A CRITICAL ANALYSIS OF THE PATENTS ACT 57 OF 1978 AND THE REFLECTION ON THE RIGHT OF ACCESS TO MEDICINES: WHEN THE RIGHT IS 'RIGHT'

by

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DECLARATION

This research is submitted in accordance with the requirements for the degree of Master of Laws (LLM) in the subject Mercantile Law at the University of South Africa (UNISA).

I declare that A critical analysis of the Patents Act 57 of 1978 and the reflection on the right of access to medicines: When the right is 'right' is my own work and that all the sources that I have used or quoted have been indicated and acknowledged by means of complete references.

I further declare that I submitted the thesis to originality checking software and that it falls within the accepted requirements of originality.

I further declare that I have not previously submitted this work, or part of it, for examination at UNISA for another qualification or at any other higher education institution.

Signature:  Date: 31/03/2023

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SUMMARY

South Africa has a membership of the United Nations, World Trade Organisation, African Union and South African Development Community.

Both United Nations' Universal Declaration of Human Rights and the International Covenant on Economic, Social and Cultural Rights recognise the protection and promotion of the right to health. The Declaration requires member states to formulate intellectual property laws and policies to protect public health. The 2030 Agenda for Sustainable Development Goals adopted by the United Nations contains plan of action to be implemented by countries such as South Africa. Goal 3 provides for the enjoyment of good health by all. It reinforces the importance of access to medicines. South Africa being one of the developing countries is faced with an unending challenge of access to cheap and affordable medicines. This is exacerbated by pharmaceutical companies using strategic patenting such as filing patents being drugs with minor alterations with intention to block potential competitors from being granted patents of the same drugs. On the same breath the pharmaceutical companies prolong their monopoly for years.

Patents Act 57 of 1978, referred to hereafter as "Patents Act", regulates patents locally. The point of departure is the exorbitant cost of cancer medicines for the majority of patients in the public and private sectors. This led to the formation of the Fix the Patent Laws, a coalition of non-governmental and non-profit organisations advocating for the reform of the Patents Act. The proposed reform is based on the following identified gaps:

a) Examination of patents applications to ensure patentability criteria,
b) Allow for patent oppositions,
c) Prevent evergreening and
d) Adopt a procedure for granting compulsory licences.

To address these challenges South Africa must tighten the Patents Act to comply with the World Trade Organisation Trade Related Aspects of Intellectual Property Rights Agreement. If the Patents Act is amended, it will offer remedy for anti-competitive behaviour to the Competition Commission of South Africa and the Companies and Intellectual Property Registration Office.

KEYWORDS: Access to medicines; Compulsory licensing; Evergreening; Health care; Novelty; Parallel importation, Patents Act, Substantive examination; TRIPS flexibilities

LIST OF ABBREVIATIONS

ABS	:	Access and Benefit Sharing, Nagoya Protocol
AHS	:	African Health Strategy
ACHPR	:	African Commission on Human and People's Rights
AIDS	:	Acquired Immunodeficiency Syndrome
ARV	:	Antiretroviral
AU	:	African Union
CANSA	:	Cancer Association of South Africa
CBD	:	Convention on Biological Diversity
CCSA	:	Competition Commission of South Africa
CIPC	:	Companies and Intellectual Property Commission
Constitution	:	Constitution of the Republic of South Africa, 1996
COSATU	:	Congress of South African Trade Unions
COVID-19	:	Coronavirus
DG	:	Director General
DoH	:	Department of Health
DSB	:	Dispute Settlement Body
DSU	:	Understanding on Rules and Procedures Governing the Settlement of Disputes
DTiC	:	Department of Trade Industry and Competition
EPC	:	European Patent Convention
EU	:	European Union
HIV	:	Human Immunodeficiency Virus
IVD	:	*in vitro* diagnostic
ICESCR	:	International Covenant on Economic, Social and Cultural Rights

NA	:	National Assembly
NCOP	:	National Council of Provinces
PCT	:	Patent Co-operation Treaty
PLWC	:	People Living with Cancer
Res	:	Resolution
R&D	:	Research and Development
SADC	:	Southern African Development Countries
SANCLBP	:	South African National Control Laboratory for Biological Products
SAHPRA	:	South African Health Products Regulatory Authority
SCA	:	Supreme Court of Appeal
SDGs	:	Sustainable Development Goals
SEP	:	Single Index Price
TAC	:	Treatment Action Campaign
TRIPS	:	Trade-Related Aspects of Intellectual Property Rights
UN	:	United Nations
USA	:	United States of America
WHO	:	World Health Organisation
WTO	:	World Trade Organisation

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CHAPTER 1 INTRODUCTION

1.1 Overview of the study

South Africa's democracy was ushered in 1994 through the 1993 interim Constitution. It introduced fundamental changes on the 27 April 1994 to recognise and protect political and civil rights, socio-economic rights, doctrine of constitutional supremacy and the separation of powers.[1] Section 2 of the Constitution of the Republic of South Africa Act 108 of 1996, referred to hereafter as "1996 Constitution", provides for constitutional supremacy that all branches of the state are bound by constitutional rules and principles. So, it is only the courts that can declare the validity of any law or conduct inconsistent with it.[2]

Chapter 2 of the 1996 Constitution, that is, section 27(1) recognises the right to health care.[3] It provides for every person's right of access to health care services and places a positive obligation on the state to ensure that it takes reasonable legislative and other measures to achieve the realisation of this right. Further, it is a socio-economic right that essentially obliges the state to do more to secure the right for everyone depending on the available resources.[4]

In the *Minister of Health v Treatment Action Campaign* case,[5] an interest group challenged the department of health's restrictions to provide antiretroviral drugs to HIV-positive pregnant women that it violated their right to health care. The Constitutional Court held that the department's decision to exclude the use of Nevirapine for the prevention of mother-to-child transmissions of HIV as per policy was unreasonable.

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1 Currie Iain and De Waal Johan, *The Bill of Rights Handbook*, (6th Edition, Juta & Co. Ltd 2018) at 2.

2 Currie and De Waal, *The Bill of Rights Handbook* at 2.

3 Act 108 of 1996.

4 *Soobramoney v Minister of Health, KwaZulu-Natal 1998(1) SA 765 (CC),* Paragraph 22.

5 2002 (5) SA 721 (CC), Paragraphs 80 and 81.

Besides Nevirapine, anti-retroviral drug, the use of drugs in South Africa is regulated in terms of the Medicines and Related Substances Act 101 of 1965, referred to hereafter as "1965 Medicines and Related Substances Act". It is a prerequisite that all drugs be registered by the Medicines Control Council.[6] The aim of registration is to provide for evaluation of medicines after years and to prohibit sampling and bonusing of medicines.[7]

South Africa, a sovereign state, was re-admitted in 1994 by the United Nations, referred to hereafter as "UN", following the transition into democracy after being suspended in 1974. Membership in the UN means that a state accepts the obligations included in the UN Charter.[8] South Africa is still to sign and, or ratify some international instruments. For example, the African Commission on Human and People's Rights adopted Resolution on Access to Health and Needed Medicines in Africa, also known as ACHPR Res. 141(XXXXIV) 08, in November 2008.[9]

The 2030 Agenda for Sustainable Development adopted by the UN in September 2015 provides for 17 Sustainable Development Goals, referred to hereafter as "SDGs". The SDGs reaffirm the importance of the Declaration of Human Rights.[10] SDG Goal 3's undertaking is to ensure healthy lives, enjoyment of good health and promote well-being for persons of all ages. This goal reinforces the vital importance of access to medicines by all human beings.[11] Accessing medicines is an essential part of the right to health care in international law and same was confirmed by courts in enforcing intellectual property rights.[12]

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6 *Minister of Health and Others v Treatment Action Campaign and Others 2002 (5) SA 721 (CC),* Paragraph 14.

7 Preamble to Medicines and Related Substances Act 101 of 1965.

8 https://www.un.org/en/about-us/member-states [Accessed on the 10/09/2020].

9 https://www.achpr.org/sessions/resolutions?id=212 [Accessed on the 10/09/2020].

10 UN General Assembly, Transforming our World: 2030 Agenda for Sustainable Development, UN Resolution No. A/RES/70/1

11 Owoeye, Olasupo Olawabusayo, 'Intellectual Property, Access to Medicines and Universal Health Coverage Through a Health Rights Lens' (2018) (Volume 40) European Intellectual Property Review at 49.

12 Owoeye, 'Intellectual Property, Access to Medicines and Universal Health Coverage Through a Health Rights Lens' at 49.

World Trade Organisation Trade-Related Aspects of Intellectual Property Rights, referred to hereafter as "WTO TRIPS", Agreement constitutes flexibilities that must be used for access to medicines which are compulsory licensing, exceptions to the exclusive right conferred by a patent, parallel importation and the status of the data submitted to obtain regulatory approval.[13]

Paris Convention for the Protection of Industrial Property 1979, referred hereunder as the "Paris Convention", guarantees extra-territorial protection of well-known trademarks in a country where it is unegistered. Similarly is section 35(3) of Trade Marks Act 194 of 1993.[14] Undeniably South Africa is bound by the Trade-Related Aspects of Intellectual Property, referred to hereafter as "TRIPS Agreement", as such, it adopted Intellectual Property Laws Amendment Act 38 of 1997.[15] It needs to be ascertained whether the latter legislation addresses TRIPS flexibilities.

1.2 Problem statement

The TRIPS Agreement provides that countries must adopt national law provisions and flexibilities to protect health and enable generic competition to address exorbitant medicine prices.[16]

Patents Act 57 of 1978 regulates how patents can be registered.[17] Section 25(1) of the Act sets out the requirements for a patent to be granted for any invention. Medicines and other related substances such as pharmaceutical products are patentable since they are not excluded by section 25(2) of the Act. Access to and affordability of medicines in South Africa is a huge problem.

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13 Matthews D N, 'TRIPS Flexibilities and Access to Medicines in Developing Countries: The Problem with Technical Assistance and Free Trade Agreements', (Intellectual, Property Research Institute, University of London 2005) at 420.

14 Kelbrick Roshana, 'The term "well-known" in South African trade mark legislation: Some Comparative interpretations', (2006) Volume 38, Comparative and International Law Journal of Southern Africa) at 438.

15 Rippel K A and De Villiers R, 'Legalising Parallel Imports under Intellectual Property Law', (2004) Stellenbosch Law Review) at 553.

16 Coral Jade Joseph, 'Access to affordable life-saving medicines: The South African response', (LLM Dissertation, University of KwaZulu-Natal 2013) at 26.

17 Act 57 of 1978.

More and more people in developing countries die every year in millions from diseases that can be treated with generic drugs and drug therapies.[18]

To this end, South Africa neglected to discharge its obligations outlined in article 65 of the TRIPS Agreement to reform its intellectual property to ensure that it is consistent with it.

This study tends to show that South African patent legislation requires amendment to meet international requirements. The Patents Act often works to the advantage of the patentee at the expense of competitors and or public interest.[19]

The weaknesses identified in the Patents Act are:

1. Section 34 of the Patents Act requires substantive examination for patent application and every complete specification ensuring that it observe the requirements of the Act before acceptance by the Patents Office, currently known as the Companies and Intellectual Property Commission, referred to hereafter as "CIPC".[20] The problem with South Africa is that there is no examination of patent applications to check if they meet the criteria of a patent. In other words, it is a non-examining country.[21] Its depository system for patents deals only with the correct paperwork, and payable fees before application is granted.[22] Article 31 of TRIPS Agreement requires that substantive and procedural requirements are satisfied before patent licence can be granted.

For example, the Indian Patents Act of 1970 requires that the application for a patent must be accessible by the general public at a reasonable, affordable price. Price is key national interest issue.[23]

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18 Visser Coenraad, 'Affordable medicines' exceptions to patent rights under the TRIPS Agreement: some pointers for South Africa', (2001) Volume 34, No. 3, CILJSA) at 377.

19 Burger J and Rens A, *Innovation and Intellectual property in South Africa: The Case for Reform,* University of Cape Town Intellectual Property Unit (2018) at 32.

20 Ndlovu Lonias, South African Patent Law and Access to Medicines, Conference Paper (2013) at 5.

21 Pouris Anthipi and Anastassios, 'Patents and economic development in South Africa: Managing intellectual property rights', (2011) Volume 107, No: 11-12, South African Journal of Science at 5.

22 Fix the Patent Laws Campaign, Patent barriers to medicine access in South Africa: A case for patent law reform, Castle Graphics) at 11.

23 Manu Thaddeus, 'Examining the Legality of Affordability Requirements as a Substantive Condition for Granting Compulsory Licences Pursuant to the TRIPS Agreement', (2015) Volume 18, The Journal of World Intellectual at 301.

2. Patents Act contains weak definition of novelty that permits evergreening. This involves a process of blocking access to more affordable generic medicines by a filing separate or multiple patents of a single product on minor modifications. Pharmaceutical companies take advantage of section 46(1) of the Patents Act by prolonging their patent protection beyond 20 years and keep them at artificially high prices.[24]

   TRIPS flexibilities are not incorporated into the Patents Act, hence evergreening. No compulsory licence was issued to address unavailable or too expensive medicine that South Africans cannot afford.

   Section 10(14) of the Trade Marks Act 194 of 1993, referred to hereafter as "Trade Marks Act", is used by big multinational pharmaceutical companies to bar generics from entering the market with cheaper versions of medicines. In *Adcock Ingram Intellectual Property (Pty) Ltd v Cipla Medpro (Pty) Ltd*,[25] the Supreme Court of Appeal, referred to hereafter as "SCA", ordered the respondent to remove the mark ZEMAX from being used as a generic medicine because it was identical to the appellant's mark ZETOMAX that the use of the mark was so similar to the goods or services in respect of the registered mark, and likely to cause confusion.

