patentability criteria.

4.7 Patentability criteria

Ghana has fully incorporated this flexibility into its patent Act.³⁷³ This section therefore examines the following challenges which accounts for Ghana’s inability to utilise patentability criteria to improve access to medicines:

- Limited expertise in patent examinations
- Limited capacity in patent infrastructure

These challenges to be discuss hereunder are important because it is only when a product is detected as having been patented that exploitation requires conditions. Experts and infrastructure for testing patentability are therefore necessary to detect patented products.

³⁷⁰ Harper J and Gyansa-Lutterodt M (2007) 22.

³⁷¹ Bansal S, Sahu D & Bakshi G et al ‘Evergreening–A Controversial Issue in Pharma Milieu’ (2009) 14 *Journal of Intellectual Property Rights* 4 302.

³⁷² FDA Guidelines 2013.

³⁷³ See Section 3.3.4 above.

4.7.1 Limited expertise in patent examinations

To determine whether an application merits a patent requires expert knowledge. Many DCs including Ghana are yet to realise the benefits of the flexibilities and have therefore failed to incorporate the TRIPS flexibilities into their laws because of the limited number of legal and technical expertise to aid in the incorporation.³⁷⁴

Thus the examination to determine inventive step, new and industrial application requires scientists or engineers with specific technical expertise in the area of inventive step and legal specialist with knowledge in patent law, regulations, novelty, inventive step, claim wording and this should be independent of the application.³⁷⁵

The challenge however is that Ghana has inadequate technical knowhow to carry out examinations to determine whether products submitted meet the criteria or not.³⁷⁶ As such, patents are granted to inventions which do not meet the patentability criteria. The result is that pharmaceutical companies are deprived of exploiting inventions which if proper examinations were carried out will not merit a patent. This affects access to medicines because pharmaceutical manufacturers have to then seek the consent of a patentee to exploit the patent.

4.7.2 Limited capacity in patent infrastructure

The limited capacity in infrastructure poses a challenge to the examination, granting and administration of patents. In reality, the limitation of infrastructure leads to the skipping of many substantive examinations.³⁷⁷ As such, where all the procedural requirements for patent applications have been met, the patent is granted without adequate examination as to whether there is a prior application of the same invention or whether the patent has been granted as a result of such an application.

In the process, inventions that meet the criteria to be exempted from patent are skipped and patents therefore granted to them. Currently the patent office does not conduct substantive

³⁷⁴ Musungu & Oh C Musungu & Oh C *The use of flexibilities in TRIPS by developing countries: Can they promote access to medicines?* (2006) 2.

³⁷⁵ WIPO Challenges and Options in Patent Examination(2012) available at http://www.wipo.int/edocs/mdocs/aspac/en/wipo_ip_han_12/wipo_ip_han_12_wipw_239204.pdf (Accessed 15 October 2018).

³⁷⁶ Anku SN *A Look at Other Options for Processing Patent Applications* (2017) available at <https://www.adamsadams.com/wp-content/uploads/2017/09/Panel-3-GHANA.pdf> (accessed 20 November 2018).

³⁷⁷ Osewe PL, Nkruma KY & Sackey EK (2008) 24.

examinations due to lack of infrastructure and capacity.³⁷⁸ This may make it easier to acquire patents but difficult to challenge because challenging it will require a thorough examination. The result is that most patentees will stay in business for a long period without any improvement to the curative aspects of medicines to help address access to medicine challenges.

The final challenges to be discussed in the next section is in relation test data protection flexibility.

