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TRIPS FLEXIBILITIES AND ACCESS TO ESSENTIAL MEDICINES IN SOUTH AFRICA

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CONTENTS

DEDICATION

To anyone who has battled and still battles with trauma and debilitating mental illness. Breathe, you will make it, dear one.

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ABSTRACT

A number of opportunities are available to South Africa through the use of international intellectual property flexibilities that are targeted and designed to protect and preserve access to medicine and health care. This dissertation discusses several influences on South Africa's accessibility to medicine through the means of intellectual property and the reasons why the current status quo exists. The dissertation first gives a synopsis of the effects patents have on access to medicine. It then contends that the use of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) flexibility known as compulsory licensing should be used to realise the need of access to medicines in South Africa and discusses how the pricing system has an immense effect on access to medicines. The TRIPS flexibility has given World Trade Organisation (WTO) members the liberty to determine and customise their policy space with regards to TRIPS obligations in a manner that is interpreted and implemented to meet and reflect their citizens' needs. This dissertation seeks to ascertain whether South Africa has made use of such means through the flexibilities in policy space and its proactive prioritisation of access to medicines in South Africa.

LIST OF ABBREVIATIONS

ARIPO	African Regional Industrial Property Organisation
CBD	Convention on Biological Diversity
CIPC	Companies and Intellectual Property Commission
COVID-19	Coronavirus
Doha Declaration	Doha Declaration on the TRIPS Agreement and public health
DNDi	Drugs for Neglected Diseases initiative
DTI	Department of Trade and Industry
DTIC	Department of Trade, Industry and Competition
EPC	European Patent Convention
EU	European Union
FTPL	Fix the Patent Laws
IP	Intellectual property
IPR	Intellectual property rights
LCD	Least developed countries
Medicines Act	Medicines and Related Substances Act
MSF	*Médecins Sans Frontières* (Doctors without Borders).
National IPR Policy	National Intellectual Property Rights Policy
NGO	Non-governmental organisation
PMA	Pharmaceutical Manufacturers Association
R&D	Research and development
SA	South Africa
SSE	Substantive search and examination
TAC	Treatment Action Campaign
TRIPS Agreement	Agreement on Trade-Related Aspects of Intellectual Property Rights
UN	United Nations
USA	United States of America
WHO	World Health Organisation
WIPO	World Intellectual Property Organisation
WTO	World Trade Organisation

Chapter 1

INTRODUCTION

1.1 Introductory remarks

The global spread of the coronavirus (COVID-19) has sensitised the world about public health and access to essential medicines. This has allowed people in academia and others around the world to once again have open and candid discussions about public health and drug procurement, including compulsory licensing, local manufacturing, and socio-economic development.

When the phrase 'intellectual property' (IP) is used, it is associated with 'creations of the mind'.[1] Such creations may be expressed in a form of a piece of original writing, a painting, a mechanical invention, a design, or a trademark name. IP is grouped into the following main groups but is not limited to these: patents, copyright works, trademarks, and industrial designs.[2] IP functions by letting authors and, by extension, owners of IP receive incentives for their creativity and originality.[3] This dissertation will be focusing exclusively on patents. The World Intellectual Property Organisation (WIPO) defines a patent as 'an exclusive right granted for an invention a product or process that provides a new way of doing something, or that offers a new technical solution to a problem'.[4]

In South Africa (SA), an invention will be granted a patent under the Patents Act of 1978, if the invention is 'new',[5] involves an 'inventive step',[6] and is 'capable of being used or applied in trade, industry or agriculture'.[7] An invention will be recognised as new if it 'does not form part of the state of the art immediately before the priority date of the invention'.[8] 'State of the art' is defined as an knowledge pertaining to an invention that 'has been made available to the public' either in or outside SA by either

[1] World Intellectual Property Organisation (WIPO) 'What is intellectual property?' (2004), available at https://www.wipo.int/publications/en/details.jsp?id=99&plang=EN (accessed 20 April 2020).
[2] Ibid.
[3] William Fisher 'Theories of intellectual property' in S Munzer, Jules L Coleman, & Gerald Postema (eds) *New Essays in the Legal and Political Theory of Property* (2001) 168.
[4] WIPO 'What is intellectual property?' (2004).
[5] South Africa Patents Act 57 of 1978 s 25.
[6] Ibid.
[7] Ibid.
[8] Ibid s 25(5).

written or oral narration, by use or any other means.[9] The principle of prior knowledge or disclosure of an invention will be overlooked in the event that the publication was obtained without the right holder's knowledge; further, when the right holder came to the understanding of the publication, he or she immediately sought protection for the invention through means of reasonable diligence.[10]

Prior disclosure may also be overlooked if it was because an experiment or reasonable technical trial of the invention was held in SA.[11] Section 25 of the South African Patents Act lists exceptions to inventions or means that may not fall under a patentable invention. SA does not examine its patents; a patent application that is filed must only satisfy all formal requirements, such as fees and proper paperwork provided for within the Patents Act, for a patent to afford protection and be issued.[12] This system of non-examination is open to abuse, as discussed later.[13] Acquiring regulatory approval in SA for the use of a patented invention will not amount to a violation under its domestic patent law.[14] This is restricted to non-commercial use. The minimum patent lifespan requirement is 20 years in the TRIPS Agreement, which is identical to the South African patent lifespan.[15]

The underlying principle behind issuing patents for pharmaceuticals is that it enables holders of patents to make money and profit from a patented product by preventing unauthorised use and economic exploitation of the product for the duration of the patent.[16] This principle means that the patentholderr retains the power to exploit its market by self-determining prices for its medicinal products.[17] Some scholars have contended that this is not the primary reason behind this rationale of patents. An alternative is that when a pharmaceutical company is allowed to recover all the financial and non-financial investment in research and development (R&D) of the new medicine, this functions as an incentive to conduct R&D for more

[9] Ibid s 25(6).
[10] Ibid s 26.
[11] Ibid s 26.
[12] Patents Companies and Intellectual Property Commission, available at http://www.cipc.co.za/index.php/trade-marks-patents-designs-copyright/patents/ (accessed 27 May 2020).
[13] Ellen 't Hoen et al 'Medicine procurement and the use of flexibilities in the Agreement on Trade-Related Aspects of Intellectual Property Rights, 2001–2016' (2018) 96 *Bulletin of the World Health Organisation* 6.
[14] WIPO 'Exceptions and limitations: Companies and Intellectual Property Commission, Republic of South Africa', available at https://www.wipo.int/scp/en/exceptions/replies/safrica.html (accessed 27 May 2020).
[15] Ibid.
[16] Article 33 Agreement on Trade-Related Aspects of Intellectual Property Rights, 15 April 1994, available at http://www.wto.org/english/docs_e/legal_e/27-TRIPS.pdf (accessed 23 April 2020).
[17] Ellen FM 't Hoen *Private Patents and Public Health: Changing Intellectual Property Rules for Access to Medicines* (2016) 1.

new medicines.[18] It is estimated that R&D for a new medicine can cost 2.7 billion US dollars.[19] Millions of people, especially in low-income countries in Africa, do not have access to effective medicines, usually because they cannot afford them and cannot obtain them.[20] The 2001 Ministerial Conference of the World Trade Organisation (WTO) adopted the Doha Declaration on the TRIPS Agreement and public health. (Doha Declaration).[21] This declaration recognises the impact of intellectual property rights (IPR) on the development of new drugs and drug prices.[22] The Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS Agreement) outlined the measures of flexibilities that WTO members can take to ensure access to medicines for all.[23] These measures include compulsory licensing of medicines.[24]

The TRIPS Agreement incorporates certain 'flexibilities'. These aim to permit developing and least-developed countries to use TRIPS-compatible norms in a manner that enables them to pursue their own public policies, either in specific fields like access to pharmaceutical products or protection of their biodiversity, or more generally, in establishing macroeconomic, institutional conditions that support economic development.[25] Under these flexibilities, WTO members can exploit creative solutions to transpose into national law and practice those concepts that the TRIPS Agreement simply enunciates but does not define. Examples of the flexibilities include concepts such as novelty and inventiveness; and of situations of extreme urgency for the purposes of compulsory licences.[26]

WTO defines compulsory licensing as when a government allows someone else to produce a patented product or process without the consent of the patent owner or plans to use the patent-protected invention

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[18] Roberto Mazzoleni & Richard R Nelson 'The benefits and costs of strong patent protection: A contribution to the current debate' (1998) 27(3) *Research Policy* 275.
[19] Matthew Herper 'The cost of developing drugs is insane. That paper that says otherwise is insanely bad' *Forbes* (16 October 2017), available at https://www.forbes.com/sites/matthewherper/2017/10/16/the-cost-of-developing-drugs-is-insane-a-paper-that-argued-otherwise-was-insanely-bad/?sh=2aada5a52d45 (accessed 5 May 2020).
[20] Nancy T Gallini 'The economics of patents: Lessons from recent US patent reform' (2002) 16(2) *Journal of Economic Perspectives* 139.
[21] Doha Declaration on the TRIPS Agreement and Public Health 14 November 2001, available at https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_TRIPS_e.htm (accessed 6 May 2020).
[22] Ibid.
[23] Agreement on Trade-Related Aspects of Intellectual Property Rights, 15 April 1994, available at http://www.wto.org/english/docs_e/legal_e/27-TRIPS.pdf.
[24] Ellen 't Hoen et al 'Medicine procurement and the use of flexibilities in the Agreement on Trade-Related Aspects of IP Rights, 2001–2016' (2018) 96 *Bulletin of the World Health Organization.*
[25] WIPO 'Advice on flexibilities under the TRIPS Agreement', available at https://www.wipo.int/ip-development/en/policy_legislative_assistance/advice_trips.html (accessed 12 November 2021).
[26] Ibid.

itself.[27] 'Use without authorisation of the right holder'[28] provided for by article 31 of the TRIPS Agreement, is what is known as a compulsory licence. Compulsory licensing extends to private and commercial use, whereas government use extends to non-commercial purposes.[29] This is one example of the patent protection flexibilities included in the TRIPS Agreement. In the case of compulsory licensing, the November 2001 Doha Ministerial Declaration on TRIPS and Public Health has not changed the rules. There are two provisions on least-developed countries and no-capacity countries that are directly related to changes in the rules of the TRIPS Agreement. For the most part, the declaration clarifies the flexibility of the TRIPS Agreement and provides governments with confidence that flexibility could be used because some governments were not sure how the flexibility would be interpreted. The patent holder still retains rights to the patent, including the right to receive compensation for copies of products made under a compulsory licence.[30]

A harmonious IPR system is essential and critical for growth, because it furthers domestic and foreign investments for the profit of a country.[31] There are always and will always be issues and disagreements about the control of IPR and legislation.[32] The Department of Trade, Industry and Competition (DTIC)[33] has the responsibility for policymaking for patents and other IP in SA.[34] The Patents Act 57 of 1978, the legislation that governs patents in SA, has been the subject of a growing body of case law in SA.[35] South Africa is signatory to a number of treaties and conventions that influence IPR, one of them being the TRIPS Agreement.[36] It establishes minimum international standards for patents, copyrights, and trademarks. It further stipulates enforcement procedures, repair procedures, and dispute resolution.[37]

The TRIPS Agreement was amended and the amendment entered into force on 23 January 2017 for WTO

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[27] World Trade Organisation (WTO) 'Compulsory licensing of pharmaceuticals and TRIPS' (18 March 2018), available at https://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm.
[28] Article 31 TRIPS Agreement.
[29] 't Hoen et al 'Medicine procurement and the use of flexibilities in the Agreement on Trade-Related Aspects of Intellectual Property Rights, 2001–2016' (2018) 96 *Bulletin of the World Health Organization.*
[30] WTO Compulsory licensing of pharmaceuticals and TRIPS (18 March 2018).
[31] Linda Yueh 'Global intellectual property rights and economic growth' (2006) 5 *Nw. J. Tech. & Intell. Prop.* 16.
[32] Peter K Yu 'A spatial critique of intellectual property law and policy' (2017) 74 *Wash. & Lee L. Rev.*
[33] Formerly the Department of Trade and Industry (DTI).
[34] Department of Trade and Industry and Competition 'Intellectual Property Policy of the Republic of South Africa Phase I' (2018), available at https://www.thedti.gov.za/news2018/IP_Policy2018-Phase_I.pdf (accessed 4 May 2020).
[35] Ibid.
[36] Ibid.
[37] Ibid.

member states, including SA, who have accepted it.[38] The amendment inserted article 31*bis* into the Agreement.[39] The amendment is a waiver solution to paragraph 6 of the 2001 Doha Declaration.[40] The temporary waiver was first agreed in the 30 August 2003 decision, and approved as an amendment to TRIPS in December 2005.[41] The TRIPS agreement allows compulsory licensing only when a country abides by the 'safeguards' articulated in article 31 of TRIPS. The purpose of article 31 is to permit member states to issue compulsory licences. Member states are further given control as to what grounds may be considered when issuing a compulsory licence.[42]

The TRIPS Agreement expressly provides for 12 strict conditions that must be satisfied before a compulsory licence may be granted in article 31. One safeguard requires one to pay sufficient compensation to the patent owner, usually in the form of royalties or a percentage in sales revenue.[43] Another of the 12 conditions was provided for in article 31*(f)*, which has since been amended by the Doha Declaration. It required that countries that had the capacity to manufacture and produce generic medication with the use of compulsory licensing should be prevented from exporting a substantial amount of the generic medication to foreign countries.[44] This condition fatally disadvantaged countries that had little to no manufacturing capacity.[45] The reason is that, this condition placed a restriction with regards to the amount of generics that may be imported and exported between such countries.[46] This section has been amended by article 31*bis*. This research will engage in depth with article 31*bis* in the chapters to come.

SA is also a member of the Paris Convention and the Convention on Biological Diversity (CBD).[47] SA's domestic IP legislation fundamentally conforms to the TRIPS Agreement. The acknowledgment of the 'priority filing date' together with the availability of patent regimes to nationals of contracting member is

[38] Agreement on Trade-Related Aspects of Intellectual Property Rights (as amended on 23 January 2017), available at https://www.wto.org/english/docs_e/legal_e/31bis_trips_01_e.htm (accessed 29 May 2020).
[39] Ibid.
[40] Doha Declaration on TRIPS and Public Health.
[41] Ibid.
[42] Article 31 TRIPS Agreement.
[43] Bess-Carolina Dolmo 'Examining global access to essential pharmaceuticals in the face of patent protection rights: The South African example' (2001) 7 *Buff. Hum. Rts. L. Rev* 8.
[44] Ibid.
[45] DN Matthews 'TRIPS flexibilities and access to medicines in developing countries: The problem with technical assistance and free trade agreements' 2005 *European Intellectual Property Review* 421.
[46] Ibid.
[47] Samantha Gregory 'Intellectual property rights and South Africa's innovation future' Trade Policy Report No. 23 (2008) https://saiia.org.za/wp-content/uploads/2013/06/23-dttp_rep_23_gregory.pdf 19 (accessed DATE).

provided for in the Paris Convention.[48] Through this acknowledgement, a national of a member state has the discretion to file an application in another national member state within 12 months of its original filing in his own country, and still retain recognition of its original priority date.[49] SA is an observer to the African Regional Intellectual Property Organisation (ARIPO) but has not joined ARIPO. Among many reasons, the initial procedure did not conform with the TRIPS Agreement.[50] Amendments have been made to the procedure to rectify those problems.[51]

Essential medicines are those that meet the population's overriding health care needs.[52] These are selected with due consideration of disease prevalence, efficacy and safety data, and comparative cost effectiveness.[53] They are expected to be available at any time in a functioning health system in the right amount and in the right dosage form with the right information and guaranteed quality at a price that individuals and society can afford. The WHO Model List of Essential Medicines (WHOML) is designed to be flexible and adaptable to a variety of situations. It is the state's responsibility to accurately determine which drugs are considered essential.[54]

Financial accessibility of essential medicines is an enduring burden faced by countries like SA.[55] SA needs to overcome the hurdles in advancing access to medicines because access to medicines is a component of the right to health.[56] Patent rights have been said by Ellen 't Hoen to limit access to medicines; this is because of their exclusive nature.[57] 't Hoen contends that competition has been demonstrated to be an efficient means of lowering the excessive prices of medicines.[58] Further, it would be difficult or even impossible to find out where there are monopolies in the pharmaceutical industry.[59] Patent flexibilities

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[48] Ibid.
[49] Intellectual Property Rights and South Africa's Innovation Future Trade Policy Report NO. 23, available at https://saiia.org.za/wp- content/uploads/2013/06/23-dttp_rep_23_gregory.pdf 21 (accessed DATE).
[50] Ibid 21.
[51] Ibid 22.
[52] WTO Essential medicines, available at https://pallipedia.org/essential-medicines/ (accessed 10 November 2021).
[53] Ibid.
[54] Ibid.
[55] Joo-Young Lee & Paul Hunt 'Human rights responsibilities of pharmaceutical companies in relation to access to medicines' (2012) *Journal of Law, Medicine & Ethics* 225–226.
[56] Holger Hestermeyer *Human Rights and the WTO: The Case of Patents and Access to Medicines* (2007). Also read with art 12 of the International Covenant on Economic, Social and Cultural Rights.
[57] Ellen 't Hoen 'TRIPS, pharmaceutical patents and access to essential medicines: Seattle, Doha and beyond Paris: National agency for AIDS research' 2003 *Chicago Journal of International Law* 41.
[58] Ibid 27–29.
[59] Ibid.

have been weakened by the pharmaceutical industry, which exploits IPR in trade agreements and settlements.[60] Adusei contends that, at best, some developing countries are incapable of fully using and applying TRIPS flexibilities because of half-hearted performance and fulfilment of patent schemes within such countries.[61] One may infer from Adusei's statement that absorbing the TRIPS flexibilities in a country's IP legislative framework to advance access to essential medicines cannot further access to medicines alone, if the patent scheme itself is defective. The government is required to improve the executive and legal framework through reasonable steps that are contributing to the realisation of the right to health care resources and medicines.[62] The actualisation of socio-economic rights has been burdensome.[63]

Khor argues that developing countries such as SA should take advantage of the TRIPS flexibilities, particularly the full use of compulsory licensing and parallel importation, which would allow public health measures to make medicines accessible and affordable.[64] This was also adopted in the Doha Ministerial Conference in 2001.[65]

Parallel importation, often known as grey marketing, is the practice of importing an item that is validly marketed under the IP regime in one country into a second country through an unofficial trade channel, contrary to the wishes of the corresponding rights holder in that second country.[66] Several forms of parallel importation are used around the world. The most common practice is known as 'passive parallel importation', which involves importers buying goods in a foreign country and selling them in the domestic market.[67] Another form is 'active parallel importation', whereby a foreign licensee or distributor of an

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[60] P Adusei 'Exploiting patent regulatory 'flexibilities' to promote access to antiretroviral drugs in sub-Saharan Africa' (2009) 9 *University of Botswana Law Journal* 3.
[61] Ibid 4.
[62] Lonias Ndlovu 'The WTO TRIPS Agreement and access to medicines in South Africa twenty years into democracy' A Paper Presented at the Conference on Twenty Years of Constitutionalism, Democracy and the Bill of Rights in South Africa Held at the University of Fort Hare, East London, South Africa, October 2013.
[63] Christof Heyns & Danie Brand 'Introduction to socio-economic rights in the South African Constitution' (1998) 2 *Law, Development & Democracy* 185–187.
[64] Martin Khor 'Implications of some WTO rules on the realization of the MDGs' TWN Trade & Development Series (August 2005) https://martinkhor.org/wp-content/uploads/2020/10/tnd26.pdf (accessed 27 May 2020) 16.
[65] The Fourth WTO Ministerial Conference, available at https://www.wto.org/english/thewto_e/minist_e/min01_e/min01_e.htm (accessed 30 May 2020).
[66] AJ Stack 'TRIPS, patent exhaustion and parallel imports' (1998) 1 *Journal of World Intellectual Property* 657–689: 666.
[67] C Fink 'Entering the jungle of intellectual property rights: Exhaustion and parallel importation' in C Fink & KE Maskus (eds) *Intellectual Property and Development: Lessons from Recent Economic Research* (2005) 171–188: 172.

