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LET'S NOT WAIT UNTIL A CRISIS FOR CHANGE TO OCCUR: A CRITICAL ANALYSIS OF PATENT LAW IN SOUTH AFRICA AND ITS ROLE IN (NOT) FULFILLING THE CONSTITUTIONAL RIGHT TO HEALTH

By

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To anyone who has ever lost their way in life, Maya Angelou wrote the poem ‘Still I Rise’ just for us. Never give up.

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Firstly, without the highest, I would not have gotten this far. ‘And He will provide for him from an unexpected source. And whosoever putteth his trust in God, He will suffice him. Surely God brings about what He decrees; God has set a measure for everything’ – Surah At-Talaq 65:3.

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ABSTRACT

The right to health is enshrined in international treaties and under section 27 of the Constitution of the Republic of South Africa. It has been established that access to affordable medicines is a fundamental element to its realisation. Research has identified patent law as a potential barrier to access. Research on how patent law creates a barrier to accessing affordable medicines has been focused on identification of the flaws within South Africa's patent regime. However, the impact of the high prices on patented medicines and what this means for the binding obligations that the right to health entails is limited. The main objective of this thesis is to determine if this impact constitutes an infringement to the constitutional right to health. The secondary objective is to analyse whether solutions suggested to improve access such as encouraging use of the TRIPS flexibilities and the implementation of the Intellectual Property Policy of the Republic of South Africa Phase I has yielded the desired result. The analysis reveals that high prices of patented medicines negatively impact the population that relies on public health systems within the country. This analysis suggests that the current patent regime has resulted in the prevalence of these high prices and as such, it stands as a barrier to the realisation of the right to health. The findings show that the suggestions to improve access are yet to be utilised. To date South Africa has not utilised compulsory licences or the 'bolar' exception as tools to improve access. Furthermore, the implementation of the IP Policy although gradual, is lacking the urgency required for the situation at hand. This thesis draws suggestions from India and Canada that may be applied to South Africa. Additionally, the thesis extracts lessons from scholars who suggest pharmaceutical companies must embody the notions of communitarian ethic as a means of replacing a profit-centred approach with a community approach when setting prices. The thesis suggests such a communitarian ethic be applied as a solution that challenges the notion of ownership and distribution in IP law.

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LIST OF ABBREVIATIONS

AIDS - Acquired Immunodeficiency Syndrome

Banjul Charter - African Charter on Human and Peoples' Rights

CAC - Competition Appeal Court

CCSA - Constitutional Court of South Africa

CCZA - Competition Commission of South Africa

CIPC - Companies and Intellectual Property Commission

CML - Chronic Myeloid Leukaemia

EPC - European Patent Convention

EC - European Communities

GDP - Gross Domestic Product

GDF - Global Drug Facility

HIV - Human Immunodeficiency Virus

ICESCR - International Covenant on Economic, Social and Cultural Rights

IPAB - Intellectual Property Appellate Board

IPRs - Intellectual Property Rights

J&J - Johnson & Johnson (Pty) Ltd

JP - Janssen Pharmaceutica (Pty) Ltd

LMICs - Low- And Middle-Income Countries

MTCT - Mother-To-Child-Transmission

NCI - National Cancer Institute

NDH - National Department of Health

NIH - National Institutes of Health

SAHPRA - South Africa Health Products Regulatory Authority

SEP - Single Exit Price

SSE - Substantive Search And Examination

TAC - Treatment Action Campaign

The Constitution - Constitution of the Republic of South Africa

The Doha Declaration - The Doha Declaration on the TRIPS Agreement and Public Health

TRIPS Agreement - Agreement on Trade-Related Aspects of Intellectual Property Rights

UDHR - Universal Declaration of Human Rights

UNCRC - United Nations Convention of the Rights of the Child

U.S. - United States of America

USPTO - United States Patents and Trademark Office

WHO - World Health Organization

WIPO - World Intellectual Property Office

WTO - World Trade Organization

CHAPTER ONE

INTRODUCTION

I. INTRODUCTION[1]

Despite global recognition of the right to health, access to affordable medicines remains a significant challenge, particularly in developing countries. In South Africa, high drug costs—largely driven by patent protection rules—continue to hinder this right, even though the country has constitutional commitments to healthcare access.[2] This issue raises critical questions about whether South Africa's current patent regime aligns with its obligations to ensure affordable essential medicines. Article 25 of the Universal Declaration of Human Rights (UDHR) affirms the right to health, stating that 'Everyone has the right to a standard of living adequate for the health and well-being of himself and his family, including food, clothing housing and medical care.[3] Similarly, Article 12 (1) of the International Covenant on Economic, Social and Cultural Rights (ICESCR) reinforces this by defining it as 'the right to the enjoyment of the highest attainable standard of physical and mental health.'[4] The United Nations Human Rights Council Resolution 12/24[5] acknowledges essential medicines as a fundamental healthcare element of the right to health.[6] It emphasises the responsibility of states to ensure access to affordable, essential medicines, without discrimination, promoting the realisation of everyone's right to the highest standard of health.[7] In South Africa section 27 of the Constitution of the Republic

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[1] This thesis is based on current law as of 1 October 2024.
[2] Fix The Patent Laws 'Key Medicines' available at *https://www.fixthepatentlaws.org/key-medicines/*, accessed on 22 August 2024, which tracks essential medicine prices in South Africa. They have observed for over a decade, a trend that shows South Africa's outdated patent laws mean that medicines are often priced out of reach to those in need; See also Medicines Sans Frontieres 'South Africa's patent system encourages profits over lives' available at *https://www.msf.org.za/news-and-resources/press-release/south-africas-patent-system-encourages-profits-over-lives*, accessed on 22 August 2024.
[3] UN 'Universal Declaration of Human Rights' at p. 7, available at *https://www.un.org/sites/un2.un.org/files/2021/03/udhr.pdf*, accessed on 23 August 2024.
[4] UN 'International Covenant on Economic, Social and Cultural Rights' *General Assembly resolution 220A (XXI)* 16 December 1966, available at *https://www.ohchr.org/sites/default/files/cescr.pdf,* accessed on 23 August 2024.
[5] UNHRC 'Access to medicine in the context of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health' at p. 2, available at *https://ap.ohchr.org/documents/sdpage_e.aspx?si=A/HRC/RES/12/24*, accessed on 23 August 2024
[6] Essential medicines 'are intended to be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality and adequate information, and at a price the individual and the community can afford.'
[7] Ibid.

of South Africa (the Constitution)[8], mandates that 'Everyone has the right to have access to healthcare services, […]'[9]. The Constitutional Court of South Africa (CCSA) has followed Resolution 12/24's line of thinking and interpreted access to healthcare in section 27 to mean both access to medicine and that the medicine must be affordable. The binding nature of these instruments on South Africa and the CCSA's decisions pertaining to the constitutional right to health are expanded on in chapter two.

Studies conducted by the World Health Organization (WHO) have indicated that developing countries, particularly African nations still struggle with access to medicines.[10] In its findings the WHO has identified a link between a country's economic wealth and the level of access its population has to medicines. This connection between economic status and access to medicines reflects a broader issue involving the organisation, funding and delivery of national health systems.[11] Some scholars agree with this view and have pointed to infrastructure, government priorities and corruption as playing a major role in depriving the population of essential medicines that are affordable.[12] Alternatively, critics of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement)[13] contend that intellectual property rights (IPRs) and the minimum standards imposed by the TRIPS Agreement for patent protection hinder access to medicines for in developing countries. They argue that these standards, among other impacts, raise medicine prices, restrict the reverse engineering of patented drugs, and postpone the availability of affordable generics.[14] Along the same lines, in recent research, Kolawole and Ncube submit that, globally the existing rules and exceptions have failed to address one underlying issue affecting access to affordable medicines – the framing of IP., i.e., to reward, profit or gain, which are individualistic in nature.[15] They

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[8] Constitution of the Republic of South Africa, 1996.
[9] Ibid at s 27.
[10] WHO 'EU/ACP/WHO Renewed Partnership Strengthening pharmaceutical systems and improving access to quality medicines in 15 African ACP countries', available at *https://cdn.who.int/media/docs/default-source/essential-medicines/medicines/emminireport.pdf,* accessed 23 August 2024.
[11] Ibid.
[12] Mercurio, B. (2007). *Resolving the Public Health Crisis in the Developing World: Problems and Barriers of Access to Essential Medicines* (SSRN Scholarly Paper 980175), at p.1. https://doi.org/10.2139/ssrn.980175
[13] Agreement on Trade-Related Aspects of Intellectual Property Rights, 1994.
[14] Motari, M., Nikiema, J.-B., Kasilo, O. M. J., Kniazkov, S., Loua, A., Sougou, A., & Tumusiime, P. (2021). The role of intellectual property rights on access to medicines in the WHO African region: 25 years after the TRIPS agreement. *BMC Public Health*, *21*(1), 490. https://doi.org/10.1186/s12889-021-10374-y; See also Islam, Md. D., Kaplan, W. A., Trachtenberg, D., Thrasher, R., Gallagher, K. P., & Wirtz, V. J. (2019). Impacts of intellectual property provisions in trade treaties on access to medicine in low and middle income countries: A systematic review. *Globalization and Health*, *15*(1), 88. https://doi.org/10.1186/s12992-019-0528-0
[15] Kolawole, O., & Ncube, C. B. (2024). Rethinking Ownership, Power and Policy in Drug Patents: The Case for an Ubuntu-Infused Approach. *Journal of African Law*, at p. 3. https://doi.org/10.1017/S0021855324000263.

posit that the rationale for patent protection in particular has steadily shifted from encouraging innovation to one that prioritises profit maximisation.[16]

South Africa, as both a developing nation and one with constitutional commitments to healthcare access, exemplifies these global challenges. Despite having the world's largest antiretroviral therapy program for HIV/AIDS the country continues to grapple with medicine affordability. Studies indicate that South Africans pay significantly more for certain patented medicines compared to other middle-income countries[17], with some essential medicines priced up to 80 times higher than available generic alternatives.[18] These high prices persist despite South Africa's progressive Constitution and its commitment to international human rights treaties that emphasize affordable access to medicines.[19]

The TRIPS Agreement is essential as it provides a framework for national patent laws, which may directly affect the affordability and accessibility of medicines in South Africa. By virtue of its membership in the World Trade Organization (WTO), South Africa is party to the TRIPS Agreement.[20] The TRIPS Agreement requires member states to develop national legislation which enshrines minimum standards for patent protection in line with those set out in this Agreement. It provides that patent protection must be granted, upon application, to inventions that meet the criteria of being novel, involving an inventive step and having industrial applicability[21] - these are referred to as patentability criteria in this thesis. When a patent is granted, the term of protection must be for no less than 20 years.[22] With the grant of a patent, the holder must have exclusive economic rights in their invention, including production and distribution.[23] Patent owners may also licence their protected ideas for use under their terms.[24] Unauthorised use of the protected invention would be considered infringement, and the patent holder is entitled to legal action.[25]

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[16] Ibid at p. 2.
[17] National Planning Commission of South Africa (NPC) 'Research on Pharmaceutical Pricing Policies' available at *https://www.nationalplanningcommission.org.za/assets/Documents/Pharmaceutical%20Pricing%20Policy_%20Report%20February%202020.pdf*, accessed on 25 August 2024; Jama, T. N. Q., & Suleman, F. (2024). Understanding medicine access strategies for innovator medicines registered in South Africa. *BMC Health Services Research*, *24*(1), 1220. https://doi.org/10.1186/s12913-024-11696-4.
[18] Ibid, at p. 37.
[19] Ibid.
[20] World Intellectual Property Organization (WIPO) 'IP Treaties Collection' available at *https://www.wipo.int/wipolex/en/treaties/parties/231*, accessed on 25 August 2024.
[21] Supra note 13 at Article 27.1.
[22] Ibid at Article 33.
[23] Ibid at Article 28.
[24] Ibid.
[25] Ibid at Article 34.