4.8 Test data protection

Protection against unfair competition which goes hand in hand with test data protection has been introduced in the legislation of Ghana. The problem however is whether this introduction satisfies the requirements for protecting data as provided under the TRIPS Agreement.³⁷⁹ The following in addition to inadequate legislation has been identified as the possible reasons for not amending the legislations to meet the standard provided for under the TRIPS Agreement:

- Exclusive Rights
- Interference with compulsory licensing

4.8.1 Exclusive rights

Exclusive rights over test data can provide patent-like protection even where pharmaceuticals are not covered by patents or, do not meet the standards of patentability in a country or, prevent the registration of a product.³⁸⁰ This may serve as a disincentive to reviewing the Protection against Unfair competition Act but also a limitation to improving access to medicines especially where the local pharmaceutical industries produce medicines on a large scale for export.

4.8.2 Interference with compulsory licensing

It is posited that developing countries such as Ghana are not likely to derive any real benefit from data exclusivity, other than as a possible boost to investment in the local pharmaceutical

³⁷⁸ Anku SN *A Look at Other Options for Processing Patent Applications* (2017) available at <https://www.adamsadams.com/wp-content/uploads/2017/09/Panel-3-GHANA.pdf> (accessed 20 November 2018).

³⁷⁹ See Section 3.3.5 above.

³⁸⁰ Musungu SF & Oh C (2006)

industry.³⁸¹ As such, the introduction of data protection legislation has been identified as causing the delay in entry of generic medicines.³⁸²

The absence of the data protection law makes it possible for generics to enter the market easily because the requirement of clinical trials is waived if the applicant can only provide bioequivalence thereby reducing applicant cost and allowing for the possibility of many generic versions to enter the market.³⁸³ This invariably drives down the prices of medicines and may serve as a disincentive to Ghana making provisions to protect test data.

4.9 Chapter conclusion

This chapter has established that in addition to the gaps identified in the Ghanaian legislations, challenges such as administrative infrastructure, technical knowhow and TRIPS-plus obligations restrict the effective utilisation of the TRIPs flexibilities incorporated into the current legislations of Ghana. It has also unravelled the challenges of uncertainty, manufacturing capacity of Ghana and political challenges as potential reasons for Ghana not signing and ratifying the amendments to the TRIPS Agreement and its implications. These challenges identified have been established as interfering with the utilisation of the flexibilities to increase access to essential patented medicines needed by Ghanaians to solve their health related matters. The final chapter of this research recognises the need to address these challenges to ensure utilisation of the flexibilities to improve access to medicines and therefore make recommendations to that effect in the next chapter.

³⁸¹ Owoeye OA Data Exclusivity and Public Health under the TRIPS Agreement (2014) *Journal of Law, Information and Science*, Vol. 23(2), 107.

³⁸² Owoeye OA (2014) 107.

³⁸³ Kunku I *The Regulation of the Distribution of Pharmaceuticals and its Impact on Access to Medicines in Ghana* (Unpublished LLM thesis Munich Intellectual Property Law Center 2014/2015) 15-6.

CHAPTER FIVE

CONCLUSIONS AND RECOMMENDATIONS

5.1 General Conclusions

This research set out to answer the central question: how can Ghana effectively utilise the Trade-Related Aspects of Intellectual Property Rights (TRIPS) flexibilities to help improve access to essential medicines? The scope of the study was limited to an examination of the current Ghanaian legislations and the extent of incorporation of the flexibilities into the legislations in comparison with that of South Africa. The study also focused on the challenges impeding the effective utilisation of the TRIPS flexibilities in Ghana apart from the legislative challenges. Based on this, the study was guided by the following four pertinent sub-research questions to help answer the main research question:

- 1.1.1 What are the flexibilities provided under the World Trade Organisation (WTO) patent regime which can be used to improve access to essential patented medicines?
- 1.1.2 What are the current national legislative frameworks put in place by Ghana to help utilise the flexibilities and what is the extent of incorporation and utilisation of these flexibilities by Ghana in comparison with that of South Africa?
- 1.1.3 What challenges does Ghana face in utilising the flexibilities incorporated in its current national legislations and what challenges does it face in incorporating other flexibilities provided by the TRIPS Agreement?
- 1.1.4 What recommendations can be made to ensure that Ghana fully utilise the TRIPS flexibilities to improve access to medicines?