IPR holder enters the domestic market to compete with the rights holder or an official domestic licensee.[68]

The exhaustion doctrine defines the point at which an IPR holder (for the purpose of this paper a patent holder) ceases to have exclusive rights over the resale of the patented product.[69] In general, a patent owner's rights are exhausted as soon as a patented product is placed on the market for sale, with the result that a purchaser can resell the article without being liable for infringement.[70] This doctrine is of greatest significance when patented products are traded internationally and patent rights in the product are held in multiple nations.[71] Where this occurs, it is necessary to ascertain which, if any, of the patent rights are exhausted by the sale of the article. If the rights have been exhausted, then parallel imports will be allowed within that particular country.

Under a regime of national exhaustion, the first sale of a patented good only 'exhausts' the patent holder's right to control subsequent sales within the country where the patented product was sold.[72] The practical effect of national exhaustion is that once a patentee sells a patented product, the purchaser holds title free and clear of the patent, including the right to resell the product to third parties. Notably, national exhaustion does not affect any patent rights in parallel patents in foreign countries. Thus, while the patentee may not control commerce in his patented product after it has been first sold within the jurisdiction, the patentee may exclude parallel imports of the same product entering from other countries.[73]

Under a doctrine of international exhaustion, the first sale of a patented good in any jurisdiction worldwide terminates the patent holder's rights in any parallel patents held in any other jurisdiction.[74] The theoretical basis of international exhaustion is that the patentee has received a reward by means of the first sale in a particular country and so should not be able to control the resale of that same product in any other country.[75] Following this approach, a patented product may move freely anywhere in the international

[68] Ibid 172.
[69] For Trade & Sustainable Dev. UNCTAD-ICTSD *Resource Book on TRIPS and Development* (2005) 629, 94
[70] DE Donnelly 'Parallel trade and international harmonization of the exhaustion of rights doctrine' (1997) 13 *Santa Clara Computer & High Technology Law Journal* 445–515: 447.
[71] Ibid 447.
[72] Ibid 497.
[73] V Chiappetta 'The desirability of agreeing to disagree: The WTO, TRIPS, international IPR exhaustion and a few other things' (2000) 21 *Michigan Journal of International Law* 333–392: 341–342.
[74] DE Donnelly 'Parallel trade and international harmonization of the exhaustion of rights doctrine' (1997) 13 *Santa Clara Computer & High Technology Law Journal* 445–515: 498.
[75] Ibid 509.

market following first sale in any jurisdiction.

1.2 Legal frameworks governing access to medicines

The registration of medicines in SA is governed by the provisions and requirements of the Medicines Act, including the regulations and the published guidelines. The introduction of the regulation of medicines in SA was initiated in the 1960s when the National Department of Health appointed the Snyman Commission to investigate the high cost of medicines and medical services in SA.[76] The WTO TRIPS Agreement is the most comprehensive multilateral agreement on IP.

The TRIPS Agreement and the Doha Declaration on Public Health continue to serve as milestones in recognising the link between the WTO system and broader public health policy issues.[77] They also serve as a reference point for international cooperation in the fields of intellectual property and public health. By combining different policies and different specialities, they have built a stronger foundation for multilateral cooperation in the areas of intellectual property and public health, and have helped governments to take advantage of the flexibility of TRIPS. For example, countries with limited manufacturing capacity can effectively use compulsory licences through the so-called 'paragraph 6 system'.[78] This gives poor countries additional flexibility to access affordable medicines under the TRIPS agreement. The paragraph 6 system, agreed on in August 2003, allows generic versions of patented drugs to be produced under a compulsory licence (ie without the consent of the patentee) and exported to countries where these drugs cannot be produced locally.

The TRIPS Agreement also covers some areas related to health. Questions regarding patent protection for pharmaceuticals is particularly important. This is an area where finding the right balance between two complementary public health goals aimed at creating incentives for future drug inventions and ensuring affordable access to existing drugs is important.[79] The TRIPS Agreement seeks to help to achieve such a balance. It contains several provisions that enable governments to implement their IP regimes in a manner that takes account of immediate and longer-term public health considerations.[80] It also provides for some

[76] HWY Snyman *Report of the Commission of Inquiry into High Cost of Medical Services and Medicines* (1965).
[77] Ibid 8.
[78] Ibid 9.
[79] Ibid 10.
[80] Ibid 10.

flexibility in the implementation of the Agreement by allowing countries, under certain conditions, to limit patent owners' exclusive rights, for instance by granting compulsory licences.[81]

Although the TRIPS Agreement should enhance incentives to research and develop new medicines, there is also concern that it may lead to drug price increases due to more stringent patent protection.[82] In this regard, the TRIPS Agreement allows WTO members, under certain circumstances, to use safeguards, such as compulsory licensing. Although there were some conflicting views regarding the conditions under which the flexibility of the TRIPS Agreement could be used, the Doha Declaration helps to clarify this issue.[83] The Declaration was seen as an important step to prevent situations where countries have considered themselves under pressure, from industry and foreign governments, not to avail themselves fully of the flexibility provided in the TRIPS Agreement.[84]

1.3 Justification and impact

Access to medicines provides a cost-effective solution to many health problems in Africa, provided the medicines are available, affordable and used appropriately.[85] Problems in obtaining medicines in Africa include, but are not limited to:

1) The current R&D model in Africa is primarily market-driven and cannot solve these problems.[86] It is not yet ready to deal with emerging infectious diseases such as Covid-19 and Ebola, as well as Neglected Tropical Diseases (NTDs), which mainly affect the population of Africa. This creates a discrepancy between the innovation that is the driving force for the development of new drugs and the lack of such drugs on the African continent.[87]
2) Pharmaceutical companies prioritise the production of certain medicines that are more profitable

[81] Ibid 11.
[82] 'Equity pricing of essential medicines in developing countries' Adapted from a presentation made by Ellen 't Hoen, Médecins Sans Frontières, at the WHO/WTO Workshop on Differential Pricing and Financing of Essential Drugs, Høsbjør, Norway, April 2001, available at https://www.wto.org/english/tratop_e/trips_e/hosbjor_presentations_e/15thoen_e.pdf.
[83] Ibid 6.
[84] Ibid 6.
[85] The Fourth WTO Ministerial Conference, available at https://www.wto.org/english/thewto_e/minist_e/min01_e/min01_e.htm (accessed 30 May 2020).
[61] World Health Organisation (WHO) 'Equitable access to essential medicines: A framework for collective action' (2004).
[86] Report of the United Nations Secretary General's High-Level Panel on Access to Medicines: Promoting Innovations and Access to Health Technologies (September 2016) 13.
[87] Ibid.

in Western countries, to the detriment of medicines needed by developing countries (Africa).[88] These medicines focus primarily on the most profitable parts of the market, such as cardiovascular disease, dermatology, oncology, neurology, and infectious diseases. Such diseases are very common in developed countries. Tropical medicine is basically outside the scope of pharmaceutical companies' priorities yet it represents a large part of the essential medicines needed in Africa.[89]

3) Counterfeit and inferior drugs also affect the procurement of essential drugs in Africa because they do not contribute to the main goal of obtaining safe and affordable drugs.[90]
4) In addition, most essential drugs required for the treatment of certain tropical diseases are progressively disappearing from the market because they are not commercially profitable.[91]
5) Developing countries, such as South Africa, lack sufficient disease diagnosis capabilities, which hinders their ability to acquire the appropriate number and type of drugs in a compulsory licence.[92]

Faced with these obstacles, new methods are needed to solve the problem of lack of essential medicines in Africa. Such an approach will be one that allows for medicine to be available, affordable and easily accessible to those that need it, while balancing the growth of R&D. SA's right to access medicines as a component of the right to health depends not only on the production, distribution and price of medicines, but also on incentives for R&D of medicines needed to treat diseases in Africa.[93]

1.4 Research question

The question that this dissertation seeks to answer is: 'To what extent has South Africa implemented the TRIPS flexibilities, particularly with reference to compulsory licensing, to ensure that access to medicines is safeguarded?'

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[88] Henry Grabowski 'The effect of pharmacoeconomics on company research and development decisions' 1997 *Pharmacoeconomics* 389–97.
[89] Ibid.
[90] Albert Wertheimer & Jeremiah Norris 'Safeguarding against substandard/counterfeit drugs: Mitigating a macroeconomic pandemic' (2009) 5 *Research in Social and Administrative Pharmacy* 13.
[91] Edward Halle 'Access to essential medicine as part of the right to health in Africa: Access to essential medicine under international human rights law, the case of Kenya and South Africa' (2017) 11 *Asia Pacific J. Health L. & Ethics* 8.
[92] Pier DeRoo 'Public non-commercial use compulsory licensing for pharmaceutical drugs in government health care programs' (2010) 32 *Mich. J. Int'l L.* 12.
[93] Halle 'Access to essential medicine as part of the right to health in Africa: Access to essential medicine under international human rights law, the case of Kenya and South Africa' (2017) 11 *Asia Pacific J. Health L. & Ethics* 12.

The following sub-questions will be asked:

1) What is the effect of the TRIPS flexibility of compulsory licensing in relation to the patenting of pharmaceuticals?
2) Does the right to access medicines conflict with the drug patent standards required by the TRIPS Agreement within the framework of South Africa?
3) How does pricing of medicine affect access to medicines?
4) To what extent does the TRIPS flexibility of compulsory licensing attend to the issue of access to medicines in the public health sector?
5) To what extent does compulsory licensing promote local manufacture and socio-economic development?

1.5 Methodology

This paper uses doctrinal legal research methodology,[94] which constitutes a technical analysis of legal rules found in major sources (decree or rule). The purpose of the method in this dissertation is to collect, organise, and explain the law. It provides a description of the source used, and then identifies and describes how the basic themes and the legal sources of the system are connected. The method also involves performing a critical and qualitative analysis of legal material that helps to answer research questions. It also identifies ambiguities and criticisms of the law, and provides solutions. The data sources used include the legal rules themselves, cases generated under the rules, legislative records where applicable, rule comments, and literature.

1.6 Thesis structure

This dissertation has five chapters. Chapter two discusses the TRIPS flexibility of compulsory licensing, and further gives a lucid explanation of the relationship between the TRIPS Agreement and the Doha Declaration and the policy space it grants member states to amend their patent laws with regard to their respective public health needs. It further discusses whether SA has used its domestic policy space and discretion to enforce any of the flexibilities, particularly compulsory licensing. Background understanding of the level of affordability of medicine in SA is also given. The chapter paints a vivid picture of the crisis

[94] Terry Hutchinson & Nigel Duncan 'Defining and describing what we do: Doctrinal legal research' (2012) 17 *Deakin L. Rev* 2.

of access to medicines for the people who need it most.

The objective of chapter three is to establish if South Africa's Patents Act has taken advantage of the patent-related flexibilities of the TRIPS Agreement. This chapter first scrutinises if SA complies with article 27(1) of the TRIPS Agreement. Second, it discusses if the Medicines and Related Substances Control Act 101 of 1965 enriches the availability and accessibility of medicine through measures it has put in place. Finally, it looks at how competition law can aid in addressing the problem of access to medicines in SA.

Chapter four explores and assesses if India has acted in accordance with the TRIPS Agreement to realise a balance between access to medicines and patent protection. It looks at ways in which SA can draw lessons from India's experience. It will examine India's use of TRIPS flexibilities together with its patent standards.

Chapter five provides a summary of the dissertation and lays down its findings and recommendations in answering the research question.

Chapter 2

INTERNATIONAL FRAMEWORKS THAT ADVANCE ACCESS TO MEDICINES IN SOUTH AFRICA

2.1 Introduction

This chapter discusses the TRIPS Agreement's provisions on compulsory licensing. Further gives a lucid explanation of the correlation between the agreement and the Doha Declaration and the policy space they grant member states to amend their patent laws, considering their respective public health needs. The chapter discusses South Africa's own patent flexibilities provided for within the Patents Act.[1] It concludes by investigating whether South Africa (SA) has used its domestic policy space and discretion to enforce any of the flexibilities, particularly compulsory licensing.

2.2 The influence of patent protection in South Africa

SA's intention for the protection of patent rights should be for economic furtherance to allow its residents to access essential medicines and contribute to the enhancement of innovation and knowledge, through the development, manufacture, and circulation of patented products to enable a flourishing environment of economic activity.[2]

The purpose of intellectual property (IP) protection is to form an equilibrium between rights of IP right holders and the rights of the users. This equilibrium has been challenging to maintain.[3] One area where this challenge is best captured is within the ongoing battle of patents and access to medicines.[4]

The advance of technology over the past century and concomitant economic activity have equipped countries to fight socio-economic issues such as poverty and protect individuals' rights to health.[5]

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[1] Patents Act 57 of 1978.
[2] Caroline B Ncube 'Enforcing patent rights against goods in transit: A new threat to trans border trade in generic medicines' (2016) *21 South African Mercantile Law Journal* 680–694.
[3] Phoebe Li 'Intellectual property for humanity: A manifesto' in D Gervais (ed) *The Future of Intellectual Property* (2021) 14.
[4] Kevin Outterson 'Pharmaceutical arbitrage: Balancing access and innovation in international prescription drug markets' (2005) 5 *Yale J. Health Pol'y L. & Ethics* 195.
[5] United Nations Conference on Trade and Development (UNCTAD) 'Technology and Innovation Report 2021', available at https://unctad.org/system/files/official-document/tir2020_en.pdf (accessed 12 April 2020).

However, despite the rapid furtherance of technology, developing countries such as SA have seen a decline in the protection of the right to health and access to medicines.[6] As the kind of diseases that affect developing countries such as SA are different from those that affect developed countries, it is imperative that developing countries find solutions that address their unique problems within their public health system.[7] Sadly, there is no urgency in the pharmaceutical industry to invest in R&D on most diseases that affect developing countries.[8] This is because developed countries control the purchasing power and development of patented medicines.[9]

The primary purpose of patents is to allow a patent owner to make a profit from his or her invention.[10] This is done by excluding users and competitors from the commercial market for a definite period of 20 years.[11] Pharmaceutical patents are also afforded such protection. A pharmaceutical company has the right to exclude and limit access to its patented medication in the commercial market to gain profits by selling its patented medication at a certain price.[12] This monopoly within pharmaceutical companies allows them to recover the huge financial investments made in R&D for new patented medications while simultaneously making profit for themselves.[13] The pharmaceutical industry contends that if there was no financial exploitation of patents there would be a great reduction in development, research, and innovation in the production and creation of medicines.[14]

For one to be afforded patent protection, one must satisfy certain conditions. One of the conditions attached to patent protection is that the patent owner is mandated to disclose important details of their invention to the public as a form of trade-off for the use of the exclusive rights granted to him or her.[15]

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[6] Innovation Commission on IP Rights et al *Public Health, Innovation and IP Rights: Report of the Commission on IP Rights, Innovation and Public Health* (2006) 34.
[7] Ibid 36.
[8] Ibid 37.
[9] Ibid 38.
[10] Li ' Intellectual property for humanity: A manifesto' in David Gervais (ed) *The Future of Intellectual Property* (2021) 16.
[11] Agreement on Trade-Related Aspects of IP Rights, 15 April 1994, available at http://www.wto.org/english/docs_e/legal_e/27-TRIPS.pdf, Article 33 (accessed 12 May 2020).
[12] Ellen FM 't Hoen *Private Patents and Public Health: Changing IP Rules for Access to Medicines* (2016) 1.
[13] Roberto Mazzoleni & Richard R Nelson 'The benefits and costs of strong patent protection: A contribution to the current debate' (1998) 27(3) *Research Policy* 275.
[14] Matthew Herper 'The cost of developing drugs is insane. That paper that says otherwise is insanely bad' *Forbes* (16 October 2017), available at https://www.forbes.com/sites/matthewherper/2017/10/16/the-cost-of-developing-drugs-is-insane-a-paper-that-argued-otherwise-was-insanely-bad/?sh=7a2b67102d45 (accessed 12 May 2020).
[15] Ellen FM 't Hoen 'TRIPS, pharmaceutical patents and access to essential medicines: Seattle, Doha and beyond' (2003) 3.*CHI. J. INT'L L* 55.