However, the implementation of the above minimum standards may result in high costs of patented medicines and inevitably constrains access to them.[26] In view of this, the TRIPS Agreement includes provisions allowing the use or exploitation of a patented invention without requiring the patent holder's permission under specific conditions. These provisions, known as TRIPS flexibilities, primarily serve as public interest mechanisms, empowering member states to address domestic needs.[27] For example, compulsory licences may be issued, especially in cases of health emergencies. Another example is the 'bolar' exception to allow generic drug manufactures to use patented inventions without the patent owner's permission for purposes of research, testing, and regulatory approval in preparation for market entry immediately after patent expiry.[28]

This thesis is not the first to investigate patent law and its impact on access to affordable medicines and identify an imbalance. Where this thesis differs is rather than identification and criticism of the South African patent regimes' flaws, which has been done numerous times before,[29] the main objective of this research is to aide in formulating solutions that enables access where a constitutional imperative to the right to health exists. Therefore, given the critical role of patent protection in medicine affordability, this thesis examines whether South Africa meets its right to health obligations under section 27 of the Constitution. Specifically, this thesis investigates whether the current patent regime under the South African Patents Act of 1978[30] hinders this right by contributing to unaffordable prices for essential patented medicines. To assist in this investigation, a brief discussion on the right to health and patent law nexus at a global level is important.

(a) The right to health and intellectual property rights

[26] WHO 'TRIPS, intellectual property rights and access to medicines'at p. 3, available at *https://iris.who.int/bitstream/handle/10665/258915/TRIPS.pdf*, accessed on 25 August 2024.
[27] Mercurio, B., Adekola, T. A., & Tsega, C. F. (2023). Pharmaceutical patent law and policy in Africa: a survey of selected SADC member states. *Legal Studies (Society of Legal Scholars)*, *43*(2), 331–350.
[28] Ibid at p. 347 – 349.
[29] See Clarence Lakpini *An Examination Of South Africa's Efforts At Patent System Reform: Trips Flexibilities Fully Appropriated For Public Health Needs?* (published LLM thesis, University of Cape Town, 2019); Elissa Duku *Trips Flexibilities and Access to Essential Medicines In South Africa* (published LLM thesis, University of Cape Town, 2021).
[30] Patents Act 57 of 1978.

For decades IP and human rights developed in virtual isolation from each other. However, in recent years, efforts to align IP with human rights and the needs of developing countries have steadily increased.[31]

IP systems aim to strike a balance between the moral and economic rights of creators and inventors and the broader needs and interests of society.[32] The all-encompassing principle behind the legal protection of patents is that innovation should be encouraged and safeguarded by giving the inventor of an invention exclusive ownership, which allows the inventor to make money off of it.[33] This fundamental idea is considered reasonable on its face since it ensures that one can be compensated for the effort that went into their inventions and creations as well as acknowledged for them.[34] Therefore, the subtle distinction from acknowledging the inventor and their labour, as well as preservation of their right to profit from their creation, invention or innovation, are ingrained in the philosophy for establishing exclusivity through IP as a whole and through the grant of a patent.[35] Crucially, they also have the right to profit exclusively or as they so choose.[36]

A human rights perspective on IP and by extension patents, brings the often-implicit balance between the rights of inventors and the public interest to the forefront, making it more explicit and demanding. Revisiting Article 12 of the ICESCR, it obligates state parties to it to recognise the right of everyone to the enjoyment of the highest attainable standard of health.[37] In pursuit of this objective, the treaty requires that state parties implement a range of measures. These include 'The prevention, treatment and control of epidemic, endemic, occupational and other diseases'[38], and equally crucial 'The creation of conditions which would assure to all medical service and medical attention in the event of sickness.'[39] A human rights approach, aligned with the norms of the ICESCR, diverges in several ways from the principles of intellectual property law. Specifically, it demands that any intellectual property regime provides protection that directly supports and advances the right to health, benefiting

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[31] Laurence R. Helfer, Human Rights and Intellectual Property: Conflict or Coexistence?, 5 MINN. *INTELL. PROP. REV.* 47 (2003) at p. 47.
[32] Ibid.
[33] Keith E Maskus *Intellectual Property Rights in the Global Economy* (2000) at p. 31.
[34] Fromer, J. C. (2010). A PSYCHOLOGY OF INTELLECTUAL PROPERTY. *Northwestern University Law Review*, *104*(4), at p. 1446.
[35] Fisher, W. (2001). *Theories of Intellectual Property*. Cambridge University Press, at p. 174.
[36] Lemley, M. A. (1997). The economics of improvement in intellectual property law. *Texas Law Review*, *75*(5), at p. 993 - 994
[37] Supra note 4 at Article 12.
[38] Ibid at (c).
[39] Ibid at (d).

individuals and society as a whole.[40] This approach imposes a higher threshold for assessing patent applications, requiring that inventions align with the inherent dignity of individuals and core human rights standards. That is to say a human rights approach to patent law elevates the standards for approval by requiring inventions to demonstrate compatibility with fundamental human rights.[41] This means patent applications must go beyond traditional criteria of novelty, non-obviousness, and utility to also show they will not enable rights violations, restrict access to essential goods, or harm vulnerable populations.[42]

Furthermore, Article 15 of the ICESCR indicates that states parties must recognise the right of everyone to 'enjoy the benefits of scientific progress and its applications.'[43] Scientific progress encompasses advancements in various fields, including healthcare and medicine.[44] UDHR Article 27 provides a similar provision.[45] This interpretation covers the development of new medicines, treatments, and medical technologies, as they are direct applications of scientific progress. In a broader human rights context, ensuring access to medicines can be seen as part of fulfilling the right to health, and the benefits of scientific innovation in medicine should be accessible to all, especially those in need. The right to 'enjoy the benefits of scientific progress and its applications' implies that both individuals and communities should have easy access to these advancements.[46] Furthermore, this thesis places emphasis on the fact that realising both these rights in the ICESCR requires thoughtful and well-crafted government legislation. Finally, a human rights perspective also includes the right to be safeguarded against any potential negative consequences arising from scientific progress.[47]

Scholars argue that human rights include a right of access to essential medicines.[48] In that same light accessibility of medicines is argued to include 'affordable' medicines.[49] However, what is initially evident from the aforementioned treaties and will be substantiated

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[40] Audrey R. Chapman 'A Human Rights Perspective on Intellectual Property, Scientific Progress, and Access to the Benefits of Science' *WIPO* n.d. at 2, available at *https://www.wipo.int/edocs/mdocs/tk/en/wipo_unhchr_ip_pnl_98/wipo_unhchr_ip_pnl_98_5.pdf*, accessed on 23 August 2024.
[41] Ibid.
[42] Philippe Cullet 'Human Rights and Intellectual Property Rights: Need for a New Perspective' *IELRC Working Paper 2004 – 4* at p. 6, available at *https://www.ielrc.org/content/w0404.pdf*, accessed on 23 August 2024.
[43] Supra note 4 at Article 15.1.(b).
[44] Supra note 31.
[45] Supra note 3 at Article 27.
[46] Supra note 3 at Article 15.
[47] Haugen, H. M. (2024). A Human Right to Science: Inadequate without Participation in Science? Human Rights as a Governance Tool in Scientific Fields. *Nordic Journal of Human Rights*, 1–18. https://doi.org/10.1080/18918131.2024.2398350 at p. 2.
[48] Sellin, J. (2014). A Human Right of Access to Medicines? In: *Access to Medicines: The Interface between Patents and Human Rights. Does One Size Fit All?* at p. 65.
[49] Ibid at p 67.

in chapter two is that such a right of access to medicines is not explicitly stated in any of the treaties that align with the right to health, it is up to state parties to codify this within their domestic space. Thus, while the right to health has been accepted as demanding affordable access to essential medicines, this must be balanced against the foundational principles of patent protection. In the context of South Africa, where section 25 of the Constitution has been interpreted as applicable to IPRs, this line of thinking raises important questions about whether its current patent regime aligns with this accepted right to health standard and if there is an imbalance presently.

II. PROBLEM STATEMENT

As discussed previously, in South Africa, the right to health is echoed in section 27 of the Constitution.[50] For the purposes of this thesis, from the onset, it is crucial to note that section 27 is contained within the Bill of Rights of the Constitution and the Bill of Rights 'applies to all law, and binds the legislature, the executive, the judiciary and all organs of state.'[51] Furthermore, 'a provision of the Bill of Rights binds a natural or a juristic person if, and to the extent that, it is applicable, taking into account the nature of the right and the nature of any duty imposed by the right.'[52]

Despite this affirmation from the international sphere and the domestic sphere that access to medicines constitutes a fundamental element of the right to health, the WHO's observations that Africa struggles with access to medicines appear to be substantiated when it comes to South Africa.[53] Notably, the aforementioned critics of the TRIPS Agreement may find validation in their claims as the issues to access to affordable medicines within South Africa can be attributed to South Africa's current patent regime. The TRIPS Agreement is a minimum rights agreement that leaves a fair amount of leeway to member countries to implement its provisions within their own legal system and practice and fine-tune the balance in light of domestic public policy considerations.[54] In South Africa's case, this leeway has not been optimally utilised, as evidenced by gaps in the legislative framework and inconsistent enforcement mechanisms that have failed to utilise public health safeguards.[55]

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[50] Supra note 8 at s 27.
[51] Ibid at s 8 (1).
[52] Ibid at s 8 (2).
[53] Supra note 40.
[54] WTO statement in Economic and Social Council Doc No. E/CN.4/Sub.2/2001/12, at p. 7, available at *https://documents.un.org/doc/undoc/gen/g01/142/02/pdf/g0114202.pdf*, accessed on 29 October 2024.
[55] Mercurio supra note 27.