Chapter one introduced this research and established health as a basic human right recognised at the national, regional and international levels, with poor access to medicines identified as one of the challenges facing Ghana, a country whose population suffers largely from diseases such as malaria, tuberculosis and HIV/AIDS. The chapter identified patents as contributing to access-to-medicines challenges in Ghana.³⁸⁴ It highlighted the fact that despite the existence of patents, the TRIPS Agreement provides some flexibilities for the exploitation of patents by Members of the WTO (hereinafter Members) so as to address their access to medicinal needs.

³⁸⁴ See Section 1.1 above.

This chapter further concluded that despite the TRIPS flexibilities which are aimed at improving access to medicines, they are not being utilised with mortality rates on the rise.³⁸⁵

Chapter two addressed the first research question: what are the flexibilities provided under the WTO patent regime which can be used to help improve access to essential patented medicines? It examined the WTO Patent regime and the historical development of intellectual property rights (IPRs).³⁸⁶ It further established a positive correlation between access to medicines as a public health concern and IPRs.³⁸⁷ The chapter further examined the flexibilities of compulsory licensing, parallel importation, and patentability subject matter, exemption from patentability, and test data protection as well as competition laws as promoting access to medicines.³⁸⁸ It concluded that the flexibilities, if well utilised, will help improve access to medicines with legal backing of the TRIPS Agreement and the Doha Declaration.³⁸⁹ The chapter however, highlighted the current reality that, the flexibilities are not self-executory and it is therefore incumbent on Members to domesticate them for effective utilisation.³⁹⁰

Chapter three addressed the second research question: what are the current national legislative frameworks put in place by Ghana to help utilise the flexibilities and what is the extent of incorporation and utilisation of these flexibilities in comparison with that of South Africa? The chapter examined the current legislations of Ghana which seek to incorporate the TRIPS flexibilities (the Patent Act, Patent Regulations, the Public Health Act, the Protection against Unfair competition Act and the Trademarks Act) to improve access to medicines in comparison with that of South Africa.³⁹¹ It established that, while the current legislations of Ghana have been reviewed and amended to take into consideration the TRIPS flexibilities, their effectiveness is limited because of numerous inherent gaps. These gaps include the failure of Ghana to fully incorporate the TRIPS flexibilities identified in chapter two. A major loophole identified by the chapter is the failure of Ghana to sign and ratify the TRIPS Amendment or notify the TRIPS Council to use it, inadequate legislations on exception to patents and test data laws not meeting the requirements of the TRIPS Agreements.³⁹² The

³⁸⁵ See Section 1.2 above.

³⁸⁶ See Section 2.2.1 above

³⁸⁷ See Section 2.3.1 above.

³⁸⁸ See Section 2.3.3 above.

³⁸⁹ See Section 2.4.2 above.

³⁹⁰ See Section 2.3.4 above.

³⁹¹ See Section 3.2.2 above.

³⁹² See Section 3.3 above.

chapter established that the extent of incorporation of the flexibilities, compared to that of South Africa, is insufficient to fully take advantage of the TRIPS flexibilities. It was also established that there has been actual usage of the flexibilities, which has improved access to medicines and reduced cost.³⁹³

Chapter four addressed the third research question: what challenges does Ghana face in utilising the flexibilities incorporated into its current national legislations and what challenges does it face in incorporating other flexibilities provided by the TRIPS Agreement? It established that, even in the situation where the statute books are filled with provisions incorporating the TRIPS flexibilities, their utilisation is still limited by other challenges which impede their full incorporation and effective use.³⁹⁴ Chapter four's analysis identified challenges such as technical knowhow, administrative and infrastructure barriers, the size of the pharmaceutical market, World Health Organisation (WHO) prequalification requirements, the questionable viability of Ghana's local pharmaceutical industry, the cost of raw materials, TRIPS-plus requirements, and pharmaceutical mark-ups, among others as impeding the utilisation of the flexibilities.³⁹⁵ The chapter also identified the status of Ghana, administrative barriers, political barriers, manufacturing capacity, and political pressures as possible reasons or challenges accounting for Ghana not signing and ratifying the TRIPS Amendment. It argued that the failure to sign the Amendment will prevent Ghana from importing or exporting medicines produced under compulsory licenses in times of emergency and reduce its foreign exchange.³⁹⁶ It concluded that, should these challenges be resolved, it will not totally erase the access to medicine challenges of Ghana but will alleviate the situation.