3. Section 69A(1) of the Patents Act is silent on the definition dealing with parallel imports as against regulation 7 and section 15C (b) of the 1965 Medicines and Related Substances Act.[26] The 1965 Medicines and Related Substances Act provides for parallel import of products marketed in the exporting country by another without the consent of the patent holder. Parallel importation of medicines is also known as permissive reimportation or gray market.[27]

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24 Fix the Patents Laws Campaign at 11;
Busch Stephanie, 'Promoting access to affordable generics: reforming South Africa's patent law to prevent evergreening', (2016) Volume 4, SAIPLJ at 110.

25 2012 (4) SA 238 (SCA).

26 Ndlovu Lonias, South African Patent Law and Access to Medicines, Conference Paper (2013) at 9-10.

27 Shubba Ghosh, 'Pills, patents and power: state creation of gray markets as a limit on patents rights', Florida Law Review (2001) at 806-807.

In *Pharmaceutical Manufacturers Association v President of the Republic of South Africa*, the Constitutional Court held that the President's decision to assent to the South African Medicines and Medical Devices Act 132 of 1998 was irrational.[28] The amendment sought to promote more affordable medicine through parallel importing; and the way the product is to be marketed and sold. Section 34(2)(d) of the Trade Marks Act provides for a defence against infringement of a trademark through parallel import of goods. It renders parallel importation of goods for distribution, sale locally as lawful provided the goods to which the trade mark was applied by or with the trade mark owner's consent.[29] In support, parallel importation of goods by a person bearing a trademark is permitted in terms of section 25(2) of the Consumer Protection Act.[30]

It is without a doubt that the Department of Trade, Industry and Competition, referred to hereafter as "DTiC", drafted the 2018 Intellectual Property Policy to address the substantial problem of intellectual property rights. Secondly, the policy responds to the unique innovation of South Africa. The goal is to strengthen the commitment of South Africa to the Convention on Biological Diversity, referred to hereafter as "CBD" and the Nagoya Protocol on Access and Benefit Sharing, referred to hereafter as "ABS" relating to generic resources.[31]

The interventions in terms of the policy highlighted include, amongst others, substantive search and examination, patent opposition, parallel importation, exceptions, voluntary and compulsory licences.[32]

How long it will take for South Africa to finalise the legislation given the Coronavirus, referred to hereafter as "COVID-19", pandemic and ongoing process of applications that are granted by the patent office for monopolies on new and repurposed medicines, and other vital health products is unclear. There are different interest groups in South Africa such as Fix the Patent Laws Campaign advocating for legislative reform.[33]

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28 2000 (3) BCLR 241 (CC) at paragraphs 89 and 90.

29 Rippel K A and De Villiers R, 'Legalising Parallel Imports under Intellectual Property Law', (2004) Stellenbosch Law Review at 561.

30 Act 68 of 2008.

31 Intellectual Property Policy of the Republic of South Africa, Phase 1 of 2018 at 4.

32 Intellectual Property Policy of the Republic of South Africa at 14.

33 Fix the Patents Laws Campaign at 3.

1.3 Research questions

The aim of the study is to discuss the problem of accessing cheap and affordable medicines locally. The right of access to medicines is put in context taking into consideration the applicable legislative prescripts and decided court decisions.

The research questions of the study are:

1.3.1 Is the right of access to medicines in South Africa adequately addressed?

1.3.2 What are the expectations of South Africa as a member of the UN, World Trade Organisation, referred to hereafter as "WTO", and other international bodies?

1.3.3 Does the Patents Act 57 of 1978 comply with the flexibilities contained in the WTO TRIPS Agreement or other international law?

1.3.4 If not, what are the barriers identified in the Patents Act regarding the right of access to medicines?

1.3.5 What amendments should be affected to address systematic shortcomings in the Patents Act by the legislature? Is it viable to benchmark against other countries?

1.4 Objective of the study

The objectives of the study are as follows:

1.4.1 To discuss the right of access to medicines.

1.4.2 To examine and analyse local, regional, and international laws for the protection of public health.

1.4.3 To establish whether South Africa complies with the above-mentioned regional and international instruments with a specific focus on the Patents Act.

1.4.4 To identify South Africa's possible solution to ensure that the Patents Act is amended.

1.5 Research methodology

The research methodology viable for this study is qualitative. It is a desktop-based study that entails the use of literature from international, regional, and local laws. The research relies primarily on sources such as journal articles, research and conference papers, the Constitution, case law, regulations, legislation and textbooks.

The study embodies a comparative review of the applicable legal principles and practices in South Africa on the right of access to medicines. The purpose of comparative is to critically scrutinize the position in South Africa with other countries.

1.6 Proposed framework of the dissertation

The dissertation consists of five chapters. It examines South Africa's Patents Act and challenges regarding access to medicines in the country.

Chapter 1 briefly introduces the topic, overview of the study, and the background of the problem pertaining to the constitutional right to health care. That includes weaknesses identified in the Patents Act. It further sets out the research background, research questions, and the methodology utilised in the study.

Chapter 2 explores the international obligation of countries to provide cheap and affordable medicines. It focuses on a comparative analysis of the right to health care in the context of multilateral instruments and legislative prescripts such as WTO TRIPS Agreement, the African Commission on Human and Peoples' Rights, referred to hereafter as "ACHPR", and the Medicines and Related Substances Act promoting the use of generic medicines.

Chapter 3 provides a critical perspective on the fundamental right of access to medicines in South Africa. It exposes Patents Act as TRIPS Agreement non-complaint and a barrier to accessing medicines. There are critical areas of concern raised by a joint coalition of non-governmental organisations advocating for reform of the Act. The desire is that the review of the Patents Act will save and change the lives of South Africans.

The Supreme Court of India in *Novartis AG v Union of India* case decision is, amongst others, a good example of preventing evergreening and ensuring that citizens access cheap medicines.[34]

Chapter 4 discusses arguments or opinions advanced by authors, as well as court decisions regarding access to medicines. There are also best practice models for improving access to medicines and benchmarking in countries such as Botswana to achieve progress. Compulsory licensing is one area of focus in opposition to patent monopolies.

Chapter 5 draws conclusions from the study with findings of the research problem made. That is followed by persuasive recommendations to the legislature and other relevant stakeholders.

[34] Ndlovu, 'Lessons for the SADC from the Indian case of Novartis AG v Union of India' at 791.

CHAPTER 2 LEGAL BACKGROUND ON THE RIGHT OF ACCESS TO HEALTH CARE

2.1 Introduction

This chapter dissects the understanding of the universal right of access to health care. This right is protected and recognised by many countries in their constitutions and it is linked to access to essential medicines.[35] There are relevant international, regional, and local legislative prescripts to be considered such as conventions, treaties, adopted resolutions, the 1996 Constitution, and legislation like the 1965 Medicines and Related Substances Act, as amended. There are relevant case laws that put the topic into context.

2.2 International Legal Framework

South Africa being a sovereign state does not exist in isolation. It is affiliated to several international and regional bodies such as WTO by extension of TRIPS Agreement, African Union, referred to hereafter as “AU”, and the Southern African Development Community, referred to hereafter as “SADC”. Consequently, it is bound to protect intellectual property rights.[36]

International Covenant on Economic, Social and Cultural Rights, referred to hereafter as “ICESCR” provides for access to medicine. Article 12 states that everyone shall have the enjoyment right to the top attainable standard of physical and mental health. It affirms the inalienable right of access to health care. South Africa ratified ICESCR in 2015.

Article 12(2)(d) of the ICESCR encourages state parties to enforce the Covenant by taking positive steps providing medical services and treatment to patients in their countries. State parties, including public civil society and private sectors are required to supply essential medicines as entailed in the right.

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35 Joseph Coral Jade, ‘Access to affordable life-saving medicines: The South African response’ (LLM Dissertation, University of KwaZulu-Natal 2013) at 15.

36 Ndlovu Lonias, South African Patent Law and Access to Medicines, Conference Paper (2013) at 1.

It is, however, important to discuss the following treaties and determine South Africa's obligations regarding access to medicines:

1. WTO TRIPS Agreement;
2. WTO Doha Declaration on the TRIPS Agreement and Public Health;
3. 2030 Agenda for Sustainable Development, UN Resolution No. A/RES/70/01; and
4. Paris Convention for the Protection of Industrial Property.

The 1996 Constitution, to be precise, Chapter 14 provides for powers of the government to enter into international agreements. Section 231(2) read together with sections 231(3)-(4) makes provision for treaties that bind the country after being approved by the National Assembly, referred to hereafter as "NA" and the National Council of Provinces, referred to hereafter as "NCOP". Self-executing treaties do not require the approval of the NA and NCOP but become binding on South Africa upon signature provided they are consistent with the Constitution or Act of Parliament.

2.2.1 *WTO TRIPS Agreement*

The Agreement provides standards for the protection of intellectual property. South Africa joined the WTO on 01 January 1995 and signed the TRIPS Agreement in 2005.

Article 1.1 of TRIPS Agreement transfers to all members the freedom to determine the suitable method of implementing provisions of the Agreement within their own legal system and practice. It seeks to balance protection of patents, being pharmaceutical products and access to medicines, and aims to allow members to take reasonable measures to protect public health.[37]

Article 27.1 of TRIPS Agreement is a non-discrimination clause that encourages WTO member states to grant patents for inventions in all fields of technology unless they are do not meet the requirements of patentability.

[37] Brin Anderson, 'Better Access to Medicines: Why Countries are getting "Tripped" up and not ratifying Article 31-bis' (2010)(Volume 1, No.2), Cape Western Reserve Journal of Law, at 165-166.

Therefore, countries must grant patents for inventions imported or produced locally, meet the requirements for patentability. Enjoyment of patent rights ought to be non-discriminatory as to the place of invention and the field of technology.[38]

Pursuant to TRIPS Agreement, flexibilities must be used effectively to ensure access to affordable medicines. Countries must take the advantage to fight diseases such as Human Immunodeficiency Virus and Acquired Immunodeficiency Syndrome, referred to hereafter as "HIV/AIDS", and cancer. The flexibilities referred to hereinabove are compulsory licensing, limiting TRIPS flexibilities through data exclusivity, exceptions to the exclusive right conferred by a patent and parallel importation.[39]

2.2.1.1 *Compulsory licensing*

Compulsory license is the non-voluntary permission to use an invention, for instance, a patent where the licence is granted by the patentee to another party of government. Authorisation granted shall allow the party to produce of generic medicines or import goods from foreign producers.[40] It is a mechanism where a third party is granted a licence by a government to exploit the invention on condition that it pays the patentee royalty. Consent of the patentee is not required. Unfortunately, the patentee is expected to allow for the use of a patent by a third party or the government for its benefit provided implementation of the exception is reasonable and does not prejudices the patentee in terms of article 30 of TRIPS Agreement.[41]

Article 31 of TRIPS Agreement allows for a compulsory licence to be granted to a third party. In this instance, the party is permitted to manufacture a patented product without the authorisation of the patentee.

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38 Nkomo Marumo, 'The TRIPS flexibilities and access to essential medicines in the developing world: are they sufficient and is our implementation adequate?', (LLM Dissertation, University of the Western Cape (2013) at 30.

39 Matthews, D N, 'TRIPS Flexibilities and Access to Medicines in Developing Countries: The Problem with Technical Assistance and Free Trade Agreements', (Intellectual Property Research Institute, University of London 2005) at 420-426.

40 Joseph, 'Access to affordable life-saving medicines', at 29.

41 Hobololo Vuyisile, 'Strategic patenting of pharmaceutical inventions and the public's right to access medicines: the South African context' (2015)(Issue no.16) The African Journal of Information and Communication at 79;
Nkomo, 'The TRIPS flexibilities and access to essential medicines in the developing world', at 24.

The grantor must be a competent national authority and the use must entail production and sale of medicines. Article 31 was amended to address the restrictions preventing governments to grant compulsory licence in certain situations as contained in Article 31(f).[42] Currently, licence is be granted where the use of the subject matter of the patent is primarily for the supply of the domestic market of the patentee. So, the restriction preventing governments with the capacity to make generics from exporting medicines to other countries was eliminated. The Protocol amending Article 31 came into operation on 23 January 2017 and South Africa already acceded to it on 23 February 2016. However, it incorporated some TRIPS flexibilities except substantive examination of prospective inventions, right of parties to oppose registration of new inventions and parallel import of medicines in Patents Act.[43] These flexibilities are to be discussed in the next chapter, together with the South African legislation, i.e. the Patents Act.

Doha Declaration on the TRIPS Agreement and Public Health, Paragraph 6 sets the grounds for granting a compulsory licence.[44] WTO members with the capacity to manufacture pharmaceutical products can import or export those products provided they meet the substantive and procedural obligations. Substantive obligation constitutes adequate payment of remuneration and non-exclusive licence granted. Procedural obligation entails a waiver of application for a licence on patent holder's terms and conditions. In cases of national emergency, for example, the WTO member may waive the requirement for authorisation in order to address the need for medicines or respond to an outbreak.[45]

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42 Matthews, 'TRIPS Flexibilities and Access to Medicines in Developing Countries', at 421; Nkomo, 'The TRIPS flexibilities and access to essential medicines in the developing world', at 64.

43 Ncube Caroline, 'The politics of national intellectual property policy design and the provision of health services in South Africa', (2015)(Volume 3) SAIPLJ at 24.

44 Jerome H. Reichman, 'Compulsory licensing of patented pharmaceutical inventions: evaluating the options', (2009)(Voume 37, No. 2) Journal of Law, Medicine and Ethics (2009) at 6.

45 Carlos M Correa, 'Will Amendment to the TRIPS agreement Enhance Access to medicines?', Routledge Handbook on the Politics of Global Health, 1st Edition (London & New York, Routledge, 2018) at 2-3.