This disclosure requirement influences the expansion of knowledge as it allows for the improvement of research in medicines.[16] It also allows other people to use the patent without restrictions once it has expired.[17]

Pharmaceutical companies advocate strongly for the protection of patents[18] because one of the principles of patent protection is that it forbids the unfair use of patents by third parties.[19] In the pharmaceutical industry, medicines are easily imitated because they can easily be reverse-engineered.[20] This is where patent protection becomes vitally important, as such imitations may lead to mass reproduction and further the excessive use of protected knowledge.[21] If this was to occur, it would negatively impact the commercial market of the patent[22] and hinder patent owners' efforts to recuperate their investment in the R&D of the medicine.[23] This would also have a negative impact on the market value of innovations and inventions, which would affect the financial interest invested in the R&D of medicines,[24] consequently affecting the right to medicines and adequate health care.[25]

Pharmaceutical industries invest in the R&D of new medicines for countries that have the financial means to invest in such medicines.[26] Due to investments made by developed countries such as the United States (US), there has been a shortfall of medicines that commonly affect developing countries like SA.[27] To indicate the scope of the problem, in 2012 *Médecins Sans Frontières* (MSF) and Drugs for Neglected Diseases initiative (DNDi) conducted research: they recorded that between the years 2000 and 2011, only 37 out of 850 new medicines were for neglected diseases.[28] Neglected diseases are viral, parasitic, and

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[16] Nancy T Gallini 'The economics of patents: Lessons from recent US patent reform' (2002) 16(2) *Journal of Economic Perspectives* 139.
[17] Ibid.
[18] Philippe Cullet 'Patents and medicines: The relationship between TRIPS and the human right to health' (2003) 79(1) *International Affairs* 132.
[19] Tim Hubbard & James Love 'A new trade framework for global healthcare R&D' (2004) 2(2) *PloS Biology* 0147.
[20] Jillian Clare Cohen & Patricia Illingworth 'The dilemma of IP rights for pharmaceuticals: The tension between ensuring access of the poor to medicines and committing to international agreements' (2003) 3(1) *Developing World Bioethics* 30.
[21] Ibid.
[22] Dan L Burk & Mark A Lemley *The patent crisis and how the courts can solve it* (2009) 8.
[23] Dean Baker, Arjun Jayadev & Joseph E Stiglitz 'Innovation, intellectual property, and development: A better set of approaches for the 21st century' (2017) 9.
[24] Ibid.
[25] Cohen & Illingworth 'The dilemma of IP rights for pharmaceuticals: The tension between ensuring access of the poor to medicines and committing to international agreements' (2003):3(1) *Developing World Bioethics* 30.
[26] 't Hoen 'TRIPS, pharmaceutical patents and access to essential medicines: Seattle, Doha and beyond' (2003) 3 *CHI. J. INT'L L* 55.
[27] Ibid.
[28] Ibid 55.

bacterial diseases that affect developing and least developed countries (LCD).[29]

2.3 South Africa's pricing system

A pharmaceutical company retains the right to set the cost of its specific patented medicine in a manner that allows for financial gain.[30] They are permitted to set such prices without considering the socio-economic condition of the people. This consequently affects access to medicines to people who need it the most.[31] This section of this chapter examines three examples of medicines: one used for the treatment of liver and thyroid cancer; a second used for the treatment of fibromyalgia and epilepsy; and the last for bipolar disorder and depression. These diseases affect a large number of South Africans. I will look at the amount an average South African earns in comparison to the cost of each medication. This will allow for background understanding of the level of affordability of medicine in SA and paint a vivid picture of the socio-economic crisis of access to medicines for the people who need it the most.

The vast majority of South Africans are unable to afford private medical insurance.[32] Such South Africans rely on government-funded public health care services.[33] A very small percentage of South Africans (16.2 per cent) can afford and have access to private health insurance.[34] It becomes hopeless and unfeasible in situations where both the government and private insurers are not able to cover exorbitant prices of medicine. As a result, people who are in dire need of the medication may never be able to access the medication, which may lead to death or reduced quality of life, which affects their dignity.[35] The following paragraphs look at the significant effect inaccessibility to medicine (generic or biosimilar) in SA has on patients in the public and private sectors.[36]

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[29] World Health Organization 'Neglected tropical diseases', available at https://www.who.int/news-room/q-a-detail/neglected-tropical-diseases (accessed 10 April).
[30] Robert C Hughes 'Pricing medicine fairly' (2020) 19 *Philosophy of Management* 12.
[31] 't Hoen 'TRIPS, pharmaceutical patents and access to essential medicines: Seattle, Doha and beyond' (2003) 3 *CHI. J. INT'L L* 41.
[32] National Health Insurance Healthcare for All South Africans Understanding National Health Insurance, available at https://www.hst.org.za/publications/NonHSTper cent 20Publications/Bookletper cent 20-per cent 20Understandingper cent 20Nationalper cent 20Healthper cent 20Insurance.pdf (accessed 3 August 2020).
[33] Ibid.
[34] National Health Act, National Health Insurance Policy: Towards universal health coverage, available at https://serve.mg.co.za/content/documents/2017/06/29/whitepaper-nhi-2017compressed.pdf 63.
[35] Ibid.
[36] Ibid.

In 2020 Giraffe analysed the average salary benchmark in SA. Giraffe is a recruitment group that gathers data on workers' reports and 'self-reported salary data' not older than the year 2018.[37] This analysis did not include high-skilled workers in SA, for example senior management and executives.[38] The analysis is a lucid representation of the great number of South African workers' average salary. From the analysis it was found that 7 per cent of the workers have a degree, 14 per cent hold a diploma, and the remainder hold a matric qualification or none.[39] The workers in the reported analysis earn between ZAR 1 000 and ZAR 90 000 per month, with an average take-home pay of ZAR 6 400.[40]

Their database included nearly one million medium-skilled workers.[41] These workers cut across all fields of industry, experience, and education.[42] The analysis embodies the majority of the working class in SA; this is because it excludes high-skilled workers, most of whom are in managerial or executive positions.[43] The inclusion of high-skilled workers would give a distorted perspective of the real salary benchmark in SA.[44] As noted above, Giraffe found that the average salary of a great number of South Africans is ZAR 6 400 per month.[45] This number differs significantly from the estimate of ZAR 21 000 that Stats SA presents as the average South African's salary.[46] This is because Stats SA includes high skilled workers, which clouds the actual narrative of the average South African's take-home pay.[47] The minimum wage in SA provided by the labour department in SA is ZAR 3 500 or ZAR 21.69 per hour, depending on the number of hours worked.[48] In spite of this, 29 per cent of South African workers earn less than the prescribed national wage.[49] Forty per cent of workers in the retail industry earn less than the prescribed minimum wage, and together with domestic workers and farmers, constitute the majority of worst paid workers.[50] The Banking and Information Technology sector employs 8 per cent of the workers in SA; they

[37] Giraffe 'South African junior-medium skilled salary benchmark', available at https://blog.giraffe.co.za/wp-content/uploads/2020/02/Giraffe-Mid-Skilled-Salary-Benchmark-2019.pdf (accessed 20 May 2021).
[38] Ibid 3.
[39] Ibid.
[40] Ibid 4.
[41] Ibid.
[42] Ibid 5.
[43] Ibid 6.
[44] Ibid.
[45] Ibid 5.
[46] Ibid.
[47] Ibid 7.
[48] Ibid.
[49] Ibid.
[50] Ibid.

are among the highest paid.[51]

With the average take-home pay of ZAR 6 400, together with the many responsibilities an average South African worker has to meet – including but not limited to rental fees, daily transport fees, and groceries – it is difficult for an average South African to access affordable medicine.[52] In the paragraph below we look at three examples of medicine in SA, listing availability and average cost of each medicine. This will be done to draw a picture of the serious problem of the need to access medicine.

The first medicine this chapter looks at is Sorafenib, an oral medicine that slows down a particular chemical reaction to treat liver, kidney, and thyroid cancer. In 2007 the South African National Cancer Registry reported 409 occurrences of kidney cancer, 405 occurrences of liver cancer, and lastly 307 occurrences of thyroid cancer.[53] Liver cancer worldwide is the third leading cause of cancer deaths.[54] Given the high cost of Sorafenib, it is not available nationally in SA.[55] The generic of Sorafenib is Nexavar, which is available in SA.[56] Generic medicines can be lawfully manufactured and traded in the course of the original patent. This can be done under compulsory licensing. Such an act will not amount to patent infringement.[57] The cost of Sorafenib in SA is ZAR 26 252 (US$ 1 856) in the private sector for a monthly treatment.[58]

The second medicine this chapter looks at is Pregabalin. Pregabalin is used to treat fibromyalgia, help neuropathic pain, and treat seizures in persons who suffer from epilepsy.[59] SA has higher reported cases of fibromyalgia than the US and Western Europe. Research was conducted in a rural area in SA. The study recorded that 3.2 per cent of the rural community is affected by fibromyalgia.[60] Given Pregabalin's high

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[51] Ibid.
[52] Ibid.
[53] Patent barriers to medicine access in South Africa: A case for patent law reform publication of the Fix the Patent Laws Campaign (September 2016), available at https://msfaccess.org/patent-barriers-medicine-access-south-africa-case- patent-law-reform (accessed 18 May 2020).
[54] Ibid 28.
[55] Ibid.
[56] Ibid 29.
[57] Ncube 'Enforcing patent rights against goods in transit: A new threat to trans border trade in generic medicines' (2016) 21 *South African Mercantile Law Journal* 680–694.
[58] Patent barriers to medicine access in South Africa: A case for patent law reform publication of the Fix the Patent Laws Campaign.
[59] Ibid 33.
[60] Ibid 34.

cost, it is not easily accessible in South Africa nor available countrywide. The cost of Pregabalin in SA ranges from ZAR 323 (US$ 23) to ZAR 646 (US$ 46) in the private sector for monthly treatment.[61]

Aripiprazole is a medicine used to treat schizophrenia, bipolar disorder, major depressive disorder and autistic disorders.[62] An estimated 17.6 million people in SA will suffer from a mental illness at a certain stage in their lifespan.[63] Given Aripiprazole's cost, it is only available nationally in SA under restricted conditions. One of the conditions is that secondary, evergreening patents be allowed to prevent different generic medicine types from being brought to the market at a 30 per cent price reduction when the initial patent expired.[64] The Supreme Court of Appeal in SA upheld Bayer's secondary patent in 2014, which means that generic use may continue to be blocked until 2024.[65] Secondary patents may block availability of generics in SA until 2033.[66] South African consumers pay up to 35 times more for Aripiprazole than consumers in India, where generic competition exists.[67] Aripiprazole is covered fully under private insurance in SA on condition that the patients have been unsuccessful in their preceding first-line of psychotic medication.[68] In SA, the cost of Aripiprazole ranges from ZAR 1 090 (US$ 77) to ZAR 2 408 (US$ 170) for a monthly treatment.[69]

A significant proportion of chronic disease morbidity and mortality can be prevented if medications are made accessible and affordable.[70] A range of policy options and technical options exist to enable governments to ensure that medicines for chronic diseases are consistently available and affordable.[71] A commitment by governments to meet the needs of their citizens who suffer from chronic diseases is

[61] Ibid 34.
[62] Patent barriers to medicine access In South Africa: A case for patent law reform publication of the Fix the Patent Laws Campaign.
[63] Ibid 38.
[64] Catherine Tomlinson et al 'Reforming South Africa's procedures for granting patents to improve medicine access' (2015) 105 *SAMJ* 5.
[65] Ibid.
[66] Ibid.
[67] Ibid.
[68] Ibid 39.
[69] Ibid.
[70] Jennifer H Mike 'A re-evaluation of the framework for the protection of patents, women's health in Nigeria and the issue of accessing pharmaceutical innovation in Africa: Designing strategies for medicines' (2019) 22 *The Journal of World Intellectual Property* 10.
[71] World Health Organization *Progress report on access to hepatitis C treatment: Focus on overcoming barriers in low-and middle-income countries* (2018).

urgently required.[72] A good is unaffordable if the individual, after the purchase, does not have enough resources left to fulfil her basic needs, ie falls below the poverty line.[73] Access to medicine in SA has become unaffordable for many South Africans who earn below or around the average salary of ZAR 6 400.[74] The TRIPS Agreement contains safeguards to ensure that legitimate patents do not prohibit access.

In the absence of access to patented drugs because of price, supply, or other challenges, governments may, under certain conditions, enforce compulsory licences to allow the manufacture, import, and use of generic or biosimilar products for the duration of the patent.[75] SA must adopt expedited administrative (non-judicial) procedures to facilitate the granting of compulsory licences.[76] This will aid in socio-economic development. Between the years 2005 and 2015 in SA, 4 064 patents were approved,[77] of which 49 were medicinal patent inventions.[78] Local manufacture of medicines is vital for the growth and advocacy for the right to adequate health care and life.[79]

The HIV pandemic is the most famous example of the problem of access to essential medication in SA.[80] At the end of 1999, 34.4 million people were estimated worldwide to have tested positive for the virus,[81] 24.5 million of whom were from sub-Saharan Africa.[82] During that time, the patented antiretroviral medicine was accessible at a cost of US$ 10 000 annually.[83] Due to the high pricing of the patented antiretroviral medicine, developing countries such as SA found it infeasible to access the medication,

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[72] Obinna O Oleribe et al 'Identifying key challenges facing healthcare systems in Africa and potential solutions' (2019) 12 *International Journal of General Medicine* 12.
[73] Colin H Ridyard & Dyfrig A Hughes 'Methods for the collection of resource use data within clinical trials: A systematic review of studies funded by the UK Health Technology Assessment Program' (2010) *Value in Health* 10.
[74] Giraffe 'South African junior-medium skilled salary benchmark'.
[75] Rutendo Chapwanya *The inaccessibility of healthcare: Are South Africa's patent laws aiding and abetting pharmaceutical companies?* (published LLM Dissertation University of Johannesburg, 2020) 9.
[76] Ibid.
[77] Jonathan Berger & Andrew Rens 'Innovation and IP in South Africa: The case for reform' (2018), available at https://www.tralac.org/documents/news/1917-innovation-and-intellectual-property-in-south-africa-the-case-for-reform-accessibsa-april-2018/file.html (accessed 11 December 2021) 11.
[78] Ibid 22.
[79] Cohen & Illingworth 'The dilemma of IP rights for pharmaceuticals: The tension between ensuring access of the poor to medicines and committing to international agreements' (2003) 3(1) *Developing World Bioethics* 33.
[80] Katrina Perehudoff 'Universal access to essential medicines as part of the right to health: A cross-national comparison of national laws, medicines policies, and health system indicators' (2020) 13 *Global Health Action* 20.
[81] Elizabeth Pisani et al *Report on the Global HIV/AIDS Epidemic, June 2000* (2000) 6.
[82] Ibid.
[83] Médecins sans Frontières *Untangling the web of antiretroviral price reductions* (July 2013) (Médecins sans Frontières, 2015) 4.

which resulted in millions of people dying from the virus.[84] At the time, 19.9 per cent of SA's population had been infected with the virus. Due to the high number of people infected and the inaccessibility of the patented antiretroviral medicine, protests broke out in SA.[85] Among other groups, the Treatment Action Campaign (TAC), joined the national protests advocating for the right to health care and life which was afforded to the citizens of SA.[86] Pressure from SA and other developing countries about the unfair pricing system[87] led to the implementation of the Doha Declaration on the TRIPS Agreement and Public Health in 2001.[88] The Doha Declaration maintained and supported the flexibilities provided for in the TRIPS agreement.[89] Evidence of the Doha Declarations support of the flexibilities and the battle against high pricing of patented medicines is provided for in paragraph 3 of the Doha Declaration.[90] The declaration provides: 'We recognize that IP protection is important for the development of new medicines. We also recognize the concerns about its effects on prices.'[91]

2.4 Doha Declaration on the TRIPS Agreement and public health

The TRIPS agreement has fundamental flexibilities that are set out to equip member states to establish an equilibrium between the rights of patent owners versus the rights of the public.[92] These flexibilities allow for member states to protect the interest of their residents by restricting the freedom and effect of the exclusive rights of patent owners in a manner that is in accordance with the TRIPS Agreement and their domestic laws.[93]

For one to have a clear understanding of the TRIPS flexibilities the Doha Declaration must be discussed. Developing countries argued that the TRIPS Agreement impeded them from taking certain actions to

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[84] Pisani et al *Report on the Global HIV/AIDS Epidemic, June 2000* (2000) 8.
[85] Ibid 9.
[86] Holger Hestermeyer *Human Rights and the WTO: The Case of Patents and Access to Medicines* (2007) 11.
[87] 't Hoen *Private Patents and Public Health: Changing IP Rules for Access to Medicines* (2016) 8.
[88] Doha Declaration on the TRIPS Agreement and Public Health 14 November 2001, available at https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_TRIPS_e.htm, (accessed 20 May 2020).
[89] Carlos Correa ' Implications of the Doha Declaration on the TRIPS Agreement and public health' (2002) 58.
[90] Berger & Rens 'Innovation and intellectual property IP in South Africa: The case for reform' (2018) 11.
[91] Cohen & Illingworth 'The dilemma of IP rights for pharmaceuticals: The tension between ensuring access of the poor to medicines and committing to international agreements' (2003) 3(1) *Developing World Bioethics* 33.
[92] WIPO 'Patent related flexibilities in the multilateral legal framework and their legislativeImplementation at the national and regional levels' (1 March 2010), available at https://www.wipo.int/meetings/en/doc_details.jsp?doc_id=131629 (accessed 12 May 2020).
[93] Ibid.

protect their respective health demands by allowing an easy flow of access to medicines.[94] Developing countries such as SA believed that the TRIPS Agreement was ambiguous with regards to the protection and rights afforded to them.[95] The Doha Declaration brought a sense of precision and clarity through use of waivers.[96] The Doha Declaration was adopted in 2001.[97] Paragraph 4 of the Declaration addressed the concern of ambiguity within the TRIPS Agreement for developing countries, by allowing member states to protect their domestic public health problems. It provided the following:

> We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all. In this connection, we reaffirm the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.[98]

It is important to know that a waiver does not infer modifications of substantive obligations. What it does is to provisionally interrupt their operation.[99] Paragraph 6 contains waivers, including one waiver to support member states from the Southern African Development Community (SADC) in 'exploiting economies for the objective of advancing purchasing power for enabling the local production of medicinal products'.[100]

The significance of technology and capacity building in the medicinal sector is provided for in paragraph 7. The Doha Declaration on the TRIPS Agreement and Public Health, and the Statement by the

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[94] Sisule F Musungu & Cecilia Oh 'The use of flexibilities in TRIPS by developing countries: Can they promote access to medicines?' (2006) 8.
[95] Ibid 10.
[96] Ibid 12.
[97] DN Matthews 'TRIPS flexibilities and access to medicines in developing countries: The problem with technical assistance and free trade agreements' 2005 *European Intellectual Property Review* 1.
[98] Doha Declaration on the TRIPS Agreement and Public Health para 6.
[99] Carlos. Correa 'Implementation of the WTO General Council Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health', available at http://www.who.int/medicines/areas/policy/WTO_DOHA_DecisionPara6final.pdf (accessed 4 June 2020).
[100] Marumo Nkomo 'The trade related aspects of intellectual property rights (TRIPS) – pharmaceuticals transitional period: Can it help build capacity in African least developed countries (LDCs)?' (2015) 10 *International Journal of African Renaissance Studies – Multi-, Inter-and Transdisciplinarity* 6.