This chapter builds on the previous chapters and advances recommendations for an effective utilisation of the TRIPS flexibilities to help improve access to essential medicines in Ghana.

5.2 Recommendations

Having identified the above issues, it is incumbent on this research to make recommendations on how Ghana can fully utilise the TRIPS flexibilities. It is important to note that 'utilisation' in the context of this research, implies the full incorporation and actual use of the flexibilities

³⁹³ See Section 3.4 above.

³⁹⁴ See Section 3.5 above.

³⁹⁵ See Section 4.1-4.5 above.

³⁹⁶ See Section 4.1.2 above.

to advance access to medicines. These recommendations flow from the key findings in the preceding chapters.

5.2.1 Amend current legislations to incorporate flexibilities to the full.

Having established that the flexibilities cannot be self-executed, this mini-thesis recommends that Ghana reviews and amends its current legislations to fully incorporate all the flexibilities discussed in the previous chapters. As such the following are specifically recommended:

- Section 11(4) of the Patent Act of 2003 which deals with the flexibility of exemption from patentability should be amended by deleting the word ‘only’ from section 11(4) of the Patent Act. This is because it seems to suggest that, apart from experimenting with the patent, the experiment cannot be used for any other purpose.³⁹⁷ Further, the Act must incorporate the bolar exception flexibility in clear and unequivocal terms by amending section 11(4) of the Patent Act to enable generic versions of medicines to enter the market immediately the patent term for medicines expires to avoid monopoly and evergreening. Though some countries like Japan³⁹⁸ interpret the experimental purpose in their legislation to include early entry, it will be in the interest of Ghana to clearly incorporate the bolar exception flexibility and use it as a sword rather than employ the Japanese approach as a shield. The provision hereunder is therefore recommended:

The rights under the patent shall not extend to acts done for scientific research or for the purpose of educating, testing, obtaining regulatory authorisations and/or registration for the purpose of commercialising the product after the cessation of the patent term.

- It is further recommended that Ghana amends its Protection against Unfair Competition (PUC) Act in order to better prevent unfair competition; the PUC Act additionally ought to incorporate a provision for the protection of test data.³⁹⁹ A provision in this regard is necessary considering the fact that such provisions will protect the data of inventors when the country exports its pharmaceutical products. The provision for test data protection is also necessary considering the fact that Ghana

³⁹⁷ See Section 3.2.3 above.

³⁹⁸ Section 69(1) Patent Act of Japan 1959; Ono Pharmaceutical Co Ltd v Kyoto Pharmaceutical Industries Ltd, Supreme Court, April 16, 199, Minshu 53(4) 627.

³⁹⁹ See Section 3.2.5 above.

does not only produce medicines but imports to supplement its medicinal needs. On this point, the provision hereunder is recommended:

1. *Where data is submitted for marketing approval and the origination of such data involves a considerable effort, such data shall be protected against unfair commercial use.*
 2. *The data submitted shall, subject to section 1, be disclosed by the Minister of Health where such data is deemed expedient and in the public interest.*
- Finally, it is recommended that Ghana adopts a comprehensive and holistic approach concerning the criteria for patentability by defining all terms without leaving any considerable policy space to patent offices or any adjudicatory body to interpret and apply the criteria at their discretion.