As discussed previously, the TRIPS Agreement sets out the patentability criteria, however, it does not define what each standard means.[56] Consequently, as will be seen in chapter three, the criteria for assessment pursuant to the South African Patents Act is subpar by international standards,[57] resulting in South Africa's patent application approval rate being significantly higher than most countries, developed or developing.[58] The lax standards are apparent when you compare South Africa's patent grant rates with countries with similar Gross Domestic Products (GDP). The disparity in population sizes among For example, in 2022 South Africa granted 11,267 patents.[59] In the same year Nigeria granted 1,081 and Egypt only 495.[60] The disparity in population sizes among these countries further highlights the disproportionate nature of these statistics, as one would typically expect larger populations to generate more patent applications.[61] Furthermore, an analysis of the World Intellectual Property Office's (WIPO) IP Statistics Data Center for the past 10 years shows South Africa has granted significantly more patents than its counterparts.[62] Research shows that many of the patents granted in South Africa have been denied registration in other countries because they fail to meet higher standards of patentability criteria.[63]

A key issue is that South Africa issues patents through a 'depository system' where patents are granted after checking only formal requirements such as forms and fees, without substantive search and examination (SSE) of the invention's novelty or inventive step.[64] This system seems to have created an environment conducive to evergreening,[65] as illustrated by the

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[56] Supra note 13 at Article 27.1.
[57] Fasan, O. (2012). Commitment and Compliance in International Law: A Study of the Implementation of the WTO TRIPS Agreement in Nigeria and South Africa. *African Journal of International and Comparative Law*, *20*(2), 191–228.
[58] Sampat, B. N., & Shadlen, K. (2016). The effects of restrictions on secondary pharmaceutical patents: Brazil and India in comparative perspective. In Proceedings of the '*Moral Economies, Economic Moralities' Conference, University of California.* 1-49.
[59] WIPO 'World Intellectual Property Office's (WIPO) IP Statistics Data Center', available at *https://www3.wipo.int/ipstats/ips-search/patent,* accessed on 5 September 2024.
[60] Ibid.
[61] According to World Bank statistics, in 2022 South Africa's population was 63.28 million, Egypt 112.6 million and Nigeria 223.3 million. *See* World Bank Group 'Population, total' available at *https://data.worldbank.org/indicator/SP.POP.TOTL*, accessed on 5 September 2024.
[62] Ibid.
[63] The Competition Commission of South Africa 'Strategic Planning and its Impact on Competition: Evidence from the South African Pharmaceutical Sector' *Working Paper CC2024/01* at p. 5, available at *https://www.compcom.co.za/wp-content/uploads/2024/03/CC202401-Strategic-patenting-and-its-impact-on-competition_Evidence-from-the-South-African-pharmaceutical-sector-.pdf*, accessed on 5 September 2024.
[64] Ibid at p.6.
[65] Evergreening is the process in which pharmaceutical companies obtain patents and to extend the length of their monopoly, by making minor changes to their products in a bid to extend the duration of the patent. The reasoning behind such manoeuvres is to delay the entry of generic competitors into the market, thereby preserving monopolistic pricing power and inflating medicine prices.

case of Trastuzumab. This drug, classified as an essential medicine by the WHO,[66] is used to treat breast cancer patients that are diagnosed with the HER2-positive subtype, a particularly virulent and aggressive strain of cancer. Trastuzumab was first approved for sale in South Africa in 2001 under the brand name Herceptin®, held globally under patent no. WO2006033700A2 and PCT/US2005/025084.[67] In 2012, Roche, the pharmaceutical company that owns, sells and markets Herceptin was granted patent no. ZA2012/07815 in South Africa for Herclon®, essentially the same product under a different name.[68] The current price of trastuzumab is R41,500 per patient, per annum (17-18 cycles).[69] Prior to this, Roche supplied Herclon to South Africa's National Department of Health (NDH) for R117,569 per patient, per annum.[70] The drop in price was due to the entry of biosimilars of trastuzumab, brand name Ogivri® entering the South African market. These biosimilar were only able to enter the South African market due to civil challenges initiated by the Cancer Alliance against South Africa's Health Products Regulatory Authority (SAHPRA) which approves medicines.[71] Only after Ogivri became available to the public at a lower price, did Roche drop the price of Herceptin.[72] The strategic patenting of Herclon in 2012 despite it being essentially the same product as Herceptin, which had been patent-protected almost a decade before this is a result of evergreening. Pharmaceutical evergreening in South Africa is expanded on through case studies of Bedaquiline, Lenalidomide and Rivaroxaban in subsequent chapters.

The Patents Act also lacks adequate mechanisms for patent oversight. Third parties are able to oppose certain actions related to patents, such as the restoration of a lapsed patent,[73] the correction of clerical errors, the amendment of documents,[74] and applications for compulsory licenses.[75] However, the Act does not allow for any form of third-party opposition, either before

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[66] The WHO provides a Model List of Essential Medicines that is updated every 2 years. Most recently updated in July 2023, and it includes Trastuzumab. See 'WHO Model List of Essential Medicines - 23rd list, 2023' available at *https://www.who.int/publications/i/item/WHO-MHP-HPS-EML-2023.02*, accessed on 6 September 2024.
[67] Google Patents 'Her2 antibody composition', available at *https://patents.google.com/patent/WO2006033700A2/*, accessed on 6 September 2024.
[68] CIPC Intellectual Property Online, available at https://iponline.cipc.co.za/Patents/Search/FreePTSearch.aspx, accessed on 6 September 2024.
[69] KnowledgeHub 'Standard Treatment Guidelines and Essential Medicines List, available at *https://knowledgehub.health.gov.za/content/standard-treatment-guidelines-and-essential-medicines-list*, accessed on 6 September 2024.
[70] Cancer Alliance 'Trastuzumab Access in South Africa' August 2018, available at *https://canceralliance.org.za/wp-content/uploads/2019/09/Breast-Cancer-and-Trastuzumab-Fact-Sheet-17-September-2018.pdf,* accessed on 6 September 2024.
[71] Ibid.
[72] Ibid.
[73] Supra note 30 at s 47.
[74] Ibid at s 50.
[75] Ibid at ss 55 and 56.

or after the grant of a patent. In other words, there is no mechanism for external parties to formally object to or challenge the grant of a patent itself.

The relationship between patent law, access to affordable medicines, and the resulting imbalances has been a subject of significant scrutiny. The Doha Declaration on the TRIPS Agreement and Public Health (the Doha Declaration) was formulated in response to the criticisms surrounding the provisions of the TRIPS Agreement and their impact on public health.[76] Scholars' analysis contends that developing countries, including South Africa, should actively utilise the TRIPS flexibilities to promote access to medicines and address public health challenges.[77] Specifically, that they should implement compulsory licensing provisions and enable accessibility mechanisms such as the 'bolar' exception that were subsequently affirmed during the 2001 Doha Ministerial Conference.[78] Despite the availability of these flexibilities, concerns persist that they are underutilised, and the favourable outcomes for which they are intended, have not been realised. To date South Africa has not granted any compulsory licences or utilised the 'bolar' exception to improve access.[79]

It would be disingenuous to suggest that the patent regime carries the burden of hindering access to affordable medicines in South Africa. The development costs for new drugs are substantial, with WHO estimates ranging from US$43.4 million to US$4.2 billion, and another controversial estimate suggesting US$2.7 billion.[80] The requirement by the SAHPRA for extensive testing prior to medicine registration can take up to 15 years. Given that the term of protection for patents is 20 years, patent holders typically have just five years to recoup significant expenses and generate profit, leading to increased medicine prices or evergreening practices.[81] Furthermore, South Africa's centralized procurement system, while aimed at securing lower prices through bulk purchasing and competitive tendering, often delays the availability of newer, less expensive drugs.[82]

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[76] Abbott, F. M. (2002). The Doha Declaration on the TRIPS Agreement and Public Health: Lighting a Dark Corner at the WTO. *Journal of International Economic Law*, 5(2), 469–505. https://doi.org/10.1093/jiel/5.2.469.
[77] WTO 'Doha Declaration on the TRIPS Agreement and Public Health' available at *https://www.wto.org/english/res_e/booksp_e/ddec_e.pdf*, accessed on 26 September 2024.
[78] Martin Khor 'Implications of some WTO rules on the realization of the MDGs' *TWN Trade & Development Series 26* at 16, available at *https://www.twn.my/title2/t&d/tnd26.pdf,* accessed on 26 September 2024.
[79] Ibid at p .32.
[80] A search of the CIPC database, published Government Gazettes and web searches at the time of thesis submission reflects an absence of compulsory licence grants.
[81] Brown, D. G., Wobst, H. J., Kapoor, A., Kenna, L. A., & Southall, N. (2021). Clinical development times for innovative drugs. *Nature Reviews Drug Discovery*, *21*(11), 793–794. https://doi.org/10.1038/d41573-021-00190-9.
[82] Alejandro Simone and Vybhavi Balasundharam 'Public Procurement in South Africa: Issues and Reform Options' (2023) 041 *IMF* 2023.

It is important to note from the outset that the answer to the question of whether the current patent regime is flawed is initially taken to be in the affirmative by implication of the 2018 Intellectual Property Policy Phase I.[83] The policy is a result of many years worth of a consultative process that took the participation of stakeholders both in the public and private sectors into account for its drafting.[84] It outlines some key proposals for reform of the current flaws in the patent regime with a strong focus on fixing the system to enable equitable access to affordable medicines while maintaining the rights of patent owners. Considering it has been 6 years since its publication, where does the implementation of its proposals stand?

As will be confirmed section 27 of the Constitution creates a human right obligation. It provides that the right to healthcare holds fundamental status, and the State bears the responsibility to safeguard, advance, and ensure the fulfillment of this right, as mandated by the Bill of Rights. Therefore, to the extent that we find that the current patent regime in South Africa does negatively impact on the right to health, what must the state do to meet its constitutional obligations while still meeting TRIPS obligations?

Therefore, it is against this backdrop that this thesis will examine whether the current patent regime in South Africa constitutes an infringement of the right to health as enshrined in the Constitution. Ultimately, this thesis posits that a combination of solutions for the legislative framework and a rethinking of the underlying principles of patent protection can aid in the fulfilment of the constitutional right to health in South Africa.

III. RESEARCH QUESTION AND RESEARCH AIM

This thesis seeks to untangle the interrelationship between intellectual property rights and the fundamental right to health. Specifically, this research seeks to shed light on the nexus point connecting the realisation of the right to health as a prerogative and the underlying rationale for patent protection. In doing so it calls into question the purported role of patents, in encouraging innovation within the pharmaceutical sector or presenting hindrances to the attainment of affordable and accessible essential medicines for the everyday South African.

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[83] DTI 'Intellectual Property Policy of the Republic of South Africa Phase I' available at *https://www.gov.za/sites/default/files/gcis_document/201808/ippolicy2018-phasei.pdf*, accessed on 3 December 2024.

[84] The aim of Phase I "is to ensure that South Africa protects IPRs and at the same time achieves its objectives of promoting national development imperatives, which include, among others, boosting local manufacturing, promoting innovation and ensuring equitable access to medicines."

The fundamental question of this research is, “Does the patent regime in South Africa in its current form negatively impact on the attainment of the fundamental right to health as enshrined in the Constitution? If so, how can the patent system be recalibrated to balance the right to health and the rights of patent holders?”

To answer this, the following sub-questions will be asked:

1. In light of section 27 of the Constitution and international human rights treaties, does the right to health inherently include the right to affordable essential medicines?
2. What is the nature of the constitutional right to health and what is the nature of the obligations imposed by that right?
3. What is the impact of the current patent regime on access to affordable medicine, and therefore the right to health?
4. What can be done to enable the realisation of the right to health through patent law?