Chairperson of the General Council are published together as the 'Chairperson's Statement'.[101] The Statement contains four mutual comprehensions of the Doha Declaration on the TRIPS Agreement and Public Health. One of the mutual comprehensions is that World Trade Organization (WTO) members 'appreciate that the regime that will be established by the Doha Declaration on the TRIPS Agreement and Public Health should be used bona fide to safeguard public health'[102] and 'not be an instrument to carry out industrial or commercial policy objectives',[103] and that member states agree that 'all reasonable measures should be taken to prevent diversion or alteration in accordance with the relevant paragraphs of the Doha Declaration on the TRIPS Agreement and Public Health'.[104] A least developed country must make certain that it has viable access to medicine; this however will only be accomplished if self-sufficiency is fixed firmly, by growing production capacity in the medicinal sector as mentioned in paragraph 7 of the Doha Declaration on the TRIPS Agreement and Public Health.[105]

One fundamental change the Doha Declaration brought was to article 31*(f)* of the TRIPS Agreement, which states the following: 'any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use.'[106] This provision was vague in that it placed developing countries that cannot produce their own generic medications in a predicament.[107] The Doha Declaration recognised this predicament and requested that the TRIPS committee provide a clear and detailed solution to the General committee of the WTO before the end of 2002.[108]

The solution that the TRIPS committee forwarded was that 'a waiver of the export restriction' should be permitted for member states that cannot manufacture their own generic medication.[109] This solution was formally adopted by the WTO committee on 30 August 2003.[110] The above revised provision is not

[101] WTO 'The General Council Chairperson's Statement' (30 August 2003), available at http://www.wto.org/english/news_e/news03_e/trips_stat_28aug03_e.htm (accessed 12 May 2021).
[102] Ibid.
[103] Nkomo 'The trade related aspects of intellectual property rights (TRIPS) – pharmaceuticals transitional period: Can it help build capacity in African least developed countries (LDCs)?' (2015) 10 *International Journal of African Renaissance Studies – Multi-, Inter- and Transdisciplinarity* 8.
[104] Ibid 10.
[105] Ibid 12.
[106] Matthews 'TRIPS flexibilities and access to medicines in developing countries: The problem with technical assistance and free trade agreements' 2005 *European Intellectual Property Review* 421.
[107] Ibid.
[108] Doha Declaration on the TRIPS Agreement and Public Health para 6.
[109] WTO 'WTO decision on the implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health', available at https://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm (accessed 11 December 2021).
[110] Ibid.

instinctively binding on member states. Member states have the responsibility to amend their domestic patent laws and ensure that they are consistent with the above provision for it to be binding.[111]

2.5 Proposals for waiving certain TRIPS obligations

India and South Africa took a radical step when they submitted a proposal to the WTO to permit WTO members through international trade laws to elect not to issue and make compulsory to implement IP, for example patents, related to COVID-19 medicine, diagnostics, inoculation, and additional technologies and items.[112] If adopted, this would remain in place for the period of the COVID-19 pandemic; alternatively, until global immunity is achieved.[113] The waiver includes the following IP: trade secrets, designs, patents, and copyright pertinent to 'manufacture, supply of diagnostics, therapeutics, inoculation, medical tools, personal protective kits, materials and substances, together with their processes and measures of production'.[114]

Coronavirus is an infectious disease causing severe respiratory illness.[115] WHO has declared it a pandemic.[116] The multi-layered consequences of the pandemic include but are not limited to brutal disorder and interruption in economies and world trade.[117] Studies are presently being conducted to find effective treatment and therapy, the production and supply of therapeutics needed to control the spread of the disease and the effectiveness of inoculations against new variants.[118]

The first proposal that was submitted was in the month of October 2020.[119] This proposal did not express a definite time period that the waiver would be active for; instead it suggested the waiver should remain

[111] Ibid.
[112] Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of Covid-19 (25 May 2021), available at https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669R1.pdf&Open=True (accessed 20 June 2021).
[113] Ibid.
[114] Ibid.
[115] WHO 'Coronavirus', available at https://www.who.int/health-topics/coronavirus#tab=tab_1 (accessed 20 June 2021).
[116] Ibid.
[117] WTO 'Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of Covid-19' (2 October 2020), available at https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669.pdf&Open=True (accessed 20 June 2021).
[118] Ibid.
[119] Ibid.

until herd immunity is achieved globally.[120] There has since been a revised proposal, which was submitted in the month of May 2021.[121] The revised proposal provided a three-year waiver period, commencing when the General Council date is set. The revised proposal has obliged the General Council to re-evaluate the exceptional circumstances validating the waiver and establish a termination date of the waiver on condition that the exceptional circumstances are no longer present.[122]

It is legal to seek for a waiver through the TRIPS Agreement. The Marrakesh Agreement Establishing the WTO under paragraphs 3 and 4 of article IX asserts that in extraordinary or unique circumstances a waiver under particular agreements under WTO treaties (for example the TRIPS Agreement) can be adopted.[123] Waivers may be accepted and implemented if article IX of the Marrakesh Agreement is fulfilled. The proposal requests that the waiver be available to all WTO members. WTO members hold the discretion to effect the use of the waiver.[124]

The application for a waiver under article IX should first be presented to the TRIPS Council and then be presented and deliberated at the Ministerial Conference or the General Council of the WTO. Informal and formal meetings are held to arrive at a decision regarding the waivers that are negotiated by WTO members in the TRIPS Council.[125] A waiver will be issued if consensus is achieved by the majority of WTO members.[126] If the General Council or the TRIPS Council fail to arrive at a consensus, they may hold a vote to decide on a waiver by the Council.[127]

If the waiver was accepted, it would permit WTO members the merit under international trade laws to not issue and make compulsory to implement IP (patents, copyright, designs and trade secrets) associated to 'manufacture, supply of diagnostics, therapeutics, inoculation, medical tools, personal protective kits, materials and substances, together with their processes and measures of production'[128] for the 'prevention,

[120] WTO 'Waiver from Certain Provisions of the Trips Agreement for the Prevention, Containmentand Treatment of Covid-19' (25 May 2021).
[121] Ibid.
[122] Ibid.
[123] Marrakesh Agreement Establishing the World Trade Organisation April 1994 art XI.
[124] Ibid.
[125] Ibid.
[126] Ibid.
[127] Ibid.
[128] WTO 'Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of Covid-19' (25 May 2021).

treatment and containment'[129] of the coronavirus.

Speedy manufacture worldwide is vital to make medical products available and affordable in all countries. This further highlights the need for local manufacture in SA of medical products and medicines to aid in their availability and accessibility to support socio-economic development.

Discussions of the waiver proposal are ongoing at the WTO.

2.6 Compulsory licensing

This section will discuss compulsory licensing in the TRIPS Agreement to give a better understanding of the role the Doha Declaration plays regarding access to essential medicines. Compulsory licensing with reference to medicinal patents, involves the manufacture of generic medications of the original patented medication for a lower cost than the original patented medication; this will be done once royalties have been paid.[130] The Doha Declaration provides that the TRIPS Agreement does not restrict the grounds for issuing a compulsory licence. Nonetheless it does provide for fixed procedural conditions, which are examined in the following paragraphs.[131] In consequence, members may issue a compulsory licence for a pharmaceutical product patent to sanction a national generic producer to make low-priced generic medicines.[132] The list of grounds provided for a compulsory licence to be granted is provided for in section 56(2) of the Patents Act. The Paris Convention, in article 5A(2), provides an option for state members to issue compulsory licences to avoid patent abuses.

Member states must comply with the conditions provided for in article 31 of the TRIPS Agreement for compulsory licensing. One traditional rule that must be adhered to is that there must have been foregoing settlements to acquire a patent licence from the patent holder.[133] In acquiring the licence, it must be

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[129] Ibid.
[130] Matthews 'TRIPS flexibilities and access to medicines in developing countries: The problem with technical assistance and free trade agreements' 2005 *European Intellectual Property Review* 1.
[131] Carlos Correa *Trade-Related Aspects of IPRs: A Commentary on the TRIPS Agreement* (2007) 314–315.
[132] Musungu and Oh (WHO) have found seven possible grounds for the granting of compulsory licences based on an analysis of current state practice around the world. Musungu & Oh 'The use of flexibilities in TRIPS by developing countries' (2006) 16–17.
[133] TRIPS Agreement art 31*(b)*.

established that the patent owner declined to licence its medicinal patent within a fixed time.[134]

A patent owner must be advised of the desire to issue a compulsory licence immediately.[135] There are three occurrences[136] where the condition to participate in prior negotiations is excused:

1) In the occurrence of a national emergency or severe urgency. It has been generally understood that a compulsory licence will be issued only for the purpose of a national emergency, however this is a misunderstanding of its use.[137] The Doha Declaration brought clarity to this misunderstanding. It provided that: 'Each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.'[138] The patent owner is required to 'be notified as soon as reasonably practicable' For example, if there happens to be a vaccine or medicine aimed at treating the coronavirus, this requirement may be excused because the virus is considered a global pandemic that SA is affected by. SA could contend that it is in a 'national emergency' or 'situation of extreme urgency'.[139] The Doha Declaration further gave each member state the liberty to define what would be a matter of national emergency within its own domestic legal system and challenges.[140]
2) In the occurrence of a public, non-commercial use. The patent owner is required to be 'informed promptly'.[141] The TRIPS Agreement fails to provide a definition for 'public commercial use.' It leaves this burden on members to define for themselves and to permit the use of a patent by a private body for the interest of the public. This can occur for instance in the manufacture of specific medicines that are disseminated to public health care entities without a profit, which would be satisfactory. Further it would be beneficial and valuable to the people who are affected and are in need.[142]
3) In the occurrence where a compulsory licence 'is permitted to remedy a practice determined after judicial or administrative process to be anticompetitive'.[143]

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[134] Ibid.
[135] Ibid.
[136] Ibid.
[137] WTO 'Compulsory licensing of pharmaceuticals and TRIPS' (18 March 2018), available at https://www.wto.org/english/tratop_e/TRIPS_e/public_health_faq_e.htm (accessed 25 May 2020).
[138] Doha Declaration on the TRIPS Agreement and Public Health para 5*(b)*.
[139] Jonathan Berger *Tripping over Patents: AIDS, Access to Treatment and the Manufacturing of Scarcity* (2007) 205.
[140] Doha Declaration on the TRIPS Agreement and Public Health para 5*(c)*.
[141] Ibid.
[142] Berger *Tripping over Patents: AIDS, Access to Treatment and the Manufacturing of Scarcity* (2001) 206.
[143] TRIPS Agreement art 31*(b)* and *(k)*.

The above occurrences are set in place for exceptional instances to make it easier, and allow for the process of issuing a compulsory licence swiftly, which heighten the effectiveness and practicality of compulsory licensing within public health. It is not clear wha constitutes an anti-competitive practice given the fact that by default patents are expected to prevent competition.[144] The phrase 'anti-competitive practice' is not defined within the TRIPS agreement.[145] Nonetheless, 'a judicial or administrative process', as provided for in article 31*(k)* of the TRIPS Agreement, must conclude what constitutes an anti-competitive practice and state members have sovereignty in interpreting this phrase.[146]

In return for granting the compulsory licence, a reasonable remuneration must be paid to the patent owner for the use of the patented medicine.[147] The authority responsible for issuing the compulsory licence retains the discretion to assess the 'economic value of the authorization'[148] in ascertaining the reasonable remuneration amount to be paid.[149] The TRIPS Agreement unfortunately does not give the definitions of 'adequate remuneration' and 'economic value of the authorization'.[150] Member states are again left with the liberty of determining what is understood by the above phrases within the context of their domestic laws.[151] The right of a patent owner to receive reasonable and sufficient compensation is not expressly provided for in section 56 of the South African Patents Act in an event where a compulsory licence for the use of a patent is issued. It is implied by section 56(10) of the Act which provides that 'subject to the conditions that may be attached to the licence, a licencee under this section shall have the same rights and obligations as any other licencee under a patent' if such obligations are taken to include paying a royalt.[152] When the Commissioner applies his discretion with regards to a compulsory licence he should consider the R&D accepted by the patent owner and the terms expressed in the licence contracts.[153] Before any measures are taken by the Commissioner, a third party may appeal against an order or judgment of the

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[144] Conde Gallego 'Intellectual Property Rights and Competition Policy' ELECD 449 in Carlos M Correa (ed) *Research Handbook on the Protection of Intellectual Property under WTO Rules* (2010) 240.
[145] Berger *Tripping over Patents: AIDS, Access to Treatment and the Manufacturing of* Scarcity (2001) 202.
[146] Gallego 'Intellectual Property Rights and Competition Policy' ELECD 449 in Carlos M Correa (ed) *Research Handbook on the Protection of Intellectual Property under WTO Rules* (2010) 246.
[147] TRIPS Agreement art 31*(g)*.
[148] Ibid.
[149] Ibid.
[150] Matthews 'TRIPS flexibilities and access to medicines in developing countries: The problem with technical assistance and free trade agreements' 2005 *European Intellectual Property Review* 420.
[151] Ibid 421.
[152] Birgit Kramer *Patentschutz und Zugang zu Medikamenten* (2007) 161.
[153] Section 56(7) South Africa Patents Act.

Commissioner. This exception is provided under section 76 of the South African Patents Act. The order or judgment may allow for a compulsory licence to be issued to accept the prospect of a review.[154]

Resolutions made by member states about the remuneration payable are 'subject to judicial review or other independent review by a distinct higher authority in that member state'.[155] Given that legal systems and processes of member states will be distinct because of respective domestic patent legislation, the conditions for review are agreed under universal terms, with member states retaining discretion in application.[156]

This provision places a liability on member states to consider the health interests of their residents counter the economic obstacle to use this procedure, which consequently may adversely affect access to essential medicine.[157]

The other requirements that should be considered and satisfied are: 'the scope and duration of such use shall be limited to the purpose for which it was authorized'[158] and that the 'individual merits' of each situation determine the grant of a compulsory licence.[159] Section 56(8) of the Patents Act satisfies the first condition of whether the licence should be restricted to the purpose for which it was endorsed.[160] The Commissioner is only mandated not to grant a compulsory licence to avoid patent abuse. In addition, the use of the licence must be 'non-exclusive',[161] and 'non-assignable', disregarding the place the assignment forms 'part of the enterprise or goodwill which enjoys such use'.[162]

Lastly, in a situation where the use of a licence is discontinued, the predicament which gave rise to the use of the licence must be expected not to occur again. Consequently, if this condition is satisfied the use must be terminated.[163] The prospects of a compulsory licence being terminated will be 'subject to adequate

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[154] Ibid s 76.
[155] Article 31*(j)* TRIPS Agreement.
[156] UNCTAD-ICTSD *Resource Book on TRIPS and Development* 477.
[157] Matthews 'TRIPS flexibilities and access to medicines in developing countries: The problem with technical assistance and free trade agreements' 2005 *European Intellectual Property Review* 421.
[158] Article 31*(c)* TRIPS Agreement.
[159] Ibid art 31*(a)*.
[160] Section 56(8) South Africa Patents Act.
[161] Article 31*(d)* TRIPS Agreement.
[162] Ibid art 31*(e)*.
[163] Ibid art 31*(g)*.

protection of the legitimate interests of the persons so authorised'.[164] A compulsory licence will be significant when it is issued to a pharmaceutical entity that permits the manufacture of generic medicines' Such pharmaceutical companies will have to produce specific investments and conditions ahead of time.

As yet SA has not granted a compulsory licence.[165] One of the reasons for this may be because the process is time consuming and the cost of litigation is expensive.[166] Another reason may also be that threats of seeking compulsory licences have resulted in voluntary licences. The right to waive the use of compulsory licences in the event of a national emergency, or extreme urgency, or event of public, non-commercial use, is at the moment not explicitly provided for within SA legislation. HIV/AIDS, tuberculosis, malaria, and other epidemics, including the new virus (coronavirus), can signify a national emergency or circumstance of extreme urgency.[167] Access to medicine is obstructed by excessive prices of medicine.[168] This makes one wonder why no compulsory licence has been issued, although countless applications have been made thus far. One reason may be because applicants were unsuccessful when they had to satisfy the evidential burden and the burden of proof of section 56.[169]

2.7 Conclusion

This chapter discussed TRIPS flexibility of compulsory licensing, and further gave a lucid understanding of the relationship between the TRIPS Agreement and the Doha Declaration and the domestic policy space TRIPS gives member states to amend their patent laws, while considering their respective public health needs. It concluded that SA has not used its liberty and discretion to enforce compulsory licensing satisfactorily.

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[164] Ibid.
[165] Tenu Avafia, Jonathan Berger & Trudi Hartzenberg 'The ability of select sub-Saharan African countries to utilize TRIPS flexibilities and competition law to ensure a sustainable supply of essential medicines: A study of producing and importing countries' (2006) 22.
[166] Matthews 'TRIPS flexibilities and access to medicines in developing countries: The problem with technical assistance and free trade agreements' 2005 *European Intellectual Property Review* 421.
[167] Christopher Heath 'Parallel imports and international trade' (1997), available at https://www.wipo.int/edocs/mdocs/sme/en/atrip_gva_99/atrip_gva_99_6.pdf (accessed 1 June 2020).
[168] Michael Kremer 'Pharmaceuticals and the developing world' (2002) 16(4) *Journal of Economic Perspectives* 74.
[169] Marco Vatta 'Why is South Africa not interested in compulsory licences?' Spoor & Fisher (24 July 2020), available at https://www.spoor.com/en/News/why-is-south-africa-not-interested-in-compulsory-licences/ (accessed 23 July 2020).

Chapter 3

THE INFLUENCE OF POLICY SPACE IN THE ADVANCEMENT OF ACCESS TO MEDICINE IN SOUTH AFRICA

3.1 Introduction

This chapter discusses the domestication of TRIPS flexibilities in South Africa (SA). It begins by outlining the reform of the Medicines Act (section 3.2), then considers the Bolar exception (section 3.3) and compulsory licensing provisions (section 3.4). Section 3.5 looks at whether competition law can advance access to medicines and addresses a legal matter that involved excessive pricing by a pharmaceutical company, which was tested using the Competition Act. Section 3.6 considers the proposal to introduce substantive search and examination put forward in the National IP Policy, Phase 1.

3.2 South Africa's gradual realisation of access to medicines

The progressive realisation of the right to health in developing countries, such as SA, is a focal instrument to achieve their human rights duties; the use of TRIPS flexibilities aids in the progressive realisation of health.[1] The framework implemented in SA to make use of the flexibilities in the TRIPS Agreement contain restrictions that weaken the practicality of using compulsory licensing to make affordable medicines accessible.[2] Compulsory licensing is particularly restricted to prevent any occurrence of abuse of patent rights.[3] Compulsory licensing is mostly used for public health purposes: in occurrences, for example, where there is a shortage in the supply of a patented medicine, which is not sustained to a satisfactory extent and on reasonable terms, or in instances where the supply of the patented medicine is sustained by importation but an excessive price is charged.

