UNIVERSITY OF CAPE TOWN
FACULTY OF LAW
SCHOOL FOR ADVANCED LEGAL STUDIES

AN EXAMINATION OF SOUTH AFRICA'S EFFORTS AT PATENT SYSTEM REFORM: TRIPS FLEXIBILITIES FULLY APPROPRIATED FOR PUBLIC HEALTH NEEDS?

By

LAKPINI CLARENCE SOKOLAMBE (LKPCLA001)

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SUPERVISOR: A/PROF. TOBIAS SCHONWETTER

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Research dissertation presented for the approval of Senate in fulfilment of part of the requirements for the LL.M Intellectual Property Law degree in approved courses and a minor dissertation. The other part of the requirement for this qualification was the completion of a programme of courses.

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DEDICATION

To my beloved aunty, Mrs. Christiana Zuyeali Akale of blessed memory. You remain one of the most amazing people I have had the privilege of knowing. I miss you dearly, but your memory lives on in my heart.

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LIST OF ABBREVIATIONS

ARIPO-	African Regional Intellectual Property Office.
ARVs-	Antiretrovirals
AZT-	*Azidothymidine.*
BW-	Burroughs Wellcome.
CFAT-	Campaign for Affordable Trastuzumab
CIPC-	Companies and Intellectual Property Commission.
DNDi-	Drugs for Neglected Diseases initiative.
Doha Declaration-	Doha Declaration on the TRIPS Agreement and public health.
DTI-	Department of Trade and Industry.
EPC-	European Patent Convention.
FTPL-	Fix the Patent Laws
HER2+-	Human Epidermal growth factor Receptor 2 positive breast cancer.
HIV-	Human Immune-Deficiency Virus.
ICESCR-	International Covenant on Economic, Social, and Cultural Rights.
ICFP-	Intellectual Property Consultative Framework
IMCIP-	Inter-Ministerial Committee on Intellectual Property
IPAB-	Intellectual Property Appellate Board
IP Policy-	Intellectual Property Policy Document Phase One (South Africa).
IPRs-	Intellectual Property Rights.
LDCs-	Least Developed Countries
Medicines Act-	Medicines and Related Substances Act.
MSF-	*Médecines Sans Frontières* (Doctors without borders).
National IPR Policy-	National Intellectual Property Rights Policy (India).
NDP-	National Development Plan.
NGO-	Non- Governmental Organization.
PEC-	Patent Enquiry Committee.
SSE-	Substantive Search and Examination.
TAC-	Treatment Action Campaign.
TRIPS-	Agreement on Trade-Related Aspects of Intellectual Property Rights.
UN-	United Nations
WHO-	World Health Organization.
WIPO-	World Intellectual Property Organization.
WTO-	World Trade Organization.

CHAPTER ONE
INTRODUCTION AND CONCEPTUAL FRAMEWORK

1.1 Background of the Study

The tense relationship between patent law and access to medicines is not one that is new to the Intellectual Property Law (IP) scene in South Africa.[1] This stand-off which originally stemmed from a dissatisfaction over the prices of antiretrovirals (ARVs) for the treatment of the Human Immunodeficiency Virus (HIV) has evolved into a campaign for patent reform in South Africa.[2] Although there has been much literature in this area in recent years, it remains one which requires effective solutions.[3] While this dissertation does not seek to reinvent the wheel, it provides a fresh perspective to this topic which is outlined in the subsequent paragraphs of this section.

The HIV angle of the patent/ access discourse is, however, relevant to this dissertation because it provides a historical context of how the patent/ access debate originated in South Africa.[4] Although reference will be made to HIV in various parts of this work, the dissertation will also consider the Human Epidermal Receptor Two Positive Breast Cancer (HER2+), which will serve to illustrate further the challenges that persist in the area of access to medicines in South Africa. The HER2+ breast cancer discussion will be introduced briefly in this section and discussed in more detail in chapter three of this dissertation.

South Africa has had its fair share of access to medicine-related protests, particularly in the wake of the shortage in access to antiretroviral therapy vaccines in the early 2000s.[5] While the fight against HIV has yielded important results, there remains a lot to be done.[6] This dissertation seeks to analyse what has been done and is being done to provide access in a balanced and equitable manner for both the producers and users of patented medicines in South Africa.

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[1] Baker, Brook K 'International collaboration on IP/access to medicines: Birth of South Africa's Fix the Patent Law Campaign' (2015) 60 *NYL Sch. L. Rev*, 298.
[2] Ibid at 299.
[3] Department of Trade and Industry '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 on 15 August 2019 at 7.
[4] Baker, Brook op cit note 1 at 98.
[5] Ellen F M't Hoen 'TRIPS, pharmaceutical patents and access to essential medicines: Seattle, Doha and beyond' (2003) 3.*CHI. J. INT'L L*, 41.
[6] Section 27, 'Standing up for our lives: A history of the access to medicines movement in South Africa' available at *https://standingupforourlives.section27.org.za/chapter-7/*, accessed on 14 September 2019.

The prevalence of the HIV pandemic drew the world's attention to South Africa.[7] However, in addition to HIV, there are several other diseases such as Hepatitis,[8] Epilepsy,[9] Drug-Resistant Tuberculosis,[10] and Cancer (such as HER2+ breast cancer),[11] posing serious health risks to various sections of South Africa's population, which have unfortunately flown under the radar.[12] Breast cancer, for instance, is the prevalent form of cancer affecting women in South Africa, and the percentage of women affected by the HER2+ strain of breast cancer ranges between 20 and 30 per cent of the breast cancer population.[13] In its early stages, it is treated using a drug called *Trastuzumab*, which is recommended as an essential medicine by the World Health Organization (WHO).[14] Although this strain of cancer is aggressive, the drug - in combination with other medications- is considered effective in treating it, with survival rates increased by up to 37 per cent.[15] Chapter three of this dissertation will provide more details regarding the access- related challenge for *Trastuzumab,* giving information on how the price of the drug has been affected by the patents held for it and how the price compares to India, where a similar challenge was experienced.[16]

In South Africa, there are currently concerted efforts geared towards patent reform, which are likely to lead to an amendment of the South African Patents Act of 1978.[17] South Africa is a Member of the World Trade Organization (WTO) and is therefore bound by the Agreement on Trade-Related Aspects of Intellectual Property (TRIPS),[18] which lays down the minimum

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[7] Piot, Peter, and Thomas C. Quinn 'The AIDS pandemic–a global health paradigm' (2013) 368(23) *The New England journal of medicine,* 2210.
[8] Fix the Patent Laws! 'Patent barriers to medicine access in South Africa: A case for patent law reform' (2016) available at *https://www.fixthepatentlaws.org/wp-content/uploads/2016/09/MSF-FTPL-report-FINAL-VERSION.pdf*, accessed on 15 August 2019, 30.
[9] Ibid at 33.
[10] Ibid at 48.
[11] Ibid at 30.
[12] Ibid at 8.
[13] Fix the Patent Laws! 'Problematic patent laws block access to critical breast cancer medicine' available at: *https://www.cansa.org.za/files/2016/02/Trastuzumab-Explanatory-Doc-3-Feb-2016.pdf*, accessed 16 December 2018.
[14] Ibid.
[15] Ibid.
[16] Fix the Patent Laws! 'Patent barriers to medicine access in South Africa: A case for patent law reform' op cit note 8 at 24.
[17] DTI Intellectual Property Policy op cit note 3.
[18]Agreement on Trade-Related Aspects of Intellectual Property Rights, April 15, 1994, available at *http://www.wto.org/english/docs_e/legal_e/27-TRIPS.pdf*, accessed on 14 August 2019.

standards for IP protection.[19] The TRIPS Agreement contains certain flexibilities referred to as TRIPS flexibilities, which allow Member States to balance the rights of IP owners and users of the products protected by IP.[20]

The Department of Trade and Industry (DTI) released the Intellectual Property Policy of South Africa- Phase I (IP Policy) in 2018, which outlines some critical proposals for reform of the current patent regime.[21] This document will be examined to ascertain whether it will aid South Africa's bid to take full advantage of TRIPS flexibilities, thereby, providing a stable legal platform for the promotion of access to pharmaceutical medicines.

It is important to note from the outset that the question of whether the TRIPS Agreement furthers or hampers human rights objectives is not within the scope of this dissertation, even though the relationship between IP and human rights is a topical and important one that remains underexplored.[22] Instead, in this thesis the IP policy is examined to determine whether its recommendations if passed into law will better the landscape of access, in line with the TRIPS flexibilities, and recommendations are made detailing how those changes should look.

1.2. Research question(s)

The **overarching question** of this research is: *Whether and to what extent does South Africa's move to amend its Patent Act, as outlined in the country's new IP Policy- take advantage of the flexibilities made available through the TRIPS Agreement?* In answering this question, this dissertation will consider the following sub-questions:

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[19]World Trade Organization 'Overview: the TRIPS Agreement' available at *https://www.wto.org/english/tratop_e/trips_e/intel2_e.htm*, accessed on 14 August 2019.

[20] World Intellectual Property Organization 'Patent related flexibilities in the multilateral legal framework and their legislative Implementation at the national and regional levels', 1 March 2010, available at *https://www.wipo.int/meetings/en/doc_details.jsp?doc_id=131629,* accessed on 25 June 2019.

[21] DTI Intellectual Property Policy op cit note 3 at 14.

[22] *See:* Helfer, Laurence R., and Graeme W. Austin. *Human Rights and Intellectual Property: Mapping the Global Interface*. Cambridge University Press, (2011); Helfer, Laurence R 'Human rights and intellectual property: Conflict or coexistence' (2003) 5 i, *Minn. Intell. Prop. Rev;* Helfer, Laurence R 'Regime shifting: the TRIPS Agreement and new dynamics of international intellectual property lawmaking' (2004) 29:1 *Yale J. Int'l L*; and Vawda, Yousuf A., and Brook K. Baker. 'Achieving social justice in the human rights/intellectual property debate: Realising the goal of access to medicines' (2013) 13, no. 1 *African Human Rights Law Journal* 1-27.

a. What are the TRIPS flexibilities available to World Trade Organization (WTO) Member States in the area of patent law?

b. How do the exceptions and limitations in the current Patent Act, measure up to these TRIPS flexibilities, and to what extent do they address the issue of access to medicines in the public health sector?

c. Whether the proposed recommendations of South Africa's IP Policy take advantage of the flexibilities in the TRIPS Agreement and whether the introduction of a substantive search and examination (SSE) system in particular solely aimed at the public health sector complies with Article 27.1 of the TRIPS Agreement?

1.3. Methodology

The dissertation utilises a qualitative, as opposed to a quantitative method. It uses the doctrinal, desktop-based approach wherein it refers to relevant literature- based publications such as legislation, policy documents and reports, books, internet sources, case law, journal articles, World Intellectual Property Organization documents, World Health Organization documents, and World Trade Organization documents.

1.4. Key Concepts

This section highlights some of the vital concepts pertinent to this dissertation and briefly discusses the meaning of intellectual property law, the definition of patents, the rationale behind the grant of patents, as well as the rationale behind the opposition to patent grants. The concepts discussed in this section are by no means exhaustive. However, for the sake of this dissertation, they will provide a foundation upon which to build the subsequent chapters.

1.4.1. The Meaning and Purpose of Intellectual Property Law

Intellectual property refers to the 'creations of the mind: inventions; literary and artistic works; and symbols, names, and images used in commerce.'[23] It has two broad categories namely: industrial property, which encompasses patents for inventions, trademarks, industrial designs, and

[23] World Intellectual Property Organization. 'What is Intellectual Property?' (2004), available at *https://www.wipo.int/publications/en/details.jsp?id=99&plang=EN,* accessed on 1 March 2019.

geographical indications,[24] and copyright, which extends protection to literary works, film, music, artistic works, and architectural designs.[25]

The safeguarding of intellectual property plays a crucial role in incentivising creativity and access to the creations of the mind.[26] In fulfilling this role, it seeks to strike a balance between the rights of intellectual property holders and the users of the works created by them.[27] This balance is often arduous to find and sometimes has far-reaching consequences, particularly regarding patents and access to affordable medicines.[28] This outlook is based on the utilitarian theory of IP and is the predominant view on IP in common law countries.[29] Another approach which is predominantly found in continental Europe is the natural rights theory which places less emphasis on balancing between the rights of IP owners and users but is more focussed on protecting the rights of the IP owner.[30] These two positions are not the only theories used to justify IP but have been highlighted to illustrate that there are different lenses through which IP is viewed, and they may vary from one jurisdiction to the other.

1.4.2. The Definition of Patents.

The World Intellectual Property Organization (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.'[31] It is also defined as monopoly rights for a limited time, which grants a patent- holder exclusive rights to exploit its inventions and prevent others from using them without consent.[32]

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[24] Ibid.
[25] Ibid.
[26] Fisher, William 'Theories of intellectual property' in Munzer, Stephen R., Jules L. Coleman, and Gerald Postema, (eds) *New essays in the legal and political theory of property* (2001) Cambridge University Press, Cambridge, 168.
[27] Ibid.
[28] Outterson, Kevin 'Pharmaceutical arbitrage: Balancing access and innovation in international prescription drug markets' (2005), 5 *Yale J. Health Pol'y L. & Ethics*, 195.
[29]Schonwetter, Tobias *Safeguarding a fair copyright balance-contemporary challenges in a changing world: lessons to be learnt from a developing country perspective* (unpublished PhD thesis, University of Cape Town, 2009) 31.
[30] Oguamanam, Chidi 'Beyond theories: intellectual property dynamics in the global knowledge economy' (2008) 9 *Wake Forest Intell. Prop. LJ*, 108.
[31] World Intellectual Property Organization 'What is Intellectual Property?' op cit note 23.
[32] Cullet, Philippe 'Patents and medicines: the relationship between TRIPS and the human right to health' (2003) 79.1 *International Affairs*, 140.