5.2.2 Implementation of further guidelines to facilitate the utilisation of the flexibilities

Ghana should provide effective guidelines and regulations for patent exploiters. The following are specifically recommended:

- The Food and Drugs Authority (FDA) must provide an effective regulation which imposes an obligation on applicants seeking market authorisation to constantly supply their products to the market, when their applications are granted for use after patent expiration. This will motivate generic companies to experiment with the patented medicines while patents are in force and even go further by adding to them in order to cure existing and emerging diseases once the market is available. This will erase any delays and encourage innovation to improve access to medicines.
- The FDA must organise seminars for prospective importers to simplify guidelines on importation. This would make it easier to get permits for parallel imports for instance, thereby cutting off all the delays associated with bureaucracy by preparing in advance the documentations that will be needed by the FDA.⁴⁰⁰
- Additionally, there is a need for a public health law or further guidelines to waive, minimise or expedite procedural and administrative requirements for medicines that are imported in response to a public emergency.⁴⁰¹ The expedited process extended to

⁴⁰⁰ See Section 4.5.1 above.

⁴⁰¹ See Section 4.4.4 above.

Ministry of Health for public procurement must also be extended to the private pharmaceutical companies considering the fact that the private sector responds more quickly to issues than the public sector, in the absence of any bureaucracies.

- This research further recommends that, guidelines be provided for flexibilities which require the payment of adequate compensation to patentees.⁴⁰² The guidelines should outline the requirement for determining the compensation and must be reasonable and not frustrate the purpose of ensuring access to medicines at the lowest possible price. For this reason royalty rates can be set at 1 to 5 per cent of the price of a generic product which can be increased or decreased by as much 2 per cent.

5.2.3 Sign and ratify Article 31 bis of the TRIPS Agreement or submit intention to use it.

Ghana may deem itself as not eligible to use article 31 *bis* because it has some manufacturing capacity.⁴⁰³ The following are however recommended:

- Ghana must ratify the TRIPS Amendment so that in cases of emergency where its local pharmaceutical companies cannot produce or support the demand for essential medicines, it can issue compulsory licenses to foreign companies to produce for the country. This will also enable it import essential medicines as it did in the year 2005 when a compulsory license was issued under the August Decision for the importation of Generic ARVs from India when a state of emergency was declared.⁴⁰⁴
- Ghana must review its procurement laws to make it consistent with the procurement laws of ECOWAS and other Member states. This will ensure easy procurement when resources are pooled together to import medicines at a relatively cheaper price.⁴⁰⁵
- The cumbersome procedures and challenges involved in invoking the Amendment may be resolved by the involvement of all the members of ECOWAS and not just a burden for Ghana alone. There should be division of labour among all members of the ECOWAS so as to lighten the burden of a single country like Ghana in terms of going through the cumbersome procedures alone.

⁴⁰² See Section 3.3.1 above.

⁴⁰³ See Section 4.1.2 above.

⁴⁰⁴ See Section 4.1.1.3 above.

⁴⁰⁵ See Section 4.3.3 above

5.2.4 Pass a functional competition law which will extend to IPRs

Competition laws in the instance of improving access to medicines, will force pharmaceutical companies to keep prices down, be innovative and ensure that consumers benefit from cheap but high quality products. The following are therefore specifically recommended;

- Ghana should review and pass its draft Competition Bill into a substantive law to help address matters of competition and price regulation. The PUC Act is not enough to address such matters needed to help improve access to medicines.⁴⁰⁶
- Furthermore, the Bill to be passed must be reviewed to fairly incorporate and elaborate more on intellectual property, with measures which will serve as deterrents to 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. As demonstrated by the case of *Hazel Tau and Others v GlaxoSmithKline and Boehringer Ingelheim*⁴⁰⁷ section 8(a) (b) and (c) of its competition Act has positively advanced access to medicine. A functional competition law can serve as the best ombudsman against monopoly, abuse of patent rights and excessive prices.
- A competition commission must be established to administer the competition law with the functions of investigating and prosecuting restrictive business practises, abuse of dominant positions and deciding on mergers and acquisition applications. This will ensure adequate and healthy competition to regulate pharmaceutical products.