In September 1997 South Africa amended its Patents Act to adapt to the TRIPS Agreement.[4] The duration

[1] Article 12 International Covenant on Economic, Social and Cultural Rights. In UNTS 999;171. New York: United Nations; 16 December 1966; art 25 Universal Declaration of Human Rights. United Nations General Assembly. Paris:United Nations; 10 December 1948.
[2] The International Association for the Protection of Intellectual Property IP Question 97: Dependent patents and their exploitation (1991), available at https://www.aippi.fr/upload/Q90-144/rs97english.pdf (accessed 5 June 2020).
[3] Laurence R Helfer & Graeme W Austin *Human Rights and Intellectual Property: Mapping the Global Interface* (2011) 58.
[4] Fix the Patent Laws 'Campaigning for pro-public health reform of South Africa's Patents Act' (26 January 2012), available at https://www.fixthepatentlaws.org/fix-the-patent-laws-campaigning-for-pro-public-health-reform-of- south-africas- patents-act/ (accessed 3 August 2020).

of patent protection was increased to 20 years and patent protection was extended to all spheres of technology including medicinal products.[5]

A pivotal point in SA relating to access to medicines occurred in November 1997 when the Medicines and Related Substances Amendment Act[6] amended the Medicines and Related Substances Act (Medicines Act).[7] The Medicines Act absorbed a number of measures to enrich the availability and commercial accessibility of medicines. This was achieved through a number of progressive amendments to the Act, which was legislated in 1965, until the present amendment in 2015. The 2003 General Regulations[8] work together with the Medicines Act to provide measures for SA to find an equilibrium between protecting patents for medicines and safeguarding access to medicines.

Section 15C of the Medicines Act confers upon the Minister of Health powers to safeguard the production of affordable medicines.[9] There is no express provision for a national or international exhaustion in the Patents Act. Section 15C allowed SA to realise international exhaustion by giving the Minister of Health the authority to order terms under which a medicine may be parallel imported into SA. Regulation 7 of the 2003 General Regulation has put the section into operation,[10] and provided guidance for its application. It has been contended that section 15C*(a)* may allow for the use of compulsory licences.[11] The General Regulations are silent as to section 15C*(a)*.[12] It would be inconsistent if section 15C*(a)* were interpreted in such a broad manner as to include the right to issue compulsory licences with reference to article 31 of the TRIPS Agreement.[13]

This section discusses how the Medicines Act enriches the availability and accessibility of medicine through measures it has put in place.One of the purposes of the Medicines Act is to accomplish medicines pricing transparency. In the past, pharmaceutical industries controlled how medicinal products were

[5] Ibid.
[6] 90 of 1997.
[7] Medicines and Related Substances Control Act 101 of 1965.
[8] General Regulations Made in Terms of the Medicines and Related Substances Act 101 of 1965.
[9] Medicines Act s 15C.
[10] Regulation 7 of the 2003 General Regulations.
[11] Eero Palmujoki 'Competing norms and norm change: Intellectual property rights and public health in the World Trade Organisation' in T Knudsen & C Navari (eds) *International Organization in the Anarchical Society* (2019) 12; and Jonathan Berger *'Health & Democracy: A Guide to Human Rights, Health Law and Policy in Post-apartheid South Africa'* (2007) 453.
[12] Birgit Kramer *Patentschutz und Zugang zu Medikamenten* (2007) 167.
[13] Birgit Kramer *Patentschutz und Zugang zu Medikamenten* (2007) 169.

ordered and distributed through the use of commercial and other rewards (bonusing), which has been barred.[14] A Pricing Committee was formed to direct the Minister of Health through the Medicines Act.[15] The Committee's duty is to guide and direct the Minister in setting up a transparent pricing method for establishing prices, in which pharmaceutical industries pay for medicine from suppliers or manufacturers. This is alternatively known as a single exit price.[16] The Committee advised the Minister of Health to publish the Regulations Number 533 concerning a Transparent Pricing System for Medicines and Scheduled Substances.[17] The Pricing Regulations were expected to come into effect on 2 May 2004.[18] The constitutionality of the Pricing Regulations was challenged, which led to the enactment being prolonged.[19]

The use of generic medicines is encouraged by section 22F of the Medicines Act, for medicines that are no longer patent protected or those manufactured under compulsory and voluntary licences. Section 22F makes use of the words 'interchangeable multi-source medicines,' ie 'medicines that contain the same active substances which are identical in strength or concentration, dosage form and route of administration and meet the same or comparable standards, which comply with the requirements for therapeutic equivalence as prescribed'.[20] These can alternatively be defined as generic medicine. Generic medicines may be used as a replacement for original patented medicines. If the relevant authorities specify that an original patented medicine cannot be replaced by a generic medicine such medicine will be non-substitutable.[21]

The amended Medicines Act introduced the use of parallel importation on condition that it is in accordance with the TRIPS flexibilities.[22] A legal framework was concluded to advance and develop the accessibility

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[14] Medicines Act s 18A.
[15] Medicines Act s 22G.
[16] Ibid.
[17] Berger *'Health & Democracy: A Guide to Human Rights, Health Law and Policy in Post-apartheid South Africa'* (2007) 454.
[18] Ibid.
[19] *Minister of Health v New Clicks South Africa (Pty) Ltd and Others* (CCT 59/2004).
[20] Medicines Act s 22F.
[21] Mor Bakhoum 'The interface between intellectual property rights and competition law: Implications for public health in sub-Saharan Africa' in Healey, Jacobs & Smith (eds) *Research Handbook on Methods and Models of Competition Law* (2020) 15; and Berger *'Health & Democracy: A Guide to Human Rights, Health Law and Policy in Post-apartheid South Africa'* (2007) 457.
[22] Clarence Sokolambe Lakpini '*An examination of South Africa's efforts at patent system reform: TRIPS flexibilities fully appropriated for public health needs?'* (LLM thesis, 2020).

of affordable medicines in SA in the Medicines Act.[23] This amended Act incorporated significant sections: generic replacements of off-patent medicines, transparent pricing of medicines, and the inclusion of parallel importation with regards to medicines that are patented.[24] The Pharmaceutical Manufacturers Association (PMA) took legal action against the South African government in February of 1998,[25]representing 37 international pharmaceutical firms.[26] The PMA's main concern was section 15C.[27] They contended that the powers it conferred on the Minister of Health were arbitrary and inconsistent with the South African Constitution and the TRIPS Agreement. In April 2001 there was international upheaval and a public relations calamity, which led the PMA to withdraw its legal action.[28]

Seemingly, in South Africa strong arm tactics were successful when applied in cutting medicine costs. This was evident in 2003, when the TAC and the Generic Anti-retroviral Procurement Project intimidated Boehringer Ingelheim. The TAC and Generic Anti-retroviral Procurement Project used section 56 of the Patents Act to take legal action to acquire a compulsory licence which would permit the civil groups to import generic Nevirapine.[29] Boehringer Ingelheim granted a voluntary licence to avoid legal action.[30]

The pivotal HIV case began the first transformation of access to medicines in SA. It showed that the use of the TRIPS flexibilities for public health needed to ensure that countries such as SA may use these provisions without the risk of either legal or political opposition.[31] Secondly, developed countries could not coerce developing countries on the premise of securing the interest of their transnational industries

[23] CPTech **'**Health Care and intellectual property: Parallel imports', available at http://www.cptech.org/ip/health/ pi/ (accessed 10 September 2020).
[24] World Health Organisation 'Globalization, TRIPS and Access to Pharmaceuticals' (March 2001) 4, available at https://apps.who.int/iris/handle/10665/66723 (accessed 11 December 2021).
[25] Mark Heywood 'Debunking "conglomo-talk": A case study of the Amicus Curiae as an instrument for advocacy, investigation and mobilisation' (2001) 5(2) *Law, Democracy & Development* 135.
[26] Ibid.
[27] Berger *'Health & Democracy: A Guide to Human Rights, Health Law and Policy in Post-apartheid South Africa'* (2007) 453.
[28] Fix the Patent Laws 'A timeline of IP reform in South Africa 1994-2015' 29 October 2015, available at https://www.fixthepatentlaws.org/a-timeline-of-intellectual-property-reform-in-south-africa-1994-2015/, (accessed 3 August 2020; and *Pharmaceutical Manufacturers Association of South Africa and Another: In re Ex Parte President of the Republic of South Africa and Others* (CCT31/99) [2000] ZACC 1.
[29] Ellen FM 't Hoen et al 'Medicine procurement and the use of flexibilities in the Agreement on Trade-Related Aspects of Intellectual Property Rights, 2001–2016' (2018) 96 *Bulletin of the World Health Organization* 11; and Berger *'Health & Democracy: A Guide to Human Rights, Health Law and Policy in Post-apartheid South Africa'* (2007) 460.
[30] Berger *'Health & Democracy: A Guide to Human Rights, Health Law and Policy in Post-apartheid South Africa'* (2007) 459.
[31] Article 31 TRIPS.

without facing the consequences domestically.[32]

3.3 Bolar exception

The exclusive rights of patent owners are provided for within the TRIPS Agreement, including its limitations. The first limitation this chapter discusses is provided in article 30 of the TRIPS Agreement, the Bolar exception. It permits the use of a patented medicine for the exclusive purpose of acquiring the approval of a generic medicine. In January 2003,[33] SA amended its Patents Act to include the Bolar exception in section 69A.[34] It provides the following:

> (1) It shall not be an act of infringement of a patent to make, use, exercise, offer to dispose of, dispose of or import the patented invention on a non-commercial scale and solely for the purposes reasonably related to the obtaining, development and submission of information required under any law that regulates the manufacture, production, distribution, use or sale of any product.
>
> (2) It shall not be permitted to possess the patented invention made, used, imported or acquired in terms of subsection (1) for any purpose other than for the obtaining, development or submission of information as contemplated in that subsection.

The Bolar exception is used to speed up the authorisation of generic medication when the lifespan of the patented medication lapses.[35] The rationale behind the exception is that, as long as a generic manufacturer is to wait for the pending lifespan of the patent to lapse prior to acquiring consent, the functioning of the patent, though necessary, will be of little significance when obtaining affordable and accessible essential medication for patients.[36]

Regulatory medicine approval is required for patented medicine to make use of the Bolar exception.[37]

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[32] Ibid.
[33] Joseph E Stiglitz et al 'Intellectual property for the twenty-first-century economy' (2017) *Project Syndicate* 4; and Berger *'Health & Democracy: A Guide to Human Rights, Health Law and Policy in Post-apartheid South Africa'* (2007) 461.
[34] South African Patents Act 56 of 1978.
[35] Rutendo Chapwanya *The Inaccessibility of Healthcare: Are South Africa's Patent Laws Aiding and Abetting Pharmaceutical Companies?* (published LLM Dissertation University of Johannesburg, 2020) 6.
[36] Ibid.
[37] Carlos Correa *The Bolar Exception: Legislative Models and Drafting Options in Contemporary Issues in Pharmaceutical Patent Law* (2017) 17.

Section 69A of the Patents Act, which allows for the Bolar exception, is consistent with the TRIPS Agreement in principle, on condition that it observes the requirements provided for in the Agreement: for the most part that the measure is 'limited' and should not 'unreasonably conflict with a normal exploitation of the patent' or 'unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties'.[38] Generic producers are given the opportunity to obtain drug regulatory approval for a generic medicine that is of the same standard as the original patented medicine during the lifespan of the innovative medicine, so that when the lifespan of the patent comes to an end, local production and trade of the generic medicine may start without delay.[39]

3.4 Compulsory licenses

In South Africa there are two occurrences where a compulsory licence may be permitted. First, a compulsory licence may be granted for a dependent patent under section 55 of the Patents Act. A dependent patent is a patent that cannot be operated without infringing any preceding patent.[40] The owner of the dependent patent will require a licence from the preceding patent owner for the dependent patent to be operative.[41] If a licensing agreement cannot be reached, the owner of the dependent patent has a right to apply to the Commissioner of Patents for a compulsory licence.[42]

The second circumstance where a compulsory licence may be granted is when a patent right is abused. Any third party who has an interest has the right to apply to the registrar for a compulsory licence, on condition that he or she can prove that the rights in the patent have been or are being abused,[43] as provided for in section 56(1). Section 56(2) provides instances where a patent right may be believed to be abused.[44] The conditions on which a compulsory licence is issued are determined by the Commissioner of Patents.[45]

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[38] TRIPS Agreement art 13.
[39] Jonathan Berger 'Tripping over patents: AIDS, access to treatment and the manufacturing of scarcity' (2001) 202; Matthew Eatough "Futures, Inc.: Fiction and intellectual property in the (South) African Renaissance' in S Deckard & S Shapiro (eds) World Literature, Neoliberalism, and the Culture of Discontent (2019) 11; and Berger 'Health & Democracy: A Guide to Human Rights, Health Law and Policy in Post-apartheid South Africa' (2007) 461.
[40] Ibid 246.
[41] Hestermeyer *Human Rights and the WTO: The Case of Patents and Access to Medicines* (2007) 248–249.
[42] South Africa Patents Act s 8.
[43] Avafia, Berger & Hartzenberg 'The ability of select sub-Saharan African countries to utilise TRIPS flexibilities and competition law to ensure a sustainable supply of essential medicines' (2006) 16; Andy Gray et al 'South Africa's National Drug Policy: 20 years and still going?' 2017 South African Health Review 11.
[44] South Africa Patents Act s 56(2)*(a)-(e)*.
[45] South Africa Patents Act s 56(4).

It is unclear whether the list of conditions is exhaustive or has identified instances only.[46] The Commissioner will retain the discretion '[i]n relation to the risks that must be supervised by the licensee, the R & D performed by the patentee and the subject matter of the invention, [to] generally consider the relevant facts, including the terms set forth in the license agreement'.[47] The Commissioner retains the discretion, in accordance with the Patents Act, to issue a compulsory licence only with the premise of evading instances of abuse that already exist.[48] Costs may be awarded against the applicant, patent owner or any third party who opposes the application.[49]

3.4.1 Judicial legal theory on compulsory licensing

In 1997 the provisions of compulsory licensing were incorporated in SA. In spite of this, no compulsory licence has been issued in the country.[50] South Africa has recorded five applications for a compulsory licence; however none has been successful. The following paragraphs will examine these cases.

In the case of *Atomic Energy Corporation of South Africa v The Du Pont Merck*[51] a dependent patent application was made. The application was met with a counterargument contending that the application be revoked because the dependent patent was invalid. The judge maintained that a dependant patent would not be recognised as a patent if it was predisposed to revocation.

In the case of *Syntheta (Pty) Ltd v Janssen Pharmaceutica NV & Another*[52] an application was made using section 56 of the Patents Act for a compulsory licence for a patent. The court, in making its judgment, deliberated on section 56 of the Patents Act, because they concluded that the abuse of patent rights was the basis of the section. The appellant needed to prove that the patented invention was not 'worked' in the country on and to the commercial scale or scope. The basic instruction that an applicant had to follow was to prepare its case in the documents submitted. However, the appellant's founding affidavit averments

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[46] Johanna Gibson *Intellectual Property, Medicine and Health* (2017) 10; and Berger *Health & Democracy: A Guide to Human Rights, Health Law and Policy in Post-apartheid South Africa'* (2007) 460.
[47] Ibid s 56(7).
[48] Ibid s 56(8).
[49] Ibid s 56(13)*(a)* & *(b)*.
[50] Christiane Fischer 'The Indian patent law and access to antiretroviral drugs in sub-Saharan Africa' (2017) in H Löfgren *The Politics of the Pharmaceutical Industry and Access to Medicines: World Pharmacy and India* (2017) 12.
[51] 1997 BIP 90 (CP).
[52] 1998 BIP 264.

were a narration of the expressions of the section instead of a statement of facts from which the court could draw legal inferences. Because of this the appeal was dismissed by the court.

In *Sanachem (Pty) Ltd v British Technology Group Plc*[53] section 56(2)*(a)* was in question. Section 56(2)*(a)* stipulates that a compulsory licence may be issued if a patented invention is not 'being worked' in the country on a commercial scale or to a sufficient extent. In the *Sanachem* case the court did not accept the applicant's argument that the respondent had not 'worked' the patented invention to a sufficient extent. The meaning of the section was being contested. The word 'work' was being contested. The court held that the word 'worked' was understood to mean 'exploited', which involved working by importation, and that the words 'sufficient extent' were understood to mean 'adequate or appropriate with the needs of the country'. The court concluded that the applicant was unsuccessful in proving that the invention could be worked in the country to a greater extent within the remaining time of the patent's term.

In *Afritra (Pty) Ltd and Another v Carlton Paper of SA (Pty) Ltd*[54] a compulsory licence was applied for, by the applicant contending that it could sell the patented product at a lower cost than the patentee. The applicant based its argument on section 56(2)*(d)* of the Patents Act. The court held that indictment of unreasonable provisions is not founded on evidence that the applicant can sell the patented product at a reduced cost. Other factors have to be considered when determining whether the patentee's prices are reasonable. Such factors include cost of production or manufacture and marketing, terms and conditions of negotiations with customers, and if the facts prove that the trade in its entirety can hold the price set. The case was dismissed.

3.4.2 The prospect of issuing a compulsory licence using section 4

A compulsory licence may be issued in terms of section 4 of the Patents Act, it has been argued, on certain occasions.[55] This is through an interpretation which some scholars believe section 4 permits. The Minister of Trade and Industry or Health, through the use of section 4 of the Patents Act, 'may use an invention for public purpose on such conditions as may be agreed upon with the patentee, or in default of agreement on such conditions as are determined by the Patent Commissioner on application by or on behalf of such

[53] 1992 BP 279 (CC).
[54] 1992 BP 331 (CC).
[55] South Africa Patents Act s 4.

Minister and after hearing the patentee'.[56] It has been contended that Ministers may use the above provision on behalf of state bodies or private bodies.[57] 'Public purpose' should be interpreted to include the issuance of a compulsory licence to safeguard public and private health to reduce medicine costs. It is the duty of the government to take reasonable steps to negotiate with the patent owner. Presently, section 4 of the Patents Act has not been used for the supply or importation of generic medicines.[58] Section 4 may be interpreted broadly because of its wording. It may be used for public and private health purposes, but this should be consistent with the conditions laid down in the TRIPS Agreement. SA's legislative framework provides several prospects for safeguarding access to a sustainable supply of affordable medicines.[59] This is because the legislative framework employed the TRIPS flexibilities to be in harmony with the Doha Declaration.[60]

A compulsory licence may not be restricted by members on any grounds that the TRIPS Agreement does not mention. However, the framework implemented by SA has loopholes regarding its consistency with the TRIPS Agreement. One of the loopholes is that there is no expressed provision of the condition to take part in negotiations with the patent owner for a voluntary licence. As a result there is an opportunity to enrich the functionality of the compulsory licensing under the Patents Act to safeguard access to affordable medicines. This may be achieved by removing restrictions for grounds on which a compulsory licence may be granted, providing reasonable and clear time frames for negotiations for voluntary and compulsory licences, and determining standards of what 'reasonable' commercial terms are when negotiating for a voluntary or compulsory licence.