1.4.3. The Rationale behind the Grant of Patents for Pharmaceuticals.

a. Incentive for Innovation

The grant of patents allows a patent-holder to commercialize a patented product by excluding other players from the market during the lifespan of the patent.[33] The rule also applies to pharmaceutical patents where an originator company can restrict the access into the market for which it has obtained a patent, thereby allowing it to maximise profits through independent price-fixing.[34] Some argue that this is not the ultimate aim of pharmaceutical patent grants, instead, when a pharmaceutical company is allowed to recoup the money spent on research and development of a new drug and also make a profit, it serves as an incentive for more research for new and more effective medications.[35]

It is estimated, somewhat controversially, that it costs about 2.7 billion dollars to develop a new drug.[36] Although pharmaceutical companies provide services to the public health sector, they still operate as private profit-making enterprises.[37] Granting monopolies to these companies is seen by proponents of patent protection as the best way to spur them into a continued investment of their resources for the development of more drugs that reduce the disease burden on the public.[38] Therefore, although the public incurs a loss in terms of pay higher monopolistic prices for access to the medicines, it has been argued by the pharmaceutical industry that if there were no financial incentive in the form of patents, there would be less innovation in drug creation.[39]

b. Facilitation of Technology Transfer through Disclosure

In principle, patent protection is a *quid pro quo* arrangement through which in exchange for the monopoly rights granted, a patent holder discloses details about an invention to the public.[40] This

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[33] TRIPS Agreement supra note18, Article 33.
[34] Ellen FM't Hoen *Private Patents and Public Health: Changing Intellectual Property Rules for Access to Medicines* (2016). Health Action International ,1.
[35] Mazzoleni, Roberto, and Richard R. Nelson. 'The benefits and costs of strong patent protection: a contribution to the current debate.' (1998) 27.3 *Research policy*, 275.
[36] 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/#3145343d2d45,* accessed on 8 March 2019.
[37] Cullet, Philippe op cit, note 32 at 142.
[38] Ibid.
[39] Ibid.
[40] Ellen F M't Hoen 'TRIPS, pharmaceutical patents and access to essential medicines: Seattle, Doha and beyond' op cit note 5 at 55.

disclosure principle is one of the pillars of the patent system and is a valid means of knowledge transfer.[41] With pharmaceutical patents, the reasoning is no different; the patent holder provides information on how it made the drug in exchange for its monopoly, and this helps to enlarge the body of knowledge while allowing others research on how to improve on the drug or to use the same drug once the patent has expired.[42]

c. Safeguarding against Free-riding

Pharmaceutical companies do not enter into business to record loses, and when they invest substantial amounts of money into making a new drug, it is unfair to have companies which did not make any financial contribution towards the drug's development, profit from such breakthrough.[43] The pharmaceutical industry favours patent protection because it prevents the unjust benefit of others from their products.[44] The act of unjustly benefiting from another person's invention is called 'free-riding', and there are concerns that if allowed to continue unabated it may lead to global underinvestment in research and development of new medicines.[45]

A 'congestion problem' also arises due to the ease with which intellectual products can be mimicked. An excellent example of how this congestion problem can be created is in the pharmaceutical industry where drugs are by nature, easily reverse-engineered.[46] Without patent protection, these drugs are easily replicated, and this leads to an over-use of knowledge.[47] What this knowledge over-use connotes is that because copying is generally easy and inexpensive, there will be competition for the patented product which will drive the prices down to the marginal cost of production, thereby making it difficult for the patent-holder to recover the initial investment made.[48] When this occurs, the economic value of innovations is diminished, thus leading to less

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[41] Gallini, Nancy T. 'The economics of patents: Lessons from recent US patent reform' (2002) 16.2 *Journal of Economic Perspectives*, 139.
[42] Ibid.
[43] Tim Hubbard & James Love 'A new trade framework for global healthcare R&D' (2004) 2(2) *PloS biology*, at 0147
[44] Ibid.
[45] Ibid.
[46] Cohen, Jillian Clare, and Patricia Illingworth. 'The dilemma of intellectual property 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.
[47]. Ibid.
[48] Baker, Dean, Arjun Jayadev, and Joseph E. Stiglitz. 'Innovation, intellectual property, and development: A better set of approaches for the 21st century.' (2017), 9.

incentive to invest in research and development of new medicines.[49] Granting exclusive rights in the form of patents helps to reduce the challenge caused by free-riding.[50]

Through a patent grant, the patent-holder is not only protected from those who would otherwise unjustly benefit but also rewarded for its innovative contribution to society.[51] Granting a pharmaceutical company the exclusive right to commercialise its product within the time-bound monopoly period helps resolve the problem of unjust benefit.[52] This commercial exploitation can either be done by the company or through licensed entities which the patent-holder grants permission to usually upon payment of royalties.[53]

1.4.4. The Rationale behind the Opposition of Pharmaceutical Patent Grants

a. Selective research and development for new drugs

Pharmaceutical companies fund research and development of new medicines for markets that can afford to pay for those drugs.[54] The discriminatory research and development have led to a shortage of drugs for diseases which primarily affect developing countries.[55] In a study carried out in 2001 by *Médecines Sans Frontières* (MSF), also known as Doctors Without Borders, along with the Drugs for Neglected Diseases working group (which later became the Drugs for Neglected Diseases initiative (DNDi)), surveyed twenty pharmaceutical companies in the US, Europe, and Japan.[56] It found that there was negligible research for neglected diseases.[57] A more recent study was carried out in 2012 by MSF, DNDi, and others; it found that between the year 2000 and the close of 2011, only 4 per cent (37) new drugs out of 850 new drugs were for neglected diseases.[58] Furthermore, only 1 per cent of almost 150,000 registered clinical trials for new medicines was for neglected diseases.[59]

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[49] Cohen op cit note 46 at 30.
[50] Ibid.
[51] Cullet, Philippe op cit, note 32 at 140.
[52]TRIPS Agreement supra note 18 Article 33.
[53] Ibid. Article 28(2).
[54] Ellen F.M.'t Hoen 'TRIPS, pharmaceutical patents and access to essential medicines: Seattle, Doha and beyond' op cit note 5 at 55.
[55] Ibid.
[56] Ibid.
[57] Ibid.
[58] Ibid.
[59] Ibid.

b. Price discrimination restricting access

As previously mentioned, one of the main features of the patent system is that it grants exclusive rights to a patentee, which helps prevent competitors from entering into the market during the lifespan of the patent, except through a licence or assignment of patent rights.[60] The situation invariably means that a pharmaceutical company which holds the patents to a drug in a particular country can set the price of its drug in that country in the most profitable way possible, even when it does not correctly reflect the economic realities of the people, this can invariably limit access to life-saving medications.[61]

The classic example of this hindrance to access stemming from high prices was the HIV pandemic. At the end of 1999, approximately 34.3 million people worldwide were infected with the virus,[62] with 24.5 million coming from sub-Saharan Africa.[63] At that time, the patented antiretroviral therapy was available at about ten thousand dollars per patient per year.[64] As a result, it was impossible for most people, particularly in developing countries, to obtain the life-saving treatment, bringing the worldwide death toll to 18.8 million people.[65] The lack of access sparked protests, particularly in South Africa, which had 19.9 per cent of its population infected,[66] making it one of the hardest hit by the virus.[67] Civil society groups such as the Treatment Action Campaign (TAC), took to the streets in protest of the unfair pricing system, which was denying many people their rights to health and life.[68] The demonstrations and pressures by South Africa and other developing countries yielded results,[69] which led to the Doha Declaration on the TRIPS Agreement and Public Health in 2001.[70]

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[60] TRIPS Agreement supra note 11 Article 28(2).
[61] Ellen F.M 't Hoen 'TRIPS, pharmaceutical patents and access to essential medicines: Seattle, Doha and beyond' op cit note 5 at 41.
[62] Pisani, Elizabeth, et al. *Report on the Global HIV/AIDS Epidemic-June 2000*. UNAIDS, 2000 at 6.
[63] Ibid at 6.
[64] Frontières, Médecins Sans 'Untangling the web of antiretroviral price reductions 2013.' *Geneva, Switzerland: Médecins Sans Frontières* 14 (2015), at 4.
[65] Pisani, Elizabeth op cit note 62 at 8.
[66] Ibid at 9.
[67] Hestermeyer, Holger. *Human Rights and the WTO: The Case of Patents and Access to Medicines*. Oxford: Oxford University Press, (2007), 11.
[68] Ibid.
[69] Ellen F.M 't Hoen *Private Patents and Public Health* op cit note 34 at 8.
[70] 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 on 15 August 2019.

While the Doha Declaration did not amend the TRIPS Agreement, it reaffirmed the flexibilities therein.[71] Paragraph 3, for instance, states: 'We recognize that intellectual property protection is important for the development of new medicines. We also recognize the concerns about its effects on prices.'[72] Since then, antiretroviral treatments have become much more affordable, even dwindling to about seventy- five dollars per patient per year in 2017.[73]

c. Monopoly inspired disinterest in research and development of new drugs

One of the key arguments put forward by proponents of pharmaceutical patent grants is that such patents serve as an incentive for research and development of more effective medicines than those that had existed at the time.[74] Unfortunately, there are prominent examples where this promise has not borne fruit; one such example is the paediatric formulation of the antiretroviral for HIV.

In 2013, about 3.2 million children lived with HIV; these children were in a particularly precarious situation because they needed the antiretroviral medication to be adapted to their specific needs since adult dosages of the drug were not suitable for them.[75] Many have died needlessly because pharmaceutical companies do not see the potential for profits from children who are unable to pay for treatment and mostly based in sub-Saharan Africa.[76] In fact, in 2011, a United Nations (UN) report stated that 'there are disincentives for manufacturers to produce paediatric formulations.[77] Clinical research of children's medicine markets is often small and fragmented owing to need for weight-specific strength.'[78] While on a positive note, the number of children below 15 living with HIV dropped to 1.8 million in 2017, the estimate is that fifty per cent of them will die before their second birthday and four-fifths before their fifth birthday.[79]

Due to the lack of robust competition in this area, pharmaceutical companies can afford to neglect research in such unprofitable areas as highlighted above and still hold a market

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[71] Carlos M. Correa & World Health Organization. *Implications of the Doha Declaration on the TRIPS Agreement and public health*. (2002). at 58.
[72] Doha Declaration supra note 70.
[73] Clinton Health Access Initiative. "ARV market report: the state of the antiretroviral drug market in low-and middle-income countries, 2016–2021." *Clinton Health Access Initiative, New York, NY* (2017).
[74] Cullet, Philippe op cit, note 36 at 142.
[75] Ellen't Hoen *Private Patents and Public Health* op cit,.note 34 at 120.
[76] Ibid.
[77] Ibid.
[78] Ibid.
[79] Drugs for Neglected Diseases initiative, 'What is Paediatric HIV?' available at, *https://www.dndi.org/diseases-projects/paediatric-hiv/* accessed on 5 March 2019.

dominance.[80] The pharmaceutical industry has dangled the research and development carrot to underline the importance of patents, but has failed to deliver on the promise in many cases.[81] This argument does not tally with the sound economic reasoning that there is less incentive for a holder of a patent monopoly to conduct research which will produce better quality than what is already generating profits as opposed to a competing entrant into the same market.[82]

d. Limitation of local-based production

A patent is an attractive asset to have for companies for many reasons, one of which is to keep competitors out of the market.[83] In South Africa, between 2005 and 2015 only 4064 patents were granted to South Africans or South African entities as opposed to 36,067 which were granted to foreign nationals and entities within the same period.[84] Only 49 of the 4064 patents granted to South Africans were granted for pharmaceutical products.[85] This situation has the effect of stifling local-based production of those patented medicines.[86] It is advantageous for countries to have vibrant local production bases for medications to meet the health needs of their people, as was the case in some states before the TRIPS Agreement.[87] India, for example, was able to develop a robust local pharmaceutical industry partly because it was able prevent the grant of pharmaceutical product patent grants because there was no international obligation compelling them to do so.[88] This will be discussed in more detail in chapter four of this dissertation. The unfortunate effect that drug patents have is that most times home-grown drug manufacturers are not able to compete with massive multi-national companies and are forced to close.[89]

Another challenge posed to local manufacturers is that they do not usually have the financial wherewithal to obtain licences from the pharmaceutical companies that hold the patents,

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[80] Ellen't Hoen *Private Patents and Public Health* op cit 34 at 120.
[81] Cohen, Jillian Clare, and Patricia Illingworth, op cit note 46 at 33.
[82] Arrow, Kenneth Joseph. "Economic welfare and the allocation of resources for invention." *Readings in industrial economics*. 1962 Palgrave, London, at 616.
[83] Lanoszka, Anna. 'The global politics of intellectual property rights and pharmaceutical drug policies in developing countries.' (2003) 24.2 *International Political Science Review*, at 183.
[84] Berger, Jonathan and Rens, Andrew 'Innovation and intellectual property in South Africa: The case for reform' (2018) at 11.
[85] Ibid at 22.
[86] Cohen, Jillian Clare, and Patricia Illingworth, op cit, note 46, at 33.
[87] Ibid.
[88] Ibid
[89] Lanoszka, Anna, op cit note 83, at 183.

and often times the pharmaceutical companies are unwilling to issue licences to them.[90] The effect of this is that the public health sector is heavily controlled by multi-national drug companies, which appears to be a key stumbling block for access due to prices that are too high.[91]

1.5 Thesis structure

Following this introductory and background- setting chapter, chapter **two** first introduces and examines the TRIPS flexibilities and then reviews the exceptions and limitations available under the current Patents Act to determine how they measure up to these TRIPS flexibilities in addressing the issue of access to medicine. Chapter **three** provides a brief historical account of the efforts that have been made to 'Fix the Patent Laws,' (FTPL) in South Africa through various civil society groups, highlighting the HER2+ breast cancer as an example of the persistent access problem and how these civil society groups have contributed to the drafting of South Africa's IP Policy. It examines the significant recommendations of the Policy to determine the extent to which they take advantage of the TRIPS flexibilities and whether there is still room for improvements in line with the TRIPS Agreement. Lastly, chapter three considers whether introducing a substantive search and examination system solely for the public health sector complies with Article 27.1 of the TRIPS Agreement. Chapter **four** discusses how India, another emerging economy which has amended its patent laws since the beginning of this millennium, has dealt with access to medicines challenges and the lessons it teaches. Finally, the concluding chapter **five** summarises; provides recommendations, including the model language of how lawmakers should draft some of the proposals made in the IP Policy; and draws general conclusions from this research.

[90] Ibid at 184.
[91] Ibid at 182.

CHAPTER TWO
THE TRIPS FLEXIBILITIES VIS-À-VIS THE EXCEPTIONS AND LIMITATIONS PROVIDED IN THE 1978 SOUTH AFRICAN PATENT ACT.

2.1. Introduction.

This chapter focusses on gaining an understanding of both the international and local frameworks which govern the patent-access nexus, with particular reference to the flexibilities available under the TRIPS Agreement and the South African Patent Act respectively. In doing this, the dissertation highlights and discusses the TRIPS Agreement and its relationship to access to medicines; TRIPS flexibilities and Doha declaration are explained, as well as the exceptions and limitations to patent-holders' rights.

2.2. The TRIPS Agreement and its relationship to access to medicine

The Members of the World Trade Organization (WTO) negotiated the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), during the 1986-94 Uruguay Round.[92] It had the effect of incorporating 'intellectual property rules into the multilateral trading system for the first time.'[93] The Agreement is unique because it covers various forms of intellectual property such as Copyright and Related Rights, Trademarks, Geographical Indications, Industrial Designs, Patents, and Layout Designs,[94] and prescribes minimum standards of protection for each which are binding on Member States.[95] These standards were set at the level which most developed countries already had in their domestic IP legislation before the Agreement, and although it would change the landscape of IP in the developing world, it maintained the status quo for most developed countries.[96] Aside its broad coverage of various types of IP, another thing that sets it apart from other multilateral intellectual property instruments is its enforceability.[97] It contains a dispute settlement procedure which is enforceable through 'mandatory adjudication backed up by the

[92] World Trade Organization 'Intellectual property: protection and enforcement', available at *https://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm7_e.htm*, accessed on 25 June 2019.
[93] Ibid.
[94] TRIPS Agreement supra note18, part 2 sections 1- 6.
[95] Ibid.
[96] World Intellectual Property Organization Patent related flexibilities op cit note 20 at 7
[97] World Trade Organization. 'Intellectual property: protection and enforcement' op cit note 92.
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threat of retaliatory sanctions.'[98] Differently put, TRIPS has an inbuilt dispute settlement mechanism; wherein, a Member State is allowed to 'bring an action against another state if there is insufficient compliance with the principles of the…Agreement in general.'[99] This state of affairs implies that every WTO Member State must carefully craft its intellectual property laws in a manner in which they will be compatible with the TRIPS Agreement.

Recourse must be made to Article 27.1 of the TRIPS Agreement to understand the nexus between the TRIPS Agreement and public health through patents for pharmaceutical medicines. It provides that:

> Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.[100]

In 1986 when the Uruguay Round, which led to the TRIPS Agreement was launched, '49 of the 98 members of the Paris Convention excluded pharmaceutical products from patent protection…'[101] This was because each country was at liberty to determine what area of technology in which to grant patents.[102] This changed with nations seeking to give effect to Article 27.1, in a bid to avoid trade sanctions. The change has brought public health firmly within the scope of the TRIPS Agreement and means that all WTO members must make allowances in their patent laws for the grant of pharmaceutical patents for at least twenty years.[103]

The new rules apply uniformly, except for Least Developed Countries (LDCs), which have been given till 2033 to comply with the TRIPS Agreement.[104] This time extension for compliance

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[98] Helfer, Laurence R. 'Regime shifting: the TRIPS Agreement and new dynamics of international intellectual property lawmaking' (2004) 29:1 *Yale J. Int'l L.*

[99]Heath, Christopher '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 on 16 August 2019 at 9.