IV. SCOPE AND METHODOLOGY

This thesis employs doctrinal legal research methodology through desktop research, analysing primary and secondary legal sources including legislation, case law, academic literature, and policy documents. The research primarily focuses on South Africa’s patent regime and its intersection with the constitutional right to health, specifically examining how patent protection impacts access to affordable medicines. The comparative analysis examines India and Canada's patent systems for several strategic reasons. India is selected for price analysis due to its similar developing country status and its successful use of compulsory licensing. Particularly India’s Patent Act, 1970 section 3(d) provision that seeks to prevent evergreening of pharmaceutical patents and sections 2(1) (ja) and 3(d) which aim to strike a balance between access to medicines and patent protection. Canada serves as a useful case study through the Canada Pharmaceutical case which gave clarity on the ‘bolar’ exception.

V. THESIS STRUCTURE

This thesis has five chapter. Following this first introductory chapter, chapter two examines South Africa's legal framework for balancing patent protections and the right to health. It analyses constitutional and international obligations, focusing on how treaties like TRIPS and ICESCR mandate access to affordable medicines. The chapter then explores the constitutional

tension between health rights (section 27) and property rights, including intellectual property (section 25).

Chapter three critically examines South Africa's patent regime under the Patents Act 57 of 1978, assessing its impact on the constitutional right to health and access to affordable medicines. The chapter reveals systemic flaws that prioritize patent holders' interests over public health. Key issues include the absence of SSE for patent applications, which enables evergreening and secondary patenting. Case studies of essential medicines like Bedaquiline, Lenalidomide, and Rivaroxaban demonstrate how these practices extend monopolies, artificially inflate drug prices, and impede generic market entry. Despite TRIPS flexibilities designed to support public health, their implementation in South Africa is severely constrained.

Chapter four proposes strategies to recalibrate South Africa's patent system, balancing the constitutional right to health with patent holders' interests. Drawing inspiration from India's patent regime and the principle of *Ubuntu*, the chapter recommends implementing SSE to prevent evergreening, ensuring patents are granted only for genuine therapeutic innovations. The chapter advocates for a more liberal approach to compulsory licensing, similar to India's model, which would enable issuing licences when medicines are unaffordable or inadequately supplied. It emphasises a communitarian ethic that challenges profit-driven patent monopolies, arguing for equitable access to medicines given the significant role of public funding in drug development. Critically, the chapter highlights the slow progress in implementing South Africa's 2018 Draft IP Policy. It calls for urgent legislative action to align the patent system with constitutional values and public health imperatives, ensuring a more balanced approach to pharmaceutical innovation and access.

Chapter five provides an overview and conclusion of the thesis, presenting key discoveries and offering recommendations that address the research question

CHAPTER TWO

RIGHT TO HEALTH AND PATENT LAW OBLIGATIONS

I. INTRODUCTION

To aide in addressing the fundamental question of this thesis, this chapter begins by examining the implications of international and constitutional obligations concerning the right to health for South Africa. Specifically, it aims to demonstrate that these obligations inherently encompass access to affordable, essential medicines through international right to health treaties and section 27 of the Constitution.

It is widely accepted by scholars and policy makers that IP law is essential to fulfilling access to affordable medicines – particularly through patented medicines.[85] To contribute to this discussion through the South African framework, the role of patents in the attainment of affordable medicine access is examined. This is done through an analysis of the obligations under the TRIPS Agreement as they pertain to patentable subject matter and patentability criteria. Following this, this chapter examines the meaning of property under section 25 of the Constitution in relation to IPRs. To conclude, a brief overview of the exceptions to patent rights under the TRIPS Agreement; compulsory licensing, and 'bolar' exception flexibilities as affirmed by the Doha Declaration follows.

II. SOUTH AFRICA'S RIGHT TO HEALTH OBLIGATIONS

(a) Treatment of Treaty Obligations in South Africa

Before analysing the treaties that encapsulate the right to health it is important to understand how their obligations affect South African domestic law, we must examine the constitutional framework governing the interplay between international and national legal systems. This analysis addresses how binding treaty obligations are incorporated into South Africa's legal landscape.

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[85] Helfer, L. R., & Austin, G. W. (2011). *Human Rights and Intellectual Property: Mapping the Global Interface* (1st ed., pp. xvi–xvi). Cambridge University Press at p. 91.

The Constitution, as the supreme law, shapes domestic law-making and application. Within it, the Bill of Rights stands as a fundamental pillar of democracy.[86] Consequently, treaty obligations can be divided into two categories: those aligning with the Bill of Rights, and those that don't. While this categorisation doesn't alter South Africa's duty to honour all international commitments in good faith, it does influence their domestic implementation. Obligations corresponding to the Bill of Rights must be fulfilled domestically.[87] This does not imply that these treaties are automatically treated as legislation. Instead, it highlights that international obligations aligned with the Bill of Rights have a *stronger persuasive force* and are more readily integrated into domestic law due to their consistency with constitutional values.[88] For obligations outside this scope, South Africa has broader discretion in implementation, subject to constitutional limits, including those set by the Bill of Rights.[89] This framework guides courts to prefer interpretations of domestic law that align with international law and to consider international law when interpreting the Bill of Rights.[90] For the purposes of the jurisdictional analysis that will follow, the constitution mandates that 'when interpreting the Bill of Rights, a court, tribunal or forum must consider international law; and may consider foreign law.'[91]

For the purposes of the discussion regarding solutions in chapter four that are influenced by international law, it is important to note that section 39 provides for the consideration of international law by the courts when interpreting the Bill of Rights. Section 39(1)(b) does not require the courts to interpret the Bill of Rights consistently with binding international law. Instead, it requires the courts to consider all international law.[92] Section 39(1)(b) states that when interpreting the Bill of Rights, courts, tribunals, and other forums 'must' consider international law. However, s 39(1)(c) provides that they 'may' consider foreign law.[93] Under s 39(1)(b), international law refers to both binding and non-binding treaties.[94] Under s 39(1)(b), the authority of international law is persuasive and serves as a

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[86] Supra note 8 at ss 7 and 8.
[87] Samtani, Sanya, "The Domestic Effect of South Africa's Treaty Obligations: The Right to Education and the Copyright Amendment Bill" (2020). *PIJIP/TLS Research Paper Series* no. 61, at p. 10. https://digitalcommons.wcl.american.edu/research/61.
[88] Ibid, at p. 45.
[89] Ibid, at p. 17.
[90] Ibid.
[91] Supra note 8 at ss 39 (1) (b) and (c).
[92] Sucker, F. (2013). Approval of an international treaty in Parliament. How does section 231(2) 'bind the republic'? *CCR, 5,* at p. 428.
[93] In *Glenister v President of the Republic of South Africa* 2011 (3) SA 347 (CC), the Constitutional Court determined the weight to be given to the term *consider* in s 39(1)(b). The judgment does little on clarifying the authority of international law in the context of s 39(1)(b). See Juha Tuovinen 'What to do with international law: Three flaws in Glenister' (2014) 5 *CCR* 435, where the author criticises the decision in Glenister and clarifies the law in this regard.
[94] *S v Makwanyane* 1995 (6) BCLR 665 (CC) para 35.

source of inspiration for the courts.[95] It provides a framework for evaluating and understanding the Bill of Rights.[96]

According to section 231(2) of the Constitution, certain types of treaties must be approved by parliament before being assented to. This allows parliament to determine whether domestic action such as amending existing laws, is required.[97] However, section 231(3) provides that 'an international agreement of a technical, administrative or executive nature, or an agreement which does not require either ratification or accession, entered by the national executive, binds the Republic without approval by the National Assembly and the National Council of Provinces'.[98] Therefore, once treaties are categorised, the constitution outlines three pathways for binding treaty obligations to have domestic legal effect: (1) through parliamentary legislation, (2) via self-executing provisions of parliament-approved treaties, and (3) by creating a normative framework for judicial interpretation.[99] Thus, once a treaty is signed and ratified through parliamentary resolutions as envisaged by s 231(2) and with self-executing treaties under s 231(3), a failure of South Africa to observe these treaties is considered a breach of international law and is actionable in appropriate international forums.[100] Should it breach its international law obligations, South Africa could incur responsibility towards other signatory states.[101]

Additionally, under section 231(4) international agreements become laws in South Africa when they are enacted into law by national legislation.[102] A statute containing domesticated provisions will often address the consequences of non-compliance with those provisions.

As such, the treaties discussed below that align with the Bill of Rights carry a stronger normative mandate for implementation by Parliament and courts compared to those that do not. This alignment creates a more compelling imperative for these treaties to be implemented within the domestic legal framework. As previously noted, the right to health is embodied within Bill of Rights in South Africa's Constitution. Thus, the treaties in relation to the right to health are binding on South Africa due to their scope falling under the Bill of Rights. Furthermore, due to South Africa being a founding member of the WTO, it is automatically

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[95] Tuovien supra note 89.
[96] Ibid.
[97] Ibid at s 231 (2).
[98] Ibid at s 231 (2).
[99] Ibid.
[100] Meiring, Jean. *South Africa's Constitution at Twenty-One*. Cape Town: Penguin Books, 2017.
[101] Ibid.
[102] Supra note 8 at s 231 (4).

party to the TRIPS Agreement. A broad analysis of this constitutional right to health, the obligations it places on the state and the implementation of the above treaties is upcoming in this chapter. Although the focus of this thesis is on South Africa's patent law in relation to the right to health, it also considers the role of private entities in the fulfilment of that constitutional right. To facilitate that discussion I must highlight section 8(2) of the Constitution which mandates that 'A provision of the Bill of Rights binds a natural or a juristic person if, and to the extent that, it is applicable, taking into account the nature of the right and the nature of any duty imposed by the right.'[103] Furthermore, that the Bill of Rights is binding upon all state entities, individuals, and legal entities within the Republic, and applies to all laws is important. How far does this obligation extend, and does it apply to private entities?

With the above in mind, what are the international treaties relevant to this thesis, and what obligations do they place?

(b) International right to health treaties

South Africa is party to several international human rights treaties that enshrine the right to health, with its obligations varying depending on the specific treaty in question. South Africa is a member state of the WHO[104], and although it is party to its constitution it is not legally bound by it.[105] In essence, South Africa's commitment to the WHO strengthens its global health accountability but does not create automatic, enforceable legal duties unless reflected in domestic law. The WHO constitution defines the right as 'the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race; religion, political belief, economic or social condition.'[106] As highlighted previously Article 25 of the UDHR further acknowledges and safeguards the right to health.[107] Although the UDHR applies universally it lacks binding force.[108]

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[103] Supra note 8 at s 8 (2).
[104] WHO 'Constitution' available at *https://www.who.int/about/governance/constitution,* accessed on 23 August 2024. Adopted in 1946 and entered into force in 1948.
[105] Ibid at p. 26. Upon joining the WHO, member states agree to be bound by its constitution, which sets out the organization's guiding principles, including the recognition of health as a fundamental right. However, the specific implementation of WHO recommendations, regulations, and decisions depends on each country's domestic laws and policies, and adherence can vary based on a state's interpretation and capacities.
[106] Ibid at p. 6.
[107] UNHDR supra note 3 at p. 7.
[108] The Universal Declaration of Human Rights, adopted by the United Nations General Assembly in 1948, is not a treaty that states can formally join. However, it represents a declaration from the international community outlining the minimum standards for state conduct and is widely recognized as expressing the human rights obligations of states under the United Nations Charter.