Carlos Correa argues that the procedural burden imposed under Doha Declaration is problematic. It consists of too many administrative requirements that a country must go through to meet the health emergency. This argument was also advanced by other scholars that considered layers of procedure as unfaithful to the Doha Declaration.[46]

There is uncertainty about the applicability of article 31 amendment by developing countries, especially in African countries. Correa's argument that developing countries or third parties that are expected to seek for a compulsory licence from the patentee to produce the drug in the exporting country must do so on commercially reasonable terms is supported fully.[47]

If the application is refused, then the party must escalate it to the competent authorities for approval to grant licence. There are conditions to be met and one of them is that remuneration was paid to the patent owner.[48]

Many developing countries, are reluctant to apply for a compulsory license to ensure access to medicines because of lack the technological capacity to utilise the flexibilities and fear of civil action instituted by the patent right holder.[49] For example, the first country to invoke its compulsory rights in 2007, since its adoption in 2001, was Rwanda. It served a notice on WTO's TRIPS Council of its intention to import licensed drugs from Canada. Licence was sought from GlaxoSmithKline, Shire, and Boehringer Ingelheim. Regrettably, the three pharmaceutical companies GlaxoSmithKline, Shire, and Boehringer were unwilling to issue the voluntary licence until the Canadian government issued a licence. The same licence was issued after a protracted process that delayed the country's ability to receive the necessary drugs.[50] The right of waiver in terms article 31 amendment is a short-term solution for countries to access to cheap medicines. Therefore, the need for medicines must not be frustrated by the comprehensive administrative process.

46 Correa, 'Will Amendment to the TRIPS agreement Enhance Access to medicines?', at 3.
47 Correa, 'Will Amendment to the TRIPS agreement Enhance Access to medicines?', at 3.
48 Correa, 'Will Amendment to the TRIPS agreement Enhance Access to medicines?', at 3.
49 Matthews, 'TRIPS Flexibilities and Access to Medicines in Developing Countries', at 421.
50 Anderson, 'Better Access to Medicines', at 180-181.

Subsequently, no licence was granted in South Africa on a pharmaceutical-related patent.[51] In support thereof, the United States of America, referred to hereafter as "USA", never issued compulsory licences easily to other countries but did so under its own domestic laws. Instead, it threatened Bayer in respect of Cipro, an anthrax antibiotic, that it would procure the drug from other sources.[52]

That was when USA wanted to stock the drug in large quantities at a reduced price. As a result, Bayer agreed to supply the USA government with large quantities of the drug at a reduced price.[53] The developed countries stand to benefit more to the detriment of developing countries because of the patent rights held by them in terms of TRIPS Agreement.[54]

In conclusion, it is advisable that if South Africa intends to invoke compulsory licencing as part of accessing medicines it must incorporate TRIPS flexibilities into its domestic legislation. It must adopt a law to accomplish the desired goal of access to cheap or affordable medicine.

2.2.1.2 *Exceptions to the exclusive right conferred by a patent*

Third parties can use TRIPS flexibility to access medicines. The exceptions confirm the position that exclusive rights conferred regarding patent rights can be excepted justifiably in terms of Article 30 of TRIPS Agreement.

In addition, Article 30 of TRIPS Agreement is applicable in exceptions where both Articles 31 and 31 amendment of TRIPS Agreement cannot be utilised for public interest to access medicines.[55] Article 30 of TRIPS Agreement identifies three conditions of exception where exclusive rights may be confered.

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51 Yousuf A. Vawda, 'Analysing South Africa's compulsory licensing jurisprudence: Is there a room for the Public Interest (PI) in Intellectual Property (IP)?', (2019)(Volume 7) SAIPLJ at 182.

52 Anderson, 'Better Access to Medicines', at 170.

53 Anderson, 'Better Access to Medicines', at 170.

54 Rippel Kerstin Maria and De Villiers Roux, 'Legalising Parallel Imports under Intellectual Property Law' Stellenbosch L R (2004), at 553.

55 Stuhldreier Marc Andre, 'The Patentability of Medical Products: Identifying Responsibilities of Pharmaceutical Corporations Towards the Right to Health', (DPhil thesis, University of Northumbria 2019) at 81.

It is an important knowledge that TRIPS Agreement does not define limited exceptions that developing countries in pursuit of public health goals can use TRIPS Agreement.[56]

The Understanding on Rules and Procedures Governing the Settlement of Disputes, referred to hereafter as "DSU", of the WTO was established to resolve disputes between member states. Usually, a complaining party can approach the Dispute Settlement Body, referred to hereafter as "DSB", to hear a dispute through an established panel. For example, Patent protection of Pharmaceutical Products (WT/DS114/R) dispute was heard by DSB panel. The panel interpreted Article 30 of TRIPS Agreement to determine whether the violation of Article 28 by Canada qualified for an exception. A report was released with a finding that the Canadian law was limiting regarding permissible acts and as a result, it abrogated the patentee's rights in its entirety.[57]

The decision in the Canadian dispute created uncertainties regarding legitimate interest of third parties to access medicines within a reasonable time. Regrettably, Article 30 was not used as a limited exception to export medicine to no-producing countries. That is primarily due to resistance from the USA administration and the research-based pharmaceutical industry.[58]

In conclusion, the conditions of the exception outlined in Article 30 are an obstacle to governments to except the patent right owner's exclusive rights to access medicines, more specifically in cases of national disasters or outbreaks. The conditions make it indirectly impossible as the interested party is expected to pass the three-legged test to protect public health.

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56 Joseph, 'Access to affordable life-saving medicines, at 28-29.

57 Visser Coenraad, 'Affordable medicines' exceptions to patent rights under the TRIPS Agreement: some pointers for South Africa', Volume 34, No: 3, CILJSA (2001) at 384-385.

58 Matthews, 'TRIPS Flexibilities and Access to Medicines in Developing Countries', at 422.

2.2.1.3 *Limiting TRIPs flexibilities through data exclusivity*

The data exclusivity provision is used to prevent generic drug manufacturers from using the patentee's data. Prevention is usually implemented by being incorporated into a trade agreement between countries. The period of prevention may be five years.[59]

Article 39.3 of TRIPS Agreement provides for the protection of undisclosed test data from unfair competition use however it is not explicit on the period of exclusivity. This depends on the agreement between third parties and government. Prominently, developing countries' right to use such data is mostly constrained through trade agreements, like the USA Bilateral trade agreements with Morocco. In other words, "it is taken away through the back door", as European Union, referred to hearefter as "EU", Trade Commissioner, Pascal Lamy, put it.[60] That is, the limitation of TRIPs' flexibilities through data exclusivity directly defeats the purpose of compulsory licencing.

For a government to incorporate that clause into the trade agreement solemnly for protecting undisclosed data implies that a third party is restrained from securing the production of generic medicines or import goods from foreign producers.

2.2.1.4 *Parallel importation*

Parallel import of goods is the introduction of a legitimately produced patent locally without the patentee's authorisation. The goods must be disposed of in the exporting country with either implied or express authorisation of the patentee.[61] It occurs when national laws allow the importation of goods sold more cheaply in another market.[62]

Article 6 of TRIPS Agreement permit parallel import of goods through the doctrine of exhaustion of intellectual property rights. WTO members implement the doctrine to resell patent products that have been marketed nationally either by the patent holder or his agent.

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59 Matthews, 'TRIPS Flexibilities and Access to Medicines in Developing Countries', at 426.
60 Matthews, 'TRIPS Flexibilities and Access to Medicines in Developing Countries' at 426.
61 Rippel and De Villiers, 'Legalising Parallel Imports under Intellectual Property Law' at 550.
62 Matthews, 'TRIPS Flexibilities and Access to Medicines in Developing Countries' at 426.

International exhaustion allows for the import of the patented product upon first sale by the patentee. In this instance, patentee has no powers to prevent resale of the patented product in international exhaustion.[63]

Medicines and Related Substances Control Amendment Act 90 of 1997, referred to hereafter as the "1997 Medicines and Related Substances Act", contains Regulations. Regulation 7 provides for parallel import of medicines. It came into force on 2 May 2004.[64] It inserted Section 15C giving the Minister the powers to protect public health and prescribe the conditions under which affordable medicines may be supplied or imported. This includes the Minister's power to grant permission for registration and the use of medicines that are protected in terms of the Patents Act within the Republic.

Therefore, parallel import of patented goods, medicines to be specific, is essential to secure cheaper medicines in South Africa. For drugs manufactured outside the country to be imported through exhaustion is dependent on Section 15C of the 1965 Medicines and Related Substances Act.

2.2.2 *WTO Doha Declaration on the TRIPS Agreement and Public Health*

The Declaration was adopted on 30 August 2003.[65] It was initiated by developed countries to remove constraints set out in Article 31(f) of TRIPS Agreement to allow countries with manufacturing capacity to grant compulsory licences to developing countries. Limitation is removed in instances where the product manufactured under the compulsory licence is for the supply of the domestic market of the patentee. Countries like India and Brazil utilised TRIPS flexibilities as a response to public health emergencies and due to rising prices of essential medicines.[66] These countries have drug manufacturing capacity.

63 Joseph, 'Access to affordable life-saving medicines' at 32.
64 Rippel and De Villiers, 'Legalising Parallel Imports under Intellectual Property Law' at 556.
65 Matthews, 'TRIPS Flexibilities and Access to Medicines in Developing Countries' at 421.
66 Reichman, 'Compulsory licensing of patented pharmaceutical inventions' at 3.

The Doha Declaration recognises the seriousness of developed and least-developed countries' public health problems. The problems include HIV/AIDS and other epidemics such as cancer.[67] Clause 4 of the Declaration reconfirms key flexibilities, guarantees the freedom of countries to take initiatives and preventative measures to promote the fundamental right of access to medicines. South Africa must capitalise on this opportunity to protect public health.

2.2.3 2030 *Agenda for Sustainable Development, UN Resolution No. A/RES/70/1*

The UN Secretary established of the High-Level Panel was established in November 2015. The Panel published a report with a finding that many people could not access essential medicines. Goal 3 of the UN SDGs recognises access to affordable medicines as a fundamental human right.[68]

South Africa must implement this plan of action to change the world. The SDGs reaffirm the importance of the Universal Declaration of Human Rights.[69]

2.2.3.1 *Goal 3: Ensure healthy lives and promote well-being for all ages*

Goal 3 of the SDGs ensures enjoyment of good health and access to health care by all. This goal reinforces the vital importance of access to affordable medicines by all human beings. It places responsibility on every member state, country, and stakeholder in collaborative partnership, to implement it..[70]

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67 Reichman, 'Compulsory licensing of patented pharmaceutical inventions' at 3.

68 Owoeye, Olasupo Olawabusayo, 'Intellectual Property, Access to Medicines and Universal Health Coverage Through a Health Rights Lens' (2018) (Volume 40) European Intellectual Property Review, at 50.

69 UN General Assembly, Transforming our World: 2030 Agenda for Sustainable Development, UN Resolution No. A/RES/70/1.

70 Owoeye, 'Intellectual Property, Access to Medicines and Universal Health' at 51.

2.2.4 *Paris Convention for the Protection of Industrial Property, 1979*

The Paris Convention guarantees extra-territorial protection of unregistered, well-known or famous trademarks in relation to goods or services of the proprietor in a country. It was ratified by South Africa in 1974.[71]

Further, article 5A(2) of the Paris Convention empowers contracting states with the right to enact legislation to protect patent rights. Section 35(3) of the Trade Marks Act also provides for the protection of well-known trade marks.[72]

It conforms with article 6 of the Paris Convention that a well-known mark must be known only in the public sector to enjoy protection. The proprietor of the trademark has rights to protect it by restraining its use within the Republic of South Africa in terms of th Trade Marks Act. That include reproduction, imitation or translation of the well-known mark where the use in relation to goods or services is similar or identical to cause confusion or deceive the consumers.[73] Interpretation of this clause is that the word “goods”, in this instance, is inclusive of marks and applies equally to medicines, and drugs imported locally. For the reason that goods is defined in terms of Consumer Protection Act 68 of 2008 as anything marketed for human consumption or tangible object that may be written or encoded on any medium, or a license to use on the intangible product.

Intellectual Property Laws Amendment Act 38 of 1997 aims to implement the Paris Convention, and to ensure compliance with the Trade Marks Act and TRIPS Agreement.[74]

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71 https://www.wipo.int/treaties/en/notifications/paris/treaty_paris_60.html [Accessed on the 25/05/2022]

72 Roshana Kelbrick, ‘The term “well-known” in South African trade mark legislation: Some Comparative interpretations’ (2006)(Volume 38) Comparative and International Law Journal of Southern Africa at 438.

73 Section 35(3) of Trade Marks Act 193 of 1993.

74 Rippel and De Villiers, ‘Legalising Parallel Imports under Intellectual Property Law’, at 556.

2.3 Regional Instruments

South Africa's membership in the AU commenced on 6 June 1994 and in April 1994 for the SADC.[75] It is important to refer to regional instruments to lay a basis for South Africa that it guarantees and promotes the right of access to health care.

2.3.1 *African Commission on Human and People's Rights*

The ACHPR places an obligation on members to protect human rights. Article 16 of the Charter guarantees everyone's right to enjoy both physical and mental health. State parties have an obligation to take the necessary measures to ensure that everyone receive the best medical services.

Since ACHPR adopted Res. 141(XXXXIV) on access to health and needed medicines, the Economic, Social, and Cultural Rights working group adopted a Treaty to establish the Medicines Agency. The treaty came into force on 5 November 2021. The Medicines Agency's role is to enhance state parties' capacity to improve access to safe, quality and effective medical products.[76]

Presently, the agency is tasked with providing guidance on regulations, scientific opinions on medical products a process that is ongoing.[77] South Africa must commit to ratify and accede to the Treaty.

2.3.2 *African Health Strategy (AHS) 2016 – 2030*

The African Health Strategy 2016 – 2030, referred hereafter as "AHS", just like the UN 2030 Agenda for SDGs, provides strategic direction to state parties on how to create better-performing health sectors and reduce the continent's burden of diseases.

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75 https://www.sadc.int/member-states/south-africa [Accessed on the 25/05/2022]; https://au.int/en/member_states/countryprofiles2 [Accessed on the 25/05/2022]

76 https://au.int/en/pressreleases/20211109/treaty-establishment-african-medicines-agency-ama-enters-force [Accessed on the 25/05/2022].

77 https://au.int/sites/default/files/pressreleases/34320-pr-press_statement_ama_treaty1.pdf [Accessed on the 25/05/2022].