3.5 Can competition law advance the need for access to medicine?

Competition law is a unique way in which access to affordable medicines can be tackled.[61] Developing

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[56] Ibid.
[57] Adriana Brigante Deorsola et al 'Intellectual property and trademark legal framework in BRICS countries: A comparative study' (2017) 49 *World Patent Information* 9 and Berger *Health & Democracy: A Guide to Human Rights, Health Law and Policy in Post-apartheid South Africa'* (2007) 451.
[58] Ellen FM 't Hoen et al 'Patent challenges in the procurement and supply of generic new essential medicines and lessons from HIV in the Southern African Development Community (SADC) region' (2018) 11 *Journal of Pharmaceutical Policy and Practice* 12.
[59] Ibid.
[60] Berger *Health & Democracy: A Guide to Human Rights, Health Law and Policy in Post-apartheid South Africa'* (2007) 451.
[61] Avafia, Berger & Hartzenberg ''The ability of select sub-Saharan African countries to utilise TRIPS flexibilities and competition law to ensure a sustainable supply of essential medicines' (2006) 29.

countries such as South Africa have a duty to take advantage of all regulatory mechanisms available to safeguard access to affordable medicines.[62] One way South Africa can achieve this is by making use of competition law. The TRIPS Agreement encourages the use of competition laws to make sure that anti-competitive systems that place limitations on the access to patented medicines are avoided.[63] With reference to article 31 of the TRIPS Agreement WTO members may waive the process of prior negotiations and use a compulsory licence if it is issued to resolve an anti-competitive system or practice. The term 'anti-competitive practice' is not defined in the TRIPS Agreement, this allows WTO members to define the term in a manner that meets the needs of its people to advance access to affordable medicine.[64]

SA has had encounters where they applied competition law and policy to safeguard a balanced production of affordable medicines. The use of competition law and policy exclusively will not be able to safeguard adequate access to medicines. The application of the TRIPS flexibilities provided for in the Doha Declaration together with the use of competition law and policy may have a positive influence on the access to medicines, however it should be known that competition law and policy should be used to balance and harmonise the TRIPS flexibilities.[65] SA's Competition Act was enacted in the year 1999. The preamble of the Act reads that 'an efficient, competitive economic environment, balancing the interests of workers, owners and consumers and focused on development, will benefit all South Africans'.[66] The preamble aims to ensure the interests of consumers are protected at all times.

The Competition Act was mandated to promote the social and economic interests of South Africans and provide consumers with competitive prices and a multiplicity of products within a market.[67] If there is a grievance or objection the Competition Act has put in place a system that handles such matters. A grievance or objection must be filed with a Competition Commission.[68] The Commission is an impartial

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[62] Frederick M Abbott *The 'Rule of Reason' and the Right to Health: Integrating Human Rights* (2003) 8.
[63] TRIPS Agreement art 31*(k)*.
[64] Berger *Tripping over Patents: AIDS, Access to Treatment and the Manufacturing of Scarcity* (2001) 202; and Emmanuel Kolawole Oke 'Is there a constitutional right to intellectual property in South Africa? Revisiting the case of In re Certification of the Constitution of the Republic of South Africa, 1996' in Shubha Ghosh (ed) *Forgotten Intellectual Property Lore* (2020) 7.
[65] Avafia, Berger & Hartzenberg 'The ability of select sub-Saharan African countries to utilise TRIPS flexibilities and competition law to ensure a sustainable supply of essential medicines' (2006) 31.
[66] Competition Act 89 of 1998.
[67] Ibid s 2.
[68] The Competition Tribunal Rules, available at https://www.compcom.co.za/the-competition-tribunal-rules/ (accessed 12 November 2020).

investigating entity.[69] The Commission has a fixed period of a year to address any grievance and objections.[70] Once the Commission has confirmed that there has been an infringement, such grievance or objection is directed to the Competition Tribunal.[71] In an event where the Commission does not direct the grievance or objection to the Competition Tribunal the party who filed the complaint has a right to direct the matter independently.[72]

The Competition Tribunal evaluates and weighs the merits of the case and makes an order.[73] The Competition Appeal Court was formed to address matters of appeal from the Competition Tribunal.[74] Further, decisions of the Competition Appeal Court may be appealed to the Constitutional Court or Supreme Court of Appeal. The Competition Act has a dedicated section with provisions that may be used in disputing anti-competitive practices and systems in the health and medicinal industry.[75]

3.5.1 Hazel Tau v GlaxoSmithKline and Boehringer Ingelheim

A class action was lodged in September 2002 against Boehringer Ingelheim (BI) and GlaxoSmithKline, (GSK) by individuals and organisations. This arose from a national battle to increase access to HIV/AIDS treatment. The cause of action was that BI and GSK were exploiting their position of retaining a dominant market. It was alleged that they did this by pricing patented antiretroviral medicines excessively. The excessive pricing of the medicine, objectively was not justified, considering external factors such as the cost of R&D, manufacture and supply, and satisfactory margin of profit.

The pharmaceutical companies' defence was that the appellants were directly at fault by their actions for the 'premature, predictable and avoidable loss of life'.[76] The Competition Commission discovered

[69] Ibid.
[70] Ibid.
[71] Ibid.
[72] Ibid.
[73] Ibid.
[74] Ibid; Berger Health & Democracy: A Guide to Human Rights, Health Law and Policy in Post-apartheid South Africa' (2007) 463; and Prasadi Wijesinghe 'Conflict between private rights and public interest in intellectual property rights law' (2018), available at SSRN 3160532 at 8.
[75] The Competition Tribunal Rules.
[76] Statement of Complaint in terms of s 49B (2)*(b)* of the Competition Act 89 of 1998 to the South African Competition Commission *Hazel Tau and others v GlaxoSmithKline and Boehringer Ingelheim* of September 2002 at 107.

evidence of infringement, which led the case to the Competition Tribunal. However, before the Tribunal could review the matter, it was decided in an out of court settlement. BI and GSK further issued a voluntary licence for the production and importation of the generic antiretroviral medicines which could additionally be sold all over Africa. This resolution led to prices for antiretroviral medicines reducing due to competition. The basis of the respondents' action was from section 49B(2)*(b)* of the Competition Act.[77] This section permits any person to 'submit a complaint against an alleged prohibited practice to the Competition Commission in the prescribed form'.[78]

The matter was brought using the Competition Act to address public health challenges faced by South Africans affected by HIV/AIDS in accessing medicines.[79] The applicants were meticulous on how they chose to direct the matter. They did not base their matter exclusively on the issue of excessive pricing, which was restricted by section 8*(a)* of the Competition Act.[80] If the respondents based their defence on excessive pricing they would have to define the relevant market together with the effect of patents on market delineation and establishing the factor of governance in the relevant market.[81] Further, the excessive pricing application would have led to an involuntary disclosure of costing paradigms. They would have to reveal why and how the price for medicinal products fixed by the respondents was rationalised and that there was no evidence of an abuse of a dominant position.[82] The applicants foresaw that the pharmaceutical companies would want to avoid such disclosure.

During its investigations, the Competition Commission found that there was an abuse of dominance by GSK and BI. They demonstrated that GSK and BI sold their patented products in South Africa at costs of 5 to 15 times above average compared to generic patented substitutes.[83] The prices of medicines were unaffordable to the vast majority of South Africans affected by the virus and patent holders had not granted

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[77] Luca Arnaudo 'Patents, intellectual property, price control and competition law in access to medicines: A concept note' (2017) 5 and Berger *Health & Democracy: A Guide to Human Rights, Health Law and Policy in Post-apartheid South Africa'* (2007) 464.
[78] Competition Act s 49B(2)*(b)*.
[79] Avafia, Berger & Hartzenberg 'The ability of select sub-Saharan African countries to utilise TRIPS flexibilities and competition law to ensure a sustainable supply of essential medicines' (2006) 36. In general at that time there were three options for patients in South Africa to receive antiretroviral treatment: by privately purchasing the required medicines from pharmacies; via a medical aid scheme ('health insurance'); or via an employer-funded workplace treatment programme for uninsured workers.
[80] Statement of Complaint *Hazel Tau and Others v GlaxoSmithKline and Boehringer Ingelheim* 17.
[81] Ibid 53.
[82] Ibid.
[83] Ibid.

licenses to generic manufacturers at a reasonable royalty. A position for which there were no valid and reasonable commercial justifications and the consequences of which were anti-competitive.[84] They had further engaged in practices of excessive pricing, refusing a competitor access to an essential resource, and of exclusionary practices which were all prohibited by the Competition Act.[85]

3.5.2 Anti-competitive activities and the patent system

There is a very complex boundary between patent law and competition law. Patents are fundamentally anti-competitive. A patent owner is given commercial domination for a limited period. The use of patent rights does not lead to 'anti-competitive activities within the scope of competition law;[86] a patent owner must abuse its patent rights for competition law to be enforced.[87] The primary cause for excessive prices of medicine is not solely because of patent protection for medicines,[88] although that the cost of R&D of original patented medicine costs more than generics.[89] For this reason it is important that SA address its patent protection for medicines to safeguard the consistent supply of medicines within its public health system.

A compulsory licensing system may be established on competition law grounds to safeguard access to essential medicines. An anti-competitive activity may be demonstrated in ruling on the quotient of remuneration believed as adequate. However, the issuance of a compulsory licence to correct an anti-competitive activity is not expressed within the South African Competition Act. Rather, section 58 of the Competition Act provides for a wide definition of 'appropriate' orders the Tribunal is permitted to give when issuing a compulsory licence.[90] The definitive authority rests on the Patents Commissioner provided for in the Patents Act. Remedying abusive pricing would be possible by issuing a compulsory licence.[91]

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[84] Ibid.
[85] The South African Competition Commission, 'Commission questions conduct of anti-retroviral companies' *Competition News: The Official Newsletter of the Competition Commission* Edition 14 (2003).
[86] Alexane Vialle 'A new referee in the intellectual property–competition law interplay?' 7; and Berger *Tripping over Patents: AIDS, Access to Treatment and the Manufacturing of Scarcity* (2001) 202.
[87] Berger *'Health & Democracy: A Guide to Human Rights, Health Law and Policy in Post-apartheid South Africa'* (2007) 462.
[88] Jennifer L Graber 'Excessive pricing of off-patent pharmaceuticals: Hatch it or ratchet' (2017) 92 *NYUL Rev* 11.
[89] Ibid.
[90] Competition Act s 58.
[91] Mostafa Bakhtiarvand & Shiva Jamali Nezhad 'Role of competition law in improving public health' (2017) 11 *Iranian Journal of Medical Law* 6; and Conde Gallego 'Intellectual Property Rights and Competition Policy ELECD449' in Carlos M Correa (ed) *Research Handbook on the Protection of Intellectual Property under WTO Rules* (2010) 258–259.

The incentive (financial investment) medicine provides is crucial when using competition law to broaden access to medicines for pharmaceutical companies to agree on granting voluntary licensing. This becomes more important when the Competition Commission has discovered evidence of anti-competitive activities. The application of competition law in this regard is new and embryonic presently.[92]

Civil society, including health advocacy groups, are vital in a country's growth in safeguarding the state's compliance with the legislative framework and its constitutional duties. This is evident in a country such as SA, where civil society practices innovative monitoring measures to improve adequate access to affordable medicines, which consequently lead to substantial results.[93] The TAC thrived in creating substantial results in SA, by revolutionising the boundary between patents and human rights.[94] The *Hazel Tau* case validated the practicality and suitability of competition law in improving access to medicines.

The WHO Guideline on Country Pharmaceutical Pricing Policies urge countries to advance and endorse the use and application of generic medicines.[95] This involves authorising immediate market entry of such medicines, using policies to reduce prices through market competition.[96] Price transparency was addressed in the new regulations. The guidelines recommend countries to further implement medicines pricing transparency measures.[97]

3.6 Proposal to introduce substantive search and examination

In 2018, the then DTI, published the National Intellectual Property Rights Policy (National IPR Policy). The development of the policy was deliberative in nature, which involved various stakeholders in its

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[92] Riccardo Sciaudone 'Book review: Jonathan DC Turner, Intellectual Property and EU Competition Law 2nd edition (Oxford University Press, 2015) 544 pp' (2017) 7 *Queen Mary Journal of Intellectual Property* 12; Berger *Health & Democracy: A Guide to Human Rights, Health Law and Policy in Post-apartheid South Africa'* (2007) 462.
[93] UN Human Rights Council, Implementation of General Assembly Resolution 60/251 of 15 March 2006 Entitled 'Human Rights Council'. Report of the Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health, Paul Hunt (UN Doc. A/HRC/4/28; 2007).
[94] Duncan Matthews 'The right to health and patents' Queen Mary University of London, School of Law, Legal Studies Research Paper No. 156/2013, (2013) 13.
[95] WHO Guideline on Country Pharmaceutical Pricing Policies (2020).
[96] Ibid.
[97] WHO 'WHO publishes pricing policy guideline to improve affordable access to medicines' (28 September 2020), available at https://www.who.int/news/item/28-09-2020-who-publishes-pricing-policy-guideline-to-improve-affordable-access-to-medicines (accessed 29 September 2020).

preparation.[98] The policy is a feature of a two-phased means to IP amelioration.[99] It provides direction on matters regarding patents and public health in the Republic.[100] In addition it considers and discusses international IP collaboration.[101] The 2018 Policy focuses on the following ameliorations: substantive search and examination, parallel importation, patent opposition, disclosure requirements, patentability criteria, voluntary licences, compulsory licences, and the nexus between IP and competition law.[102]

In SA for a patent to be awarded, the Companies and Intellectual Property Commission (CIPC) must ensure that all the formalities in the filing process are satisfied. This system is called the depository system, [103] This system poses a setback with regard to substantiation of the patentability criteria.[104] The 2018 policy proposes that the current depository system be substituted with a substantive search and examination system (SSE).[105] The policy advised that, while the depository system is cost effective,[106] the SSE system would allow for legal security for the public and patent owners.[107] The SSE system will safeguard a patent through the patent examination process whereby patents will be accepted on condition that they satisfy the patentability criteria. In so doing it will prevent monopolies by medicines that do not satisfy the criteria.[108]

The SSE system has presented uncertainty on how the phased approach will materialise.[109] This approach has attracted criticism, because it was argued that the health sector would seek to restrict the patent examination to medicinal patent applications, which would be prejudicial towards the pharmaceutical industry. Moreover, it was argued that this would infringe article 27(1) of the TRIPS Agreement, which

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[98] Department of Trade, Industry and Competition 'IP Policy of the Republic of South Africa Phase I' (2018) (DTIC IP Policy), available at https://www.thedti.gov.za/news2018/IP_Policy2018-Phase_I.pdf (accessed 3 August 2020).
[99] Companies and IP Commission 'Submission by South Africa: Exceptions and limitations' WIPO (9 October 2017), available at https://www.wipo.int/export/sites/www/scp/en/meetings/session_27/3rdparty_comments/south_africa.pdf (accessed 10 August 2020).
[100] DTIC IP Policy.
[101] Ibid.
[102] Ibid.
[103] Patents Act of South Africa ss 34–36.
[104] Robyn-Leigh Merry 'The intention to become a substantive search and examination office' (16 October 2017), available at https://www.dennemeyer.com/ip-blog/news/the-intention-to-become-a-substantive-search-and-examination-office/ (accessed 5 August 2020).
[105] DTIC IP Policy 17.
[106] Ibid 3.
[107] Ibid 17.
[108] Ibid 18.
[109] The Anton Mostert Chair of IP Law 'Commentary on the draft IP policy of the Republic of South Africa Phase 1 2017' (8 November 2017), available at https://blogs.sun.ac.za/iplaw/2017/11/08/commentary-draft-intellectual-property-policy-phase-1-2017/ (accessed 7 August 2020).

allows for patents in all areas of technology.[110] Fortunately, the 2018 policy foresaw such criticisms. The then DTI stated in their defence that this limitation will not infringe the TRIPS Agreement for the following reasons:

1) Article 27(1) allows for patents of all areas of technology in three respects, namely

   'the place of invention, the field of technology and whether products are imported or locally produced and only in relation to the availability and 'patent rights enjoyable'. Therefore, that provision could not be the basis for a successful complaint where the examination of the examination of patent applications within the sovereign territory of South Africa is a key component of an evolved IP ecosystem.'[111]
2) The envisioned plan of the government is that the SSE system will eventually be used in other fields of technology, taking into consideration the proportionate growth in its capacity.[112]
3) Competent, trained patent examiners have been assigned by the CIPC to examine patent applications to ensure that all formalities are adhered to.[113]

The phased approach of the SSE system adopted by SA is encouraged by WIPO, which is conscious of the intricacy involved in establishing a SSE system.[114] WIPO states that—

> 'patent search and examination work heavily depends on skills and competencies of each examiner, which can be developed mostly through his/her experiences. Therefore, gradually enlarging the scope and extent of patent search and examination is an option for patent offices, particularly those that have limited experience in this area'.[115]

3.7 Conclusion

The Medicines Act and the Patents Act attempt to achieve an equilibrium by offering definite measures for the state to implement, with the purpose of developing and enriching access to medicines, using the Bolar exception and compulsory licensing, amongst other flexibilities. As shown above, SA has employed TRIPS flexibilities consistent with the Doha Declaration in domestic legislation, although there are limitations in these laws. It has been argued that Competition law could be further used to improve access to medicine. Finally, proposed reforms such as introducing SSE would also improve the situation.

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[110] Ibid 10.
[111] DTIC IP Policy 17.
[112] DTIC IP Policy 19.
[113] Ibid.
[114] WIPO 'Alternatives in patent search and examination: Policy guide' (2014), available at https://www.wipo.int/edocs/pubdocs/en/wipo_pub_guide_patentsearch.pdf (accessed 7 August 2020).
[115] Ibid 3.

Chapter 4

COUNTRY STUDY: LESSONS SOUTH AFRICA CAN LEARN FROM INDIA

4.1 Introduction

The objective of including India as a country study in this chapter is to explore and assess if India has acted in accordance with the TRIPS Agreement to realise a balance between access to medicines and patent protection. This chapter looks at the ways in which South Africa (SA) can draw lessons from india's experiences. This chapter examines India's use of TRIPS flexibilities within its patent standards. This is achieved by looking at the measures India has applied to its domestic patent system and further looking at the *Bayer v Natco*[1] case, which established the groundwork in India for transformation. This was established through India's analysis of their judicial regime to incorporate the TRIPS flexibilities into their domestic patent laws, which is discussed further in this chapter.

4.1.1 India: Pharmacy of the developing world

India is a fascinating and striking country study. This is because it took advantage of medicinal products in the absence of a patent system, leading to its robust generic medicinal production for national and export purposes. India is a WTO member.[2] It is among the primary and significant manufacturers and exporters of generic medicines. India, like most other countries, has attempted to take advantage of the TRIPS flexibilities. This is evident through its incorporation of section 3d in its Patents Act.[3] Section 3d provides for instances where evergreening should be avoided.