The ICESCR provides an authoritative provision on the right to health.[109] South Africa signed the ICESCR in 1994, and it ratified the treaty in 2015.[110] As a result, the CCSA must consider the ICESCR when making constitutional decisions pertaining to the right to health.[111] Article 12(1) not only recognises the right of everyone to 'the enjoyment of the highest attainable standard of physical and mental health'[112], it also instructs that the provision of these rights must be progressively realised. Article 2 directs 'each State Party […] to take steps, individually and through international assistance and cooperation, particularly in economic and technical areas, to the maximum of its available resources, with the aim of progressively achieving the full realization of the rights acknowledged in this Covenant through all appropriate means, including the adoption of legislative measures.'[113] The obligation to 'progressively realize' highlights the responsibility of states to guarantee that healthcare is accessible and available to all individuals and groups. General Comment No. 14 confirms that this obligation is subject to availability of state resources.[114] It defines progressive realization to mean 'that State parties have a specific and continuing obligation to move as expeditiously and effectively as possible towards the full realization of article 12.'[115] This suggests that this progressive realisation requires some level of urgency.

The question of whether the right to health encompasses access to medicines has been thoroughly examined by the CCSA, particularly concerning essential medicines and public healthcare. Furthermore, General Comment No. 14 of the ICESCR stipulates that healthcare services, including essential medicines as defined by the WHO Essential Medicines List, must be economically accessible to all people, implying that the costs of essential drugs cannot be so exorbitant as to render them unaffordable for impoverished patients.[116]

In addition, South Africa has ratified the African Charter on Human and Peoples' Rights (Banjul Charter).[117] Article 16 of the African Charter recognises and guarantees the right to health. It states: 1. 'Every individual shall have the right to enjoy the best attainable state of

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[109] ICESCR supra note 4.
[110] UNHR 'Status of Ratification Interactive Dashboard', available at *https://indicators.ohchr.org/,* accessed on 24 August 2024.
[111] UN 'Vienna Convention on the Law of Treaties' 23 May 1969 at Articles 2 (1) (b), (14) (1) and 15, available at *https://legal.un.org/ilc/texts/instruments/english/conventions/1_1_1969.pdf*, accessed on 24 August 2024.
[112] Supra note 4 at Article 12 (1).
[113] Ibid at Article 2.
[114] Supra note 5 at 30.
[115] Ibid at 31.
[116] Ibid.
[117] According to the African Union treaty ratification table, 54 out of 55 member states have ratified the Banjul Charter. South Africa ratified the Charter in 1996. See ACHPR 'State Parties to the African Charter' Available from *https://achpr.au.int/en/states*.

physical and mental health,' and 2. 'State Parties to the present Charter shall take the necessary measures to protect the health of their people and to ensure that they receive medical attention when they are sick.'[118] The Charter places obligations on state parties to ensure access to timely, acceptable, and affordable healthcare of appropriate quality. This includes making essential medicines affordable and accessible within their resource limitations, as these are critical to realising the right to health.[119]

Moreover, in 1995 South Africa ratified the UN Convention of the Rights of the Child (UNCRC).[120] The treaty provides that 'States Parties recognize the right of the child to the enjoyment of the highest attainable standard of health and to facilities for the treatment of illness and rehabilitation of health. States Parties shall strive to ensure that no child is deprived of his or her right of access to such health care services.'[121] Having ratified the UN Convention on the Rights of Persons with Disabilities, South Africa bears obligations to ensure persons with disabilities have the right to the enjoyment of the highest attainable standard of health and to provide persons with disabilities with affordable health.[122]

Accordingly, South Africa is obligated by the aforementioned treaties to implement, the aforementioned human rights to health for all individuals. This is especially crucial where disadvantaged individuals cannot afford essential medicines, which the above international treaties emphasise as a fundamental component of the right to health.

(c) Domestic right to health treatment

The South African Constitution enshrines fundamental rights within its Bill of Rights chapter. These rights are regarded as the bedrock of the nation's democracy, upholding the values of human dignity, equality, and freedom.[123] The State is duty-bound to safeguard, advance, and fulfil the rights outlined in the Bill of Rights.[124] As discussed previously, South Africa is required to fulfill any international obligations that map onto the Bill of Rights as mandated by

[118] AU 'African Charter on Human and Peoples' Rights' *OAU* at Article 9, available at *https://au.int/sites/default/files/treaties/36390-treaty-0011_-_african_charter_on_human_and_peoples_rights_e.pdf*, accessed on 25 August 2024.
[119] Ibid.
[120] UN 'Convention of the Rights of the Child' available at *https://www.ohchr.org/en/instruments-mechanisms/instruments/convention-rights-child*, accessed on 25 August 2024.
[121] Ibid at Article 24.
[122] Ibid at Article 25.
[123] Meiring supra note 96.
[124] Supra note 8.

section 7(2) of the Constitution.[125] Notably, among the fundamental rights in the Bill of Rights, is section 27 which establishes the right to healthcare, food, water, and social security:[126]

> (1) Everyone has the right to have access to—
>
> (a) health care services, including reproductive health care;
>
> (b) sufficient food and water; and
>
> (c) social security, including, if they are unable to support themselves and their dependants, appropriate social assistance.
>
> (2) The state must take reasonable legislative and other measures, within its available resources, to achieve the progressive realisation of each of these rights.
>
> (3) No one may be refused emergency medical treatment.

The meaning of the right to health is not immediately clear. Thus, while the right is established by s 27, it has been affirmed and given substantive meaning through several landmark cases before the CCSA which clarify that the state's obligation extends to ensuring that life-saving and essential medicines are economically accessible to all. The cases range from *Competition Commission v Mediclinic*[127] that considers competition law and the right to health within the public interest, to *Minister of Health and Others v Treatment Action Campaign and Others*[128] a landmark decision was made concerning access to medicines and healthcare and includes *Minister of Health v. New Clicks*[129] where the court ruled that the right to health also encompasses the right to access affordable medicines, and that the State bears a constitutional obligation to 'promote access to medicines that are affordable.'[130].

Competition Commission concerned the proposed merger of two private healthcare providers Matlosana and Mediclinic.[131] Matlosana, a member of the National Healthcare Network (NHN) consortium, operated two hospitals in Krugersdorp. Concurrently, prior to the proposed merger, Mediclinic already maintained a hospital in Potchefstroom, a town located 86 minutes from Krugersdorp. It is worth noting that South Africa has a two-tiered, and highly unequal, healthcare system. The public sector is state-funded and caters to the majority 71% of the population.[132] The private sector is largely funded through individual contributions to

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[125] Ibid at s 7 (2).
[126] Ibid at s 27.
[127] *Competition Commission of South Africa v Mediclinic Southern Africa (Pty) Ltd and Another* (CCT 31/20) [2021] ZACC 35.
[128] *Minister of Health and Others v Treatment Action Campaign and Others (No 2)* (CCT8/02) [2002] ZACC 15
[129] *Minister of Health and Another v New Clicks South Africa (Pty) Ltd and Others* (CCT 59/2004) [2005] ZACC 14.
[130] Ibid para 514.
[131] Supra note 122.
[132] Russell Rensburg 'Healthcare in South Africa: how inequity is contributing to inefficiency' *University of the Witwatersrand* 7 July 2021, available at *https://www.wits.ac.za/news/latest-news/opinion/2021/2021-07/healthcare-in-south-africa-how-inequity-is-contributing-to-inefficiency.html,* accessed on 3 December 2024.

medical aid schemes or health insurance and serves around 27% of the population.[133] The private healthcare landscape in South Africa is dominated by a handful of major national players.[134]

The Competition Commission, a statutory body responsible for approving or prohibiting mergers, recommended that the proposed merger between Matlosana and Mediclinic be barred due to its potential anti-competitive effects and public interest concerns, specifically the impact on uninsured patients whose private healthcare costs would escalate. The Competition Commission's concerns align with international human rights law guidelines on the right to health, which emphasise non-discrimination and economic affordability as key considerations in realising this right.[135] The Competition Tribunal upheld the Commission's decision, which was subsequently appealed to the Competition Appeal Court (CAC). CAC endorsed the merger but imposed certain conditions.[136] Ultimately, the CCSA was tasked with delivering the final verdict on whether the merger should be prohibited or permitted, given its potentially adverse impact on the constitutionally enshrined right to health.

The CCSA ruled that the proposed merger should be prohibited, basing its decision on foregrounding the paramount importance of the right to health when determining whether a merger between two private healthcare providers should be sanctioned. In arriving at its verdict, the Court had to evaluate competition law principles against constitutionally enshrined economic and social rights, such as the right to health. The Court's reasoning held significant implications for the following reasons: guaranteeing dignity and well-being for all, at every stage of life; pursuing substantive equality, dismantling intersecting inequalities and systems of oppression; and addressing power imbalances within the economy. This is evident from the context in which the Court situated the conflict between the right to health and traditional notions of the free market, where it underscored the importance of building an 'inclusive, ethical, truly human rights-oriented and vibrant or prosperous economy.'[137]Against this

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[133] Human Rights Watch 'African Governments Falling Short on Healthcare Funding' available at *https://www.hrw.org/news/2024/04/26/african-governments-falling-short-healthcare-funding*, accessed on 1 September 2024, The public sector is underfunded while most South Africans cannot afford the cost of private care.

[134] Ibid. Netcare controlling 24.9%, the National Healthcare Network (NHN) commanding 24.7%, Life Healthcare with 21.3%, and Mediclinic holding 20.3% of the market share.

[135] UN Committee on Economic, Social and Cultural Rights (CESCR), *General comment No. 20: Non-discrimination in economic, social and cultural rights (art. 2, para. 2 of the International Covenant on Economic, Social and Cultural Rights),* E/C.12/GC/20, 2 July 2009, *https://www.refworld.org/legal/general/cescr/2009/en/68520*, accessed 26 August 2024.

[136] *Mediclinic Southern Africa (Pty) Ltd and Another v Competition Commission* (172/CAC/Feb19) [2020] ZACAC 3.

[137] Ibid, para 2.

backdrop, the Court ascribed a substantive meaning to the right to health in competition law in two significant ways. First, it stressed that in considering whether a merger will lessen competition, one should not only consider the potential increase in price but also evaluate any impact it may have on human rights, including the right to health. Second, it acknowledged the impact a merger would have on economic and social rights, including the right to health, as a substantive public interest concern.