Technically, the AHS is a 15-year plan of action that calls on state parties to invest in, and establish collaborations and partnerships with community organisations with a vision to promote health.[78]

Despite the existing AHS plan of action, there is a need for the establishment of the Monitoring and Evaluation Framework with indicators, targets, reporting, and accountability systems to enable state parties to monitor progress.[79]

2.3.3 *SADC Protocol on Health 1999*

South Africa signed the Protocol on Health on 18 August 1999. Interm State parties are expected to coordinate efforts in their countries to prepare themselves against epidemics and preventative measures to deal with them.[80] Furthermore, state parties are expected to establish institutional mechanisms within their health sectors to effectively implement the Protocol.

2.4 South African legal framework

The right to health care is duly recognised in the 1996 Constitution. It is a socio-economic right that the government is expected to promote and protect.[81]

2.4.1 *Right to health care*

Section 27(a) of the Constitution clearly guarantees everyone's right of access to health care services. The state is obliged to respect, protect, promote and fulfil the rights contained in the bill of rights in terms of section 7(2). This right is recognised as a second-generation.[82]

78 Africa Health Strategy 2016 -2030.
79 Africa Health Strategy.
80 https://pmg.org.za/committee-meeting/4412/ [Accessed on the 25/05/2022].
81 Act 108 of 1996.
82 Currie and De Waal, *The Bill of Rights Handbook* at 564.

2.4.2 *What must the state do to promote the enjoyment of the right to health care?*

Section 27(2) urges government to take reasonable steps within its available resources to ensure that the right to health care services is realised. It confers to the legislature the mandate to develop policies and pass laws in accordance with the Constitution to achieve protection of public health. So, it is expected that health policies and programmes developed must be reasonable in conception and implementation.[83] No person may be refused access to emergency medical treatment since section 27(3) requires equal treatment of patients.

2.4.2.1. *Soobramoney v Minister of Health, KwaZulu-Natal 1998(1) SA 765 (CC)*

In the Soobramoney case,[84] the Constitutional Court looked at the appellant's argument that government had to provide emergency medical treatment to a terminally ill patient by discharging its obligation as required by section 27(3); and further that section 27(3) must be interpreted to mean the right to life, especially for patients that cannot afford to pay for treatment themselves.

The Court interpreted section 27(3) and held that the wording was expressed in negative terms that the right not to be refused emergency medical treatment meant that treatment is to be given to patients in an emergency, and not unreasonably frustrated.[85] Therefore, the appellant's claim was dismissed in that he failed to prove breach committed by the state under section 27(3).

It stated that the appellant's apparent demand to receive dialysis treatment must be determined in terms of both sections 27(1) and (2); and not only section 27(3).[86]

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83 Currie and De Waal, *The Bill of Rights Handbook* at 575.
84 Paragraphs 12 to 14.
85 Paragraph 20.
86 Paragraph 22.

2.4.2.2 *Minister of Health v Treatment Action Campaign 2002 (5) SA 721 (CC)*

In the Minister of Health case, the Constitutional Court had to determine if the applicants successfully proved that the measures adopted by government to provide access to health care services for HIV-positive pregnant mothers failed to meet its constitutional obligations. It remarked that section 27(1) does not give rise to a selfstanding positive right enforceable without consideration of section 27(2), and therefore, section 27(1) must be read together with section 27(2). It ruled that the government's policy to confine Nevirapine only to research and training sites failed to address the needs of pregnant mothers and their unborn children, especially those who cannot access the identified sites.[87]

Essentially, the government must develop a comprehensive programme that will yield positive results. Policies and any legislation enacted must be possible, and have the desire to assist in combating diseases and other epidemics.

2.5 Medicines and Related Substances Act 101 of 1965, amended

South Africa promulgated amendment to the 1965 Medicines and Related Substances Act to regulate the use of drugs. Medicines and 1997 Medicines and Related Substances Act, deals significantly with access to essential medicines. South African Health Products Regulatory Authority, referred to hereafter "SAHPRA", was established in terms of the 2017 Government Regulations. It replaced the Medicines Control Council.[88] It is a prerequisite that drugs must be registered before use.[89]

2.5.1 *Registration of Medicines and Related Substances*

The restriction on the prohibition of the sale of unregistered medicines is contained under section 14(1), read together with sections 21 and 22A, of the 1965 Medicines and Related Substances Act.

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87 Paragraphs 23, 25, 39 and 67.

88 https://pharmaciae.org.za/keeping-up-to-date-with-legislation-2 [Accessed on the 20/05/2022].

89 Pharmaceutical Manufacturers Association v President of South Africa 2000(3) BCLR 241 (CC) at Paragraph 60.

Summarily, section 14(1) restricts the sale, manufacture or possession any medicine or Scheduled substance without the Minister's resolution. Significantly, registration of medicines is subject to strict compliance in that they must be safe, efficacious and quality assurance to protect the health. SAHPRA, that replaced Medicines Control Council, has the mandate to monitor, evaluate, investigate, inspect and register all health products.[90]

2.5.2 *Measures for the supply of more affordable medicines*

Generally, medicines must be suitable for the purpose they are intended. Section 15C of the 1965 Medicines and Related Substances Act provides for conditions the Minister may prescribe for the supply of affordable medicines. The Minister is vested with powers to pass regulations to protect public health. Section 15C(a) gives the Minister wider authority to override exclusive rights in patents whilst section 15C(b) deals with parallel importation narrowly.

In *Pharmaceutical Manufacturers Association v President of South Africa,*[91] the Minister of Health's power to issue Government Notice R567 was questioned. The bone of contention was that the 1998 South African Medicines and Medical Devices Regulatory Authority Act repealed Schedules 1 to 9 of the 1965 Medicines and Related Substances Act. As a result, the Constitutional Court held that Proclamation R49, issued by the President, was of no force or effect and null.[92]

Section 15C(b) of the 1965 Medicines and Related Substances Act allows for parallel import of medicines that are identical in composition, and are intended to have the same proprietary name as that of medicines registered within the Republic.[93] This aspect will be addressed appropriately as part of the identified defects in the Patents Act in the next chapter.

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90 https://www.sahpra.org.za/who-we-are [Accessed 25/05/2022].
91 2000(3) BCLR 241 (CC).
92 Paragraph 94.
93 Rippel and De Villiers, 'Legalising Parallel Imports under Intellectual Property Law' at 564.

2.5.3 *Supply of cheaper medicines*

Sections 18A and 18B of the 1997 Medicines and Related Substances Act provide for restrictions that no person shall supply any medicine according to a rebate system or any other incentive scheme and lastly, sample any medicine.

Further, section 22G places the responsibility on the Minister to appoint persons who are fit to serve in the pricing committee. No committee is appointed by the Minister to regulate prices of medicines. It is a fact that majority of South Africans rely on the government's public healthcare for services because they cannot afford private medical insurance.[94]

Besides the need for access to cheaper medicines, there is an outcry about the shortage of medicines in public hospitals and community healthcare centres. For example, there are essential medicines recommended by the World Health Organisation, referred to hereafter as “WHO”, which are Trastuzumab and Sorafenib. Trastuzumab treats breast and stomach cancer, and Sorafenib treats advanced kidney, liver, and thyroid cancer. However, these medicines are not readily available in the public sector but affordable by only a few South Africans with some medical insurance due to cost cover.[95]

2.5.4 *Promote the use of generic medicines*

According to section 22F(1) of the 1997 Medicines and Related Substances Act pharmacists are obliged to inform their clients the benefits of the substitution for a branded medicine, or take precautionary steps to inform the person who prescribe the medicine of substitution and dispense such generic medicines rather than the prescribed one unless expressly forbidden by the patient.

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94 Fix the Patent Laws Campaign, Patent barriers to medicine access in South Africa: A case for patent law reform. Castle Graphics (2016) at 9.

95 Fix the Patent Laws Campaign, Patent barriers to medicine in South Africa at 9.

2.6 Conclusion

It is without a doubt the right of access to medicines is a universal right recognised and protected; and that South Africa does not comply with the prescripts of TRIPS Agreement. Its failure to take the opportunity to exercise the rights in terms of flexibility for everyone to access cheap medicines is a sad reality. The lack of resources would be an unjustifiable excuse for non-compliance. The effective use of 1997 Medicines and Related Substances Amendment Act today remains unclear.

The AU's AHS 2016 – 2030 and the SADC's Protocol on Health 1999 are merely plans of action calling on countries, such as South Africa, to take initiatives in the health sectors. Unfortunately, there are no regional instruments to enforce locally for the realisation of the inalienable right to health care services. Implementation of TRIPS flexibilities is imperative. Essentially, the need for the AU and SADC to establish a working group consisting of experts that will monitor and report on successes; and ultimately, provide advice and guidance to their member states.

CHAPTER 3 PATENT LEGISLATION AND COMPLIANCE WITH TRIPS AGREEMENT

3.1 Introduction

Notwithstanding that South African Patents Act fails to provide for improved access to cheap medicines, there is a need for the amendment of the latter. It is commendable that there is a bold step taken to address this problem and reform the current legislation through intellectual property policy.[96]

The discussion in this chapter, centres around amendments to be made to the Patents Act, that is, improvement of the critical areas identified being a substantial technical assessment of prospective inventions, issuance of unnecessary secondary patents and evergreening, incorporating TRIPS flexibilities and compulsory licences, and the recommended best practices.

3.2 Intellectual Property Policy Phase 1 of 2018

The Intellectual Property Policy was developed by the DTiC in 2018. It endeavour to address the substantial problem of intellectual property rights in South Africa such as substantive search and examination for patents, use TRIPS Agreement flexibilities, commit South Africa to international instruments it signed and promote international best practices in intellectual property aligned with South Africa's development objectives.[97]

The real problem is that no substantial search and examinations of patent applications is conducted. As a result, South Africa granted 93% of patents, a higher percentage than any other country in the world. The second in line was the US with 61%, the EU with 51%, 29% in Japan, 19% in India, and 14% in Brazil of patent applications granted.[98]

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96 Intellectual Property Policy of the Republic of South Africa, Phase 1 of 2018.

97 Intellectual Property Policy of the Republic of South Africa, Phase 1 of 2018 at 5.

98 Intellectual Property Policy at 7. This is a comparative study conducted by scholars from Columbia and Harvard Universities among developing countries having World Intellectual Property Organisation (WIPO) membership.

Although the strategy of the policy is to enable the government to pursue an urgent action to conduct in-depth-study and consultation, one can conclude that there is slow progress.

No implementation of substantive search and examination of patents or right of parties to oppose patents applications, criteria of patents, parallel importation, exceptions, voluntary and compulsory licences and intellectual property.[99]

Besides that, Lonias Ndlovu recommended that SADC countries such as South Africa follow best practices from other countries and grab the opportunities afforded by TRIPS flexibilities to it as a member of the WTO to craft a new Patents Act.[100] Therefore, the recommendation that South Africa and SADC state parties must ensure protection of public health is a best action. Further, South Africans must have access to affordable medicines imported or produced locally.

3.3 Amendment Acts to Patents Act, 1978

It is noted that the legislature amended the existing Patents Act. The amendments were effected through these Acts of Parliament, that is, the Patents Amendment Act 58 of 2002, and the Patents Amendment Act 20 of 2005 respectively.

3.3.1 *Patents Amendment Act 58 of 2002*

The Patents Amendment Act 58 of 2002, referred to hereafter as "2002 Patents Act" came into operation on 15 January 2003. Its purpose is to bring provisions of the Patents Act to be in line with TRIPS Agreement, provide circumstances for the non-infringement of a patent; and provide further for matters incidental thereto.[101]

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99 Intellectual Property Policy at 14.

100 Ndlovu Lonias, 'Lessons for the SADC from the Indian case of Novartis AG v Union of India', (2015) Volume 18, Potchefstroom Electronic Law Journal at 803.

101 Purpose of the Patents Amendment Act 58 of 2002 outlined at 2.

3.3.2 *Patents Amendment Act 20 of 2005*

The Patents Amendment Act 20 of 2005, referred to hereafter to as "2005 Patents Act" came into operation on 14 December 2007. Its purpose is to require the patent applicant to furnish information relating to the role played by a generic resource, or traditional knowledge or use in an invention.[102]

If one takes a critical look at both Acts, the 2002 Patents Act, section 43A, recognises the obligations of the Patent Co-operation Treaty, referred to hereafter as "PCT", as a focal point. That entails international filing of patent applications for protection.

The 2005 Patents Act, section 2A, focuses on traditional knowledge and indigenous biological resource. None of these Acts promote public health or fundamental right of access to adequate medicines.

3.4 South African Health Products Regulatory Authority (SAHPRA)

SAHPRA is the National Department of Health's public entity established in 2017. Its vested powers are registration of medicines, cosmetics, or in vitro diagnostic, referred to hereafter as "IVD" devices, and make decisions through its board. Its function is to ensure that the periodic re-evaluation and monitoring of medicines, medical devices and IVD devices.[103]

TRIPS Agreement, on the other hand, encourages countries to adopt national law provisions and flexibilities to protect health and introduce generic medicines to address unaffordable prices. To this end, South Africa had not discharged its obligations to reform its intellectual property law as expressed under Article 65 of TRIPS Agreement; hence the draft intellectual property policy.

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102 Purpose of the Patents Amendment Act 20 of 2005 outlined at 2.

103 Saidi T and Douglas T S, 'Medical device regulation in South Africa: the Medicines and Related Substances Amendment Act 14 of 2015', (2018) Volume 108, South African Medical Journal, at 168.