5.2.5 Pass a concrete consumer protection law and protect the borders

The government of Ghana must pass a concrete consumer protection law to protect the consumer. Additionally, it must man the country's borders to prevent the influx of counterfeit products. The following are recommended in line with this suggestion:

- A concrete consumer protection law must include the introduction of greater transparency and awareness about pharmaceutical products, promotion of competition in the pharmaceutical industries, education of users of pharmaceutical products and eradication of unfair practices. This will circumvent any consequences medicines may have on consumers. The protection provided in the Public Health Act can alternatively be amended to include the provision below:

⁴⁰⁶ See Section 2.5.

⁴⁰⁷ See Section 3.4 above.

A person who offers or agrees to supply, or supplies, any goods that have been re-formed or re-modelled must bear the original producer's trademark and a conspicuous notice stating they have been reformed or remodelled.

- All ports of entry must be equipped with the necessary equipment to test and detect counterfeit and substandard medicines.⁴⁰⁸ If such medicines are detected, they should be prevented from entering the market to compete with imported medicines by destroying them.

5.2.6 Regulate the distribution and pricing of medicines.

The chaotic nature of the distribution system and the pricing makes medicines inaccessible. The following are therefore recommended:

- The government must partner with pharmaceuticals industries in the private sector to ensure the distribution of pharmaceuticals to patients at reasonable prices which may reduce the formation of cartels and the hoarding of pharmaceutical products by the big pharmaceutical companies. As such, the functions of wholesalers, distributors and retailers should be clearly delineated with licenses issued for particular purposes. A combination of any of these licenses leads to the formation of cartels and mark-ups.
- In addition to this, the guidelines for price mark-ups must be enforced with fines for pharmaceutical companies which do not adhere to the guidelines. This may serve a deterrent to other pharmaceutical companies engaging in mark-up activities.

5.2.7 Provide technical assistance for World Health Organisation prequalification requirements.

Ghana must strengthen its partnership with the WTO, the WHO and the Global Fund in order for them to support it by providing simple guidelines and technical assistance to local pharmaceutical manufacturing companies on the requirements for WHO prequalification. The assistance will avoid delays associated with the application process and enable manufacturing companies to be contracted to produce generic versions of medicines to help improve access to the said medicines. The assistance will also ensure that government gets the necessary aid

⁴⁰⁸ See Section 4.5.2 above.

from donor funders to pay for these pharmaceuticals and not rely on its tight budget as was done in the case of Danadams.⁴⁰⁹

5.2.8 Strengthen local pharmaceutical manufacturing companies

A strengthened pharmaceutical industry in Ghana will contribute to improved access to essential and new medicines. As a result of this observation, the following are specifically recommended:

- The government of Ghana must partner with pharmaceutical companies to ensure they meet the good manufacturing practices expected by Ghana and the world as a whole. The government can do this through equitable partnerships where it will inject some amount of money into these companies to enable them purchase the necessary equipment and active ingredients needed in the production of essential medicines. This will encourage local production of essential medicines and reduce the cost associated with the importation of medicines.
- It is further recommended that, inasmuch as Ghana has a duty to strengthen its local pharmaceutical industry, local pharmaceutical companies on the other hand should strategically partner with big pharmaceutical companies in the industrialised world to facilitate technology transfers in order to enhance local production. The government of Ghana must however, support this initiative by ensuring that there are no barriers created to impede these strategic partnerships.
- The government must establish a one-stop-special-purpose zone by delineating a geographical area close to any port of entry specifically for pharmaceuticals. Such delineated one-stop area should make provisions for the operator, the regulators and service providers within one space. This will prevent any delays because these regulatory authorities will only be dealing with the pharmaceutical companies within the enclave and this will facilitate the exportation to other countries. The tax breaks that will be enjoyed by virtue of being a free zone will be a motivation for pharmaceutical companies to move to the enclave and produce medicines to improve access. This can also attract foreign pharmaceutical companies to partner with local ones to improve access to medicines.