The CCSA dealt with the link between access to medicines and the right to health at the peak of the Human Immunodeficiency Virus (HIV)/Acquired Immunodeficiency Syndrome (AIDS) in the late 1990s and 2000s through *Minister of Health v TAC.* In 2000 newborn HIV infections reached alarming levels of approximately 80,000 cases annually, the antiretroviral (ARV) drug Nevirapine presented a promising potential to prevent the transmission of the virus to 30,000 to 40,000 children each year.[138] The pharmaceutical company that owned the pharmaceutical patent, Boehringer Ingelheim, offered the South African government free access to the drug for a period of five years. However, the government announced that it would introduce the Mother-To-Child-Transmission (MTCT) prevention program only at selected pilot sites and delay its implementation for a year, effectively denying access to treatment for the majority of expectant mothers.[139]

In response, the Treatment Action Campaign (TAC) initiated a constitutional challenge, alleging a violation of the right to access healthcare services and demanding a nationwide program to make the drug available.[140] Judge Chris Botha of the High Court ruled in favour of TAC, ordering the government to provide Nevirapine to HIV-positive mothers giving birth in state institutions and to present a plan to the court outlining the extension of medication provision to all birthing facilities across the country.[141] The government appealed the decision to the CCSA, and Judge Botha granted interim relief pending the appeal.[142] Ultimately, the CCSA rejected the government's appeal, concluding that the restrictions limiting Nevirapine to pilot sites excluded those who could reasonably be included in the program.[143] The Court ordered the government to extend the availability of Nevirapine to hospitals and clinics, provide counsellors, and take reasonable measures to expand testing and counselling facilities

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[138] *See* UNAIDS 'AIDS epidemic update' December 2000, available at *https://data.unaids.org/publications/irc-pub05/aidsepidemicreport2000en.pdf., accessed on 11 March 2025.*
[139] Supra at note 128.
[140] Ibid, para 4.
[141] Ibid, para 10.
[142] Ibid, para 9.
[143] Ibid, para 67.

throughout the public health sector.[144] The Court also dismissed the argument advanced by one of the interveners for a distinction between a minimum core content of the right to healthcare and the obligations imposed on the state in section 27(2) of the Constitution, which are subject to progressive realisation and available resources.[145]

In 1997, the Medicines Act underwent amendments to facilitate access to more affordable drugs.[146] Among other measures, the amendment established a pricing committee tasked with making recommendations for introducing a comprehensive pricing system governing all medicines sold within South Africa.[147] The litigation in *New Clicks* arose out of the validity of regulations made to give effect to the pricing system for the sale of medicines by the Minister of Health, on the recommendation of the pricing committee. The Regulations established a pricing framework for medicines and scheduled substances, aiming to enhance affordability. This framework introduced a 'single exit price' (SEP) for each medicine sold by manufacturers or importers. The pharmacies contested the SEP, arguing that it amounted to a price control system not sanctioned by the Medicines Act. The CCSA rejected this argument, ruling that the Medicines Act not only allowed but mandated the creation and enforcement of price control mechanisms affecting all participants in the supply chain. The Court further held that the decision to regulate prices was a policy matter within the authority of the Legislative and Executive branches, and therefore, it would not intervene. Per Justice Sachs, 'preventing excessive profit-taking from the manufacturing, distribution and sale of medicines is more than an option for government. It is a constitutional obligation flowing from its duties under section 27(2).'[148] Justice Moseneke in his judgement echoed that:

> 'It seems self-evident that there can be no adequate access to medicines if they are not within one's means. Prohibitive pricing of medicine would, in effect, equate to a denial of the right of access to health care. Equally true is that the state bears the obligation to everyone to facilitate equity in the access to essential drugs, which in turn affects the quality of care.'[149]

Therefore, South Africa's constitutional framework, reinforced by key judicial decisions, unequivocally recognises that the right to health encompasses access to affordable essential medicines.

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[144] Ibid, para 135 (3) (a).
[145] Ibid, para 81.
[146] The Medicines and Related Substances Control Amendment Act 90 of 1997.
[147] Ibid at s 22G.
[148] Supra at note 129 para 659.
[149] Ibid para 706.

III. SOUTH AFRICA'S PATENT PROTECTION OBLIGATIONS

(a) TRIPS Agreement Obligations

The TRIPS Agreement is seen as the most detailed and extensive framework for various types of IP including patents, copyright, trademarks and trade secrets, globally.[150] The minimum standards it sets out may be described as 'baseline protection' or the lowest acceptable level of protection.[151] That is to say member states can choose to offer *stronger protection* but not *weaker* than what the TRIPS Agreement sets. This is affirmed in Article 1 which outlines the nature and scope of the obligations of WTO members under the agreement. It states that –

> 'Members shall give effect to the provisions of this Agreement. Members may, but shall not be obliged to, implement in their law more extensive protection than is required by this Agreement, provided that such protection does not contravene the provisions of this Agreement. Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice.'[152]

First, it implicitly reaffirms the international legal principle of performing agreements in good faith.[153] Second, it allows members, though not requiring them, to provide higher levels of protection than those mandated by it, as long as these enhanced protections do not conflict with the Agreement's provisions.[154] Third, it grants members flexibility in how they implement the Agreement, allowing them to interpret and apply TRIPS in accordance with their national legal systems and policy objectives, provided that the minimum standards are upheld, and the implementation is 'appropriate' to the domestic context.[155]

The TRIPS Agreement further outlines a framework for the governance of patents, among other types of IP. Article 7 emphasises that –

> '… the protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to

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[150] Correa, Carlos Maria, *Trade Related Aspects of Intellectual Property Rights: A Commentary on the TRIPS Agreement*, 2nd Edition, Oxford Commentaries on International Law (2020; online edn, Oxford Academic)
[151] Ibid.
[152] Supra note 13 at Article 1.
[153] Supra note 107 at Article 26.
[154] UNCTAD-ICTSD. (2005). *Resource Book on TRIPS and Development* (1st ed.). Cambridge University Press at p.17.
[155] Ibid at p. 18.

> the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.'[156]

The phrasing of Article 7 'the protection and enforcement of intellectual property rights should contribute to […]' can be interpreted as indicating that this provision is primarily promotional in nature rather than a binding obligation as 'shall give effect' in Article 1.1.[157] . If the thesis is to take this view, an argument could be put forward that the aforementioned flexibilities form a stronger provision and outweigh the protections of owners of IPRs as opposed to the public interest that encapsulates the right to health. However, this discussion is better suited in chapter four regarding proposals and solutions. Furthermore, the three goals outlined in Article 7 primarily centre on technological advancement and may not encompass other types of intellectual property. Article 8(1) of the TRIPS Agreement grants member states permission to -

> '[…] formulate or amend their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development [...]'[158]

Articles 1, 7 and 8 briefly discussed above relate to all types of IP. However, for the purposes of answering the fundamental question, the next section focuses on specific provisions in the TRIPS Agreement related to patents, particularly those that impact access to affordable medicines.

Article 27.1 of the TRIPS Agreement provides for the protection of patents in the following terms. It stipulates that –

> 'Subject to the provisions 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.'[159]

As we can see, Article 27 mandates that patent protection for products and process be granted. Product patents cover the actual product, which is a real technological advancement or chemical compound.[160] On the other hand, process patents describe a method or process

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[156] Supra note 13 Article 7.
[157] Supra note 150 at p. 18.
[158] Supra note 13 at Article 8 (1).
[159] UNCTAD-ICTSD Supra note 150.
[160] Supra note 13 at Article 28.1(a).

used to create a product.[161] Regarding the latter, a process patent is not infringed if the result is achieved by different proceedings. This is in contrast to a product patent, which is infringed by any reproduction, regardless of *how* it was made, provided that it complies with patent's claims.[162]

Article 27 also provides what may be excluded from patentability. Under Article 27 (2) and (3) which state –

> '2. Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law. 3. Members may also exclude from patentability: (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals; […]'[163]

In exchange for publicly disclosing a new invention, a patent holder gets exclusive rights[164] to that invention for a standard 20-year term.[165] Under Article 28.1 this means that others cannot make, use, or sell the patented invention domestically or internationally without the patent holder's permission.

However, these rights are not absolute, and provision is made to balance public interests, namely Article 30, which allows for limited exceptions to the exclusive rights conferred by a patent, and Article 31, which addresses compulsory licensing and the use of a patent without authorisation of the right holder under certain conditions.[166] These, as will be shown below, are pivotal to our discussion on the right to health and access to affordable medicines and will be explored later as key mechanisms to ensure equitable access.

Given the TRIPS imperatives set out in Article 27, along with Article 8 indicates Members have flexibility, the question arises as to how Members can use this discretion when Article 27 obliges them to provide patent protection without discrimination.

From the above, it is established that members have the flexibility to determine what subject may be patentable under domestic legislation. After an invention is considered eligible for a patent, the actual granting of the patent hinges on three criteria outlined in Article 27.1: novelty, inventiveness, and industrial applicability.[167] These standards are designed to ensure

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[161] Ibid at Article 28.1(b).
[162] See also article 28 TRIPS; CORREA, Trade-Related Aspects of IPRs: A Commentary on the TRIPS Agreement, at 271.
[163] Supra note 13 at Article 27
[164] Ibid at Article 28.
[165] Ibid at Article 33.
[166] Ibid at Articles 30 and 31.
[167] UNCTAD-ICTSD supra note 150 at p. 357.

that only genuinely innovative, previously undiscovered, and socially beneficial inventions are granted exclusive rights through a patent.[168] Since the definition of these criteria is left to the discretion of WTO members, as long as they adhere to the fundamental meaning of these criteria, members are free to implement them in accordance with their national policies.

The first of the criteria is the universal requirement of novelty. This means that, at the time of filing, the invention of filing the application for a patent, the invention must not have been publicly disclosed in any form—written or otherwise—anywhere in the world, and thus, it should not be part of the state of the art (or prior art).[169] This requirement aims to prevent the re-patenting of existing inventions, ensure that publicly available knowledge is not monopolised, and encourages genuine innovation.[170] Generally, to defeat novelty, the disclosed information must enable a person skilled in the relevant field to replicate the invention without additional guidance. Simply publishing a statement about the existence of the invention is not sufficient to destroy its novelty.[171] Under the TRIPS Agreement, the requirement that an invention must involve an inventive step is meant to justify the granting of strong monopoly rights, ensuring that minor or insignificant improvements do not receive the same level of protection and remain accessible in the public domain.[172]

The need for an invention to involve an inventive step forms the second criterion. The requirement that an invention must involve an inventive step serves to justify the significant monopoly rights granted through patents and ensures that minor or obvious enhancements do not receive the same level of protection, keeping them in the public domain.[173] Generally, an invention that represents a simple or obvious improvement to the existing state of the art, as judged by someone skilled in the field, does not qualify for patent protection.[174] While the TRIPS Agreement does not explicitly define 'inventiveness,' it clarifies in a footnote that the term is synonymous with 'non-obviousness.'[175] In the United States of America (US/USA) patent law under U.S. Code § 103, non-obviousness is taken to mean that an invention must not be obvious to a person having ordinary skill in the art at the time the invention was made.[176] In the European Patent Convention (EPC), under Article 56 to assess inventiveness the following questions must be asked: what is comprised within the state of the art; what is meant

[168] Ibid.
[169] Ibid at p. 359.
[170] Ibid.
[171] Ibid.
[172] Ibid at p. 360.
[173] Supra note 13 at Article 27.2
[174] Supra note 150 at p. 359.
[175] Supra note 13 at Article 27.1.
[176] 35 U.S. Code § 103 - Conditions for patentability; non-obvious subject matter.

with a person skilled in the art; and finally when do we know that something is "obvious" to a person skilled in the art?[177] The purpose of highlighting these two examples is to demonstrate that approaches to this criterion vary widely in different countries and to illustrate that the TRIPS Agreement encourages members to establish their own standards for the level of inventiveness required to grant patent protection.[178] Gamharter put forward that inventiveness also implies that the invention should offer some societal benefit.[179] This is particularly relevant to this thesis as will be shown in the next chapter, in the pharmaceutical industry, some patent applications do not involve genuinely new or innovative chemical compounds but rather focus on minor modifications, new production methods, or different formulations of existing drugs – the evergreening problem. Unfortunately, the TRIPS Agreement does not provide members with specific guidance on this matter.