The following number of weaknesses come into the picture:

1. Substantial technical assessment of prospective inventions;
2. Issuance of unnecessary secondary patents and evergreening;
3. Incorporate TRIPS flexibilities; and
4. Compulsory licences.[104]

Adverse criticisms of the Patents Act were led by several civil society activists and interest groups calling for reform. Amongst others is the Fix the Patent Laws Campaign, Treatment Action Campaign, referred to hereafter as "TAC", Section 27, Cancer Association of South Africa, referred to hereafter as "CANSA", Pancreatic Cancer Network, People Living with Cancer, referred to hereafter as "PLWC", etc.[105]

Also, Burger and Rens argue that the Patents Act works to a patentee's advantage at the expense of competitors and, or public interest on the following aspects, amongst others, third parties that seek to invoke invalidity of a patent bear the the onus to prove infringement.[106]

Besides that, Dr. Poku Adusei criticised the patent system of sub-Saharan Africa as dysfunctional. The main reasons he advanced were that it establishes a monopoly that the first world countries benefit more based on the economic ideology of self-interest that destroy human values and the practices of indigenous communities. The system further dismally fail to treat access to life-saving drugs.[107] The criticism paints an accurate picture of a genuine challenge of access to cheap and affordable medicines in sub-Saharan Africa.

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104 Matthews D N, 'TRIPS Flexibilities and Access to Medicines in Developing Countries: The Problem with Technical Assistance and Free Trade Agreements', (Intellectual, Property Research Institute, University of London 2005), at 420-427;
Ndlovu Lonias, 'South African Patent Law and Access to Medicines', Conference Paper (2013), at 1-2, 4-7.

105 Fix the Patent Laws Campaign, Patent Barriers to medicine access in South Africa: A case of patent law reform, Castle Graphics (2016) at 3.

106 Burger J and Rens A, "Innovation and Intellectual property in South Africa: The Case for Reform" University of Cape Town Intellectual Property Unit (2018) at 32.

107 Busch Stephanie, 'Promoting access to affordable generics: reforming South Africa's patent law to prevent evergreening', (2016) Volume 4, SAIPLJ, 109-110.

3.4.1 *Substantial technical assessment of prospective inventions*

South Africa is a non-examining country in respect of patent applications.[108] There is no substantive examination of patents prior to granting every application.

It is advisable that this critical function of examination of inventions must vest with the CIPC. In the same vein, patent applications must undergo substantive examination; whereas those made through PCT must be subjected to international search to establish if they comply with the requirements of patentability set out in Section 25 of the Patents Act.[109] The Registrar, through appointed officers with the relevant expertise, must assess prospective inventions and not only do paperwork on an invention.

Although Section 34 of the Patents Act provides for the examination of patents it is, however, defied.[110] It is questionable that since South Africa does not conduct substantive search and examination of applications is being conducted; hence, too many applications are granted by the Registrar.[111]

Section 36 of the Patents Act sets out the powers that the Registrar may squarely exercise to refuse an application for a patent. The following applications maybe refused:

1. Invention contrary to well established natural laws and
2. Invention that encourages offensive or immoral behaviour.

It follows logically that the Registrar must refer applications to examiners familiar with the technology of the invention for confirmation. India, Argentina, Brazil, and Egypt have developed strong substantive examination measures to combat evergreening.

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108 Pouris Anthipi and Anastassios, 'Patents and economic development in South Africa: Managing intellectual property rights, South African Journal of Science', (2011) Vol.107 No. 11-12, at 5;
Yousuf A. Vawda, 'Analysing South Africa's compulsory licensing jurisprudence: Is there a room for the Public Interest (PI) in Intellectual Property (IP)?', (2019) Volume 7, SAIPLJ at 183.

109 Ncube Caroline, The politics of national intellectual property policy design and the provision of health services in South Africa, at 22-23.

110 Ndlovu, 'South African Patent Law and Access to Medicines', at 5.

111 Tomlinson C, Waterhouse C, Hu Y Q, Meyer S and Moyo H, 'How patent law reform can improve affordability and accessibility of medicines in South Africa: four medicine case studies', (2019) Volume 109, South African Medical Journal, at 388;
Ndlovu, 'South African Patent Law and Access to Medicines, Conference Paper' at 5.

Further than that, India, Argentina and the European Patent Convention, referred to hereafter as "EPC", allow third parties to oppose patent applications before a patent application can be granted.[112]

Since South Africa developed an intellectual property policy it is, therefore, recommended that the Registrar must set a stricter patentability criterion with the right to object rather than parties having to engage in a lengthy, expensive litigation process.

Only strong patents must be granted where third parties are granted an opportunity to file a notice to oppose the granting of patents, just like in the EPC.[113] Litigation in this instance is usually initiated by affected parties or those with a vested interest seeking a declaratory order to prevent the approval of applications for patents. Unlike South Africa, India allow for opposition of patent applications.[114] Section 3(d) of the Indian Patents Amendment Act, 2005 sets out the requirements that an invention must be new to enhance efficacy of the substance.

Significantly, this section introduced a high standard of inventiveness that what is patentable elsewhere may not be patentable in India. Moreover, it prohibits the granting of patents that would cause public disorder.[115] More information on section 3(d) is discussed under evergreening below.

3.4.2 *Issuance of unnecessary secondary patents and evergreening*

So long as the depository system for patent applications is maintained locally, the unending stream of secondary evergreening patents will persist. Evergreening is known as stockpiling, layering or life-cycle management. That is, pharmaceutical companies or patent rights owners in respect of medicines continue to acquire separate patents on multiple attributes of a single product.[116]

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112 Tomlinson C, Waterhouse C, Hu Y Q, Meyer S and Moyo H, 'How patent law reform can improve affordability and accessibility of medicines in South Africa: four medicine case studies', (2019) Volume 109, South African Medical Journal, at 388;
Busch Stephanie, 'Promoting access to affordable generics', at 115-116.

113 Busch, 'Promoting access to affordable generics', at 115.

114 Indian Patent Amendment Act 15 of 2005 that amended Patents Act of 1070.

115 Ndlovu, 'Lessons for the SADC from the Indian case of Novartis AG v Union of India', at 789.

116 Busch, 'Promoting access to affordable generics', at 110.

The common standard practice is that they unnecessarily extend the protection of the patent to go beyond 20 years for two reasons, that is, to keep the expensive prices of medicines or create monopolistic prices, and extend the life span of the patent through secondary patents to block affordable generic competitors to bring new products in the market.

Unfair advantage is taken where changes of little clinical or therapeutic value are made to the original product to retain the high prices of medicines.[117] The reform of the Patents Act must introduce a provision that disclaim inventions that fail to demonstrate enhanced efficacy to curb evergreening.[118]

3.4.2.1 *Novartis AG v Union of India & Others*

In *Novartis AG case*,[119] India's Supreme Court entertained the question whether the Glivec drug was a patentable invention.[120] Glivec was for treatment of chronic myeloid leukaemia. The question was decided with reference to the Indian Patents Amendment Act, 2005 particularly section 3(d).

The court dismissed the submissions of Novartis and confirmed the order of the Chennai Patents Office that Glivec failed to enhance therapeutic efficacy. It further discussed the objectives of section 3(d) which are preventing evergreen and provide access to life-saving drugs to Indians.[121]

The judgment provided different lessons such that the interpretation of the Indian Amendment Act established the intention of the legislature not to tolerate the proliferation of evergreen patents. Secondly, the court of relied on the expansive approach to decide the question on economic and political context taking into consideration the interests of the society.[122]

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117 Busch, 'Promoting access to affordable generics', at 111.

118 Ndlovu, 'Lessons for the SADC from the Indian case of Novartis AG v Union of India' at 798-799;

119 Supreme Court of India, Civil Appeal No 2706-2716 of 1 April 2013.

120 Ndlovu, 'Lessons for the SADC from the Indian case of Novartis AG v Union of India' at 790.

121 Ndlovu, 'Lessons for the SADC from the Indian case of Novartis AG v Union of India', at 789-791.

122 Yousuf A. Vawda, 'After the Novartis judgement – Evergreening' will never be the same again, Law Democracy Development', (2014) Vol.18 Cape Town, at 315.

In conclusion, the bid by Novartis for registration of Imatinib Mesylate as a patent in India was refused. The decision of India's Supreme Court is the best practice for South Africa to emulate and counteract the effect of, and curb evergreening. That is, patenting of medicines that do not display increased efficacy should be barred.

3.4.3 *Incorporate TRIPS flexibilities*

Patents Act is expected to incorporate TRIPS flexibilities. Article 30 of TRIPS Agreement invites countries to introduce laws that promote public health. Section 3(d) of the Indian Amendment Act capacitates the country to examine patents and allow interested parties to object, including the Registrar's powers to refuse to disapprove patent applications and, or register a patent.

It is enthralling that the provisions of the Indian Amendment Act do not violate article 27 of TRIPS Agreement.[123] Article 27.2 encourages member states to incorporate into their national laws the strict testing powers of patents. Although South Africa took a bold step in articulating through the 2018 Draft Intellectual Property Policy that incremental patenting and proliferation of evergreen patents will not be tolerated, it must still amend the Patents Act. Parallel imports of goods is recognised under section 45(2) of the Act.[124] Parallel importation of medicines is restricted that it shall be on the patentee's rights or licence granted. The prerequisite is that the party intending to import medicine from another country must obtain a licence from the patentee. Section 15C(b) of 1997 Medicines and Related Substances Act legalises parallel import of medicines, generic substitution of patented and off-patented drugs, and pricing control measures. The prerequisite is that the drugs must be identical in composition and meet quality standard with intention to have the same drug name as that of other medicines registered locally.[125]

123 Busch, 'Promoting access to affordable generics', at 117.

124 Ncube, 'The politics of national intellectual property policy design and the provision of health services in South Africa' at 24.

125 Rippel and De Villiers, 'Legalising Parallel Imports under Intellectual Property Law' at 558.

South Africa presented a proposal to WTO in October 2020 to waive implementation of TRIPS Agreement in response to the COVID-19 pandemic. Unfortunately, it was opposed by a number of developed states in the EU that argued that the intellectual property waiver may undermine Research and Development, referred to hereafter as "R&D" and new technology. To add, that it would reduce profits.[126]

Regulation 5(1) of the 2017 General Regulations provides the grounds upon which imported medicines with the consent of the patentee may be sold locally provided they are declared, registered in terms of the 1965 Medicines and Related Substances Act.

Regulations 5(2)-(7) provide for compliance with the set administrative processes, whereas Regulation 6 identifies ports of entry for medicines imported into the Republic.

Based on the above-mentioned experiences, it would be in the interest of the public that SAHPRA is capacitated to ensure that it carries out its mandate without the challenges of backlog due to the exhausting administration process.

There is excessive highly administrative desk work to do such as application forms of persons intending to import medicines, certified copies identity copies and certificates of registrations of applicants, licences in respect of premises, proof of medicine registration in the country of export and amongst others.[127] Capacitating SAHPRA with adequate administrative personnel will ensure that applications for registration of medicines are processed as speedily as possible to deal with epidemics or pandemics that South Africa may experience in the future.

3.4.4 *Compulsory licences*

Compulsory licences is another flexibility that was incorporated in the Patents Act under Sections 55 and 56.[128] Both of them provide for instances where compulsory licences maybe granted either in cases of dependent patents or abuse of patent rights.

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126 Dos Santos F, Ncube CB and Ouma M, 'Intellectual property framework responses to health emergencies – options for Africa', (2022) Volume 118, SAJS at 3.

127 Medicines and Related Substances Act, General Regulations 2017 at 54-57.

128 Act 57 of 1978.

3.4.4.1 *Dependent Patents*

Section 55 of the Patents Act provides for the use of a licence in instances of dependent patents on a patentee's prior patent.[129] Licence will be granted where prior patentee's permission is obtained in the working of the subsequent patent without infringement. In other words, the application must be on agreement with the patent owner.[130]

Where permission is refused, application for a licence must be made to the Commissioner of Patents. To secure a licence, the applicant must prove that the attempt for the application was sought on reasonable terms from the patent owner; however, authorisation was unsuccessful. That is, the patent owner is uncooperative and blocked the dependent patent.[131]

Secondly, the application for a licence must either be for technological advancement of invention or cross-licence was granted by the patentee on reasonable terms, or the authorised use of prior patent was assigned by the dependent patent in terms of section 44 of the Intellectual Property Amendment Act 38 of 1997. Section 55 further empowers the Commissioner of Patents to exercise the compulsory-licensing right on medicines or pharmaceutical products. It may grant licence by imposing conditions.[132]

The process of granting compulsory licence was never an easy passage. For example, Abbott the manufacturer of Kaletra, an essential Antiretroviral, referred to hereafter as "ARV" drug, withdrew its registration application in 2007 for the new form of the drug in protest against the Thai government. It did so by withdrawing the supply of Kaletra to the government of Thailand's unwillingness to support their patent.[133]

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129 Hobololo Vuyisile, 'Strategic patenting of pharmaceutical inventions and the public's right to access medicines: the South African context' (2015)(Issue no.16) The African Journal of Information and Communication at 80.

130 Hobololo Vuyisile, 'Strategic patenting of pharmaceutical inventions and the public's right to access medicines: the South African context' (2015)(Issue no.16) The African Journal of Information and Communication at 80.

131 Hobololo, 'Strategic patenting of pharmaceutical inventions and the public's right to access medicines at 80.

132 Joseph, 'Access to affordable life-saving medicines' at 45 - 46.

133 Joseph, 'Access to affordable life-saving medicines' at 69-70.

3.4.4.2 *Abuse of Patent*

Article 5(A)(2) of the Paris Convention was amended on 28 September 1979 to empower countries of Union to apply for licences to prevent abuse of patent rights.

Section 56(2) of the Patents Act empowers the Commissioner to consider the application on merits by either granting or refuse the application to manufacture patented products.[134] Paragraph (a) provides for application for a licence where the patent is not worked on locally on a commercial scale four years after its expiry date of application of the patent, or three years subsequent to the date of invention.

Article 5(A) of the Paris Convention makes provision for abuse of work where there exists inadequate satisfactory reasons. The decision in *Sanachem* case [135] set precedence that must be considered in proving working of a patent.

It is dominant that the applicant must have technological capabilities before applying for a licence.[136] It is also advisable to South Africa that it wants to do so, there must exist sufficient medical reasons for working the patent, such as the need to curb viruses or infections. Take, for example, monkeypox outbreak was declared a public health emergency by the WHO and the USA. USA took initiative to develop the vaccine known as Jynneos to combat the virus.[137] Botswana domesticated all important TRIPS Agreement flexibilities such as compulsory licence, regime permitting parallel import of medicines, and rights of third parties to oppose patent applications and examination.[138]

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134 Joseph, 'Access to affordable life-saving medicines' at 46.