[100] TRIPS Agreement supra note 18.

[101] Ellen't Hoen *Private Patents and Public Health* op cit note 34 at 20

[102]. Ibid.

[103] Suerie Moon, Jorge Bermudez & Ellen 't Hoen 'Innovation and access to medicines for neglected populations: could a treaty address a broken pharmaceutical R&D system?' (2012) 9(5) *PloS medicines* at 1.

[104] United Nations Committee for Development Policy 'WTO drugs patent waiver for LDCs extended until 2033.' 19 November 2015, *https://www.un.org/ldcportal/wto-drugs-patent-waiver-for-ldcs-extended-until-2033/*,accessed on 25 June 2019.

is made possible the transition periods which the TRIPS Agreement provides.[105] There are three time-frames provided by the TRIPS Agreement which allowed Member States the time to comply with the standards set by the Agreement.[106] The first period was between 1995 and 2000,[107] at the end of which developing countries were required to implement to the 20-year patent term and the grant of both product and process patents for all fields of technology in their national laws.[108] The second period was from 2000 to 2005, and it allowed Member States time to extend patent protection to areas of technology which were not protected under their laws at the time.[109] This was on the condition that they would accept patent applications from 1995, to process them in 2005.[110] This method is known as the 'mailbox' system.[111] Also, they had to grant exclusive marketing rights for such applications, if marketing approval had been granted and the applicant had obtained a patent for the same product in another country.[112] The last time frame applies to LDCs, and while initially they were allowed up till 2006, due to their constraints the Agreement allows them to apply for extensions,[113] this is the reason why they now have up till 2033 as stated above.

2.3 The TRIPS flexibilities and Doha Declaration explained.

The TRIP Agreement has been criticised, particularly in terms of its access to medicine implications on developing country Member States.[114] Despite this, there are certain built-in flexibilities which serve to enable the Member States to strike a balance between the rights of patent holders and the public.[115] These flexibilities allow WTO Members to cater for the interests of their citizens by limiting the scope and effect of the exclusive rights granted to patent-holders in a way that is consistent with the Agreement as well as their national laws.[116]

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[105] TRIPS Agreement supra note18 at Article 66.1.
[106] Ibid Articles 65- 66.
[107] Ibid Article 6.2.
[108] Ibid Articles 33 and 27.
[109] Ibid Article 65.4.
[110] Ibid Article 70.8.
[111] Musungu, Sisule F., Cecilia Oh, and World Health Organization. *The use of flexibilities in TRIPS by developing countries: can they promote access to medicines?* (2006) Geneva, South Centre.
[112] TRIPS Agreement supra note18 at Article 70.9.
[113] Ibid Article 66.1.
[114] Ellen't Hoen *Private Patents and Public Health:* op cit,.note 34 at 119.
[115] World Intellectual Property Organization Patent related flexibilities op cit note 20 at 4.
[116] Ibid at 12.

The flexibilities available under TRIPS can broadly be classified into two categories, 'those regarding transition periods, and "substantive" flexibilities….'[117] The transition flexibility expired for South Africa in 2005 and is, therefore, no longer applicable.[118] It is worth mentioning that the 20- year minimum duration of a patent set by the TRIPS Agreement is also a flexibility, as countries can decide to go above the minimum term prescribed. This will not form part of the discussion here as the dissertation will focus on flexibilities which scale down patent protection to enable access to medicines. The substantive flexibilities relevant to access to medicines which will be discussed in this chapter are: compulsory, and government-use licencing, exhaustion of rights/parallel importation, exceptions to rights conferred by a patent and exemptions from patentability.[119]

No discussion about the TRIPS flexibilities is complete without understanding the meaning and purpose of the Doha Declaration.[120] The narrow interpretation of TRIPS flexibilities by developed countries that in exercising them, little discretion was allowed led developing countries to push back at this interpretation.[121] The developing countries argued that the Agreement did not bar them from taking steps to cater to their public health needs by creating access to medicines.[122] They sought greater clarity regarding what was available to them under the TRIPS, and the Declaration set out to provide that clarity.[123] The WTO Fourth Ministerial Conference adopted the Declaration in 2001.[124] Central to the Doha Declaration is Paragraph 4, which provides as follows:

> 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.'[125]

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[117] Ibid.
[118] Diane Nicol and Olasupo Owoeye 'Using TRIPS flexibilities to facilitate access to medicines' available at *https://www.who.int/bulletin/volumes/91/7/12-115865/en/*, accessed on 19 August 2019.
[119] Matthews, D N 'TRIPS flexibilities and access to medicines in developing countries: the problem with technical assistance and free trade agreements' *European Intellectual Property Review* 2005 at 1.
[120] Doha Declaration supra note 70.
[121] Musungu, Sisule F op cit note 111 at 9.
[122] Ibid.
[123] Ibid.
[124] Ibid.
[125] Doha Declaration supra note 70 at paragraph 4.

In discussing the TRIPS flexibilities, the relevant portions of the Doha Declaration will be highlighted to give a more holistic view of the flexibilities available to the WTO Member States. These flexibilities along with the corresponding Declarations are discussed below.

2.3.1 Compulsory and government use licencing

'Compulsory licensing is 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 itself.'[126] In the case of pharmaceutical patents, this enables the production of generic versions of the proprietary medicines at fractions of the costs of the branded versions, upon the payment of reasonable royalties.[127] Article 31 of the TRIPS Agreement lays down the conditions for compulsory licences which must be contained in the national compulsory licensing provision of Member States. One of the main requirements is that as a general rule, there must have been prior negotiations to obtain a patent between the patent-holder and the third party seeking the licence, which ended in a refusal of the patent-holder to licence its patent within a reasonable time.[128] However, Member States are allowed to waive this condition when there is: 'a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use.'[129] In each case, the rights holder must be informed of the intention to issue a compulsory licence promptly.[130] There is a misconception that the state will only grant a compulsory licence for a national emergency, but this is not true.[131] This misconception was clarified by the Doha Declaration, which provides that: 'Each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.'[132] It went on to give room for the Member States to determine what would represent a matter of national emergency or extreme urgency within the context of their legal systems.[133]

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[126] World Trade Organization. '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 on 25 June 2019.
[127] Matthews, D N op cit note 119 at 1.
[128] TRIPS Agreement supra note 18, Article 31(b).
[129] Ibid.
[130] Ibid.
[131] World Trade Organization 'Compulsory licensing of pharmaceuticals and TRIPS' op cit note 126.
[132]Doha Declaration supra note 70 at paragraph 5(b).
[133] Ibid at paragraph. 5(c).

Also, there must be adequate remuneration of the patent-holder for the use of its patented item, in this case, drug.[134] The issuing authority considers the 'economic value of the authorization' in determining the amount of remuneration payable.[135] The TRIPS Agreement does not define what is meant by 'adequate remuneration' or 'economic value of the authorization.'[136] The above consideration means that each Member State is left to determine what these terms mean according to its national laws, and this interpretation will vary from one country to the other.[137] The concern here is that developing countries may find it challenging to determine these indices due to its complexity.[138]

The compulsory licences are 'subject to judicial review or other independent review by a distinct higher authority in that member.'[139] Also, decisions made by the Member State regarding remuneration are 'subject to judicial review or other independent review by a distinct higher authority in that member state.'[140] The drawback of these provisions is that it is likely to deter the Member States from issuing compulsory licences for fear of costly litigation.[141] In the context of access to medicines, this means that countries are likely to weigh the health of their citizens against the economic disincentive to use this mechanism, thereby negatively impacting access.[142]

Article 31(f) of TRIPS provides that 'any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use.'[143] The wording of this provision creates significant uncertainty for developing countries which cannot manufacture their generics in the face of a health crisis.[144] In paragraph 6 of the Doha Declaration, instructions were given to the TRIPS Council to proffer a solution and report to the General Council of the WTO before the close of 2002.[145] The General Council of the WTO adopted the decision which came on

[134] TRIPS Agreement supra note 18 at Article 31(g).
[135] Ibid.
[136] Matthews, D N op cit note 119 at 420.
[137] World Trade Organization. 'Compulsory licensing of pharmaceuticals and TRIPS.' op cit note 126.
[138] Matthews, D N op cit note 119 at 421.
[139] TRIPS Agreement supra note 18 at Article 31(i).
[140] Ibid at Article 31(j)
[141] Matthews, D N op cit note 119 at 421.
[142] Ibid.
[143] TRIPS Agreement supra note 18.
[144] Matthews, D N op cit note 119 at 421.
[145] Doha Declaration supra note 70 at paragraph 6.

the 30th of August 2003.[146] The solution reached was that 'a waiver of the export restriction,' would be granted to countries that cannot produce generics.[147] The decision is not automatically binding on the Member States; consequently, amendments of national patent laws are required to take advantage of it.[148] Canada and Norway, are two developed countries that have amended their patent laws to aid the issuance of compulsory licences to allow the export of patented pharmaceuticals to countries that cannot produce.[149]

The other conditions are straightforward, among which are that: the 'individual merits' of each situation determine the grant of a compulsory licence;[150] 'the scope and duration of such use shall be limited to the purpose for which it was authorized….[151] The use must be 'non-exclusive,'[152] the use must generally be 'non-assignable,' except where the assignment constitutes 'part of the enterprise or goodwill which enjoys such use.[153] Where the purpose for the use ceases to exist, and the circumstances which necessitated the use are unlikely to recur, then the use must be terminated.'[154] Finally, the conditions laid down in subparagraphs (b) and (f) will not apply where a practice by the patentee is found by a 'judicial or administrative process to be anti-competitive.[155]

Some view the compulsory licence as a means of inducing voluntary licences by countries threatening to issue compulsory licences.[156] The United States used this strategy in October 2001, when it had an anthrax scare.[157] Bayer held the patent for a drug called Cipro, which could be used to treat anthrax infections.[158] The US government expressed concerns that Bayer could not produce

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[146] World Health Organization. 'WTO decision on the implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health.', available at *https://www.who.int/medicines/areas/policy/wto_impl_para6/en/*, accessed on 29 June 2019.
[147] Ibid.
[148] Ibid.
[149] Matthews D N op cit note 119 at 421.
[150] TRIPS Agreement supra note 18 Article 31(a).
[151] Ibid at Article 31(c)
[152] Ibid at Article 31(d).
[153] Ibid at Article 31(e).
[154] Ibid at Article 31(g)
[155] Ibid at Article 31(k).
[156] World Intellectual Property Organization Patent related flexibilities op cit note 20 at 15.
[157] Mullin, Thomas F 'AIDS, anthrax, and compulsory licensing: has the United States learned anything-a comment on recent decisions on the international intellectual property rights of pharmaceutical patents' (2002) 9 *ILSA J. Int'l & Comp. L* 200.
[158] Ibid at 199.

an adequate amount of the drug to cater for the population.[159] While all this was going on, the Canadian Minister of Health signed an agreement with some Pharmaceutical companies for the production of Cipro, stating that Bayer was unable to meet the demand needed by the country.[160] Their stance was that they were willing to obtain and use generic versions of the drug if Bayer was unable to produce to the capacity that satisfied their need.[161] The actions of Canada encouraged the US to threaten Bayer that it would alter its laws to 'break the Cipro patent.'[162] Canada eventually agreed with Bayer to purchase Cipro at a fraction of the cost, this enabled the US to do the same, and they were able to save eighty-two million dollars and avoid litigation.[163] The US Secretary for Health later stated in a hearing before Congress that the main issue they had with Cipro at the time of the anthrax scare was the cost and not the ability of Bayer to supply the market adequately.[164] Despite this type of situation, some still feel that that the positive or negative effects of the threat of use of compulsory licences to strengthen the bargaining power of countries for voluntary licences is difficult to ascertain.[165]

2.3.2 Exhaustion of rights/parallel importation

The exhaustion of IPRs, also known as the 'first-sale doctrine,' entails that once a patented product is put on sale by a patent holder or by someone else with its consent, it loses the right to control the resale of that product.[166] This enables a third party through a principle called parallel importation to legally purchase and import the patented product at lower prices without the permission of the rights holder, from another country where it is under patent protection.[167] Parallel importation is possible because the monopoly held by the patent-holder makes it possible for it to engage in differential pricing of its products from country to country.[168] The territorial nature of

[159] Ibid.
[160] Ibid at 201.
[161] Ibid.
[162] Ibid at 202.
[163] Ibid.
[164] Ibid.
[165] World Intellectual Property Organization Patent related flexibilities op cit note 20 at 16.
[166] Bonadio, Enrico 'Parallel imports in a global market: should a generalised international exhaustion be the next step?' (2011) 33 no. 3 *European Intellectual Property Review* 153.
[167] Heath, Christopher op cit note 101 at 1.
[168] Kremer, Michael 'Pharmaceuticals and the developing world' (2002)16, no 4 *Journal of Economic Perspectives* at 74.

patent rights means that a patentee can hold patents for the same product in different countries at the same time, with the rights in each country differing from the other

This right has been made subject to Article 6 of the TRIPS Agreement, which does not make exhaustion subject to dispute settlement under the Agreement[169]. The exhaustion exception can help developing countries access medicines at more reasonable prices than are being sold on their domestic markets.[170] Like other flexibilities, there is a need for each country to domesticate it into its national laws because it is not automatic.[171] As stated above, for exhaustion to work, the patent-holder must have put the patented product or process on the market or consented to same.[172] This means that 'the patent owner's rights in respect of that product are terminated. This limitation assures free circulation of products.'[173]

Under the TRIPS Agreement, Article 6 provides that '[f]or the purpose of dispute settlement under this Agreement, subject to Articles 3 and 4 nothing in this Agreement shall be used to address the issue of exhaustion of intellectual property rights.' Parallel importation is not included expressly as the compulsory licence has been; instead, the TRIPS provides a lee-way for the Member States to have their exhaustion regimes without fear of breaching the Agreement.[174] The drafters made it this way because, during negotiations, there was a failure to agree on how specific 'parallel importation' provisions would look in the text of the Agreement.[175] The ability of a patent-holder to stop the importation of a product into a country where it owns a patent is dependent on the strength or weakness of that country's provisions on exhaustion.[176]

2.3.3 Exceptions to the Rights Conferred.

This flexibility places limitations on the patent holder by limiting the reach of its rights to promote the public's access to the patented invention, in this case, medicines.[177] The reason for providing these exceptions is to 'facilitate the dissemination of knowledge, encourage innovation, promoting

[169]World Intellectual Property Organization Patent related flexibilities op cit note 20 at 17.
[170] Musungu, Sisule F op cit note 111 at 47.
[171] Matthews, D N op cit note 119 at 420.
[172] World Intellectual Property Organization Patent related flexibilities op cit note 20 at 18.
[173] Ibid.
[174] Heath, Christopher op cit note 99 at 8.
[175] Ibid.
[176] World Intellectual Property Organization Patent related flexibilities op cit note 20 at 17.
[177] Musungu, Sisule F op cit note 111 at 53.

education, and protecting other public interests.'[178] Article 30 of the TRIPS Agreement provides that: 'Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.' The conditions stand independently and must be satisfied as such. Also, in interpreting one condition, the other two are to be considered.[179]

The TRIPS Agreement only created a general rule regarding these exceptions, and no list was provided for states to follow.[180] As a result of this, Member States are free to develop suitable exceptions which best represent their needs. Examples of some specific exceptions are the: early-working or 'Bolar exception', which enables a generic company to obtain speedy approval of their product before the expiration of the patent to allow them to commercialize their product as soon as the patent expires;[181] use of the invention for experimental and research purposes, be they scientific or commercial.[182] The exceptions highlighted are only examples of a non-exhaustive list.