For the third criterion, the TRIPS Agreement requires that an invention must be capable of industrial application, meaning it should possess an industrial or technical character.[180] While TRIPS does not define this term explicitly, a footnote indicates that industrial applicability is equivalent to being 'useful.'[181] Further it is important to highlight that Article 1.3 of the Paris Convention for the Protection of Industrial Property (the Paris Convention) provides a further definition that 'Industrial property shall be understood in the broadest sense and shall apply not only to industry and commerce proper, but likewise to agricultural and extractive industries and to all manufactured or natural products, […].'[182]

(b) The Constitutional Right to Property

While the TRIPS Agreement establishes essential requirements for patent protection, South Africa's implementation of these obligations must be examined through the lens of its constitutional framework, particularly section 25 on property rights. This context is essential in addressing the fundamental thesis question. Examining section 25 helps assess whether the

[177] European Patent Convention at Article 56.
[178] Correa supra note 146 at p. 276.
[179] Katharina Gamharter *Access to Affordable Medicines – Developing Responses under the TRIPS Agreement and EC Law* (2004) at p. 24.
[180] Supra note 13 at Article 27.1.
[181] Ibid.
[182] WIPO 'Paris Convention for the Protection of Industrial Property' *WIPO* 28 September 1979, available at *https://www.wipo.int/wipolex/en/text/28755*, accessed on 26 October 2024.

system overly favours patent holders and highlights how TRIPS flexibilities can be used to balance patent rights with equitable access to essential medicines.

Section 25 of the Constitution, often referred to as 'the property clause', safeguards against arbitrary deprivation of property[183] and further ensures that property rights are balanced with the public interest by making provision for the expropriation of property when it is in the public interest and subject to compensation.[184]

A cursory reading of section 25 suggests this provision is for tangible property i.e., corporeal moveable and immovable property such as land. However, in *Certification of the Constitution of the Republic of South Africa*[185], the CCSA dealt with the validity of the Constitution. In particular, one objection was raised that the Constitution did not specifically protect IP rights.[186] The Court ruled that it is not a universally accepted practice to enshrine intellectual property rights in a separate constitutional provision.[187] It concluded that the term 'property,' when used in a general property clause, is broad enough to encompass rights and interests that require protection under international human rights standards. As a result, a separate clause for IP was deemed unnecessary, as the property clause provides the required constitutional protection. In *Laugh It Off Promotions v South African Breweries*,[188] the CCSA upheld this line of thinking, that IP fell within the definition of property under section 25. Thus, while it is widely acknowledged that IP likely enjoys constitutional protection under section 25,[189] Samtani has suggested that the question of whether IP definitely qualifies as constitutionally protected remains unresolved, as the courts have not yet explicitly ruled on this matter.[190] Although her work refers to copyright, the same applies for patents.

A critical aspect of section 25 is the requirement that the regulation or limitation of property rights must be justifiable in an open and democratic society based on human dignity, equality, and freedom. This principle aligns with the need to balance patent protection with the right to health, enshrined in section 27 of the Constitution. More importantly, as has been highlighted by scholars, the Constitution envisions property rights not as an end in themselves

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[183] Supra note 8 at s 25 (1)
[184] Ibid at s 25 (2) a and b
[185] *Certification of the Constitution of the Republic of South Africa, 1996 (CCT 23/96) [1996] ZACC 26*.
[186] Ibid at para 75.
[187] Ibid.
[188] *Laugh It Off Promotions CC v South African Breweries International (Finance) BV t/a Sabmark International and Another (CCT42/04) [2005] ZACC 7*.
[189] Van der Walt, A. J. (Andries J. (2011). *Constitutional property law* (3rd ed.). Juta Law, at p. 143-50; Alexander, G. S. (2006). *The global debate over constitutional property: lessons for American takings jurisprudence*. University of Chicago Press, at p. 163.
[190] Sanya Samtani *The right of access to educational materials and copyright: International and domestic law* (published PhD thesis, Oxford University, 2021) at p. 240.

but as a means to achieve broader socio-economic objectives,[191] and in *Government of the Republic of South Africa v Grootboom* where the court held that the realisation of these socio-economic objectives must be realised progressively, but within the constraints of available resources.[192] This in turn puts forward the questions of whether overly restrictive patent protections that hinder access to affordable medicines could be deemed inconsistent with constitutional values.

Furthermore, it is important to note that the recognition of IP as a property in the Constitution does not serve to insulate IP rights completely.[193] As seen with section 25(1) to (3) the rights to property can be deprived and expropriated. More importantly, like all rights, property rights may also be limited by section 36 of the Bill of Rights which provides that –

> 'The Rights in the Bill of Rights may be limited only in terms of law of general application to the extent that the limitation is reasonable and justifiable in an open and democratic society based on human dignity, equality and freedom, taking into account all relevant factors, […].'[194]

In light of this, section 25 not only underscores the constitutional protection of IP but also emphasises that such rights must be balanced against broader socio-economic objectives, particularly the right to health under section 27. This foundation highlights the importance of leveraging TRIPS flexibilities to prevent overly restrictive patent protections from undermining equitable access to essential medicines, ensuring that South Africa's patent regime aligns with its constitutional values.

IV. THE TRIPS FLEXIBILITIES FOR ACCESS TO MEDICINES

Although the TRIPS Agreement grants a twenty-year monopoly and confers exclusive rights to a patent owner, it also offers exceptions to those rights that members can integrate into their domestic laws to prevent patents from hindering access to essential medicines. Notably, Article 30 establishes the requirements for the exceptions to be admissible. One example of the exceptions that will be examined in this section under Article 30 is the 'Bolar' exception which allows for conducting experiments to obtain regulatory approval for a product's marketing after

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[191] Chidede, T. (2022). The role of intellectual property rights' protection in advancing development in South Africa. *Law, Democracy & Development*, *26*(1), at p. 170; Du Bois, M. (2012). Intellectual property as a constitutional property right: the South African approach. *SA Mercantile Law Journal*, *24*(2), 177–193.
[192] *Government of the Republic of South Africa and Others v Grootboom and Others (CCT11/00) [2000] ZACC 19* at para 45.
[193] Du Bois, M. D. (2013). Protection of Intellectual Property Rights as Human Rights in International Law. *South African Yearbook of International Law*, *38*, at p. 115.
[194] Supra note 8 at s 36.

a patent expires.[195] The second and most significant exception is found under Article 31 which provides for the use of a patented invention without the right holder's authorisation subject to numerous conditions. This exception is often known as a compulsory licence.[196] The reason this thesis posits this exception is the most important is partly because of the fact that the exception in Article 30 can only be utilised in the case that the Article 31 exceptions do not apply.[197]

In order to fully grasp the TRIPS flexibilities that will be discussed, it is crucial to discuss the Doha Declaration. The Doha Declaration was formulated in response to the criticisms surrounding the provisions of the TRIPS Agreement and their impact on public health.[198] It was said that the TRIPS Agreement adopted a uniform approach – and the Doha Declaration aimed at addressing and rectifying this approach.[199] The consensus among Least Developed Countries (LDCs) was that the TRIPS Agreement created a barrier to accessing essential medicines.[200] Paragraph 4 of the Declaration clarifies the shortcomings of the TRIPS Agreement for developing countries in order for member states to address their domestic public health challenges:

> '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.'[201]

While acknowledging the importance of IPRs in fostering innovation in new medicines, the Doha Declaration acknowledges apprehensions regarding its impact on pricing. In doing so, it reaffirms that the objective of the TRIPS Agreement is not to hinder member states from acting in the public interest to safeguard the right to health.[202] The Doha Declaration contains

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[195] Supra note 13 at Article 30.
[196] Hestermeyer, H. (2008). *Human rights and the WTO: the case of patents and access to medicines*. Oxford University Press at p. 239.
[197] Ibid.
[198] Abbott supra note 76.
[199] ibid.
[200] South Africa was among developing nations that held the view that the TRIPS Agreement lacked clarity regarding the protection and entitlements granted to them. Sykes, A. O. (2002). TRIPS, pharmaceuticals, developing countries, and the Doha "solution." *Chicago Journal of International Law*, 3(1), 47–68.
[201] Doha Declaration supra note 73 at para 4.
[202] Nkomo, Marumo. (2010). *The WTO medicines decision in light of its utilization: resolution or resignation?* LAP, Lambert Academic Publishing.

various aspects of the TRIPS Agreement, including the authority to grant compulsory licences and the discretion to assess the grounds for issuing such licences, as well as the authority to assess a national emergency and situations of extreme urgency, along with the discretion to establish the system of exhaustion of IPRs.[203]

Before examining the flexibilities, it is crucial to highlight that in 1986, during the launch of the Uruguay Round, which eventually resulted in the TRIPS Agreement, 49 out of the 98 members of the Paris Convention excluded pharmaceutical products from patent protection.[204] This was due to the discretion each country had in deciding which technological areas to grant patents for.[205] However, this changed as countries began to comply with Article 27.1 to avoid trade sanctions. This firmly incorporated public health into the TRIPS Agreement, mandating all WTO members to amend their patent laws to allow for the granting of pharmaceutical patents for a minimum duration of twenty years.[206] The new regulations are universally applicable, except for LDCs, which have been granted until 2033 to adhere to the TRIPS Agreement.[207] This extension for compliance is facilitated by the transition periods outlined in the TRIPS Agreement.[208]

As such, the flexibilities provided by the TRIPS Agreement can generally be divided into two main types: those concerning transition period flexibilities and those related to flexibilities.[209] For the purposes of this thesis the transition flexibility ceased to apply to South Africa in 2005 and is therefore irrelevant to the discussion.