India is a developing country. The status quo in India relating to medicinal products and its patent system is of intercontinental significance. India has become known as an international source of affordable medicines.[4] The country has a few reputable medicinal corporations: Ranbaxy Laboratories, Cipla, and Dr. Reddy's Laboratories. These corporations are among many groups that are emerging with essential R&D capacity. One of the purposes of India's Patents Act of 1970 (the 1970 Act) was to control the effect

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[1] *Natco v Bayer* OA/35/2012/PT/MUM; *Bayer v Union of India*, W.P. Number 1323 of 2013, available at http://164.100.79.154/index.html, (accessed 20 February 2021).
[2] India and WTO, available at https://www.wto.org/english/thewto_e/countries_e/india_e.htm (accessed 15 February2021).
[3] The Indian Patents Act 37 of 1970.
[4] Radhika Bhattacharya 'Are developing countries going too far on TRIPS? A closer look at the new laws in India' (2008) 34 *American Journal of Law & Medicine* 395–421 396; Chaudhuri *The WTO and India's Pharmaceuticals Industry* 223.

of foreign businesses together with foreign-owned patents.[5] The 1970 Act developed the accessibility of compulsory licensing.[6] With that goal in mind, India at the time did not sign any IP conventions, with its desire to increase self-sufficiency.[7] The 1970 Act triggered a substantial surge and development in its national manufacture of generic medicines.[8] This resulted in a drop in medicine prices.[9] The definition of 'inventive step' in India is distinct. This is because it outlines stringent conditions as compared to other countries.[10] One of the conditions is that it demands that an invention include a 'technical advance' or 'economic significance' and on some occasions both. This requirement will be satisfied when the invention is not obvious to a skilled person in the specific art.[11]

Section 3*(d)* of the 1970 Act introduced the idea of 'efficacy' with regards to secondary patents. This section has been a contentious section[12] and the 2005 Patents Amendment Act amended section 3*(d)* to address these issues. The test of discovery from an invention was introduced in this section.[13] It confirmed the crossing point in India between patents and access to medicines, by highlighting frivolous patents and evergreening.[14] Variations of old amalgamations are not entirely prohibited in India from patentability, on condition that they prove 'efficacy' and that it has been improved extensively.[15]

4.1.2 India and South Africa's affinity

India has been called the 'pharmacy of the developing world and the 'pharmacy of the poor'.[16] India had

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[5] Janice M Mueller 'The tiger awakens: The tumultuous transformation of India's patent system and the rise of Indian pharmaceutical innovation' (2007) 68(3) *University of Pittsburgh Law Review* 505.
[6] Ibid 510.
[7] Ibid 512.
[8] Brenda Pamela Mey 'Unfettered consumer access to affordable therapies in the post-TRIPS era: A dead-end journey for patients? Kenya and India case studies' (2010) 13(3) *The Journal of World Intellectual Property* 411.
[9] Ibid.
[10] Cynthia Ho *Access to Medicine in the Global Economy* (2011) 97; Amy KapczynskI 'Harmonisation and its discontents: A case study of TRIPS implementation in India's pharmaceutical sector' 1593; The Patent Office India *The 2011 Manual of Patent Office Practice and Procedure* (The Office of Controller General of Patents, Designs & Trademarks) 8.
[11] Ibid.
[12] Mueller 'The tiger awakens: The tumultuous transformation of India's patent system and the rise of Indian pharmaceutical innovation' (2007) 68(3) *University of Pittsburgh Law Review* 550.
[13] The Patent Office India *The 2011 Manual of Patent Office Practice and Procedure*.
[14] Mey 'Unfettered consumer access to affordable therapies in the post-TRIPS era: A dead-end journey for patients? Kenya and India case studies' (2010) 13(3) *The Journal of World Intellectual Property* 440.
[15] Duncan Matthews *The Right to Health and Patents*, *Research Handbook on Human Rights and Intellectual Property* 7.
[16] WIPO & Bhaven Sampat 'Institutional innovation or institutional imitation? The impacts of TRIPS on India's patent law and practice' (2010) 13 *WIPO Seminar Series on The Economics of Intellectual Property* 4.

to transition from its Patents and Designs Act,[17] to its Patents Act[18] in keeping with obligations under the TRIPS Agreement.[19] The shared commonality between SA and India is their particularly soaring revenue and the inequality of take-home pay. Ten per cent of India's residents controlled 77 per cent of India's wealth in 2018.[20] Similarly, 1 per cent of South Africa's residents possessed 70.9 per cent of the country's wealth.[21]

When the generic trading floor thrives the availability of affordable alternatives to original patented medicines enrich both manufacture for the community market and exportation to foreign countries such as SA, Uganda, and Rwanda.[22] Many of these foreign countries lack the ability and legal framework to be able to develop the manufacture of alternative medicines.[23] India has on the face of it been able to ensure that appropriate and necessary provisions are provided for, to serve the health of its residents without encroaching upon the TRIPS Agreement.[24] Currently, SA is on the same course of action.

4.2 India's historical groundwork towards access to medicines

The heart of this chapter is a preview of the historical groundwork of India's patent system. Before the TRIPS Agreement came into force, access to medicines was easy under the Indian patent system.[25] In 1856 the first legislation that dealt with patents was enacted – Act VI of 1846. This Act conferred exclusive rights to inventors of new inventions for a fixed period of 14 years.[26] An intriguing feature of the Act was the meaning of the word 'inventor'. The definition covered not only the genuine inventor or creator of the

[17] Act II of 1911.
[18] Ibid.
[19] S*ee* National Cancer Institute 'NCI dictionary of cancer terms' available at https://www.cancer.gov/publications/dictionaries/cancer-terms/def/biosimilar-drug (accessed via Brook K Baker); 'International collaboration on ip/access to medicines: Birth of South Africa's Fix the Patent Law Campaign' (2015) 60 *NYL Sch. L. Rev* 297.
[20] Oxfam International 'India: Extreme inequality in numbers', available at https://www.oxfam.org/en/india-extreme-inequality-numbers (accessed 20 January 2021).
[21] Nico Gous 'SA most unequal country in world: Poverty shows apartheid's enduring legacy' (4 April 2018), available at https://www.timeslive.co.za/news/south-africa/2018-04-04-poverty-shows-how-apartheid-legacy-endures-in-south-africa/ (accessed 20 January 2021).
[22] Jodie Liu 'Compulsory licensing and anti-evergreening: Interpreting the TRIPS flexibilities in sections 84 and 3(d) of the Indian Patents Act' (2015) 56 *Harv. Int'l LJ* 207.
[23] Ibid 211.
[24] Jae Sundaram 'India's trade-related aspects of intellectual property rights compliant pharmaceutical patent laws: What lessons for India and other developing countries?' (2014) 23(1) *Information & Communications Technology Law* 12.
[25] Ibid 2.
[26] P Narayanan *Patent Law* 4 2013) 6.

original patented product, but included a rightholder who carries or imports an invention into India.[27] Such a rightholder had the exclusive right to approve the manufacture, and a monopoly or use of the invention for the fixed lifespan of 14 years from the minute the specification file was approved.[28] Act V of 1859 amended the Act. The amended Act was established on the principles of the English Patents Act of 1852. Act V of 1859 moved away from the definition of 'inventor' that Act VI of 1856 provided for. Since section XVII of Act V of 1859 explicitly stipulated that an importer of a patented invention 'shall not be deemed to be an inventor',[29] the only way an importer could attain exclusive rights was through proper application from the 'inventor'.

The protection of industrial designs was enacted in the 1872 Patents and Designs Protection Act. The protection of inventions was on its own governed by the Protection of Inventions Act, which was enacted in 1883. In 1888 the two Acts were amalgamated. The Indian Patent and Designs Act was enacted by the British Government in 1911. This formed a regime of patent management and processing in India under the governance of the Controller of Patents.[30] The Patent and Designs Act of 1911 firmly expressed what inventions were patentable and had the effect of excluding local companies due to the high application costs.[31] The Patents and Designs Act of 1911 was still in force and it was the primary Act governing patents in 1947, which was the year of India's independence.[32]

An examination of medicinal patents reveals that foreign companies retained most of the medicinal products.[33] India's domestic pharmaceutical industry expressed their frustration at the circumstances. They appealed for a patent system that would stimulate and advocate industrial growth and advancement in India.[34] The Indian government listened to their complaints: it established two committees which

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[27] Rajesh Sagar 'Introduction of exclusive privileges/patents in colonial India: Why and for whose benefit?' (2007) 2 *Intellectual Property Quarterly 6* at 11.
[28] Narayanan *Patent Law* (2013).
[29] Sagar 'Introduction of exclusive privileges/patents in colonial India: Why and for whose benefit?' (2007) 2 *Intellectual Property Quarterly 6* at 12.
[30] VK Unni 'Indian patent law and TRIPS: Redrawing the flexibility framework in the context of public policy and health' (2012) 25 *Pac. McGeorge Global Bus. & Dev. L.J.* 323 (2012).
[31] Sagar 'Introduction of exclusive privileges/patents in colonial India: Why and for whose benefit?' (2007) 2 *Intellectual Property Quarterly 6* at 8.
[32] Act II of 1911.
[33] WIPO & Sampat 'Institutional innovation or institutional imitation? The impacts of TRIPS on India's patent law and practice' (2010) 13 *WIPO Seminar Series on The Economics of Intellectual Property* 3.
[34] MZM Nomani et al 'Legal & intellectual property dimension of health & access to medicines in India' (2020) 14 *Indian Journal of Forensic Medicine & Toxicology* 6; and Jae Sundaram *Pharmaceutical Patent Protection and World Trade Law:*

significantly influenced India's patent transformation.[35]

A Patent Enquiry Committee was one of the two committees that was established in 1948. The committee was responsible for appraising the Patents and Designs Act of 1911.[36] The Patent Enquiry Committee 'put forward, a report proposing strings of modifications, which involved the establishment of compulsory licensing, and the conception of a steady and committed legal structure to contend with the abuse of patents.'[37]

The Ayyangar Committee was the second committee. The committee released a report in 1959,[38] which shaped the heart of the Indian Patents Act.[39] An estimate of 80 to 90 per cent of issued patents endowed to foreign companies did not benefit India's economy at all.[40] The committee further reported that these companies did not intend to start production within India.[41] These patents gave foreign companies domination of the market, and through expansion they prevented their direct competitors from other countries from exporting their patented products to India.[42]

As a result, Indians had to pay high prices for patented products from patent rightholders. They were further prevented from procuring affordable alternatives because of patent monopolies.[43] Proposals were brought forward by the committee. It was to India's advantage to mould a patent system that endorsed and advocated for 'access to resources at lower prices'.[44] There was either a diminutive or entirely no domestic manufacturing capacity for medicine production, and a controlled health care system was absent.[45] These facts indicate that India was underprovided with regards to making affordable medicines available to its residents, apart from the small minority of wealthy people.[46] During that period a shocking 80 per cent of

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The Unresolved Problem of Access to Medicines (2018) 3, available at https://doi.org/10.4324/9781315267692 (accessed 3 August 2020).
[35] Ibid.
[36] Ibid.
[37] Ibid.
[38] Ibid 4.
[39] 37 of 1970.
[40] Anita Ramanna 'Interest groups and patent reform in India' (2003) Indira Gandhi Institute ofDevelopment Research, Working Paper, Mumbai, India 3.
[41] Ibid.
[42] Shamnad Basheer 'Policy style reasoning at the Indian Patent Office' (2005) 3 *Intellectual Property Quarterly* 8.
[43] Ibid.
[44] Ibid 11.
[45] Ibid.
[46] Ibid 12.

medicinal companies in India were owned by foreign conglomerate companies who retained a great number of medicinal patents.[47] All of these circumstances led to the Indian Patents Act of 1970 being enacted and enforced on 20 April 1972.[48] Its objective was to 'improve the Indian economic growth by means of local technology development, [which] was to bring about the rewards of technological innovations to be accessible for public purposes'.[49] The Act allowed for medicinal process patents, which are distinct from patented products themselves.[50] The patent lifespan was shortened from 16 years to 14 years within the patents broad-spectrum, and seven years for medicinal patents.[51] These changes strived to carry India's medicine production to the frontline. This was done by supporting domestic trade and regulating the potency of patents by developing compulsory licences and incorporating an allowance for research.[52]

When the TRIPS Agreement was enforced major underlying forces changed.[53] India's government used the transitioning period as a tactic and delayed modifying its domestic legislation until 2005 to conform its Patents Act to the TRIPS Agreement.[54] A 'mailbox' system was set up in India.[55] The system was responsible for patent submissions and requests that were filed for inspection in accordance with article 70(8)*(a)* of the TRIPS Agreement, while waiting for the amendment to the Act.[56] The mailbox system was put into action when the Patents (Amendment) Act of 1999 was enacted.[57] In 2002 an additional amendment was made to India's patent legislation, which further aligned it with the TRIPS Agreement.[58] This amendment led to a 20-year lifespan for patents in India, the process of patent infringement burden of proof being invalidated, and to revised compulsory licensing requirements.[59] India's Patents Act was

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[47] Ibid.
[48] The Indian Patents Act 37 of 1970.
[49] Sundaram *Pharmaceutical Patent Protection and World Trade Law: The Unresolved Problem of Access to Medicines* (2018) 5.
[50] Ibid.
[51] Liu 'Compulsory licensing and anti-evergreening: Interpreting the TRIPS Flexibilities in Sections 84 and 3(d) of the Indian Patents Act' (2015) 56(1) *Harv. Int'l LJ* 211.
[52] Ibid.
[53] WIPO & Sampat 'Institutional innovation or institutional imitation? The impacts of TRIPS on India's patent law and practice' (2010) 13 *WIPO Seminar Series on The Economics of Intellectual Property* 3.
[54] Ibid 9.
[55] Niloufer Sohrabji & Kaitlyn Maloney 'Section 3(d) and pharmaceutical patents in India' (2020) 25(3–4) *JIPR* 7.
[56] Jagdish Wamanrao Khobragade 'Interface between human rights and intellectual property rights with special reference to patent regime and right to health in India' (2020) 7; and Sundaram *Pharmaceutical Patent Protection and World Trade Law: The Unresolved Problem of Access to Medicines* (2018) 10.
[57] The Patents (Amendment) Act 17 of 1999, India.
[58] The Patents (Amendment) Act 17 of 2002, India.
[59] Sundaram *Pharmaceutical Patent Protection and World Trade Law: The Unresolved Problem of Access to Medicines* (2018) 11.

reformed to mirror the minimum standards of the TRIPS Agreement in March 2005.[60] The amendments allowed India to freely grant patents for inventions in all spheres of technology,[61] including the pharmaceutical industry.[62]

Despite India's efforts to align its patent system with the TRIPS Agreement, international pharmaceutical industries in the EU and the USA contested India's patent laws, but India continued to provide compulsory licences and it narrowly define 'new chemical entities'[63] to limit evergreening.

India is proof that being a member of WTO should not prevent member states from strengthening and developing a patent system that serves its communal health demands.[64] A balanced and effective patent regime requires compliance with the TRIPS Agreement, while not being exaggeratedly protected.[65] There has been a mistaken belief over the years that robust patent protection indicates conformity and fulfilment of the TRIPS Agreement,[66] whilst the better view is that TRIPS obligations and flexibilities are sound means to acquire the fruits of the post-TRIPS system.[67]

4.3 *Bayer v Natco*: The court's interpretation of section 84 of the Patents Act in India[68]

This section looks at India's judicial system. It looks at the extent to which India made use of the TRIPS flexibilities, which they incorporated into their domestic Patents Act. The case of *Bayer v Natco* will be discussed from the perspective of the flexibilities that have been implemented. In India, *Bayer v Natco* has been the only case that has been successful in its use of a compulsory licence.

The limits of a compulsory licence under the 1970 Act were maintained in the 2005 Amendment Act when

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[60] Ibid.
[61] K Jafar & P Sajna 'Access to medicines and performance of the Indian pharmaceutical industry: Examining India's experience in the new patent regime' (2018) 20(4) *Journal of Health Management* 4.
[62] The Patents (Amendment) Act 15 of 2005, India.
[63] George T Haley & CV Haley 'India: A study in patent-law effects' in *The Global Challenge of Intellectual Property Rights* (2009) 100.
[64] Liu 'Compulsory licensing and anti-evergreening: Interpreting the TRIPS flexibilities in sections 84 and 3*(d)*of the Indian Patents Act' (2015) 56(1) *Harvard International Law Journal* 208.
[65] WIPO & Sampat 'Institutional innovation or institutional imitation? The impacts of TRIPS on India's patent law and practice' (2010) 13 *WIPO Seminar Series on The Economics of Intellectual Property* 5.
[66] Ibid 3.
[67] Ibid.
[68] Indian Patents Act of 2005; *Bayer Corporation v Natco Pharma Ltd*., Order No. 45/2013 (Intellectual Property Appellate Board, Chennai), available at http://www.ipab.tn.nic.in/045-2013.htm (accessed 27 February 2021).

a grant was requested.[69] Section 84 of the Act governs compulsory licences. The Act provides an opportunity for an applicant to apply three years after the issuance of a patent. The applicant may get a compulsory licence on stringent conditions, which include the unavailability of 'the patented invention …to the public at a reasonable price…'.[70]

A compulsory licence was granted to Natco, which Bayer was not in favour of. The Intellectual Property Appellate Board (IPAB) was summoned to look carefully at the requested grant using section 84 of the Patents Act as a yardstick to interpret the compulsory licence issued.[71] The Officer of Patents issued a compulsory licence in favour of Natco. The officer granted the application, firstly because it was in the public's interest that the application be granted, and secondly because the application had satisfied the three basic conditions provided for in Section 84.[72] A petition was filed in the High Court against the compulsory licence that was granted by the Officer of Patents under Section 84 of the Indian Patents Act (1970).[73]

The medication that was being requested was called *Sorafenib Tosylate*. The medicine was used for the treatment of kidney and liver cancer.[74] The patented medication was issued to the applicant in 2008. The medication was sold and promoted using the name *Nexavar*.[75] The applicant, Bayer, questioned the approach in which section 84 of the Act was employed.[76]

The *Bayer v Natco* case was the first application that requested a compulsory licence to be granted in India after it became a signatory to the TRIPS Agreement and revised its domestic legislation in the years 2003 and 2005.[77] A voluntary licence application was requested to produce and market the patented medicine from the applicant, on the grounds that the patented medicine 'had not met the reasonable requirement of

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[69] Edward Halle 'Access to essential medicine as part of the right to health in Africa: Access to essential medicine under international human rights law, the case of Kenya and South Africa' (2017) 11 *Asia Pacific J. Health L. & Ethics* 9; and Sundaram *Pharmaceutical Patent Protection and World Trade Law: The Unresolved Problem of Access to Medicines* (2018) 13.
[70] Indian Patents Act of 2005 s 84(1).
[71] *Bayer Corporation v Natco Pharma Ltd* supra.
[72] Ibid.
[73] Ibid.
[74] PH Kurian 'The compulsory licence application from M/S Natco Pharma Ltd' (2011) and Vipin Mathur 'Patenting of pharmaceuticals: An Indian perspective' (2012) 4 *Int J Drug Dev Res* 4.
[75] Ibid.
[76] Ibid.
[77] Ibid.