2.3.4 Exemptions from Patentability

This flexibility is not a traditional one but is implicit in the sense that the TRIPS gives room for interpretation of what is patentable or not.[183] Article 27.1 of TRIPS states that for a patent to be granted, a work must be 'new, involve an inventive step' and be 'capable of industrial application.' As mentioned earlier, this was not the case before the TRIPS Agreement, where countries were able to exclude certain types of inventions from patentability.[184] Even though Article 27.1 mandates the issuance of patents in all fields of technology that meet the patentability criteria, how each country interprets these criteria varies from country to country since the TRIPS does not define these terms.[185] If the requirements for 'novelty' and 'inventiveness' is low, it becomes easier

[178] Ibid.
[179] Ibid at 54.
[180] Ibid at 55.
[181] Ibid.
[182] Ibid.
[183] Helfer, Laurence R., and Graeme W. Austin. *Human Rights and Intellectual Property* op cit note 22 at 120.
[184] Ibid at 58.
[185] Ibid.

for pharmaceutical companies to obtain patents and to even extend the length of their monopoly by making minor changes to their products; a practice known as 'evergreening.'[186]

2.4 The flexibilities available under the Patent Act.

The South African Patents Act[187] provides some flexibilities of its own, which will be examined in this section. The flexibilities which South Africa's Patent Act contains are the compulsory licence, which deals with compulsory licences for dependent patents, and in cases of abuse of patents;[188] and 'Bolar exception.' In addition to the flexibilities contained in the Patent Act, section 15(C) of the Medicines and Related Substances Control Act,[189] provides for parallel importation of patented medicines which will be discussed in chapter three of this dissertation. The flexibilities contained in the Patent Act are discussed as follows:

2.4.1 Compulsory licences for dependent patents and abuse of patents

A dependent patent is a patent which as a matter of law cannot be worked without falling within the scope of protection of another patent.'[190] This subsequent invention requires a licence from the patent-holder to function, and where such licence is not granted voluntarily, the commissioner for patents has the right to issue a licence to the subsequent inventor without recourse to the patentee.[191] The dependent compulsory licence is given happens where there is: an essential technical advancement which is economically significant to the prior patent from which the licence is sought. The original patent-holder grants a cross-licence to the owner of the dependent patent on reasonable terms to the owner of the primary patent and the licence granted will not be assignable by the licensee of the dependent invention.[192]

Section 56 gives room for an application to the commissioner for patents to issue compulsory licences where a patent-holder is proved by another party to have engaged in an abuse

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[186] Ibid.
[187] Patents Act 57 of 1978.
[188] Ibid at sections 55 and 56.
[189] 101 of 1965.
[190] The International Association for the Protection of Intellectual Property 'Question 97 Dependent patents and their exploitation' (1991) available at *https://www.aippi.fr/upload/Q90-144/rs97english.pdf,* accessed on 20 August 2019.
[191] Patent Act 57 supra note 179 at section 55
[192] Ibid at section 55(b).

of its patent.[193] There are four pre-conditions upon which a compulsory licence can be granted for abuse of patent as follows:

> (a) the patented invention is not being worked in the Republic on a commercial scale or to an adequate extent, after the expiry of a period of four years subsequent to the date of the application for the patent or three years subsequent to the date on which that patent was sealed, whichever period last expires, and there is in the opinion of the commissioner no satisfactory reason for such non-working;
>
> (b) . . . . . .
>
> (c) the demand for the patented Article in the Republic is not being met to an adequate extent and on reasonable terms;
>
> (d) by reason of the refusal of the patentee to grant a licence or licences upon reasonable terms, the trade or industry or agriculture of the Republic or the trade of any person or class of persons trading in the Republic, or the establishment of any new trade or industry in the Republic, is being prejudiced, and it is in the public interest that a licence or licences should be granted; or
>
> (e) the demand in the Republic for the patented Article is being met by importation and the price charged by the patentee, his licensee or agent for the patented Article is excessive in relation to the price charged therefore in countries where the patented Article is manufactured by or under licence from the patentee or his predecessor or successor in title.

To date, South Africa has not issued a compulsory licence despite having these provisions in its Patent Act.[194] This reluctance has been attributed to the difficulty in fulfilling the requirements as well as the cost of litigation.[195]

2.4.2 The 'Bolar exception.'

Section 69(A) of the Act makes provision for what is called the 'bolar exception.' The section provides that:

> (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

[193] Ibid at section 56(1)
[194] Avafia, Tenu, Jonathan Berger, and 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 *ICTSD, UNCTAD, TRALAC* at 22.
[195] Matthews, D N op cit note 111 at 421.

> 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 import of this exception is that it serves the purpose of speeding up the approval of generic medications upon the expiry of the patented drug.[196] The logic is that if a generic manufacturer is to wait until the patent expires before obtaining the relevant approval, it will be a clog in the wheel of affordable access to medicines, which is counterproductive.[197]

2.5 Conclusion

This chapter has looked at the TRIPS Agreement through the lenses of its flexibilities, and as seen above, there are opportunities which the WTO Member States can seize in crafting their patent laws in ways that promote access. The chapter considered the role of the Doha Declaration and its centrality to giving WTO Members the confidence to craft their patent laws with public health concerns at the forefront of their consideration. Lastly, it considered the South African exceptions and found that not all the flexibilities in the TRIPS Agreement have been taken advantage of and there is still room to expand the scope of the flexibilities in the Patent Act. The next chapter will consider what South Africa has done and is doing to properly access the additional flexibilities.

[196] World Intellectual Property Organization Patent related flexibilities op cit note 20 at 23.
[197] Ibid.

CHAPTER THREE
REFORM OF THE SOUTH AFRICAN PATENT SYSTEM: THE STORY SO FAR

3.1. Introduction

This chapter attempts to capture the rationale behind South Africa's ongoing patent reform. It starts by giving a historical background of the 'fix the patent laws' movement and how it birthed moves to reform South Africa's patent landscape. Subsequently, it highlights key recommendations of the IP policy which have been proposed to amend the Patent Act.

3.2. The History and Effect of the 'Fix the Patent Laws' Movement in South Africa.

A discourse on the way the 'fix the patent laws' movement developed and evolved is incomplete without furnishing a brief background on the effect of the pricing of anti-retroviral drugs on the patent- access debate in South Africa.[198] At the front and centre of treating HIV was a chemical compound called *azidothymidine* (AZT), for which pharmaceutical company Burroughs Wellcome (BW) obtained a patent.[199] This patent gave BW a monopoly of the market for antiretroviral drugs, and as a result, it was able to charge $10 000 per patient per year for the treatment.[200] To provide some context, at that time, 11 per cent of South Africans were living on less than one US Dollar a day and 34 per cent on less than two US Dollars per day.[201] With about 4.2 million people infected in the year 2000, [202] many were unable to afford the anti-retroviral treatments, and this contributed to a death toll of about 250,000 people a year.[203] As discussed previously in this dissertation, the outcries from civil society increased, and this, in part, led to the Doha Declaration.

South Africa had amended its Patent Act in September 1997 to conform to the TRIPS Agreement.[204]Although the amendment increased the patent term from 17 to 20 years and allowed

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[198] Hestermeyer, Holger op cit note 67 at 1.
[199] Ibid at 5.
[200] Ibid.
[201] Huddart, Sophie et al 'The Doha declaration in action: An examination of patent law flexibilities in the South African acquired immunodeficiency syndrome epidemic' (2017) 5(1) *Journal of Health Specialties* 31.
[202] Pisani, Elizabeth, et al. *Report on the Global HIV/AIDS Epidemic-June 2000*. UNAIDS, 2000.
[203] Barnard, David 'In the high court of South Africa, case no. 4138/98: the global politics of access to low-cost AIDS drugs in poor countries' (2002) 12.2 *Kennedy Institute of Ethics Journal* 160.
[204] Fix the Patent Laws 'Campaigning for pro-public health reform of South Africa's Patent 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 on 8 July 2019.

for the grant of patents for inventions in all fields of technology, it did not take full advantage of the TRIPS flexibilities which were safeguards for public health.[205] November 1997 was a crucial period in the balancing act between patents and access when President Nelson Mandela signed into the law the amendment of the Medicines Act.[206] The change allowed for the use of parallel importation of medicines, in line with the TRIPS flexibilities.[207] This move was met with ire by the pharmaceutical establishment, and in February 1998, the Pharmaceutical Manufacturers Association (PMA) sued the South African government on behalf of 37 international pharmaceutical companies.[208] They aimed to block the amendment of the Medicines Act from entering into force.[209] They withdrew the suit in April 2001 in the wake of an international uproar and a public relations disaster.[210]

The Treatment Action Campaign (TAC) was established in 1998, with the aims of fighting for the prevention of mother- to- child transmission of HIV and securing a more proactive response from the South African government to the HIV pandemic.[211] They played a role in protesting against the against the PMA when it brought its suit opposing the amendment of the Medicines Act.[212] Also, their sustained protests pressured Pfizer, an American pharmaceutical company to make one of its brand-name drugs- *fluconazole* 'available free of cost in South Africa to the government and non-governmental organizations for the treatment of cryptococcal meningitis and esophageal candidiasis, opportunistic infections commonly affecting those with AIDS.'[213] On 11 November 2011, exactly ten years after the Doha Declaration TAC, MSF and SECTION 27 launched the 'Fix the Patent Laws' campaign (FTPL), a coalition which has grown to include 40

[205] Ibid.
[206] Medicines and Related Substances Control Act 101 of 1965.
[207] Fix the Patent Laws 'Campaigning for pro-public health reform of South Africa's Patent Act' op cit note 204.
[208] Heywood, Mark 'Debunking 'conglomo-talk': A case study of the Amicus Curiae as an instrument for advocacy, investigation and mobilisation' (2001) 5 no.2 *Law, Democracy & Development* at 135.
[209] Ibid.
[210] Fix the Patent Laws 'A timeline of intellectual property 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 on 8 July 2019.
[211] Baker, Brook K 'International Collaboration on IP/Access to Medicines: Birth of South Africa's Fix the Patent Law Campaign' (2015) 60 *NYL Sch. L. Rev* 297.
[212] Ibid at 306.
[213] Ibid at 305.

organisations.[214] The movement was borne out the realisation that, fighting against exorbitant drug prices without addressing the structural barriers to access such as the laws, was inadequate.[215]

In 2016, the FTPL coalition produced a publication which covered other diseases which did not receive much attention as a means of creating awareness of the persistent access challenges.[216] The HER 2+ Breast Cancer which was briefly introduced in chapter one is one of the diseases contained in that report.[217] Some more details will be provided here to illustrate the challenge that patents cause for the medicine that can help treat this disease. This analysis serves as proxy of the many diseases detailed in the report for which prices impede access.

As stated in chapter one, *Trastuzumab* is a drug which is effective in treating HER2+ breast cancer.[218] Unfortunately, many women have not been able to afford it because of its high price. It was estimated that in the private health sector, a 12-month treatment course cost about R485, 800 ($ 34,356) per patient.[219] The FTPL coalition argued that the extremely high price which serves to the impede access is linked to the patents held by 'Roche and Genentech (which provides exclusive marketing rights to Roche) in South Africa….'[220] Unfortunately, there is a patent monopoly which could block the entry of biosimilar [221]versions into the South African market until 2033 for this drug.[222] This is in stark contrast to India, whose handling of its *Trastuzumab* crisis is highlighted below.

In 2012 the Campaign for Affordable Trastuzumab (CFAT) was embarked on in India.[223] Their goal to draw attention to the 'exorbitant prices charged by Roche in India for patent

[214] Section 27, op cit note 4.
[215] Ibid.
[216] Fix the Patent Laws! 'Patent barriers to medicine access in South Africa: A case for patent law reform' op cit note 20.
[217] Ibid.
[218] Ibid.
[219] Ibid.
[220] Ibid.
[221] These are drugs which 'are made from living organisms but they may be made in different ways and of slightly different substances. To be called a biosimilar drug, a biological drug must be shown to be as safe as, work as well as, and work in the same way as its reference drug.' S*ee* National Cancer Institute 'NCI dictionary of Cancer terms' available at *https://www.cancer.gov/publications/dictionaries/cancer-terms/def/biosimilar-drug*, accessed on 14 September 2019.
[222] Fix the Patent Laws! 'Patent barriers to medicine access in South Africa: A case for patent law reform' op cit note 20.
[223] Ibid at 24.

trastuzumab.'[224] Their efforts led the government to consider issuing a compulsory licence for the production of a biosimilar version of the drug.[225] In the face of pressures from both the CFAT and the Indian government, Roche went into a partnership with Emcure to make a more affordable rebranded originator version.[226] Although this lowered the price of the drug, it still was not insufficient and in 2013 the pending patent applications before the Indian Patent Office (IPO) which would have extended Roche's monopoly 'dismissed by the patent office and withdrawn by Roche in the face of calls for compulsory licensing.'[227] This allowed a biosimilar version of the drug marketed by Biocon and Mylan enter the market at 70 per cent less than the price charged by Roche for the branded version, and 45 percent lower than the price charged by Emcure and Roche for their rebranded originator product.'[228] Sadly, this is just one of many examples of the challenges that are faced in procuring life-saving medicines in South Africa. The next section of this research examines the Intellectual Property Policy Document, Phase I, 2018 of the Department of Trade and Industry (DTI), which is meant to shape the IP landscape in South Africa and its key recommendations.

3.3. The Intellectual Property Policy Phase One and its Key Recommendations.

It took many years of going back and forth for the DTI to produce an Intellectual Property policy in 2018. The process was consultative and took the stakeholders on both sides of the divide into consideration in its preparation.[229] It is part of a two-phased approach to IP reform by the Intellectual Property Consultative Framework (IPCF), which set up the Inter-Ministerial Committee on Intellectual Property (IMCIP).[230] It provides some recommendations on patents and public health,[231] which will be examined in this section and deals with international IP cooperation.[232] The second phase of IP reform 'will focus on mainly developmental goals for South

[224] Ibid.
[225] Ibid.
[226] Ibid.
[227] Ibid at 24.
[228] Ibid.
[229] DTI IP Policy op cit note 3.
[230] Companies and Intellectual Property Commission 'Submission by South Africa: Exceptions and Limitations' available at *https://www.wipo.int/export/sites/www/scp/en/meetings/session_27/3rdparty_comments/south_africa.pdf*, accessed on 10 September 2019.
[231] DTI IP Policy op cit note 3.
[232] Ibid.