135 *Sanachem (Pty) Ltd. V. British technology Group Plc 1992 BP 279 (CC).*

136 Hobololo, 'Strategic patenting of pharmaceutical inventions and the public's right to access medicines' at 80.

137 https://www.nytimes.com/2022/08/04/health/monkeypox-emergency-us.html [Accessed on the 06/08/2022].

138 Ndlovu, 'Domesticating the World Trade Organisation's Trade-Related Aspects of Intellectual Property Rights (TRIPS) flexibilities to access essential medicines' at 365-367.

3.4.5 *Doha Declaration on the TRIPS Agreement and Public Health*

Doha Declaration affirms the rights member states to grant compulsory licences on set grounds.[139] The 2001 WTO Ministerial Decision was adopted to address the developing countries' need for cheaper drugs at lower prices.[140]

Prior to the adoption of the 2001 WTO Ministerial Decision, countries could invoke article 31 of TRIPS Agreement to issue compulsory licences.[141] Both Article 31(f) and Paragraph 5(b) of the Declaration set the grounds to grant a licence.[142]

Article 31(f) of TRIPS Agreement frustrated access to affordable medicines as it prohibits the granting of a licence to the manufacture of generic medicines for export. Production of generic medicines had to be supplied only locally then.[143] This led to the 2003 Ministerial Declaration amending article 31 of TRIPS Agreement to remedy the problem of access to cheap and affordable medicines. Waiver, emanating from the 2003 Decision, permitted for the issue of compulsory license to export medicine subject to adequate compensation payable to the patentee.[144]

3.4.6 *Competition Act 89 of 1989*

The Competition Act 89 of 1989, referred to hereafter as "Competition Act", provides for remedies that can be resorted to in so-called strategic patenting. These remedies are for anti-competitive behaviour that allows any person to report a complaint with the Competition Commission of South Africa, referred to hereafter as "CCSA". Complaint maybe on allegations of engagement in an exclusionary act by the patentee, or refusal to give competitors access to essential facility by the patentee.[145]

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139 Yousuf A. Vawda, 'Analysing South Africa's compulsory licensing jurisprudence: Is there a room for the Public Interest (PI) in Intellectual Property (IP)?', (2019) Volume 7, SAIPLJ, at 193.

140 Jerome H. Reichman, 'Compulsory Licensing of Patented Pharmaceutical Inventions: Evaluating the Options', (2009) Volume 37 No. 2, Journal of Law, Medicine and Ethics, at 3.

141 Jerome H. Reichman, 'Compulsory Licensing of Patented Pharmaceutical Inventions: Evaluating the Options', (2009) Volume 37 No. 2, Journal of Law, Medicine and Ethics, at 3.

142 Nkomo Marumo, 'The TRIPS flexibilities and access to essential medicines in the developing world: are they sufficient and is our implementation adequate?', (LLM Dissertation, University of the Western Cape (2013) at 59.

143 Nkomo, 'The TRIPS flexibilities and access to essential medicines in the developing world: are they sufficient and is our implementation adequate?' at 64.

144 Nkomo, 'The TRIPS flexibilities and access to essential medicines in the developing world: are they sufficient and is our implementation adequate?' at 65-66.

145 Hobololo, 'Strategic patenting of pharmaceutical inventions and the public's right to access medicines' at 80.

In *Hazel Tau v GlaxoSmithKline and Boehringer Ingelheim*, Ms Hazel Tau lodged a complaint against two pharmaceutical companies with the CCSA. She was joined by other complainants such as TAC, Congress of South African Trade Unions, referred to hereafter as "COSATU" and medical practitioners.[146] The nature of the complaint involved pharmaceutical companies's conduct engaging in a prohibited practice charging excessive prices for ARV drugs prejudicial to the consumers. Her submission was that premature deaths of persons living with HIV/AIDS was due to excessive pricing of ARVs, a barrier to accessing medicines. Furthermore, it was alleged that they refused to grant a licence to local generic manufacturers.[147]

The CCSA made a finding in favour of the complainant that those pharmaceutical companies contravened Sections 8(a)-(c) of the Competition Act as the prices for ARVs were found to be between five and fifteen times higher than those of generic equivalents.

A settlement was reached on the following terms:

1. GlaxoSmithKline and Boehringer Ingelheim undertook to grant compulsory licence to manufacturers of generic versions of drugs protected by them,
2. Import drugs into South Africa and export the same drugs to Sub-Saharan countries.[148]

After their commitment, seven voluntary licenses were granted to generic manufacturers leading to a high supply and reduction of prices in essential HIV drugs to patients.[149] There is a need more licences to be issued and transparent medicine prices to help patients make informed choices.[150]

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146 https://section27.org.za/wp-content/uploads/2010/10/TauvGSKevidenceAndLegalSubmissions.pdf [Accessed 06/08/2022].

147 https://section27.org.za/wp-content/uploads/2010/10/TauvGSKevidenceAndLegalSubmissions.pdf Paragraphs 17, 18, 46 and 54 [Accessed 06/08/2022].

148 http://www.compcom.co.za/wp-content/uploads/2014/09/March-04-Newsletter.pdf [Accessed on the 06/08/2022].

149 Heywood Mark, 'South Africa's Treatment Action Campaign: Combining Law and Social Mobilization to Realise the Right to Health', (2009) Volume 1 Journal of Human Rights Practice at 25.

150 Bangalee V and Suleman F, 'Is there transparency in the pricing of medicines in the South African private sector?' (2018) Volume 108, South African Medical Journal at 83.

3.5 Conclusion

South Africa, a member of the WTO and SADC, must accept without reservation that when it comes to taking decisions on health issues, the patient's needs take precedence. It must consider the good practice in the *Novartis* case to prevent evergreening and ensure that it provides access to life-saving drugs to everyone.

Apart from domesticating TRIPS Flexibilities into Patents Act, just like Botswana's 2010 Industrial Property Act,[151] flowing from the IP Policy the Draft Bill must be developed and introduced in the NA and the NCOP as a Section 76 Bill.[152] Thus TRIPS Flexibilities must be enacted into law by national legislation in terms of Section 231(4) of the 1996 Constitution.

The legislative process must kickstart with public participation and debates by the legislature in that areas such as parallel imports and compulsory licences are properly addressed, and procedures clearly explained.

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151 Ndlovu Lonias, 'Domesticating the World Trade Organisation's Trade-Related Aspects of Intellectual Property Rights (TRIPS) flexibilities to access essential medicines: any lessons for the SADC from Botswana?', (2017) Volume 50, Comparative and International Law Journal of Southern Africa at 355.

152 Constitution Act 108 of 1996, Section 76 Bill is a bill affecting provinces that must be referred to the National Council of Provinces after being passed by the National Assembly. The National Council of Provinces will either pass the bill, pass an amendment to the bill or reject the bill. If the Bill is passed or amendment passed by the National Council of Provinces, then it will be submitted to the President for assent.

CHAPTER 4 PATENTS ACT AND CHALLENGES

4.1 Introduction

Accessibility of essential medicines is neither a South African public health crisis nor challenge only but also human rights problem. It is without a doubt that there are no key measures to address access to essential medicines. No legislative amendments have been implemented consequent to the Doha Declaration.[153] Secondly, it is a well-known experience that cancer patients cannot access medicines or treatment because of exorbitant prices.[154] The concentration of the study was the history of the Patents Act, and the problem areas identified within the legislation discussed in the previous chapters. The criticism of the Patents Act was supported by interesting arguments advanced in courts, as well those of different authors.

4.2 Patents Act 57 of 1978

Patents Act is an Anglo-American system incorporated from English law that permits parallel import of patented goods provided they were sold with the consent of the patentee. Where there is no consent the principle of exhaustion then becomes applicable to prove implied consent.[155]

Paris Convention and PCT necessitated few amendments of the Patents Act and adoption of Regulations to give effect to TRIPS Agreement.[156] South Africa implemented TRIPS Agreement through Intellectual Property Laws Amendment Act in 1997 for political and economic reasons. That was done solemnly to circumvent trade sanctions by other member states of the WTO.[157]

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153 Joseph Coral Jade, 'Access to affordable life-saving medicines: The South African response' (LLM Dissertation, University of KwaZulu-Natal 2013) at 11.

154 Fix the Patent Laws Campaign, Patent barriers to medicine access in South Africa: A case for patent law reform, Castle Graphics (2016) at 9.

155 Rippel K A and De Villiers R, 'Legalising Parallel Imports under Intellectual Property Law', (2004) Stellenbosch Law Review at 557.

156 Yousuf A. Vawda, 'Analysing South Africa's compulsory licensing jurisprudence: Is there a room for the Public Interest (PI) in Intellectual Property (IP)?', (2019) Volume 7, SAIPLJ at 183.

157 Rippel and De Villiers, 'Legalising Parallel Imports under Intellectual Property Law' at 553.

4.3 Requirements for a Patent

Requirements for an invention to be granted as a patent is delineated under section 25(1) of the Patents Act. A patent shall be granted on invention that is new, involve an inventive step and is capable of used of being used or applied in trade or industry or agriculture. Section 25(1) is similar to article 27.1 of TRIPS Agreement.

4.3.1 *New*

Section 25(5) of the Patents Act provides that "new" is that an invention must not form part of the state of art prior to the date of invention or claim of the invention. An invention that involves a substance for treatment of humans or animals that forms state of the art, must not have been used before.[158] Sections 25(6) to (8) further explain what constitute the state-of-the-art invention. It says it must not have been made available to the public locally by use, or in any other way, used secretly and shall be an application filed at the patent office, open to public inspection.

4.3.2 *Inventive step*

An inventive step as contained in section 25(1) read together with subsections (6) and (10) of the Patents Act mean that the invention must not be obvious to the person skilled in the art prior to date of the invention. It is common knowledge that he who alleges that the invention lacks inventive steps bears the burden of proof. In *Ensign-Bickford (Pty) Ltd and others v AECI Explosives and Chemicals Ltd*, the court remarked that the onus of proof on the allegations of infringement is on the plaintiff.[159]

Usually, parties call expert witnesses to prove that the invention lacks an inventive step as a ground for the patent to be revoked. The judgment in *Sandvik v Outokumpu OYJ case*,[160] changed the position that the expert witness ought to be skilled prior to the date of the invention. The SCA held that authority for an expert to be skilled in the art of the patent prior to the date of invention would not assist the court.[161]

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158 Joseph, 'Access to affordable life-saving medicines' at 41.
159 1999 (1) SA 70 (SCA), Page 8 of the judgement
160 2020 (4) SA 441 (SCA).
161 Paragraph 21.

It follows that an expert may be any person unskilled in the art of the patent. It is worthy of comment that the requirement of 'involve an inventive step' is notoriously a strenuous question to answer rather safe to rely on evidence of an expert witness who is an expert in the field of technology covered by the patent.[162]

Having regard to patents on medicines, it is important to comment that medicines such as pharmaceutical products are patentable since they are not excluded under section 25(2) of the Patents Act. The provision sets out inventions that may not be patented. In the absence of the express term, it is quite safe to make assumption that medicines are patented.

4.3.3 *Capable of industrial application*

It is essential that a patent must be capable of being used in trade or industry or agriculture. In other words, it must have a practical utility or be useful and not obvious as contained in section 25(1) of the Patents Act.

4.4 Companies and Intellectual Property Commission (CIPC)

It was established by Section 5 of the Patents Act. The Registrar controls the patent office. Although the powers of the Registrar are administrative as conferred by section 15 of the Act, there is a provision for discretionary powers to be exercised by both Registrar and Commissioners under section 16 which are:

1. Receive evidence and determine evidence to be given by affidavit or viva voce;
2. Grant costs;
3. Tax costs which are reviewable by the commissioner; and
4. Enforce payment of taxed costs reviewed by the Commissioner.

[162] 2020 (4) SA 441 (SCA) Paragraph 25.

In contrast, the Commissioner exercises powers in terms of section 17 which are:

1. Execute duties like a judge in a civil action before any high court division;
2. Direct parties to furnish security for costs in the proceedings;
3. Review taxed costs.

The powers of both the Registrar and Commissioner manifested herein above are purely administrative with no recognition of substantive examination of patents.

4.5 Application of the Patents Act

Section 3 of the Patents Act provides that the Act applies to all patents granted before or after its commencement.

More and more people in developing countries die every year in millions from different diseases that can be treated by generic drugs[163] People with private medical insurances enjoy the luxury of access to medicines. Majority of them are denied quality care and treatment due to their costs. Implementation of 1997 Medicines and Related Substances Act in South Africa remains a struggle.[164]

4.6 Patents Act: The crisis of Access to Medicines

The reality is that access to health care for everyone in South Africa is a challenge that led to the formation of the TAC.[165] The problem areas identified in the Patents Act are substantial technical assessment of prospective inventions, incorporate TRIPS flexibilities, issuance of unnecessary secondary patents and evergreening, and compulsory licences.[166] They are still to be properly addressed.

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163 Visser Coenraad, 'Affordable medicines' exceptions to patent rights under the TRIPS Agreement: some pointers for South Africa', (2001) Volume 34, No. 3, CILJSA at 377.

164 Shubba Ghosh, Pills, patents and power: state creation of gray markets as a limit on patents rights Florida Law Review (2001) at 815.

165 Heywood Mark, 'South Africa's Treatment Action Campaign: Combining Law and Social Mobilization to Realise the Right to Health', (2009) Volume 1, Journal of Human Rights Practice at 15.

166 Ndlovu Lonias, 'South African Patent Law and Access to Medicines, Conference Paper', (2013) at 5-8.

4.6.1 *Substantial technical assessment of prospective inventions*

Section 34 of the Patents Act provides for examination of patents applications by the Registrar. It empowers the registrar to do paperwork only and no scientific examination of the invention is required.