the public nor was it reasonably priced nor was it worked in the territory of India'.[78] The application was rejected by the supplicant on 27 December 2010.[79] The respondent decided to apply for a compulsory licence when it was evident that the voluntary licence was denied and no concessions would be concluded.[80] The High Court dismissed the application following careful interpretation of the application and section 84. The High Court dismissed the application primarily because all the requirements for the issuance of a compulsory licence were met.[81] The supplicant further filed a Special Leave Application to the Supreme Court, opposed to the High Court's judgment, which was dismissed.[82]

4.4 Lessons South Africa can learn from India

India's generic market is significantly wider, compared to South Africa's market. This, however, is not something that should hold back SA. This presents SA with a gateway to develop its prospects and grow to be the biggest and fastest exporter of medicines on the African continent, while competing with other foreign developing countries that cannot manufacture their own patented medicine. The South African government is working towards realising a manufacturing capacity market. This strategy is evident through SA's IP policy, which provides a framework of its objective to expand the local capacity of its medicinal industry to meet the demands of its residents and develop the export market.[83]

India is a useful and admirable example of how a country may elect to make use of a compulsory licence system 'to best promote short-term access to medicine in a manner consistent with TRIPS'.[84] Compulsory licensing is one of the key components of a 'middle path between extreme patent protectionism and patent abolitionism'.[85]

For pharmaceutical companies, balancing manufacturing costs, profitability, and drug availability to

[78] Ibid 6.
[79] Ibid.
[80] Ibid 7.
[81] Mathur 'Patenting of pharmaceuticals: An Indian perspective' (2012) 4 *Int J Drug Dev Res* 52.
[82] *Natco v Bayer* OA/35/2012/PT/MUM; *Bayer v Union of India*, W.P. Number 1323 of 2013, available at http://164.100.79.154/index.html (accessed 27 February 2021).
[83] DTIC IP Policy 15.
[84] Ho *Access to Medicine in the Global Economy: International Agreements on Patents and Related Rights* (2011) 141.
[85] Patralekha Chatterjee 'India's first compulsory licence upheld, but legal fights likely to continue' *Intellectual Property Watch* (4 March 2013), available at: http://www.ip-watch.org/2013/03/04/indias-first-compulsory-licence- upheld-but-legal-fights-likely-to-continue/ (accessed 10 March 2021).

consumers is a sensitive issue, and there is a natural temptation to ignore economics to maximise profits.[86] Large pharmaceutical companies are often criticised for not doing enough to ensure the availability and affordability of essential medicines, especially in poor and developing countries.[87] These criticisms are gradually producing positive results. Several pharmaceutical companies, such as GlaxoSmithKline and Johnson and Johnson, are stepping up initiatives to make medicines more affordable and accessible in less affluent markets.[88] These efforts are reflected in the Access to Medicine Index published in 2012 by the Foundation for Access to Medicine. Initiatives for pharmaceutical manufacturers include a variety of activities, including differentiation and price reduction, technology transfer under licene agreements, and donations.[89] Secondly a Centralized Manufacturing Authorization System is key in advancing access to medicine. The state has no power to stop out-of-state production of substandard drugs. It is necessary to change the regulatory structure to promote better cooperation and coordination.[90]

A comprehensive reform policy should include a systematic selection of essential medicines to improve availability, centralised procurement and tendering at the local level, price control policies, and stricter quality and safety standards. Effective use of TRIPS flexibility to advocate for public health depends on three factors.[91] The political will to:

1) integrate TRIPS flexibility into domestic law,
2) increase the country's production capacity, and
3) use the public interest guarantees provided by domestic law, which have a key role in regulating expensive patented drugs and health needs.

In theory, increased patent and data lifespan or market exclusivity can increase profits, and, if properly reinvested in R&D, can lead to innovation. However, there is no evidence that innovation thrives when exclusivity conditions are extended.[92] One of the main challenges is ensuring that patent protection for

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[86] WIPO & Bhaven Sampat 'Institutional innovation or institutional imitation? The impacts of TRIPS on India's patent law and practice' (2010) 13 *WIPO Seminar Series on The Economics of Intellectual Property* 4.
[87] Ibid 5.
[88] Christiane Fischer 'The Indian patent law and access to antiretroviral drugs in sub-Saharan Africa' in H Löfgren *The Politics of the Pharmaceutical Industry and Access to Medicines: World Pharmacy and India* (2017) 10.
[89] Ibid 12.
[90] Ibid 14.
[91] Ibid 14.
[92] Nomani et al 'Legal & intellectual property dimension of health & access to medicines in India' (2020) 14 *Indian Journal of Forensic Medicine & Toxicology* 14.

pharmaceuticals creates incentives for R&D and does not impede patient access in developing countries. Accelerating generic medicines is an important strategy to increase access to medicines.[93] For example, strengthening the patent system could have a direct impact on knowledge-intensive sectors such as pharmaceuticals. Research shows that the former (process) patent system has helped the Indian pharmaceutical industry achieve sustainable growth. It has become a 'pharmacy of the southern hemisphere'[94] by supplying essential medicines at low prices to domestic and overseas markets.[95] Thus, India's experience of reintroducing product patent protection in 2005 provides a new perspective on the development impact of intellectual property rights.

4.5 Conclusion

India has drawn heavy criticism and pressure from foreign countries in its pursuit of providing accessible and affordable medicine for its people. Nonetheless, it has endured and remained resilient in its resolutions. India's fortitude and vision in upholding the needs of its people has facilitated in making available medicine in reasonable prices that reflect the status quo of the economic situation of its people. Because of this it has afforded itself and retained its title as the 'pharmacy of the developing world'. India's regime offers SA a model and positive proof of how it can exploit the patent system for the interest of its residents too.

[93] Ibid 15.
[94] Ibid 15.
[95] Ibid.

Chapter 5

CONCLUSION

5.1 Summary

This dissertation made use of doctrinal legal research methodology in its findings and application. The essential question that this dissertation sought to find out was: 'To what extent has South Africa implemented the TRIPS flexibilities particularly with reference to compulsory licensing to ensure that access to medicines is safeguarded?' The dissertation focused on addressing the flexibility of compulsory licensing. This is the reason that most of the dissertation discusses compulsory licensing. As a result the other flexibilities were not discussed in depth.

The following sub-questions were asked and are answered in summary:

1) What is the effect of the TRIPS' flexibility of compulsory licensing in relation to the patenting of pharmaceuticals?

The TRIPS Agreement provides for flexibilities including compulsory licensing in article 31 of the Agreement. Compulsory licensing can be an effective means for developing countries to use in safeguarding access to medicines and patented medicinal products. Pharmaceutical companies have the option of issuing a third party a voluntary licence to manufacture and use a patented product. However, in a situation where a pharmaceutical company refuses to issue a voluntary licence, a compulsory licence may be issued. Merely the threat of a compulsory licence can also be effective in facilitating access to medicines, to increase generic manufacture, importation and local trading, and to curb medicine costs.

An advantage that member states have is that the TRIPS Agreement gives them the right to decide the appropriate and reasonable grounds of when a compulsory licence may be granted to facilitate access to medicines in respective countries. Compulsory licensing will only be operative and promote generic medicinal monopoly if the process of obtaining a compulsory licence is straightforward and undemanding. In addition, the mandatory royalty fees must be reasonable to ensure that generic medicinal manufacture remains commercially feasible and sustainable. The Doha Declaration contains various administrative requirements, which may delay and impede the primary purpose motivating its

use. As a result, access to medicine is provided through the use of compulsory licence in theory; however, the TRIPS Agreement has numerous conditions, including but not limited to article 31*bis,* which are complicated, difficult to carry out, and process, together with the fear of potential trade sanctions. These problems may be the reason why few developing countries such as South Africa have chosen to make use of compulsory licensing when ensuring access to medicine is achieved; together with local generic manufacture, importation, and local monopoly of medicine to control medicine prices. The significance and usefulness of compulsory licensing rests on the threat of its use rather than its actual use.

2) Does the right to access medicines conflict with the drug patent standards required by the TRIPS Agreement within the framework of South Africa?

Article 31 sets out in detail the principles and directives to be respected where a member country allows for the use of a patent without the authority of the patent owner, including use by the government or third parties authorised by the government. The framework set out in article 31 is viewed as a fair and workable mechanism inasmuch as a number of checks and balances have been provided for, such as that:

a) use by third parties must be considered on individual merit;
b) efforts must first be made to obtain authorisation from the patentee on reasonable commercial terms;
c) the authorised use will be to supply predominantly the domestic market:
d) adequate remuneration is to be paid to the patentee; and
e) the legal validity of the decision must be subject to judicial review.

The framework contemplated in article 31 is generally accepted to be embodied in a system of compulsory licences, as provided for in section 56 of the Patents Act 1978. The South African Patents Act already contains provisions in section 56 for the granting of compulsory licences in circumstances where patent rights are abused. These provisions provide a useful framework for a mechanism which could have been used to achieve the curtailment of patent rights as apparently envisaged by section 15e*(a)*. The compulsory licence mechanism of section 56 generally conforms with the provisions of article 31 of TRIPS, where the requirements for use of a patent without the authority of the right holder,

including use by government or third parties authorised by government, are set out.

3) How does pricing of medicine affect access to medicines?

Access to health care is a fundamental human right, enshrined in international treaties and recognised by governments throughout the world. However, without equitable access to essential medicines, national policies, medicine pricing and procurement strategies are required to ensure that medicines are affordable. While policies are also greatly needed to improve health infrastructure and financing and to ensure the rational use of medicines, high medicine prices are one of the biggest obstacles to access. Nevertheless, even in the face of a weak infrastructure and poverty, improvements in access can be achieved. Any new pricing policies for medicines must aim to achieve equitable pricing if they are to have real impact on the lives of patients. No single strategy will be sufficient to achieve and sustain equity pricing. Rather, what is needed is a comprehensive system of mutually supportive strategies. These strategies are:

a) encouraging generic competition
b) using differential pricing of drugs
c) adopting TRIPS safeguards in national legislation
d) creating high volume/high demand through global/regional procurement; and
e) encouraging local production through voluntary licensing and technology transfer.

4) To what extent does the TRIPS flexibility of compulsory licensing attend to the issue of access to medicines in the public health sector?

A compulsory licence can be issued by a government to a manufacturer of generic products, allowing them to produce copies without consent of the patent owner. The original TRIPS Agreement imposed conditions on the use of compulsory licences to avoid undermining the whole system. The precise scope allowed by these conditions has been the subject of many debates. For access to medicines the most important condition was that the production of copies should predominantly be for use in the country whose government issued the licence. The power of compulsory licences is most obvious when governments use them effectively. However, compulsory licences also have power when governments warn patent owners that they will use them if necessary. Thus threatening to use a compulsory licence may be as effective as formally issuing one The Doha declaration solution is

cumbersome to apply effectively, but it does give countries – even those without domestic manufacturing capacity – the power to threaten to use a compulsory licence. This may have an influence on prices.

5) To what extent does compulsory licensing promote local manufacture and socio-economic development?

For African countries to take full advantage of compulsory licensing they must develop substantial local manufacturing capacity. SA has a limited primary manufacturing capacity (it is capable of producing active pharmaceutical ingredients).[1] Some locally produced medicines are less expensive than foreign made counterparts, this is shown in chapter four in the Indian country study. If SA intentionally makes it their goal to promote innovation by empowering inventors, it will expand local manufacture, which will consequently provide employment and address the socio-economic issues in the country.

The first chapter of this dissertation provided background to the study and argued that in the setting of this research, access implies that medicine is physically accessible, available, and affordable. It further discussed justifications and impacts of this research. Where an inventor has the prospects to recuperate his investment (in the commercial market) through patent protection, this provides an incentive to invent. Sadly, many people who need medicines live in developing countries such as SA, which lack resources to provide a lucrative commercial market. As a result, research and development (R&D) is capitalised in developed countries such as the US. There has been a gradual and stable growth in the finance for R&D in the health sector. However, with this, there is great concern because there is little growth of new developed medicines for neglected diseases that affect developing countries such as South Africa. For that reason, it becomes paramount for developing countries such as SA to develop a patent regime that addresses the needs of its people, and assisting them in finding an equilibrium between safeguarding access to medicines and cultivating a patent regime that encourages local R&D. This can be done by the application of local manufacture to address socio-economic development.

[1] M Berger et al 'Strengthening pharmaceutical innovation in Africa: Designing strategies for national pharmaceutical innovation: Choices for decision makers and countries' African Union, Council on Health Research for Development & The New Partnership for Africa's Development (2010).

Chapter two discussed the TRIPS flexibility of compulsory licensing, and further gave a lucid explanation of the relationship between the TRIPS agreement and the Doha Declaration and the policy space it granted member states to amend their patent laws considering their respective public health needs. It further discussed whether SA has used its domestic policy space and discretion to enforce any of the flexibilities, particularly compulsory licensing. Chapter two examined three examples of medicines: the first used for the treatment of liver and thyroid cancer; the second for the treatment of fibromyalgia and epilepsy; and the last for bipolar disorder and depression. It examined the amount an average South African earns in comparison to the cost of each medication. This allowed for background understanding of the level of affordability of medicine in South Africa and painted a vivid picture of the crisis of access to medicines for the people who need it the most.

The objective of chapter three was to establish if South Africa's Patents Act has taken advantage of the TRIPS Agreement's patent-related flexibilities. This chapter first scrutinised if South Africa complies with article 27(1) of the TRIPS Agreement. Then it discussed if the Medicines Act enriches the availability and accessibility of medicine through measures it has put in place. Finally, it addressed a legal matter that involved excessive pricing by a pharmaceutical company which was tested using the Competition Act. It looked at how competition law could aid in addressing the problem of access to medicines in South Africa.

Chapter four explored and assessed if India has acted in accordance with the TRIPS Agreement to realise a balance between access to medicines and patent protection. It looked at the ways in which South Africa can draw lessons from India's experience. It examined India's use of TRIPS' flexibilities together within its patent standards. This was achieved by looking at the developments India has applied to its domestic patent system and further looking at the *Bayer v Natco* case, which has established the groundwork in India for transformation.

5.2 Findings and recommendations

If there is one devastating force that has helped us embrace the intergenerational struggle and recognise the importance of public health to economic prosperity and trade, it is COVID-19. As noted in the summary above , the TRIPS Agreement provides for flexibilities, including compulsory licensing in article 31. Compulsory licensing will only be operative and promote generic medicinal monopoly if the process

of obtaining a compulsory licence is straightforward and undemanding together with the mandatory royalty fees are reasonable to safeguard that generic medicinal manufacture remains commercially feasible and sustainable.[2] The Doha Declaration contains various administrative requirements, which may delay and impede the primary purpose motivating its use.[3] As a result, access to medicine is provided as a means through the use of compulsory licence in theory, in spite, of that the TRIPS Agreement has numerous conditions, including but not limited to article 31*bis* which are complicated, difficult in carrying and managing out in procedure, together with the apprehension of potential trade sanctions, these may be the reasons why few developing countries such as South Africa have chosen to make use of when ensuring access to medicine is achieved together with local generic manufacture, importation and local monopoly of medicine to control medicine prices.[4] The significance and usefulness of compulsory licence rests on the threat of its use as compared to its actual use.

Inherently, WTO member states have not adopted a uniform approach to implementing the TRIPS Agreement in safeguarding intellectual property rights (IPRs). This is where due diligence will be needed, to take into cognisance the unique needs each developing country may have to ensure access to medicines is achieved. Below are recommended routes SA can use to safeguard access to medicines:

1) Introducing speedy implementation of patent examination. In developing countries such as SA, as resources are limited, patent applications are not examined to establish if they satisfy all the patentability criteria, which include the test of novelty, inventive step, and industrial use. Therefore, it becomes crucial that member states focus on making sure that patent applications are examined to meet the requirements rather than focusing on the exceptions to patent rights. The National IP policy in 2018 stated that patent examination would be introduced incrementally, starting with priority sectors. However, up to date this has not been implemented. If patent examination through the incorporation of a substantive search and examination system (SSE) is speedily introduced, it will allow for legal certainty for right holders and safeguard the country's

[2] Urias & Ramani 'Access to medicines after TRIPS: Is compulsory licensing an effective mechanism to lower drug prices? A review of the existing evidence' (2020) 3 *Journal of International Business Policy* 10.
[3] Yousuf A Vawda & Bonginkosi Shozi 'Eighteen years after Doha: An analysis of the use of public health TRIPS flexibilities in Africa' (2020) 4.
[4] SK Verma 'The Doha Declaration and access to medicines by countries without manufacturing capacity' in Carlos M Correa (ed) *Research Handbook on the Protection of Intellectual Property under WTO Rules* (2010) 640.

interest by making sure that the patent regime advances innovation.[5]

2) Implementing a speedy, uncomplicated, effective and functioning compulsory licence regime. This can be done by incorporating the following:
   a) restricting the justifications for compulsory licensing;
   b) establishing a reasonable and definite timespan for duty to first consult on an application for voluntary licence or the issuance of a compulsory licence;
   c) determining a clear definition of 'reasonable' in terms of commercial conditions when processing a request for a voluntary licence; and
   d) providing directives on what factors to consider when establishing adequate remuneration, while taking account of public health benefits and ensuring access to affordable medicine.[6]
3) Local manufacture of medicines will allow the country to meet its residents' needs and build export prospects on the continent and internationally. It will further influence sustainability of production and aid in achieving health demands in the country, to safeguard the availability and accessibility of medicine. Local manufacture in SA will supplement the restricted medicine suppliers SA depends on for generic medicines and allow more affordable medicine prices because there will be competition.[7] One important way of advancing access to medicine is encouraging reasonable pricing by using miscellaneous supply chains through local manufacture.[8]

This dissertation contended that the well-established thinking about the controversy between IPRs and competition should be reassessed. Both competition law and patent law can be used to effect TRIPS flexibilities and promote South Africa's welfare. IPRs, like any means of property, are essential for the operation of competitive market financial prudence. Prices and production are controlled naturally by the supply of and demand for goods and services.[9] Securing profits by using IPRs either by the inventor or by third parties through licensing, is an advantage for inventive power and an incentive to establish R&D efforts.[10]

[5] DTIC IP Policy 5.
[6] Ibid 6.
[7] Ibid 8.
[8] Ibid.
[9] Rutger Daems 'Are pharmaceutical prices excessive and unfair? A competition policy and regulatory framework (2018) MSM Working Paper 5.
[10] Ibid 4.

When restrictions are put on generic medicinal production, it is contended that the TRIPS Agreement will encumber the dissemination of information and knowledge together with inventive abilities in countries of generic medicine production such as India. South Africa is duty-bound by its constitution and authorised by international law to take diligent and reasonable steps in the realisation and protection of measures set in place to promote access to medicine and health. As a final point, it must be mentioned that IP on its own will not be able to bring the necessary change when advancing access to medicines, it is one fraction of the broader set of changes that may contribute in promoting access to medicine in South Africa.

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