Africa and considering international best practices,…' in consultation with experts in the area.[233] This is not the first time that an attempt has been made at IP reform, in 2013 a Draft National Policy on Intellectual Property[234] was released but did not sail through.[235] The key reform proposals of the 2018 Policy concern substantive search and examination, patent opposition, patentability criteria, disclosure requirements, parallel importation, exceptions, voluntary licences, compulsory licences, and the nexus between IP and competition law.[236] Highlighted below is each of the recommendations:

3.3.1. Substantive search and examination:

The depository system governs patent grants in South Africa, whereby the commissioner for patents grants a patent once all the formalities regarding filing are fulfilled[237] Verification of the patentability criteria is a challenge under this system.[238] The advantage of this system is that it puts the financial burden of proving the validity of the patent on the interested parties when a patent is challenged before the commissioner of patents.[239]

The policy recommends that the depository system be replaced by a substantive search and examination system (SSE), regarding, at first, patents for pharmaceuticals.[240] Although it points out that in terms of cost, the depository system is advantageous, the outlook is that for the medium and long-term, a move towards the SSE is more in keeping with the National Development Plan of South Africa.[241] The policy states that an SSE system will lead to greater legal certainty for both the patent owners and the public.[242] A patent examination ensures that a patent is issued for medicines that meet the patentability criteria, thereby forestalling unnecessary monopolies for drugs that do not deserve patents.[243] The examination system strengthens the patent holder's

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[233] Ibid.
[234] Department of Trade and Industry 'Draft National Policy on Intellectual Property, 2013' available at *http://ip-unit.org/wp-content/uploads/2013/09/DRAFT-IP-POLICY.pdf*, accessed on 11 September 2019.
[235] Fix the Patent Laws 'A timeline of intellectual property reform in South Africa 1994-2015' op cit note 200.
[236] DTI IP Policy op cit note 3 at 14.
[237] Patent Act of South Africa supra note 187 at sections 34-36.
[238] Robyn- Leigh Merry 'The intention to become a substantive search and examination office' 16 October 2017, available on *https://blog.dennemeyer.com/intention-become-substantive-search-examination office?utm_source=Mondaq&utm_medium=syndication&utm_campaign=View-Original* accessed on 20 May 2019.
[239] DTI IP Policy op cit note 3 at 17.
[240] Ibid at 17.
[241] Ibid at 3.
[242] Ibid at 17.
[243] Ibid at 18.

position in the sense that it has more certainty of obtaining a valid patent, having passed through an examination process.[244]

Concerns have been raised about the phased approach to the examination process.[245] Critics have branded the phased examination system in the public health sector, which will initially limit the patent examination to pharmaceutical patent applications as discriminatory against the pharmaceutical industry, and in violation of Article 27.1 of the TRIPS Agreement which provides for the grant of patents in all fields of technology.[246] In defence of this policy objective, the DTI has stated that this move does not violate the TRIPS Agreement for the following reasons:

a. Article 27.1 of the TRIPS only refers to discrimination in three instances- the place of invention, the field of technology, and whether products are imported or locally produced.[247] It clarifies that the provision refers to handing out patents and not differentiation in the way patents are granted and that the fact that an examination system will exist for pharmaceutical patents will not preclude the grant of patents in other fields of technology.[248]

b. It is the aim of the government to, in the long run, extend the use of the examination system to other areas of technology, commensurate with its increase in capacity in the future.[249]

c. The Companies and Intellectual Property Commission (CIPC) has already trained highly qualified patent examiners who will be able to handle the task of examining these patent application.[250]

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[244] Ibid.
[245] The Anton Mostert Chair of Intellectual Property Law 'Commentary on the draft intellectual property 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 on 15 August 2019
[246]Ibid at 10.
[247] TRIPS Agreement supra note 18 at Article 27.
[248] DTI IP Policy op cit note 3 at 18-19.
[249] Ibid at 19.
[250] Ibid.

d. South Africa will not be the first in Africa to adopt an examination system; Egypt, Ethiopia, and the African Regional Intellectual Property Office (ARIPO) use this system. Therefore, it should come as no surprise that South Africa plans to adopt it.[251]

In addition to these, WIPO, recognizes the complexity of implementing an SSE system and endorses a phased approach in some cases.[252] It states that '[p]atent 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.'[253] Although it is not the focus of this dissertation, an exciting area for further research will be to see how the government implements this method, and what effect it will have on the number and quality of patents granted under a search and examination system.

3.3.2. Patent opposition

Under the current Patent Act, third parties can oppose applications for the restoration of a lapsed patent,[254] correction of clerical errors and amendment of documents,[255] amendment of a specification,[256] and an application for a compulsory licence.[257] The Act does not provide for any form of third- party opposition to the grant of a patent, be it pre or post-grant.[258]

The Policy outlines three avenues through which a patent opposition can be made. The first is a system which allows third parties to submit 'information that is relevant to the consideration of an application for a patent….'[259] This is also referred to as a third-party observation mechanism.[260] The second is the pre-grant procedure, whereby a third-party is allowed to oppose the grant of a patent 'at some point between the submission of the application and the making of a

[251] Ibid.
[252] World Intellectual Property Organization. 'Alternatives in patent search and examination: Policy guide.' (2014), available at *https://www.wipo.int/edocs/pubdocs/en/wipo_pub_guide_patentsearch.pdf* accessed on 15 August 2019.
[253] Ibid at 3.
[254] Patent Act of South Africa supra note 187 at section 47.
[255] Ibid section 50.
[256] Ibid section 51.
[257] Ibid section 56.
[258] Berger, Jonathan op cit note 84 at 29.
[259] Ibid at 20.
[260] Ibid.

decision on whether the patent should be granted.'[261] The post-grant procedure is the last type of opposition sought, and it prompts a review of patent grants within a specific period.[262]

There is an admittance that without proper safeguards, these avenues can be abused.[263] This is why the policy stresses that 'appropriate safeguards' will be included in the opposition process to prevent its abuse.[264] Time was also taken to justify its proposed introduction by stating that it is not an alien concept to other IP regimes as such and is used under the European Patent Convention, which provides 'for post-grant opposition procedure in Articles 99 to 101.'[265]

3.3.3. Patentability criteria

As discussed in chapter two, the TRIPS Agreement lays down the patentability criteria as novelty, inventive step and capability to be used in industry for the grant of a patent, but does not define what each standard means.[266] In this equation, the requirement of an inventive step or 'non-obviousness' is the most flexible of the three conditions.[267] The policy iterates the need to interpret these requirements in line with South Africa's Constitution.[268] It further strengthens its assertion of freedom of interpretation by referring to Article 1.1 of the TRIPS Agreement, which allows WTO members to choose the best way in which to implement the Agreement.[269] Article 1.1 along with Article 8.1, which enables South Africa to make IP laws which adequately cater for its health and nutritional needs, means that the country is within its rights to interpret the patentability criteria in a way that is compatible with its Constitution and National Development Plan.[270] The aim is to craft the patentability criteria in such a way that only medicines which are genuinely innovative will be granted patents.[271] This will go hand in hand with the SSE system, which is recommended as the way forward in the nation's quest to improve its public health sector and promote access to life-saving medicines.

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[261] Ibid.
[262] Ibid.
[263] Ibid.
[264] Ibid.
[265] Ibid at 21.
[266] TRIPS Agreement supra note 18 at Article 27.1.
[267] DTI IP Policy op cit note 3 at 22.
[268] Ibid at 22.
[269] Ibid.
[270] Ibid.
[271] Ibid.

3.3.4. Disclosure requirements

Disclosure of an invention is a cardinal principle in patent law; it lies on the other side of the coin of allowing patent owners to enjoy a monopoly over their inventions.[272] While access to affordable medications is the ultimate goal, there also needs to be a transfer of the knowledge behind the development of these medicines.[273] Article 29.1 of the TRIPS Agreement requires WTO members to disclose their invention in such a way that it is 'sufficiently clear and complete for the invention to be carried out by a person skilled in the art.'[274] This can be done by providing 'information concerning the applicant's corresponding foreign applications and grants.'[275] An applicant for a patent under the current Act does not need to furnish information regarding prior applications, and this is something which a revised Patent Act will seek to remedy.[276]

3.3.5. Parallel importation

The policy clearly states that the concept of parallel importation is not new to South African law. Section 15(1)(*C*) of the Medicines and Related Substances Act provides for parallel importation as follows:

> The Minister [of Health] may prescribe conditions for the supply of more affordable medicines in certain circumstances to protect the health of the public, and in particular may-
>
> (a) Notwithstanding anything to the contrary contained in the Patents Act, 1978 (ACT 57 of 1978), determine that the rights with regard to any medicines under a patent granted in the Republic shall not extend to acts in respect of the medicine, or with his or her consent:
>
> (b) Prescribe the conditions on which any medicine which is identical in composition, meet the same quality standard and is intended to have the same proprietary name as that of another medicine already registered in the Republic, but which is imported by a person other than the person who is the holder of the registration certificate of the medicine already registered and which originates from any site of manufacture of the original manufacture of the original manufacturer as approved by the Authority in the prescribed manner, may be imported;

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[272] Ellen F.M.'t Hoen 'TRIPS, pharmaceutical patents and access to essential medicines: Seattle, Doha and beyond' op cit note 5 at 55.
[273] Ibid.
[274] TRIPS Agreement supra note 18.
[275] Ibid at Article 29(2).
[276] DTI IP Policy op cit note 3 at 23.

> (c) Prescribe the registration procedure for, as well as the use of, the medicine referred to in paragraph (b).

It is made clear that the importation referred to here is well guarded against counterfeits, and there need not be fear about whether utilizing this method will jeopardize the quality of drugs which are imported into the country.[277] This is because of the robust provisions which have been made in the Medicines Act in this regard.

The challenge arises when there is a narrow interpretation of section 45(2) of the Patent Act to make it challenging to obtain parallel imports.[278] The policy seems to suggest that this can be resolved by expressly stating that the provisions on parallel importation in the Medicines Act do not constitute an infringement of the patentee's right under the Patent Act. [279] It makes it clear that this will apply precisely to the public health sector and that if this flexibility is required in any other industry, there is a need for the Ministry which caters for it to 'sanction sector-specific parallel importation in a controlled manner through legislative provisions similar to section 15C of the Medicines Act….'[280]

3.3.6. Exceptions

The policy right from the outset strives to strike a balance between 'technological innovation and …the transfer and dissemination of technology.'[281] The TRIPS Agreement gives room to the Member States to provide limited but adequate exceptions in their patent systems.[282] One such exception which South Africa has already adopted is the 'Bolar exception,' which was captured in the 2002 amendment of the Patent Act. It aims to ensure that 'generic producers to research, create and test a patented product before the end of the term of the patent, thereby allowing the entry into the market as soon as possible once the patentee's exclusive rights lapse.'[283] The amendment of the Act will not affect the status of this exception.

Research and experimental use is another crucial exception which, according to the IP Policy, needs to be catered for to create and maintain that atmosphere of knowledge flow and

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[277] Ibid at 24.
[278] Ibid at 25.
[279] Ibid.
[280] Ibid.
[281] Ibid.
[282] Ibid.
[283] Ibid at 26

transfer in South Africa.[284] When experimental applications of a patented product are blocked, it reduces the likelihood of being able to improve on the way things are done, hence a technological or innovative loss is made.[285] To forestall this loss, the Policy indicates an intent to craft robust exceptions for research and experimental activities which comply with the TRIPS Agreement through a consultative process. [286]

3.3.7. Voluntary licensing

This is a non-confrontational way through which access to medicines can be obtained and is a route which the policy seeks to explore. The primary consideration in the policy is how a voluntary licencing mechanism can be used to provide incentives to negotiate fair terms with patent-holders.[287] The idea behind having a voluntary licencing system is to ease the transfer of technology and make it easier for South Africa to boost its production of pharmaceuticals in such a way that is in line with the TRIPS Agreement.[288] This method is one that may help foster better collaboration between the international pharmaceutical companies and the local generic manufacturers.[289] Creating a generally non-confrontational environment for the transfer of technology is a viable way through which South Africa can achieve its development goals in the health sector.

3.3.8. Compulsory licences

The policy makes it clear that voluntary licences are the preferred route to take, but there are instances where it is impossible to reach an agreement regarding the same.[290] In such cases, compulsory licences come into play to ensure that there is no deprivation of access to life-saving medication.[291] The policy points out that the current form in which the compulsory licencing scheme is provided for is akin to litigation and is expensive to obtain; and, therefore, envisions a more efficient and cost-effective method.[292] Even though it does not go into detail to describe what

[284] Ibid.
[285] World Intellectual Property Organization Patent related flexibilities op cit note 20 at 21.
[286] DTI IP Policy op cit note 3 at 26
[287] Ibid at 28.
[288] Ibid.
[289] Ibid.
[290] Ibid at 27.
[291] Ibid.
[292] Ibid at 29.

this new proposed system will entail, it clearly states the desire to make it in line with both the TRIPS Agreement and South Africa's development objectives.[293]

Another type of compulsory licence which this section discusses, and which is also part of South Africa's Patent Law is the government use licence, which the second chapter discussed. The current challenge with this is that the procedure is quite cumbersome in the sense that for the government to grant a compulsory licence for this purpose, it first has to have had prior negotiations for a voluntary licence which failed.[294] Article 31 of the TRIPS Agreement does not impose prior negotiation as a precondition for the issuance of a government use licence; therefore, the policy seeks to make an amendment that better reflects the position of the TRIPS Agreement.[295]

South Africa has the most developed generic pharmaceutical market on the continent, and with the proposed changes is pushing to improve local production and export of medicines.[296] Unfortunately, there are countries which are unable to produce the needed medications for their health needs even when they can issue compulsory licences- this is where compulsory licences for exports come to the fore. The policy states that the government seeks to take a consultative approach to create a system that helps to actualise Paragraph 6 of the Doha Declaration, which addresses the issue of insufficient manufacturing capacities.[297]

3.3.9. IP and Competition law

There is an acknowledgment in the IP Policy of the intersection between IP and Competition law.[298] It is an area which requires collaboration with the Competition Commission in determining the scope of intersection between the two fields.[299] Competition law plays a role in ensuring that patents are not used to create anti-competitive monopolies.[300] As a product of the collaboration between IP and Competition law arises the idea that 'competition-related TRIPS flexibilities…' should be made with a consumer-focussed outlook.[301] An important point which the policy

[293] Ibid.
[294] Patent Act South Africa supra note 187 at section 4.
[295] DTI IP Policy op cit note 3 at 30.
[296] Invest SA 'Pharmaceuticals' available *at http://www.investsa.gov.za/investment-opportunities/advanced-manufacturing/pharmaceuticals/*, accessed on 20 August 2019.
[297] DTI IP Policy op cit note 3 at 30.
[298] Ibid at 29.
[299] Ibid.
[300] Ibid at 30.
[301] Ibid.

document makes is that the enforcement of competition must be done in an exemplary manner while ensuring that the gains made from IP are considered.[302] It stresses that the relationship between IP and Competition Law is still in its foetal stage, which provides room to 'develop fields of work and guiding principles.'[303]

To illustrate how minimal the contact between Competition law and IP has been, a study of seven countries and how their IP legislations relate to Competition law found that only the US Patent Code[304] made any reference to competition.[305] Paragraph 200 of the US patent policy states that 'to ensure that inventions made by non-profit organizations and small business firms are used in a manner to promote free competition and enterprise without unduly encumbering future research and discovery.'[306] Besides, section 209 is to the effect the government will not grant a licence for an invention it owns if it violates antitrust law and suppresses competition.[307] Egypt also does an excellent job at incorporating competition-related provisions into its law.[308] This provision will be used as a guide to draft the proposal for IP and Competition Law in the final chapter of this dissertation and therefore, will not be repeated here. It is not surprising that there is little interface with Competition law from the patent angle because the competition is not one of the requirements for the grant of a patent.[309] The collaborative approach called for by the IP Policy is a step in the right direction, and it should help yield fruit in line with the vision cast by the South African Government.

3.4. Conclusion

This chapter covered themes central to South Africa's IP reform to ascertain whether it takes proper advantage of the TRIPS Agreement. The balancing act between the public's health and the rights of patent holders is a tricky one. However, the policy which has been proposed by the Department of Trade and Industry represents a balanced approach. The phased approach to IP

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[302] Ibid.
[303] Ibid.
[304] U.S. Patent Code USC 35.
[305] Oliveira, Gesner, Thomas Fujiwara and Eduardo L Machado 'Intellectual Property and Competition Policy' 2007 at 30.
[306] U.S. Patent Code supra note 304.
[307] Ibid.
[308] Law No. 82 of 2002 Pertaining to the Protection of Intellectual Property Rights, available at *https://www.wipo.int/edocs/lexdocs/laws/en/eg/eg001en.pdf*, accessed on 20 August 2019 at article 23(5).
[309] Oliveira, Gesner op cit note 305 at 30.

reform shows that the nation is being realistic about its current capabilities and is more concerned about getting things right through a progressive approach, rather than making sweeping changes that it may not be able to maintain in the long run.

CHAPTER FOUR
HOW INDIA'S PATENT REFORM CAN HELP SOUTH AFRICA TO IMPLEMENT ITS PATENT REFORM

4.1. Introduction.

To undertake a task as complicated and controversial as reform of the IP system, particularly patents and public health, the experience of other jurisdictions must be drawn on. India is a classic example of the benefits and challenges that arise from patent law reform and presents an excellent example from which South Africa can draw. This chapter first justifies why it is essential to study India's reform. Next, it considers how India reformed its patent laws to conform with the TRIPS Agreement while taking advantages of the flexibilities it provides; its use of the TRIPS flexibilities is also examined. In addition to this, it examines the current state of India's patent system and the lessons South Africa can learn from India in this regard.