⁴⁰⁹ See Section 3.3.1 above.

5.2.9 Build patent infrastructure and technical knowhow

In order to build an effective patent infrastructure and technical knowhow, the following are specifically recommended:

- The Registrar General's department should be well equipped with the necessary patent infrastructure needed for patent examinations as well as patent searches. This infrastructure should be manned by experts and other technical staff who could also be trained on the job. The expertise should comprise of Ghana's research institutions and universities such as the Noguchi Centre for Medical Research. Technical assistance could also be sought from the World Intellectual Property Organisation (WIPO) and other WTO members in that specific regard. The availability of experts and infrastructure will reduce delays.
- To facilitate applications, matters involving documentations must be migrated to the paperless system and accessible in any part of the world without prospective patentees or exploiters coming to Ghana to ascertain such information.⁴¹⁰ On the other hand all substantive examinations, especially to identify whether or not an invention meets the patentability criteria, should be carried out in Ghana or any designated country once the infrastructure is available and decentralised to avoid any delays just at one registry.⁴¹¹ Thus Ghana can at least have a registry for its southern sector as well as one for its northern sector with 5 regions in each sector.
- The databases of the registries must be regularly updated with current data to ensure that searches for patents are not delayed.⁴¹² Ghana, as a member of the Africa Regional Intellectual Property Organisation (ARIPO) should let its voice be heard at meetings of this body on matters concerning patent applications by recommending that it establishes a reliable database to facilitate the search for patent status to strengthen information flow and facilitate the utilisation of the TRIPS flexibilities.

⁴¹⁰ See Section 4.2.1 above.

⁴¹¹ See Section 4.7.2 above.

⁴¹² See Section 4.2.1 above.

5.2.10 Avoid TRIPS-plus Agreements

It is recommended that Ghana carefully assesses the implications of signing any agreement which imposes higher burdens than that expected from the TRIPS Agreement before signing such agreements.⁴¹³ Ghana must refrain from signing agreements which appear to discourage the use of the flexibilities as a means of attracting foreign investment and ignore any trade sanctions used as a means of circumventing the use of the flexibilities.

5.3 Conclusion

From the findings of this research, it is clear that incorporating TRIPS flexibilities into national legislations does not automatically yield better access to medicine. One thing which is certain however is that, the first step to utilising the flexibility either for local production or importation of medicines is incorporating them into national legislations to avoid any protracted legal battles. While it is acknowledged that fully incorporating the flexibilities into national legislations will have its own challenges, it is without a shadow of doubt that it is the most appropriate course to follow if the flexibilities are to be fully and effectively utilised. As already discussed, there is the need to further provide guidelines in support of the flexibilities once they are fully incorporated. There is no doubt that having clear and unambiguous guidelines will greatly enhance efforts to avert all incidences of misinterpretation and delays associated with granting of licenses to use the flexibilities. It is clear, from the findings of this study that despite having incorporated these flexibilities, Ghana has up to now been unable to fully utilise them. This has mostly been attributed to other challenges beyond the law. Ghana therefore can effectively utilise the flexibilities to improve access to essential medicines in the country if the recommendations suggested above are implemented.

⁴¹³ See Section 4.2.7 above.

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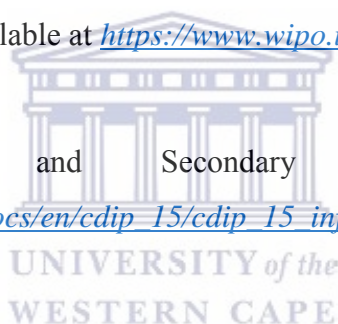
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