The problem with South Africa is that it is a non-examinng country.[167] Its depository system for patents deals only with correct paperwork before the application is granted.[168] The Registrar conducts the tick-box-approach to all patent applications. The dilemma with the Patents Act is that it abolished opposition proceedings of the 1952 Act. Actually, the right to oppose an application within three (3) months of the advertisement has been taken away and replaced by the formal examination of patents.[169]

In *Strix Ltd v Nu-World Industries (Pty) Ltd*[170] the SCA had to decide whether the defence on the invalidity of a patent on the reason that it lacks novelty was properly pleaded before the Commissioner of Patents, and whether novelty was rightfully the main issue at trial. It ruled that the defence of obviousness was never raised and as such the invention cannot be regarded as a patent and therefore, Nu-World Industries was interdicted.[171] This is a case where Strix Ltd instituted an action against Nu-World interdicting it from infringing its patent of an electric kettle and claiming damages as well.[172] For the patentee to continue enjoying benefits from the market in respect of a novelty is unfair because of South Africa's non-examination of patents.

The Patents Act shifts the responsibility to the patentee to be a watchdog of patents, as well as exposing them to unreasonable costs of litigation. Interested parties must be properly sensitised on the grounds to revoke a patent in terms of section 61 of the Patents Act.[173]

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167 Pouris Anthipi and Anastassios, 'Patents and economic development in South Africa: Managing intellectual property rights', (2011) Volume 107, No: 11-12, South African Journal of Science at 5.

168 Fix the Patent Laws Campaign, Patent barriers to medicine access in South Africa: A case for patent law reform, Castle Graphics (2016) at 11.

169 Joseph, 'Access to affordable life-saving medicines' at 49.

170 2016 (1) SA 387 (SCA)

171 Paragraphs 14, 15 and 25.

172 Paragraph 8.

173 Ndlovu, 'South African Patent Law and Access to Medicines, Conference Paper' at 11.

The SCA did not make an order of referral of a patent for substantive examination by the Registrar, hence weaker patents are granted and sold at expensive prices. For example, TAC once complained that South Africa pays artificially inflated prices for medicines due to the non-examination system. Another example is the Linezolid drug, which remains out of reach for South Africans due to its unaffordable price.[174]

This is alarming that if left unattended, South Africa will continue to experience steep medicine prices with more and more patients, specifically cancer patients, dying.

4.6.1.1 *South African National Control Laboratory for Biological Products*

South African National Control Laboratory for Biological Products referred to hereafter as "SANCLBP" is an accredited pharmaceutical testing laboratory based in Bloemfontein, established in terms of the agreement of service between the Department of Health, referred to hereafter as "DoH" and the University of the Free State, referred to hereafter as "UFS". Although it is a WHO-contracted laboratory its primary function is to test vaccines for human use in South Africa.[175]

This should not be confused with the testing of patent applications. The examination process by SANCLBP excludes the requirements of new inventions that involve inventive steps.

4.6.1.2 *Competition Commission of South Africa*

CCSA is a statutory body established in terms of section 19 of the Competition Act. Its primary mandate is to investigate complaints against commercial entities operating within the Republic, control business practices and mergers in order to achieve equity in the local economy.[176]

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174 Busch Stephanie, 'Promoting access to affordable generics: reforming South Africa's patent law to prevent evergreening', (2016) Volume 4, SAIPLJ at 112-113.

175 https://www.ufs.ac.za/health/departments-and-divisions/national-control-laboratory-for-biological-products-home [Accessed on the 25/08/2022].

176 https://www.compcom.co.za/ [Accessed on the 02/06/2022].

CCSA embarked on an investigation against Roche Holding AG; Pfizer Inc; and Aspen Pharmaceutical Holdings Ltd in 2017. This emanated from a complaint of alleged excessive pricing of cancer medicines, price discrimination and exclusionary conduct relating to breast cancer medicine.[177] Prior to the complaint, the CCSA had information that Trastuzumab was sold at an excessive price by Roche Holding AG and its subsidiaries to the extent that it was unaffordable to patients, that Roche used strategies such as evergreening to block breast cancer drugs from entering local market, and lastly, that Roche charged different prices for breast cancer medicines. Public health sector was charged double the price.[178]

As per the CCSA statement released on 8 February 2022, it found that there was excessive pricing by Roche Holding AG in all healthcare sectors, that is, private and public. Although Roche refused to provide cost data to the CCSA on the reason that its offices sit in Switzerland; the CCSA referred the complaint to Competition Tribunal for prosecution.[179]

What can be deduced from the statement is that it took the CCSA five (5) years to investigate and finalise the complaint of exorbitant pricing of cancer medicines. This support the view that there is no pricing committee appointed by the Minister to assist with investigations because if there had been one, the investigation would have been finalised earlier. Section 22G of the 1997 Medicines and Related Substances Act succinctly provides for the designation of the pricing committee.

The prices of medicines was also in question in *Cipla Medpro (Pty) Ltd v Aventis Pharma SA* case,[180]where the SCA had to consider costs of various medicines in dispute. Aventis's pharmaceutical product was known as Taxotere, with Docetaxel as the active ingredient, expired in 2007 whereas Cipla's pharmaceutical product was Cipla Docetaxel that it intended to register. Both were used for treatment of several types of cancers. Aventis was the owner and seller of Taxotere.

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177 Bangalee V and Suleman F, 'Is there transparency in the pricing of medicines in the South African private sector?' (2018) Volume 108, South African Medical Journal at 82.

178 https://one.oecd.org/document/DAF/COMP(2018)12/en/pdf [Accessed on the 02/06/2022].

179 https://www.compcom.co.za/wp-content/uploads/2022/02/COMPETITION-COMMISSION-PROSECUTES-A-MULTINATIONAL-HEALTHCARE-COMPANY-ROCHE-FOR-EXCESSIVE-PRICING-OF-A-BREAST-CANCER-TREATMENT-DRUG.pdf [Accessed on the 02/06/2022].

180 2013(4) SA 579 (SCA).

Cipla, on the other hand, intended to import and sell Cipla Docetaxel, an equivalent of Taxotere. Taxotere, Docetere and Cipla Docetaxel were sold in dosages of 20 and 80 milligrams respectively. The single exit price, refereed to hereafter as "SEP", set by Aventis was higher than that of Cipla.[181] That is, the price of Taxotere and Docetaxel was higher than that of Cipla Docetaxel.

The SCA granted an interdict in favour of Aventis Pharma SA on the reasons that Cipla Medpro's intention to sell Docetaxel to the public at a cheaper price was intended to incite, aid, and abet Aventis' Taxotere and Docetaxel. Furthermore, the SCA held that Cipla and TAC failed to prove prejudice that the public will suffer if an interdict was granted.[182] Introduction of SEP within pharmaceuticals failed to address high medicine prices.[183]

What is debatable regarding the decision of the court is that it neglected to use the liberal, human rights-based approach in considering TAC's constitutional argument and Cipla's submissions. TAC argued that access to healthcare is inclusive of the right of access to medicines. Therefore, Patents Act ought to have been interpreted in the light of the Constitution in that cancer patients who can afford Cipla's Docetaxel would be prejudiced if Cipla is prohibited from distributing it within the Republic of South Africa.[184] Conversely, Cipla contested commercial advantage of the drugs' first entry to the generic market for the supply of cheaper products to the benefit of cancer sufferers.[185] The arguments advanced by Cipla and TAC that the interdict application was supposed to be dismissed holds water in that the criterion of affordability of medicine, that is, the price of the cancer drug ought to have been considered by the court for public interest.

181 Paragraph 57.
182 2013(4) SA 579 (SCA),Paragraphs 40 and 59.
183 Bangalee and Suleman, 'Is there transparency in the pricing of medicines in the South African private sector?' at 82-83.
184 Paragraphs 44 and 56.
185 Paragraph 42.

4.6.2 *Incorporate TRIPS flexibilities*

The second problem with the South African Patents Act is that it neither incorporates nor implements TRIPS flexibilities.

The DTiC together with Parliament within the South African Machinery has not discharged its obligation to amend the Act.[186] South Africa must take advantage of TRIPS flexibilities, amongst others, to be able to produce drugs domestically.

It is expected to guard against a conflict between the right conferred and normal patent exploitation, as well as the prejudice of the patentee interests. That is, stricking a balance between the rights of the patentee and those of third parties to ensure that generic drugs are made available to the patients.

Section 22A(a) of the Medicines and Related Substances Amendment Act 59 of 2002, referred hereafter as "2002 Medicines and Related Substances Act", makes provision for sale of Schedule 5 or Schedule 6 pharmaceutical products by a manufacturer or wholesale dealer; and exception to register medicines prior to manufacture and sale within the Republic. The Registrar is expected to keep a register that clearly reflects quantity of Scheduled 5 of Schedule 6 substances in stock. Possession of Schedule 8 substance shall be permissible on the Director-General, referred to hereafter as "DG" of the DoH's authorisation and recommendation of SAHPRA in terms of section 22A(b) of the 2002 Medicines and Related Substances Act.

It is implored that South Africa must invoke section 15 of the 1997 Medicines and Related Substances Act. This section empowers the Registrar to follow the lengthy administrative process of acknowledgement of receipt of the application, ensuring it appears on the Essential Drug List or it is essential for national health in the opinion of the Minister of Health, as well as to the satisfaction of SAHPRA, expedite the registration thereof.[187] For example, when the first case of COVID-19 was detected in March 2020 in South Africa, no vaccine was registered with SAHPRA then. Nine months thereafter, SAHPRA issued guidance on registration of COVID-19 vaccine by applicants.[188]

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186 Ndlovu, 'South African Patent Law and Access to Medicines' at 5.

187 Act 90 of 1997.

188 https://www.sahpra.org.za/news-and-updates/information-and-guidance-on-application-for-registration-of-candidate-covid-19-vaccine/ [Accessed on the 14/06/2022].

4.6.3 *Issuance of unnecessary secondary patents and evergreening*

Evergreening is described as the practice the patentee employ to abuse the patent system. For example, the patentee would file an application for an existing patented product. The said application would be an unnecessary variation to the original product and inessential extension of the patent parent.[189]

The weak definition of novelty in South Africa's Patents Act allows evergreening hence the criticism that it effortlessly grants an excessive number of pharmaceutical patents.[190] New patents for minor, incremental increments are permitted because of low standards of patentability leading to an increase in low-quality patents. As a result, patentees obtain multiple patents of a single product.[191] With so-called secondary patents patentees use this to lengthen their protection beyond 20 years period and keep medicine prices high.[192] To add to that, the CIPC Office's database of pending and granted patent applications are not available, either electronic or in print, for public inspection, via electronic or print, to allow third parties to object to those patent applications to eliminate evergreen patents.

Section 10(14) of the Trade Marks Act provides for unregistrable trademarks. Such mark shall be registrable if the registered trademark owner gives consent. In *Adcock Ingram Intellectual Property (Pty) Ltd v Cipla Medpro (Pty) Ltd* case,[193] the SCA ordered the respondent to remove the mark ZEMAX from being used as a generic medicine because it was identical to the appellant's mark ZETOMAX. It ruled that the use of the mark ZEMAX in tablets would cause confusion amongst consumers because it was the same as ZETOMAX tablets, a registered mark.

The appellant had to discharge the burden of a reasonable probability of confusion amongst purchasers, something which the court a quo ruled on that it failed to make out a case.[194] The question, to be precise, was whether ZEMAX is deceitful and likely to cause confusion.

189 Busch, 'Promoting access to affordable generics' at 110.
190 Ndlovu, 'South African Patent Law and Access to Medicines' at Paragraph 1.
191 Busch, 'Promoting access to affordable generics' at 110.
192 Fix the Patent Laws Campaign at 11.
193 2012 (4) SA 238 (SCA).
194 Paragraph 16.

The complication with granting evergreen patents leads to a delay in entry of generic medicines into the local market[195] For example, in the *Adcock Ingram Intellectual Property (Pty) Ltd case*, Cipla was prevented from selling ZEMAX, a generic medicine, although registered by the then Medicine Control Council.[196] Also, Novartis AG, a Swiss American multinational pharmaceutical corporation, registered in South Africa, Imatinib that expired in 2022.[197] In contrast, evergreening gives pharmaceutical companies an unfair advantage to maintain high prices of their medicines for more than 20 years.[198]

4.6.4 *Compulsory licences*

Licence is granted in two ways, which is, dependent patent or in instances of abuse of patent rights.[199] It is one of the flexibilities to protect health.[200] TRIPS Agreement give the applicant of the licence the discretion to do so taking into consideration its public health system.[201]

This will be the focus of the discussion, underpinned by relevant case law. Article 5 of the Paris Convention provides for an exception to the patentee's exclusive right, breaking cartels and monopolies, on patent rights on the condition that the exception is reasonable.[202]

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195 Ndlovu, 'South African Patent Law and Access to Medicines' at 5.

196 *Adcock Ingram Intellectual Property (Pty) Ltd and Another v Cipla Medpro (Pty) Ltd and Another* 2012 (4) SA 238 (SCA) at paragraph 33.

197 https://www.novartis.co.za/about-us/company-history [Accessed on the 14/06/2020];
Ndlovu, 'Lessons for the SADC from the Indian case of Novartis AG v Union of India' at 804.

198 Busch, 'Promoting access to affordable generics' at 110-111;
Section 46 of Patents Act 57 of 1978

199 Hobololo Vuyisile, 'Strategic patenting of pharmaceutical inventions and the public's right to access medicines: the South African context' (2015) Issue 16 The African Journal of Information and Communication at 80.

200 Carlos M Correa, 'Will Amendment to the TRIPS agreement Enhance Access to medicines?', Routledge Handbook on the Politics of Global Health, 1st Edition (London & New York, Routledge, 2018) at ;
Tomlinson C, Waterhouse C, Hu Y Q, Meyer S and Moyo H, 'How patent law reform can improve affordability and accessibility of medicines in South Africa: four medicine case studies', (2019) Volume 109, South African Medical Journal at

201 Nkomo Marumo, 'The TRIPS flexibilities and access to essential medicines in the developing world: are they sufficient and is our implementation adequate?' (LLM Dissertation, University of the Western Cape 2013) at 24.