4.2. The Importance of Studying India's Reform to South Africa.

At first glance there is little similarity between India and South Africa, India, with a population of over 1.37 billion people is the second-most populous nation in the world only behind China,[310] while South Africa has a population of only 58.8 million people.[311] One thing both countries have in common though is their extremely high-income inequality rates. In 2018, it was estimated that the top 10 per cent of the Indian Population possessed 77 per cent of the country's wealth.[312] In South Africa, it is estimated that the top 1 per cent of the country's population controls 70.9 per cent of its wealth.[313] In providing context as to why India is at the forefront of patent reform, it is essential to point out that it is the world's foremost producer of affordable generic medicines and is often informally referred to as the 'pharmacy of the developing world.'[314] The growth of its local drug manufacturing industry is partly because before the implementation of its responsibilities

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[310] Statistics Times 'Population of India' 3 May 2019 available at *http://statisticstimes.com/demographics/population-of-india.php*, accessed on 20 August 2019.
[311] Department of Statistics, Republic of South Africa 'SA population reaches 58.8 million' available at *http://www.statssa.gov.za/?p=12362*, accessed on 20 August 2019.
[312] OXFAM International 'India: extreme inequality in numbers' available at *https://www.oxfam.org/en/even-it/india-extreme-inequality-numbers*, accessed on 11 September 2019.
[313] 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 on 11 September 2019.
[314] Sampat, Bhaven '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* at 4.

under the TRIPS Agreement it did not provide for the patenting of pharmaceutical products.[315]The booming generic market means that the availability of these cheaper alternatives to branded pharmaceuticals enhance both production for its local market, as well as exportation to other countries around the world, some of which do not have the capacity and or the legal frameworks to enhance the production of alternatives to patented medications.[316]

That said, India is a country that had to move from a Patent Act that was not in line with the TRIPS Agreement to one which complies with and recognises its minimum standards.[317] Although a tricky move and one that was opposed by civil society groups, India has seemingly managed to ensure that it has made adequate provisions that cater to the health of its citizens without violating the TRIPS Agreement.[318] South Africa is still in that process, and it will be useful to examine what has been done in India to ascertain South Africa's best route to effective reform.

4.3. India's Successful Implementation of the TRIPS Agreement and its Use of the TRIPS Flexibilities.

At this point, it behoves us to peek at the historical underpinnings of India's Patent system. Before the TRIPS Agreement coming into force, India's patent system was friendly in terms of access to pharmaceutical medicines.[319] The first patent law which India had was enacted by the British in 1856, and as one expects, catered mainly for British economic interests.[320]At the time of India's independence in 1947, the Patents and Designs Act of 1911 was in force.[321]The pharmaceutical landscape was dominated by foreign companies who held most of the pharmaceutical patents, with 8 out of every 10 pharmaceutical companies of foreign origin.[322] The local pharmaceutical industry expressed their dissatisfaction of the status quo, calling for a patent system that would promote

[315] Ibid at 3.
[316] Liu, Jodie '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* 56 at 207.
[317]Ibid at 211.
[318] Sundaram, Jae 'India's trade-related aspects of Intellectual Property Rights compliant pharmaceutical patent laws: what lessons for India and other developing countries?' (2014) 23, no.1 *Information & Communications Technology Law* at 12
[319] Ibid at 2.
[320] Ibid.
[321] Act II of 1911.
[322] Sundaram, Jae op cit note 314 at 3.

industrial growth and development within the country.[323] The India government gave ear to their concerns by setting up two committees which largely contributed to patent reform in India.[324]

The first was a Patent Enquiry Committee was set up by the government in 1948 and was responsible for reviewing the 1911 Patents and Designs Act.[325] In April 1950, three years after India's independence, the committee led by Justice Bakshi Tek Chand, 'submitted a report, recommending a series of changes, including the introduction of compulsory licensing, and the creation of a more stable legal framework to tackle the abuse of patents.'[326] This report served as the basis for a bill which was proposed before the lower house of parliament, but which lapsed due to the dissolution of the lower house.[327]

The second committee, known as the 'Ayyangar Committee,' was headed by Justice Rajogopala Ayyangar, which issued a report in 1959[328] that formed the basis of the Indian Patent Act.[329] The committee found that between 80-90 per cent of the patents granted by India were awarded to foreign companies with no interest in the country's economic and no intent to manufacture within the state.[330] The companies' strategy was to obtain these patents, which granted them a monopoly of the market and by extension, stopped competitors in the same field from other countries from exporting their products to India.

Consequently, Indians had no option but to pay the high prices for the products on offer by the patent holder(s) and were stopped from purchasing cheaper alternatives because of the patent monopolies.[331] Owing to these challenges, the committee recommended that it was in the country's interest to sculpt a patent system which promoted 'access to resources at lower prices…'[332] It is worth noting that at the time of its independence, over two-thirds of the population lived in rural areas in an agrarian economy.[333] This was coupled with the fact that there was little to no local

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[323] Ibid.
[324] Ibid.
[325] Ibid.
[326] Ibid.
[327] Ibid 4
[328] Ibid.
[329] The Indian Patent Act no 37 of 1970.
[330]Ramanna, Anita 'Interest groups and patent reform in India' (2003) 2003-006. Indira Gandhi Institute of Development Research, Working Paper, Mumbai, India at 3.
[331] Ibid.
[332] Ibid.
[333] Sundaram, Jae op cit note 318 at 3.

capacity for drug production, and an organised health care system was lacking.[334] These factors meant that the country did poorly in providing access to affordable medicines for its people, except for the wealthy who were few.[335] At that time, 80 per cent of the pharmaceutical companies in India belonged to foreign multinational companies who held most of the pharmaceutical patents.[336]

The events described above led to the enactment of the Indian Patent Act of 1970,[337] which came into force on 20 April 1972 and set out to 'boost the Indian economic growth through indigenous technology development, to make the fruits of technological innovations to be accessible for public purposes….'[338] The Act granted pharmaceutical process patents as opposed to patents for the products themselves.[339] The patent term was also downscaled from sixteen to fourteen years in general, and seven years for pharmaceutical patents in particular.[340] These reforms aimed to bring Indian medicine production to the fore by encouraging local content by limiting the strength of patents, broadening the scope of compulsory licences and including an exception for research purposes.[341]

With the TRIPS Agreement coming into force, however, everything changed. This change did not come unopposed by developing countries, including India.[342] India has been historically opposed to the TRIPS Agreement as it made it mandatory for WTO countries, including India, to patent pharmaceutical products in addition to the processes which were already subject to patent rights before the TRIPS Agreement.[343] The opposition manifested itself both locally and internationally and was championed by 'Industry and NGO groups who protested against change. While Industry stressed the losses and price rises in drugs that would occur if TRIPS was adhered to, NGOs pointed out the negative implications on…access to medicine….'[344] Both Industry and the NGOs had to revise their previously tough stance against reform for the amendment of the

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[334] Ibid.
[335] Ibid.
[336] Ibid.
[337] Indian Patent Act supra note 329.
[338]Sundaram, Jae op cit note 318 at 5
[339] Ibid.
[340] Liu, Jodie op cit note 316 at 211.
[341] Ibid.
[342] Sampat, Bhaven 'Institutional innovation or institutional imitation? The impacts of TRIPS on India's patent law and practice' op cit 314 at 3.
[343] Ibid.
[344] Ramanna, Anita op cit note 330 at 4.

Patent Act to take place.[345]The government took advantage of the transition period and waited till 2005 to make its Patent Act comply with the TRIPS Agreement.[346] While the process patent system was still in place, India had to create a 'mailbox' wherein patent applications were filed for examination, per Article 70.8(a) of the TRIPS Agreement, pending the amendment of the Act.[347] This procedure was implemented through the enactment of the Patents (Amendment) Act of 1999.[348] The second amendment which brought the country's patent laws further in line with the TRIPS Agreement took place in 2002,[349] 'which introduced the Indian 20-year patent term, reversed the burden of proof for process patent infringement, and also modified the compulsory licensing requirements.'[350]

In March 2005,[351] the Patent Act was amended to reflect the necessary changes for TRIPS compatibility.[352] This shift meant that India would start to issue product patents in all areas of technology, including the pharmaceutical sector and also increase the patent term to 20 years from the date of application in line with TRIPS.[353] This did not end the criticism of the reform by the Western pharmaceutical industry who argued that India patent laws 'define products narrowly as "new chemical entities"; fail to guarantee data protection; continue to provide for compulsory licensing if the Controller of patents determines that public interest is not being served.'[354]

Section 3(d) is central to the Indian Patent Amendment Act of 2005. It provides that: 'the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.'[355] This section was enacted specifically to combat a practice called 'evergreening.' It arises when a pharmaceutical company

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[345] Ibid,
[346] Ibid at 9.
[347] Sundaram, Jae op cit note 318 at 10
[348] The Patents (Amendment) Act 1999, No. 17, Acts of Parliament, India, 1999.
[349] The Patents (Amendment) Act 2002, No. 38, Acts of Parliament, India, 2002.
[350] Sundaram, Jae op cit note 318 at 11.
[351] Ibid.
[352] The Patent (Amendment) Act 2005, No 15 of 2005, Acts of Parliament, India, 2005.
[353] Jafar, K., and P. Sajna 'Access to medicines and performance of the Indian pharmaceutical industry: Examining India's experience in the new patent regime1' (2018) 20 (4) *Journal of Health Management* at 4.
[354] Haley, George T., and Usha CV Haley 'India: a study in patent-law effects' in *The Global Challenge of Intellectual Property Rights* (2009) at 100.
[355] Indian Patents Act of 2005 supra note 352 at section 3(d).

applies for a patent for 'incremental innovations' on a particular drug, thereby extending its monopoly of the market for that drug.[356] An example of India's response to evergreening is the case of *Novartis v. Union of India,*[357] which will be discussed later in this chapter.[358] The transition of India is proof that membership to the WTO does not stop a Member State from maintaining a patent regime which caters for the health needs of its people.[359] TRIPS compliance should not be evidenced by overly strong patent protection, but a balanced and effective one.[360] There has been a longstanding misconception that stronger patent protection signifies better compliance with the TRIPS Agreement.[361] The claim is a half-truth; efficient balancing of TRIPS responsibilities and flexibilities are the best way to obtain maximum benefits under the post-TRIPS regime.[362]

4.4. The Use of TRIPS Flexibilities in Indian Patent Laws.

This section looks at how India, through its judicial system, has taken advantage of the flexibilities which are built into its patent laws. There have been a couple of high-profile cases in recent years, which have arisen from India's use of TRIPS flexibilities which are built into its patent law, and they will be discussed in the context of the flexibilities which have been exercised below.

4.4.1. The court's interpretation of Section 84 of the Patent Act in the Case of Bayer v Natco.[363]

Regarding compulsory licences under the 2005 Amendment, the scope within which they could be granted under the 1970 Act was maintained.[364] The section of the Act which governs the grant of compulsory licences is section 84. An applicant may apply three years after the grant of the patent, to obtain a compulsory licence, provided: 'reasonable requirements of the public with respect to the patented invention have not been satisfied…the patented invention is not available

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[356] Sara Beth Myers 'A healthy solution for patients and patents: How India's legal victory against a pharmaceutical giant reconciles human rights with intellectual property rights' (2008) 10 (3) *Vanderbilt Journal of Entertainment and Technology Law* at 773.
[357] *Novartis AG v. Union of India*, 2007 A.I.R. 24759 (2013) (Madras H.C.).
[358] See 4.4.2.
[359] Liu, Jodie op cit note 316 at 208.
[360] Sampat, Bhaven 'Institutional innovation or institutional imitation? The impacts of TRIPS on India's patent law and practice' op cit 314 at 5.
[361] Ibid at 3.
[362] Ibid.
[363] Indian Patents Act of 2005 supra note 352.
[364] Sundaram, Jae op cit note 318 at 13.

to the public at a reasonable price…,' and the invention has not been worked in India in the period between its issuance and the application.[365]

In this case, the Intellectual Property Appellate Board (IPAB) was called upon to interpret the import of the issuance of a compulsory licence in favour of Natco against Bayer, based on section 84 of the Patent Act.[366] The Controller of Patents granted a compulsory licence against Bayer giving the reason that it was in the public's interest to do so and that the application had met the three requirements needed for the grant of a compulsory licence.[367] Bayer petitioned the High Court of India in opposition to the compulsory licence issued by the Controller of Patents against it in favour of Natco Pharmaceuticals Limited (Natco), under section 84 of the Indian Patent Act (1970).[368] The licence was granted for a drug called *Sorafenib Tosylate*, which the petitioner was granted the patent to in 2008 and which was marketed under the brand name *Nexavar*.[369] The petitioner Bayer challenged the 'manner in which…Section 84 of the Act…,' was applied.[370] It is worth noting that this was the first compulsory licence issued by India since it became a signatory to the TRIPS Agreement and amended its Patent Act in 2003 and 2005 respectively.[371]

The respondent had earlier applied for a voluntary licence to manufacture and sell the drug from the petitioner because the drug 'had not met the reasonable requirement of the public nor was it reasonably priced nor was it worked in the territory of India.'[372] Although the petitioner rejected the respondent's application, in a response dated 27 December 2010, it 'left the issue open by asking Natco to approach them within 14 days in case they [the petitioners] have anything further to add.'[373] Nothing further was added by the petitioner, and this prompted the respondent to apply for the compulsory licence.[374] After considering the facts, the court dismissed the petition of the petitioner on the ground that the requirements for the grant of a compulsory licence were satisfied,

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[365] Indian Patents Act of 2005 supra note 352 at section 84(1).
[366] *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 on 20 August 2019.
[367] Ibid.
[368] Ibid at 2.
[369] Ibid.
[370] Ibid.
[371] Ibid.
[372] Ibid at 6.
[373] Ibid.
[374] Ibid at 7.

thereby upholding the decision of the Controller of Patents.[375] The petitioner made a Special Leave Petition to the Supreme Court, against the High Court's judgment which was dismissed in line with the decision of the lower court.[376]

4.4.2. The court's interpretation of section 3(d) of the Indian Patent Act in the case of Novartis v. Union of India.[377]

Shortly after the amendment of the Patent Act, Novartis questioned the validity of those changes. The case between the Indian government and the pharmaceutical company was over a cancer medicine called Gleevec.[378] The company's application for a patent for a beta crystalline form of *imatinib mesylate* which it already held a patent for was refused by the patent office.[379] The refusal was based on section 3(d) of the Act.[380]

The Patent office stated that the medicine was not significantly different from an out of patent version which was freely available as a generic and granting a patent for such a minute change will lead to a significant increase in the cost of the medication.[381] In response to this, Novartis instituted an action against the Indian government calling into question the constitutionality and level of compliance of section 3(d) with the TRIPS Agreement.[382] Novartis argued that the clause in section 3(d) which stated that 'a new form of a known substance which does not result in the enhancement of the known efficacy of that substance,'[383] was not enforceable because it was unclear. [384] It also argued that the law 'denies patent protection to new versions of drugs invented before 1995….'[385] The High Court dismissed the suit on the ground that section 3(d) was not in conflict with the Constitution. On the second ground, it claimed that it had no jurisdiction to rule on the compliance of the section with the TRIPS Agreement.

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[375] Ibid at 52.
[376] *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 on 10 September 2019.
[377] *Novartis AG* supra note 35.
[378] Sara Beth Myers op cit note 356 at 765.
[379] Ibid at 767.
[380] *Novartis* supra note 357.
[381] Sara Beth Myers op cit note 356 at 767.
[382] Ibid.
[383] Indian Patents Act of 2005 supra note 352 at section 3(d).
[384] *Novartis* supra note 357.
[385] Sara Beth Myers op cit note 356 at 768.

The ruling of the court affected both India's generic market as well as the other pharmaceutical markets that are dependent on it.[386] Had the decision gone in favour of Novartis, it would have allowed for the sustained practice of 'evergreening' in India, a situation where a pharmaceutical company makes minor changes to medicine or develops an alternate use for it which allows it to extend its patent protection above its original term.[387] The implication of this is that many drugs which should be off-patent would enjoy an extended lifespan. This delays the production of generic versions which may help to provide cheaper alternatives to the branded medicines.

Even with its controversial wordings and effect, as seen in the Novartis case, section 3(d), is an exciting way through which India has made wise use of the system. This section gives the patent office the discretion to reject patent applications, which it determines do not to meet up to the patentability criteria. This is the first line of defence against prohibitively high prices and is a cost-effective way of addressing the issue. In practice, it has been found that despite the application of this section in the Novartis case, the Indian Patent Office has not done a commendable job in reducing the issuance of secondary patents.[388] It has been estimated that between 2009 and 2016, 72 per cent of the pharmaceuticals granted have been secondary patents.[389] This shows that it is not enough to have strict patentability criteria, but the administering authority also has to be willing and able to apply such criteria.

4.5 India's new IP policy and what it means for public health

So far, this chapter has lauded India's past efforts toward the protection of the health of its citizens and secondary markets using TRIPS flexibilities. Three years ago, India came up with its IP Policy,[390] with a view to craft the future IP landscape of the country. The policy has courted significant criticism and has been tainted by controversy since its release.[391] The pressures from

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[386] Ibid.
[387] Holman, Christopher M., Timo Minssen, and Eric M. Solovy 'Patentability standards for follow-on pharmaceutical innovation' (2018) 37(3) *Biotechnology Law Report* 37, 131.
[388] Ali, Feros, et al 'Pharmaceutical patent grants in India: how our safeguards against evergreening have failed, and why the system must be reformed.' (2018) at 6.
[389] Ibid.
[390] National Intellectual Property Rights Policy, May 12, 2016, available at *http://dipp.nic.in/English/Schemes/Intellectual_Property_Rights/National_IPR_Policy_08.08.2016.pdf* accessed on 12 August 2019.
[391] Shamnad Basheer and Pankhuri Agarwal 'India's new IP policy: A bare act?' (2018) 13 *Indian Journal of Law and Technology* 1.

the global North, particularly the US, have influenced India's move to reform its IP system.[392] When plans to change the Indian IP system were still in their nascent stage, the government enlisted the help of IP experts in the academia to help prepare 'a base document for a National IPR Policy.'[393] The think tank consisting IP experts from academia submitted a draft copy[394] of the base policy, but rather than acknowledge receipt; the Indian government set up another think tank, made up differently from the first one, whose findings now form the basis of the current IP policy.[395]

The second point of the mission statement for the policy states that it seeks to build an IP system which will 'focus on enhancing access to healthcare….'[396] In keeping with this, it goes on to state that it will continue to utilize the TRIPS flexibilities and adhere to the Doha Declaration on Public Health.[397] It has been heavily criticised and labelled as '… long on seductive slogans and short on substance; containing nothing more than a mouth of multitudinous platitudes and trite solutions.'[398] What exactly has birthed such criticism and more importantly, is it justified? The subsequent paragraphs in this section will briefly examine the main criticisms levelled against the policy as it relates to patents and access to medicines.

The major criticism, which is within the scope of this dissertation is that there is a significant disconnect between IP and the existing health policy of the nation.[399] The policy is said to only offer 'lip service to the use of flexibilities and does not offer any measures to optimise the use of the flexibilities.'[400] This is a valid criticism, while the policy does make a passing remark on its intent to walk in line with both the TRIPS flexibilities and Doha declaration,[401] it does not go further to provide helpful recommendations on how it intends to do so.[402]

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[392] Manufacturing Chemist 'Indian draft IPR policy critised by antiglobalisation group.' 16 April 2015, available at *https://www.manufacturingchemist.com/news/Article_page/Indian_draft_IPR_policy_criticised_by_antiglobalisation_group/107624,* accessed on 13 August 2019.
[393] Shamnad Basheer and Pankhuri Agarwal op cit note 391 at 2.
[394] Shamnad Basheer and Yogesh Pai, Indian Intellectual Property Policy: A Baseline Draft, available at *https://spicyip.com/wp-content/uploads/2014/11/National-IP-Policy-final-1E. pdf* accessed on 13 August 2019.
[395] Ibid at 2.
[396] Ibid at 7.
[397] Ibid at 14.
[398] Ibid.
[399] Shirin Syed 'Why India's IP policy needs a South African tweak' available at *https://www.thehindubusinessline.com/specials/pulse/why-indias-ip-policy-needs-a-south-african-tweak/Article24476145.ece,* accessed on 13 August 2019.
[400] Ibid.
[401] National Intellectual Property Rights Policy (India) op cit note 390 at 14.
[402] Ibid.

Entwined in any patent/access to medicine discourse is the balancing of the patent-holders' rights with those of the public to access the patented drugs. The policy makes mention of the need to have that balance; in fact, the policy states that 'it is equally important to balance the rights of the public in a manner conducive to social and economic welfare and to prevent misuse or abuse of IP rights.[403] Unfortunately, once again, no helpful recommendations are made regarding how this balanced may be achieved.[404] The draft made by the first think tank[405] made attempts to address this issue by proposing the use of 'measures such as compulsory licensing and price control to effectuate a better balance between private IP rights and the larger public interest.'[406] Rather than use the opportunity to make helpful recommendations, there seems to be a stronger push for more oppressive enforcement of IP as a panacea to the problems that face the IP sector.[407]

The final criticism which will be considered here is the general tone of the policy, which seems to suggest IP as an end in itself and an automatic stimulant for innovation.[408] The problem here is not so much the view that IP promotes innovation, but the fact that there is no acknowledgment that in some cases IP may serve to block innovation.[409] The policy states that:

> A nation-wide program of promotion should be launched with an aim to improve the awareness about the benefits of IPRs and their value to the rights-holders and the public. Such a program will build an atmosphere where creativity and innovation are encouraged in public and private sectors, R&D centers, industry, and academia, leading to the generation of protectable IP that can be commercialized.[410]

The above suggests that a heightened focus on promoting the advantages of IP bears a direct linkage to more innovation as the last sentence alludes. The assumption is rooted in the belief that if only people knew that they could protect the things which they create, it would serve as an incentive to produce more. The first chapter of the dissertation considered this argument in the context of public health, and it was shown that sometimes owning the monopoly right granted by a patent may serve as a disincentive for production.[411]

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[403] Ibid at 24.
[404] Shamnad Basheer and Pankhuri Agarwal op cit note 391 at 15.
[405] Shamnad Basheer and Yogesh Pai op cit note 394.
[406] Shamnad Basheer and Pankhuri Agarwal op cit note 391 at 15.
[407] National Intellectual Property Rights Policy (India) op cit note 390 at 24.
[408] Shamnad Basheer and Pankhuri Agarwal op cit note 391 at 6.
[409] Ibid.
[410] National Intellectual Property Rights Policy (India) op cit note 390 at 8.
[411] See 1.4.4 (c) in chapter one of this dissertation.

Closely linked to this line of thought is the assumption that stronger IP laws, particularly patents, will lead to a faster rate of development.[412] A study was conducted to ascertain the accuracy of this assumption to determine what contribution IP makes towards the process of development.[413] It stated that WIPO was created based on the belief that there was a significant 'causal link' between IP, technology, and development.[414] The research concluded that IP is a two-sided coin which presents both a burden and an opportunity.[415] It suggested that careful thought must go into crafting IP laws which will serve to stimulate development.[416] A second study[417] found that there is a misunderstanding of the link between IP and economic development.[418] The previous stance was that the stronger the IP, the higher the likelihood of economic growth, but this is coming under increasing scrutiny.[419] Developed countries more often than not started with relaxed IP standards and scaled them up as they grew.

For instance, Brazil, Russia, India, and China are pointers to the fact that the model which developed nations used before they developed is still viable today.[420] The research ended with a poignant note of caution by recommending that ratcheting up IP with the hope of speeding up development is not the answer.[421] Instead, a more nuanced approach which merges the need to incentivise IP creators and consumers is needed.[422] What is interesting is that from the second study, we can see that India has done positively in terms of economic growth with a more relaxed IP system when compared to South Africa. One wonders why the new IP policy of India seems to move more closely to the system which it left behind many years ago.

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[412] National Intellectual Property Rights Policy (India) op cit note 390 at 10.
[413] Blakeney, Michael, and Getachew Mengistie 'Intellectual property and economic development in sub-Saharan Africa' (2011) 14(3-4) *The Journal of World Intellectual Property* at 239.
[414] Ibid.
[415] Ibid.
[416] Ibid.
[417] Ncube, Caroline Bongiwe 'Harnessing intellectual property for development: some thoughts on an appropriate theoretical framework.' (2013) 16(4) *Potchefstroom Electronic Law Journal/Potchefstroomse Elektroniese Regsblad* at 368.
[418] Ibid.
[419] Ibid at 371.
[420] Ibid at 372.
[421] Ibid at 382
[422] Ibid at 382.

4.6 Lessons South Africa Can Learn from India in Patent Reform.

In its quest to create a more efficient patent system, South Africa needs to ensure that lessons are learned from countries that have successfully made similar moves. The first thing which is essential to draw from India is the willingness to go against the grain and ensure that the health needs of the country are met in a way that is compliant to the TRIPS Agreement. The Indian Patent Act has come under criticism from the developed world, and it has had to make difficult decisions in a quest to address the issues that have arisen.

South Africa may not be as big as India in terms of the size of its generic market; however, there is an opportunity to expand its horizons and become the biggest exporter of medicines in Africa, particularly to countries which cannot produce on their own. It is promising that the South African government is showing such foresight through the IP policy where it outlines its aim to increase the local capacity of its pharmaceutical industry to provide for its needs and enhance export to other countries.[423]

Embedded in these lessons is a note of caution to South Africa. Although India has been at the forefront of access-friendly policies and actions in its patent regime, the new India IP policy seems to signal a paradigm shift to stricter and less access-friendly laws. There have been calls in India to adjust its IP policy to mirror what has been done in South Africa.[424] South Africa is on the right path in its quest to deliver a more balanced IP system, and the best lesson it can learn from India is to stay the course and not bow to the internal and external pressures that forcefully claim that a change in this new direction will spell doom and gloom for the country.

4.7 *Conclusion.*

India has come under high waves of criticism from the global North for its approach to patents. Despite the criticism, it has continually made difficult decisions, which has helped it make drugs available at reasonable prices while maintaining its status as the ‘pharmacy of the developing world.’ Although South Africa does not have the production capacity of India, the Indian model presents an inspiring example of how to best harness the patent system for the good of the nation.

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[423] DTI IP Policy op cit note 3 at 15.
[424] Shirin Syed op cit note 399.

The Indian model is not perfect, but it is undeniably useful; South Africa could do much worse than learning from India in this regard.

CHAPTER FIVE
SUMMARY, RECOMMENDATIONS, AND CONCLUSIONS/FINDINGS

5.1. Summary

This dissertation was carried out using a purely desktop-based doctrinal approach. The primary research question was: *Whether and to what extent does South Africa's move to amend its Patent Act, as outlined in the country's new IP Policy- take advantage of the flexibilities made available through the TRIPS Agreement?* In answering this question, the following sub-questions were considered:

a. What are the TRIPS flexibilities available to World Trade Organization (WTO) Member States in the area of patent law?

b. How do the exceptions and limitations in the current Patent Act, measure up to these TRIPS flexibilities, and to what extent do they address the issue of access to medicines in the public health sector?

c. Whether the proposed recommendations of South Africa's IP Policy take advantage of the flexibilities in the TRIPS Agreement and whether the introduction of a substantive search and examination (SSE) system in particular solely aimed at the public health sector complies with Article 27.1 of the TRIPS Agreement?

The first chapter of this dissertation set out the background of the study, the research questions, the methodology of the research, the definition of concepts relevant to the research and the outline of the dissertation.

In chapter two, the following TRIPS flexibilities were examined:

- Compulsory, and government- use licencing;[425]
- Exhaustion of rights/parallel importation;[426]
- Exceptions to rights conferred by a patent;[427] and

[425] See 2.3.1.
[426] See 2.3.2.
[427] See 2.3.3.

- Exemptions from patentability.[428]

In addition, the exceptions and limitations to patent rights available under South Africa's Patent Act were discussed as follows:

- Compulsory licences for dependent patents, and in cases of abuse of patents;[429] and
- The 'Bolar exception.'

The third chapter provided a brief history of the FTPL movement and how it birthed attempts to reform South Africa's patent system. Specific focus was put on the IP Policy Phase One, along with its recommendations and how they lined up with the TRIPS flexibilities discussed in chapter two. The relevant recommendations contained in South Africa's IP Policy which were discussed in this thesis were:

- Substantive search and examination;[430]
- Patent opposition;[431]
- Patentability criteria; [432]
- Disclosure requirements;[433]
- Parallel importation;[434]
- Exceptions;[435]
- Voluntary licences;[436]
- Compulsory licences;[437] and
- IP and Competition Law.[438]

Chapter four studied India and its approach towards balancing public health and its obligations under the TRIPS Agreement. The chapter went on to consider how it had made use of its patent laws to promote access to medicines. The current state of India's IP system was briefly

[428] See 2.3.4.
[429] See 2.4.1.
[430] See 3.3.1.
[431] See 3.3.2.
[432] See 3.3.3.
[433] See 3.3.4.
[434] See 3.3.5.
[435] See 3.3.6.
[436] See 3.3.7.
[437] See 3.3.8.
[438] See 3.3.9.

touched on, with some thoughts on the reaction to its new IP Policy. Finally, the chapter looked at the lessons South Africa can learn from India in its pursuit of a reformed patent system. This final chapter strives to make some recommendations and proposes model language of the key reform objectives which policymakers may refer to during the patent law amendment process. It ends by drawing conclusions based on the findings made in the previous chapters.

5.2. Recommendations

The need for patent law reform in South Africa has been laid out in this dissertation and the Policy recommendations examined. The recommendations in the policy are used as a basis upon which model language provisions will be drafted in this section. The model language provisions drafted below, are inspired by the Patent Acts of India, the United Kingdom, and Egypt and are aimed at addressing the issues raised in the IP Policy. While these countries' legal frameworks were not discussed in the previous chapters, their laws seem to align with some of the findings and conclusions made in this dissertation. Therefore, in in the interest of relying on international best practices, languages used in their laws are being utilised.

Under each recommendation, the jurisdiction where inspiration is drawn from will be indicated, along with a citation of the relevant section where the provision was obtained, as well as the reason(s) for the preference of the language used. Some sections may be taken verbatim, with minor technical changes, while some may be sufficiently adapted to be more in line with the objectives laid down in the Policy. It is essential to keep in mind that because of the limited scope of this dissertation, it will not be possible to go into great detail for each of the sections.

5.2.1. Substantive search and examination.

The IP policy recommends the SSE system as an essential change which is required in the Patent Act, to improve the quality of patents that are granted. The following provisions are drafted to cater for the public health sector in keeping with the phased approach of the South African government. This dissertation recommends that at the initial stage, this feature should be made optional and should be upon the request of the applicant for a pharmaceutical patent or an interested party. The Indian Patent Act[439] clearly illustrates this, and it is on this basis that the model

[439] Indian Patent Act supra note 352 at sections 11B-14.

provisions for substantive search and examination have been drafted. To make this work seamlessly, sections 34A-34D will be inserted into the Act and will lay down the procedure for obtaining a pharmaceutical patent. The proposal below reads:

Section 34A. Request for examination of pharmaceutical patent applications-

1) No application for a pharmaceutical patent shall be examined unless the applicant or any other interested person makes a request in the prescribed manner for such examination within the prescribed period.

2) In case the applicant or any other interested person does not make a request for examination of the application for a pharmaceutical patent within the period as specified under subsection (1) the patent application shall be subject solely to the examination process prescribed in section 34.