202 Hobololo, 'Strategic patenting of pharmaceutical inventions and the public's right to access medicines' at 79-80.

Using the compulsory licence system, it is a prerequisite that the country that intends to import a pharmaceutical product must send a notification to the Council for TRIPS Agreement.[203]

4.6.4.1 *Dependent patents*

In order for the applicant to succeed in the application, he must discharge the evidence that the royalty to be offered to the patent right holder is reasonable.[204] Section 44 sets out instances where a licence can be granted, being, dependent patent involving technical advance of economic significance, cross-licence granted by the patentee to the proprietor of the dependent patent to use the invention which is not assignable.

The amendment was put to the test in *Atomic Energy Corporation of South Africa v The Du Pont Merck* 1997 BIP 90 (CP). This involved an application for a dependent patent that the respondent made allegations that it was invalid. The court remarked that the applicant bear the onus to show on a balance of probabilities that it offered a reasonable royalty. Due to a genuine dispute of fact the application for an interdict could not be decided there but it was referred to trial for a decision.[205] The rationale behind the respondent's decision to oppose the application was to deny the applicant a licence. Secondly, the court neglected to entertain the issue of reasonable royalty, a requirement before a compulsory licence can be granted.[206]

Applicant must prove that the patentee unreasonably denies him with a licence.[207] A good example will be where no agreement is reached between the proprietor of the prior patent and the dependant patent or that there is no cooperation between them at all. Vawda submits that no a single compulsory licence was granted locally.[208] To augment the submission, no licence was accorded even thereafter as of 2021.[209]

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203 Correa, 'Will Amendment to the TRIPS agreement Enhance Access to medicines' at 2.

204 Yousuf A. Vawda, 'Analysing South Africa's compulsory licensing jurisprudence: Is there a room for the Public Interest (PI) in Intellectual Property (IP)?', (2019) Volume 7, SAIPLJ at 186.

205 Vawda, 'Analysing South Africa's Compulsory Licencing Jurisprudence' at 186-187.

206 Vawda, 'Analysing South Africa's Compulsory Licencing Jurisprudence' at 186-187.

207 Hobololo, 'Strategic patenting of pharmaceutical inventions and the public's right to access medicines' at 80.

208 Vawda, 'Analysing South Africa's Compulsory Licencing Jurisprudence' at 182.

209 http://patentblog.kluweriplaw.com/2021/05/17/south-africa-compulsory-licensing/ [Accessed on the 14/06/2022].

4.6.4.2 *Abuse of patent*

Section 56 of the Act provides for a licence to be granted where the applicant genuinely believes that the patented invention is abused.[210]

A good example of non-working of patents may be where the patentee refuses the generic manufacturer with a licence. Therefore, the applicant must prove that there exists no reason for not working the patent by the patentee.[211] Section 56(2 (a)–(e) of the Patents Act sets out reasons which the applicant can rely on when making an application for a licence.[212]

In *Sanachem (Pty) Ltd v British Technology Group* PLC 1992 BP 276 (CP), the applicant contested insufficient working of the patent locally on a commercial scale. Unfortunately, the argument that was rejected.[213] In essence, the applicant was expected to prove that the invention can be worked locally through assignment to the State or third parties.[214]

In *Syntheta (Pty) Ltd v Janssen Pharmaceutical NV* 1998 BIP 264 the Appeal Court found that the appellant failed to prove non-working of the invention locally. There was a deficiency in the appellant's application regarding Sections 56(2)(a) and (d) of the Patents Act that it failed to show the local public would benefit more when the product is exported.[215] Section 56(2)(c) also requires the applicant to prove that the public is dissatisfied with the prices at which the patented innovation is sold.

Section 56(2)(e) provides that compulsory licence shall be granted if the patentee charges excessive price than other countries for importing the patented invention which is in high demand.[216]

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210 Joseph, 'Access to affordable life-saving medicines' at 46.
211 Hobololo, 'Strategic patenting of pharmaceutical inventions and the public's right to access medicines' at 80.
212 Act 57 of 1978.
213 Vawda, 'Analysing South Africa's Compulsory Licencing Jurisprudence' at 187.
214 Hobololo, 'Strategic patenting of pharmaceutical inventions and the public's right to access medicines' at 80.
215 Joseph, 'Access to affordable life-saving medicines' at 47.
216 Vawda, 'Analysing South Africa's Compulsory Licencing Jurisprudence' at 189.

4.7 Conclusion

Substantive search and examination of patents is very important so as to prevent evergreening. Incorporation of TRIPS Flexibilities one critical area to reinforce for South Africa to produce drugs, such as cancer drugs, locally.

Vawda submitted that the provision for compulsory licence, Patents Act, have not evolved since promulgated and were unsuccessful in the adjudication of patent disputes.[217] The judgments in *Atomic Energy Corporation of South Africa* and *Sanachem (Pty) Ltd* and *Syntheta (Pty) Ltd* cases serve as testimony it is burdensome to obtain compulsory licence on either dependant or abuse of patents. Importantly, it is unfortunate that no licence was granted and that it highly probable that may never be granted produce generic medicines as ventilated in a number of case laws.

The Commissioner, too, must exercise extraordinary caution whenever they preside over applications for licenses. Section 16 of Patents Act bestows on the Commissioner the discretionary power to hear the applicant version in the application for a licence. So, the arguments presented must be considered, and if not, then the South African Government must seek judicial assistance. There is the office of the state law advisors that can be consulted for legal opinions.[218]

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217 Vawda, 'Analysing South Africa's Compulsory Licencing Jurisprudence' at 193.

218 https://justice.gov.za/ocsla/index.html#:~:text=It%20is%20the%20responsibility%20of,development%20of%20our%20constitutional%20jurisprudence. [Accessed on the 14/06/2022]

CHAPTER 5 CONCLUSION AND RECOMMENDATIONS

5.1 Introduction

Apart from the call for reform of intellectual property laws, that is, the Patents Act, it is imperative that South Africa invests in pharmaceutical research and development rather than relying on the law of competition for securing access to medicines. Investment would squarely improve access to cheaper drugs, specifically cancer drugs. Compulsory licences granted would also benefit the general public.

The Doha Declaration affirms the rights of each and every government to implement measures to protect public health.[219] South Africa must benchmark against other countries like India, Brazil and Rwanda that took steps to realise the TRIPS flexibilities. India and Brazil have manufacturing capacity of drugs at lower prices that patentee.[220] Rwanda made use of Waiver, also known as the decision of 30th August 2003, to import generic ARVs from Canada.[221] AU and SADC instruments, such as ACHPR Resolution 141(XXXXIV), AH 2016-2030 and SADC Protocol on Health 1999 do not clearly display processes to promote public health except the establishment of regulatory guidelines, monitoring, and evaluation framework, and establishment of institutional mechanisms within the health sectors by countries.

5.2 Conclusion

Finally, the chapter put forward the answers to research questions of the study. It is demonstrated that South Africa through the Patents Act fails to provide cheap, affordable and generic medicines in that pharmaceutical companies through evergreening process take advantage of section 46(1) of the Patents Act by prolonging their rights in patents and keep them at artificially high prices.[222]

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219 Coral Jade Joseph, 'Access to affordable life-saving medicines: The South African response', (LLM Dissertation, University of KwaZulu-Natal 2013) at 77.

220 Reichman, 'Compulsory licensing of patented pharmaceutical inventions' at 3.

221 Coral Jade Joseph, 'Access to affordable life-saving medicines: The South African response', (LLM Dissertation, University of KwaZulu-Natal 2013) at 39.

222 Fix the Patents Laws Campaign at 11.

In *Adcock Ingram Intellectual Property (Pty) Ltd case*, the sale of ZEMAX, a generic medicine, was blocked by registered ZETOMAX tablets.

South Africa is expected to implement the 2030 SDGs action plan, protocols, and policies to ensure that citizens access cheaper and affordable medicines. Legislature bears the responsibility to introduce a bill in parliament to that effect that it incorporates the TRIPS flexibilities and above all, diligently address examination of patents, allow for patent oppositions, prevent evergreening and adopt a procedure for granting compulsory licences.

In general, the amendment must emphasise the general welfare of the public and address the unaffordability of essential medicines as key for waiver implementation.

5.3 Recommendations

Based on the answered research questions above and the conclusion in this study, the researcher recommends as follows:

(a) Research and Development

Even though Article 30 of TRIPS Agreement encourages member states to take proactive measures to produce medicine, South Africa must invest more capital in R&D of new pharmaceutical inventions to protect its intellectual property rights.[223] Investment would help in development or manufacture of medicines in cure for diseases after a thorough research is conducted.

Research in this instance would extend to single exit price regulation in the pharmaceutical industry and to improve pricing transparency in the supply chain.[224] Patent right owners, too, stand to benefit from disclosure of information pertaining to invention.

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223 Busch Stephanie, 'Promoting access to affordable generics: reforming South Africa's patent law to prevent evergreening', (2016) Volume 4, SAIPLJ 101-119 at 102.

224 Bangalee V and Suleman F, 'Is there transparency in the pricing of medicines in the South African private sector?' (2018) Volume 108, South African Medical Journal at 82-83.

The benefits, amongst others, that patent rights owners will derive include issuing of compulsory licences subject to payment of royalty.[225]

(b) *Substantive Examination and Opposition Procedures*

South Africa should move away from non-examining, cheapest registration regime to a patent examining regime. First and foremost, invention has to be novel, not obvious to the one with ordinary skill in that area and capable of industrial application.[226]

CIPC bears the responsibility to register for patents, however it must have the power to examine them prior to that. However, third parties must be given opportunity to file opposition against frivolous patents being generic drugs, rather than relying on revocation of granted patent.[227] Substantive examination at CIPC would require examiners that possess the necessary and required experience. It is expected that the same examiners must understand the technological aspect of patent examination.[228]

The importance of setting stricter patentability criteria will combat patent evergreening, issuance of secondary patents would be more than helpful to prevent exclusive right to monopoly; and artificially high medicine prices kept by pharmaceutical companies.[229] It would be better if South Africa's Patents Act conforms with the decision in *Novartis AG* case that no patent application should be granted if it has the potential to cause public disorder. India Supreme Court of appeal ruled that Glivec drug was not patentable for it failed to enhance efficacy after taking into consideration the interests of the society.[230]

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225 Pouris Anthipi and Anastassios, 'Patents and economic development in South Africa: Managing intellectual property rights', (2011) Volume 107, No: 11-12, South African Journal of Science at 2.

226 Pouris, 'Patents and economic development in South Africa: Managing intellectual property rights' at 5-6.

227 Busch, 'Promoting access to affordable generics: reforming South Africa's patent law to prevent evergreening' at 115-116.

228 Busch, 'Promoting access to affordable generics: reforming South Africa's patent law to prevent evergreening' at 115.

229 Busch, 'Promoting access to affordable generics: reforming South Africa's patent law to prevent evergreening' at 111-111;
Yousuf A. Vawda, 'After the Novartis judgement – 'Evergreening' will never be the same again', (2014) Volume 18, Law Democracy Development, Cape Town at 314-315.

230 Ndlovu, 'Lessons for the SADC from the Indian case of Novartis AG v Union of India', at 789-791.

Since section 34 of the Patents Act provides for exmainatin of patents, it must be implemented so as not to allow weaker patents being granted.

It is noteworthy that the IP Policy 2018 makes provision for TRIPS flexibilities to be incorporated into domestic legislations, as part of moving towards a substantive patent-examination system from a depository system.[231] However, currently there is no national bill introduced in Parliament to that effect. Although the mandate of SANCLBP is primarily testing all vaccines for human use in South Africa, it does not examine patents. The testing of vaccines is very far from substantive examination of patents since that falls within the mandate of SAHPRA.

(c) Parallel Import

Regulation 7 of the 1997 Medicines and Related Substances Control Amendment Act lay out for the parallel import of affordable medicines. The Minister must invoke Section 15C of the Medicines and Related Substances Amendment Act to authorise import of affordable medicines.

(d) Compulsory Licence

There is a need for South Africa to utilise the procedures to grant compulsory licences as contemplated in the Patents Act. So long as the applicant satisfies prerequisites, such as, authorisation subject to payment of a reasonable compensation. It is crucial that the decision in *Sanachem (Pty) Ltd* case of technological capabilities or manufacturing capacity be considered. In the alternative, Waiver,[232] can be resorted to. Countries with WTO membership have until 31 December 2023 to accept the amendment.[233] South Africa accepted only the 2003 waiver on 23 February 2016, but still to accept the 2005 waiver.[234]

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231 Intellectual Property Policy of the Republic of South Africa, Phase 1 of 2018 at 5.

232 Doha Ministerial Declaration on TRIPS and Public Health of 30 August 2003.

233 Dos Santos F, Ncube CB and Ouma M, 'Intellectual property framework responses to health emergencies – options for Africa', (2022) Volume 118, SAJS at 2.

234 https://www.wto.org/english/tratop_e/trips_e/amendment_e.htm#:~:text=The%20amendment%20took%20effect%20on,WT%2FL%2F1122 [Accessed on the 25/08/2022].

What is of significant importance is that South Africa must extensively use the TRIPS waiver system. It must act swiftly to accept the 2005 waiver. Service of notice by South Africa on the exporting state and negotiation for a compulsory licence, is complicated and not viable. It's a long process that frustrates the need to provide medicines in emergency situations. For example, it took Rwanda three years to obtain a compulsory licence from Canada. Alternatively, South Africa can enter into an option agreement to export pharmaceutical patents just like Bolivia.[235]

Although South Africa has the manufacturing capacity to COVID-19 vaccine to address the health emergency, there is a need for the adoption of a regional or international exhaustion of intellectual property by African countries. The purpose of adoption is to ensure adequate manufacture and distribution of pharmaceutical patents and devices across the countries.[236]

235 Dos Santos, Ncube and Ouma, Intellectual property framework responses to health emergencies at 3.

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