Section 34B. Search for anticipation by previous publication and by a prior claim.

(1) The examiner to whom an application for a pharmaceutical patent is referred under section 34C shall make an investigation for the purpose of ascertaining whether the invention so far as claimed in any claim of the complete specification—

(a) has been anticipated by publication before the date of filing of the applicant's complete specification in any specification filed in pursuance of an application for a patent made in South Africa and dated before the priority date of the application;

(b) is claimed in any claim of any other complete specification published on or after the date of filing of the applicant's complete specification, being a specification filed in pursuance of an application for a patent made in South Africa and dated before or claiming the priority date earlier than that date.

(2) The examiner shall, in addition, make such investigation for the purpose of ascertaining whether the invention, so far as claimed in any claim of the complete specification, has been anticipated by publication in South Africa or elsewhere in any document other than those mentioned in sub-section (1) before the date of filing of the applicant's complete specification.

(3) Where a complete specification is amended under the provisions of this Act before the grant of a patent, the amended specification shall be examined and investigated in like manner as the original specification.

(4) The examination and investigations required under section 34C and this section shall not be deemed in any way to warrant the validity of any patent, and no liability shall be incurred by the Government or any officer thereof by reason of, or in connection

with, any such examination or investigation or any report or other proceedings consequent thereon.

Section 34C Examination of pharmaceutical patent application.
(1) Upon a request for examination with respect to a pharmaceutical patent application in the prescribed manner under subsection (1) of section 34B, the application and specification and other documents related thereto shall be referred at the earliest by the Registrar to an examiner for making a report to him in respect of the following matters, namely:
(a) whether the application and the specification and other documents relating thereto are in accordance with the requirements of this Act and any rules made thereunder;
(b) whether there is any lawful ground of objection to the grant of the patent under this Act in pursuance of the application;
(c) the result of investigations made under section 34B; and
(d) any other matter which may be prescribed.
(2) The examiner to whom the application and the specification and other documents relating thereto are referred under sub-section (1) shall ordinarily make the report to the Registrar within such period as may be prescribed.

Section 34D. Consideration of the report of examiner by Registrar.
Where, in respect of an application for a pharmaceutical patent, the report of the examiner received by the Registrar is adverse to the applicant or requires any amendment of the application, the specification or other documents to ensure compliance with the provisions of this Act or of the rules made thereunder, the Registrar, before proceeding to dispose of the application in accordance with the provisions hereinafter appearing, shall communicate as expeditiously as possible a brief summary of the objections to the applicant and shall, if so required by the applicant within the prescribed period, give him an opportunity of being heard

5.2.2. Patent opposition

The IP policy makes some helpful recommendations in this regard. It admits that there are resource constraints which may require phasing in of the patent opposition mechanism which it seeks to introduce. The short-term plan is to introduce a third- party observation mechanism which will help cut the costs of opposition and then phase in the pre and post-grant opposition mechanisms over time. This proposed section captures only the third-party observation and is based on a

provision in the UK Patent Act.[440] It is proposed that it be inserted under section 43 of the Act, as sub-section 5. The proposal reads:

> **Section 43(5) Observations by third party on patentability**
> (a) Where an application for a patent has been published, but a patent has not been granted to the applicant, any other person may make observations in writing to the registrar on the question whether the invention is patentable, stating reasons for the observations, and the registrar shall consider the observations in accordance with rules.
> (b) It is hereby declared that a person does not become a party to any proceedings under this Act before the commissioner by reason only that he makes observations under this section

5.2.3. Patentability criteria

Clarifying and strengthening the requirements for the grant of patents is one of the objectives the IP policy set out to achieve. The approach of the Indian Patent Act in section 3(d) is viewed as ideal for South Africa at this point. More detailed explanations will be left for the Regulations. However, it is proposed that a replica of the India provision be made in section 25(4) *(c)* of the Patent Act as an invention for which a patent will not be granted thus:

> **Section 25(4)** A patent shall not be granted
> ***(c)*** for the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.

5.2.4. Disclosure requirement

The IP policy recommends that in addition to the disclosure provision made in the Act, there should be a provision which requires an applicant to furnish information regarding foreign applications which it has made. This proposed section is made below in line with the Indian Patent Act.[441]

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[440] The Patent Act of 1977 (as amended) section 21.
[441] Indian Patent Act supra note 352 at section 8.

Section 32(3)(c) Information and undertaking regarding foreign applications.

(1) Where an applicant for a patent under this Act is prosecuting either alone or jointly with any other person an application for a patent in any country outside South Africa in respect of the same or substantially the same invention, or where to his knowledge such an application is being prosecuted by some person through whom he claims or by some person deriving title from him, he shall file along with his application or subsequently within the prescribed period as the Registrar may allow—

(a) a statement setting out detailed particulars of such application; and

(b) an undertaking that, up to the date of grant of patent in South Africa, he would keep the Registrar informed in writing, from time to time, of detailed particulars as required under clause (a) in respect of every other application relating to the same or substantially the same invention, if any, filed in any country outside South Africa subsequently to the filing of the statement referred to in the aforesaid clause, within the prescribed time.

(2) At any time after an application for patent is filed in South Africa and till the grant of a patent or refusal to grant of a patent made thereon, the Registrar may also require the applicant to furnish details, as may be prescribed, relating to the processing of the application in a country outside South Africa, and in that event the applicant shall furnish to the Registrar information available to him within such period as may be prescribed.

5.2.5. Parallel importation

The IP policy made explicit reference to the provision for parallel importation in the Medicines and Related Substance Act [442] and stated that there is a need for clarification in the Patent Act that the use of that section does not infringe on the rights of a patent-holder. A brief section is drafted below to serve as an appendage to section 45. It will come as the third sub-section in the section as drafted below:

Section 45(3)

Without prejudice to the rights conferred on a patent holder in this section, the use of parallel importation as prescribed in section 15(1)*(c)* of the Medicines and Related Substances Act 101 of 1965 in the area of public health shall not constitute an act of infringement of a patent under this Act.

[442] Section 15(1)*(c)*.

5.2.6. Exception

In addition to the 'bolar exception' in section 69A(1) of the Patent Act, it is proposed that a section permitting experimental use should be introduced. This section will repeal section 69A(2) and replace it. The experimental use section is drafted based on section 60(5)(b) of the UK's Patent Act which has been adapted to suit South Africa. The proposed section reads:

> **Section 69A(2)-**
> 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 for experimental purpose relating to the subject-matter of the invention.

5.2.7. Compulsory licence

This dissertation recommends the repeal of sections 55 and 56 of the current Patent Act and the drafting of a section which is dedicated to both compulsory licences for abuse of patents and dependent patents. The draft is based on Articles 23 to 24 of Egypt's Patent Act. The proposed sections read as follows:

> **Section 55. Compulsory licences**
> The Patent Office may, subject to the approval of a ministerial committee to be established by a decision of the President, grant compulsory licences for the exploitation of an invention. The committee decides the financial rights of the patent owner when such licences are issued, in any of the following cases:
> (1) Where the competent Minister finds - under the circumstance - that the exploitation of the patent will benefit the following:
> (a) Public non-commercial interest. This includes the preservation of national security, health, environment, and food safety.
> (b) Cases of emergency or circumstances of extreme urgency. A compulsory licence to counter the conditions mentioned in items 1 and 2 is granted without prior negotiations with the patent owner or after a certain period of negotiations with the patent owner or offering reasonable conditions to acquire his agreement to the exploitation.
> (c) Support of national efforts in vital sectors for economic, social, and technological development, without unreasonable prejudice to the rights of the patent owner and taking into consideration the legitimate interests of third parties.

In cases stated in items 1 and 3, the owner of the patent shall be notified promptly of the decision of compulsory exploitation, and as soon as reasonably practicable in cases stated in the item

(2) Upon the request of the Minister of Health, when the quantity of patented medicine, made available fail to adequately meet the national needs, due to their poor quality or if they are offered at a prohibitive price, or if the patent is related to medicines addressing critical cases, incurable or endemic diseases or products used in the prevention of these diseases, or where the invention is related to the medicines, their manufacturing process, the raw materials necessary for their preparation or the process of manufacturing of those materials. In all these cases, the decision to grant a compulsory licence shall be communicated promptly to the owner of the patent.

(3) Where the patent owner refuses to grant a licence to a third party seeking the exploitation of the invention, whatever the purpose of the exploitation, and despite the offer of suitable terms and the lapse of reasonable negotiation time. In this case, the party requesting the compulsory licence shall provide evidence that he has made serious efforts to obtain a voluntary licence from the patent owner.

(4) If the owner of the patent fails to exploit the invention in South Africa, himself or through his consent; or if the patent was not sufficiently exploited after the lapse of four years since the date of the application or three years since the grant of the patent, whichever comes later; or if the patent owner suspended, without a valid reason, the exploitation of the patent for more than one year.

The exploitation of a patent shall be through the manufacturing of the patented product or the use of the patented process in South Africa.

Nevertheless, where the Patent Office finds that, despite the expiration of either of the above-mentioned time limits, failure to exploit the invention was due to legal, technical or economic reasons beyond the power of the owner of the patent, it may decide to allow him a sufficient period of grace for the exploitation of the invention.

(5) Where the exploitation of an invention by the legitimate patent holder requires inevitably the use of another invention, underlying concrete technical advance as well as technical and economic significance compared to the other, he shall be entitled to obtain a compulsory licence for the exploitation of the other invention, in which case the other patent holder shall equally have the same right

The licenced exploitation of one patent may not be assigned without the corresponding assignment of the other.

Section 56. Matters to be considered in granting a compulsory licence.

Where a compulsory licence is to be issued, the following elements shall be taken into account:

(1) A request for the grant of the compulsory licence shall be considered on the merits of each case. The licence shall mainly seek to satisfy the needs of the domestic market.
(2) The requesting party shall prove that he has made serious attempts during a reasonable period of time to obtain a voluntary licence from the patent holder against fair compensation and that he failed.
(3) The patent owner may, within one month from his notification of the grant of the licence, appeal to the Commissioner and in accordance with the conditions and procedures stipulated by the Regulations, against the decision to grant the compulsory licence to a third party.
(4) The party requesting the grant of a compulsory licence, or the party to whom a compulsory licence is granted, must have the capacity to efficiently exploit the invention in South Africa.
(5) The licencee must abide by the scope, terms, and period prescribed by the decision granting such a licence. The Patent Office may extend the duration of the licence if it expires without achieving its purpose.
(6) The use of the compulsory licence shall be limited to the applicant; the Patent Office may, however, grant it to a third party.
(7) The beneficiary shall not assign the rights of a compulsory licence to a third party except with the enterprise or the part related to the exploitation of the patent.
(8) The patent owner shall be entitled to fair compensation for the exploitation of his invention. The amount of compensation shall be fixed on the basis of the economic value of the invention. He shall have the right to appeal against the compensation assessment, within 30 days of being notified the decision, before the Commissioner, in accordance with the rules and procedures prescribed by the Regulations.
(9) The compulsory licence shall lapse on the expiry of its duration. Nonetheless, the Patent Office may decide to terminate the compulsory licence if the reasons which led to its grant cease to exist and are unlikely to reoccur, in which case, the procedure prescribed by the Regulations shall apply.
(10) The patent owner may request the termination of the compulsory licence before its expiry, if the reasons, which led to its grant, cease to exist and are unlikely to reoccur.
(11) Where a compulsory licence is terminated before its term, the legitimate interests of the licencee shall be taken into account.
(12) The compulsory licence may be terminated or its terms amended by the Patent Office, or upon a request from any interested party, if within two years after the grant of the compulsory licence, the licencee fails to exploit the subject matter of the licence or to meet his obligations as prescribed by the licence.

5.2.8. IP and competition

The provision that covers IP and Competition in this section will form part of the Compulsory licence provision; however, for the sake of clarity, it is drafted separately in this section. The provisions are drafted to closely resemble the provisions in the Egyptian Patent law.[443] It is proposed that the sub-sections which deal with competition come directly after section 55(5). It is drafted below as follows:

> **Section 55-**
>
> (6) If it is determined that the patent owner has abused or exercised the rights conferred by the patent in a manner that is contrary to fair competition, such as:
> (a) Fixing exorbitant prices for the patented products or preferential treatment of agents with regards to prices and sales conditions.
> (b) Failure to supply the local market with the patented product or supplying it under prohibitive terms.
> (c) Stopping the production of the patented item or its production in a disproportionate manner, given the production capacity and the market needs.
> (d) Undertaking acts or practices which have an adverse effect on the free competition,
> according to the prescribed legal norms.
> (e) Exercising of the rights conferred by this Law in a manner that adversely affects the
> transfer of technology.
> In all above cases, the compulsory licence is granted without recourse to negotiation or the expiry of a time limit thereto, even if the compulsory licence is not intended to satisfy the needs of the domestic market.
> The Patent Office may refuse to terminate the compulsory licence, where the conditions that called for it are likely to remain or to reoccur.
> The compensation due to the owner of the patent shall take into account the prejudice caused by his arbitrary or unfair competition practices.
> The Patent Office may revoke the patent if, two years after the grant of a compulsory licence, it became clear that the grant, of that licence, was not adequate to remedy the adverse effects caused to the national economy by the patent owner`s abuse of his rights or his unfair competition practices.

[443] Law No. 82 of 2002 Pertaining to the Protection of Intellectual Property Rights supra note 308.

> Any concerned party may challenge the revocation of a patent before the Commissioner, and in accordance with the conditions and procedures prescribed in the Regulations.

5.3. Conclusions/Findings

Having considered the flexibilities which the TRIPS Agreement makes available and juxtaposed them with the exceptions in South Africa's Patents Act, it is apparent that there is an urgent need for patent reform. The only exceptions which are currently available in South Africa's Patent Act are the compulsory licences for dependent patents and abuse of patents and the 'bolar exception.' This lends credence to the calls for the amendment of the Patent Act to accommodate the full range of flexibilities contained in the TRIPS Agreement as a means of promoting better access to medicines.

The dissertation examined the recommendations made in the IP Policy in chapter three. The Policy is more closely aligned to the TRIPS flexibilities and seeks to provide a balanced and holistic view of patents in a way which benefits both rights-holders and the public. The choice to adopt a phased approach to patent examination, initially limiting its scope to pharmaceutical patent application was criticised as discriminatory against the pharmaceutical industry. This prompted the DTI to provide justifications for its decision, illustrating that it does not offend South Africa's treaty obligations and that the scope of SSE will be expanded to other areas of technology in the future.

Based on the analysis of both the TRIPS Agreement and the IP Policy, with proper implementation of the recommendations in the IP Policy, full advantage will be taken of the TRIPS flexibilities. It remains to be seen, however, how these recommendations will be implemented and to what extent the recommendations will be adopted. It is refreshing to see that from the language of the IP Policy, the reforms that may result are viewed as a part of the more expansive fabric of reforms aimed at meeting South Africa's National Development Plan (NDP) in 2030. The willingness to take a piece-meal approach to patent reform rather than make sweeping, unsustainable changes appears to be a wise decision for policymakers in the long-run.

Studying India's patent ecosystem provides a helpful example of things which South Africa may emulate in its reform process and pitfall which should be avoided First, it was found that in the past, India had efficiently used the patent system to the advantage of its booming generics

industry. This was met by waves of criticism and pressure from the global North in an attempt to make the country push for more rigid IP protection, which leans more in favour of the patent-holder. It is against this backdrop, it seems, that India's 2016 IP Policy Document can be understood. Critics of the Policy have pointed out the disconnect between IP and public health in its approach and called for India to toe the line which South Africa has toed in creating an IP Policy which recognises and embraces that link. It is clear from the Indian example that at no point in time will a chosen approach to IP garner unanimous support; therefore, South Africa must persevere on the path it has chosen and work to speedily bring the much needed reform, which promises a more equitable patent system that caters for the health needs of the country, as well as the need to create a competitive and attractive environment where pharmaceutical companies can thrive.

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