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[203] WIPO *'Patent related flexibilities in the multilateral legal framework and their legislative Implementation at the national and regional levels*', 1 March 2010, available from https://www.wipo.int/meetings/en/doc_details.jsp?doc_id=131629, accessed on 15 September 2024.
[204] Hestermeyer supra note 191 at chapter. 2.
[205] ibid.
[206] TRIPS Agreement supra note 13 at Article 33.
[207] World Trade Organization 'WTO members agree to extend drug patent exemption for poorest members' 6 November 2015, *https://www.wto.org/english/news_e/news15_e/trip_06nov15_e.htm*, accessed on 15 September 2024.
[208] Articles 66, 66.1 and 65 of the TRIPS Agreement. There are three specified time frames provided by the TRIPS Agreement to allow Member States to conform to the standards set by the Agreement. The initial period spanned from 1995 to 2000, by the end of which developing countries were mandated to adopt the 20-year patent term and grant both product and process patents across all technological fields in their national laws. The subsequent period, from 2000 to 2005, afforded Member States time to extend patent protection to technological areas not covered by their laws at that time. This was contingent upon accepting patent applications starting from 1995 and processing them by 2005, a procedure known as the 'mailbox' system. Additionally, they were required to offer 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. The final timeframe pertains to LDCs, initially granted until 2006 for compliance. However, due to their constraints, the Agreement permits them to request extensions, hence extending their deadline to 2033.
[209] Hestermeyer supra note 191.

(a) Compulsory Licensing

With regard to patented medicines, compulsory licensing is at the forefront of solutions to access.[210] The Doha Declaration affirms that the TRIPS Agreement does not impose restrictions on the grounds for granting a compulsory licence. However, it does outline specific procedural requirements, which will be examined in this section. Consequently, member states have the authority to grant a compulsory licence for a pharmaceutical drug patent, thereby permitting domestic generic manufacturers to produce affordable generic medicines. Compulsory licences are regarded as significant tools that can help curb the monopolistic power of patent owners when specific public policy goals need to be met.[211]

Article 31 establishes the criteria for compulsory licences, which must be outlined in the national compulsory licensing regulations of member states.[212] One key condition is that typically, there must have been prior negotiations for a patent licence between the pharmaceutical patent holder and the party seeking the licence, with the patent holder refusing to grant the licence within a reasonable fixed timeframe.[213] However, member states have the authority to waive this requirement under certain circumstances, such as during a national emergency or other situations of extreme urgency, or in cases of public non-commercial use.[214] In each instance, the rights holder must be promptly notified of the intention to issue a compulsory licence.[215] There is a common misconception that compulsory licences can only be issued in the case of a national emergency - this is incorrect. The Doha Declaration addressed this misconception in para 5 (b) stating that: 'Each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.'[216] In such instances the patent holder must 'be notified as soon as reasonably practicable'. An additional condition is that there must be proper compensation provided to the patent holder for the utilisation of its patented product.[217] The authority issuing the compulsory licence takes into account the 'economic value of the authorization' when determining the

[210] WIPO 'Patent related flexibilities in the multilateral legal framework and their legislative Implementation at the national and regional levels', 1 March 2010, available from *https://www.wipo.int/meetings/en/doc_details.jsp?doc_id=131629* at p. 4.
[211] Ibid.
[212] TRIPS Agreement supra note 13 at Article 31.
[213] ibid.
[214] ibid.
[215] ibid.
[216] Doha Declaration, para 5 (c).
[217] WTO 'Compulsory licensing of pharmaceuticals and TRIPS.' 18 March 2018, available from *https://www.wto.org/english/tratop_e/TRIPS_e/public_health_faq_e.htm.*

amount of compensation owed.[218] The TRIPS Agreement does not provide specific definitions for "adequate remuneration" or 'economic value of the authorization.' This implies that each member state is tasked with defining these terms according to its national laws, leading to variations in interpretation from one country to another.[219] The concern arises particularly for developing countries, which may encounter challenges in determining these indices due to their convolutedness.[220] The other conditions are clear, including the requirement that each situation is assessed individually to determine whether a compulsory licence should be granted.[221] The scope and duration of such use should be limited to the authorised purpose,[222] and the use must be non-exclusive[223] and generally non-assignable, except in cases where the assignment is part of the enterprise or goodwill enjoying such use.[224] If the circumstances necessitating the use cease to exist and are unlikely to recur, then the use must be terminated.[225] Additionally, conditions outlined in subparagraphs (b) and (f)[226] do not apply if a judicial or administrative process finds the patentee's practice to be unfairly competitive.[227]

Compulsory licences are also subject to evaluation through judicial or independent review by a higher authority within the member state.[228] Similarly, decisions concerning remuneration are also subject to review by a distinct higher authority in that member state.[229] This provision may discourage member states from issuing compulsory licences due to the potential for costly legal proceedings.[230] This dilemma poses a challenge in the context of access to medicines, as countries may hesitate to prioritise the health of their citizens over the

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[218] Supra note 13 at Article 31 (g).
[219] Supra note 13.
[220] Correa supra note 146.
[221] Supra note 13 at Article 31 (f).
[222] ibid.
[223] ibid.
[224] ibid.
[225] ibid.
[226] TRIPS Agreement Article 31 (b) such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly; 31 (f) any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use.
[227] Ibid.
[228] Article 31 (i) of the TRIPS Agreement.
[229] Article 31 (j) of the TRIPS Agreement.
[230] Olatunji, O. A. (2022). Historical account of dwindling national flexibilities from the Paris Convention to post-TRIPS era: What implications for access-to-medicines in low-and-middle-income-countries? *The Journal of World Intellectual Property*, 25(2), 391–411. https://doi.org/10.1111/jwip.12228

economic disincentive associated with utilising this flexibility, thus potentially impeding access to essential medications.[231]

In 2003, the WTO issued a General Council Decision, following up on the Doha Declaration, commonly referred to as the 'Paragraph 6 Waiver.' This 'waiver of the export restriction' allows for the export of drugs produced under a compulsory licence to countries lacking manufacturing capabilities.[232] This is particularly crucial as many developing nations have limited or no capacity to produce their own drugs. Article 31(f) of the TRIPS Agreement stipulates that products manufactured under compulsory licensing must primarily be intended for domestic supply. Without this waiver, numerous developing countries would be unable to effectively utilise the protections afforded by the TRIPS Agreement.[233]

(b) The 'Bolar' Exception/Regulatory Review

The Bolar exception aids the market entry of generic drugs by permitting third parties to use a patented invention without the patent holder's consent solely for obtaining regulatory approval.[234] This serves as a critical safeguard for generic manufacturers, enabling them to conduct necessary studies and trials to meet regulatory requirements. By doing so, the Bolar exception supports a public policy goal of promoting competition in the pharmaceutical market and helping to reduce medication prices. Once a patent monopoly expires, it no longer legally prevents competitors from producing or commercialising the previously protected product or process.[235] However, other barriers, such as regulatory requirements for market authorization, still exist.[236] The patent status of the original product can hinder competitors from beginning the necessary regulatory work until the patent expires unless an exception, like the Bolar exception, permits it. Without such exceptions, competitors cannot prepare for regulatory approval until the patent term ends, effectively extending the original patent's monopoly period. To address this issue, many countries have adopted the Bolar exception including South Africa.

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[231] ibid.
[232] Bourgeois, J. H. J., & Burns, T. J. (2002). Implementing Paragraph 6 of the Doha Declaration on Trips and Public Health: The Waiver Solution. *The Journal of World Intellectual Property*, *5*(6), 835–864. https://doi.org/10.1111/j.1747-1796.2002.tb00184.x.
[233] ibid.
[234] Ghanotakis, E. (2004). How the U.S. Interpretation of Flexibilities Inherent in Trips affects Access to Medicines for Developing Countries. *The Journal of World Intellectual Property*, *7*(4), 563–591. https://doi.org/10.1111/j.1747-1796.2004.tb00220.x.
[235] ibid.
[236] ibid.

The legality and scope of the Bolar exception was addressed at the WTO in the Canada *Patent Protection for Pharmaceutical Products* case[237] Sections 55.2(1) and 55.2(2) of Canada's Patent Act pertaining to the Bolar exception were challenged by the European Communities (EC).[238] These provisions effectively permitted third parties to use the patented product to obtain regulatory approval before the patent expired and permitted them to market the generic version directly once the patent expired.[239] The EC argued that section 55.2(1) violated the non-discrimination requirement under Article 27.1 of the TRIPS Agreement because pharmaceutical inventions were treated less favourably than inventions in other fields of technology.[240] Canada countered by asserting that the provision was a justifiable limited exception under Article 30.[241] The EC's argument was rejected.[242] The WTO panel concluded that the Bolar exception was consistent with Article 28, as it was justified by the exception in Article 30.[243]

V. CONCLUDING REMARKS

This chapter has demonstrated that South Africa's constitutional right to health, reinforced by international obligations, requires access to affordable medicines. Concurrently, we note that the constitutional right to property, including IP, must be balanced against public health needs. The current patent regime, while protecting patent holders' rights under section 25 of the Constitution, must be critically assessed to ensure that this protection does not undermine section 27's right to health.

TRIPS flexibilities offer mechanisms to balance these competing rights. However, their implementation within South Africa's patent regime must be analysed for their role in addressing the country's public health needs.

Therefore, chapter three will examine how the above TRIPS Agreement obligations have been implemented through South Africa's Patents Act. Ultimately, it assesses what the

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[237] *Canada - Patent Protection for Pharmaceutical Products.*
[238] Patents Act (R.S.C., 1985, c. P-4), s 55.2(1) provides that it is not an infringement of a patent for any person to make, construct, use or sell the patented invention solely for uses reasonably related to the development and submission of information required under any law of Canada, a province or a country other than Canada that regulates the manufacture, construction, use or sale of any product. S 55.2(2) later repealed was a stockpiling provision which permitted individuals to manufacture and store patented products intended for sale after the date of patent expiry.
[239] Ibid.
[240] Supra note 232 at §7.105.
[241] Ibid at §7.84.
[242] Ibid at §7.105.
[243] Ibid at §7.45.

impact of the current regime has on access to affordable medicines and by implication, the right to health.

CHAPTER THREE

THE PATENTS ACT 57 OF 1978 AND ACCESS TO AFFORDABLE MEDICINES

I. INTRODUCTION

The aim of this chapter is to answer the first part of the fundamental thesis question: Does the patent regime in South Africa in its current form negatively impact on the attainment of the fundamental right to health as enshrined in the Constitution?

As has been established in chapter two, the constitutional right to health encompasses the critical dimension of access to affordable medicines. Furthermore, through the Trastuzumab analysis in chapter one, indicates pharmaceutical patent protections as a potential barrier to healthcare accessibility.

Building upon this foundational understanding, this chapter examines how the current patent regime may impact the realisation of the fundamental right to health. To do so, it begins by analysing the implementation of TRIPS obligations and the TRIPS flexibilities discussed in chapter two, within the Patents Act. Following this, it considers how this implementation and the provisions of the Patents Act may impact the right to health. This will be done through a combination of pharmaceutical patent case studies and judicial decisions relating to pharmaceutical patents in South Africa. Furthermore, this chapter will assess the implementation and use of compulsory licensing and the 'bolar' exception for the realisation of the right to health in South Africa.

This analysis ultimately leads into the determination of whether the current patent regime infringes the constitutional right to health and by extension, international right to health obligations.

II. THE PATENTS ACT 57 OF 1978

(a) How has Article 27 of the TRIPS Agreement been implemented into South African law?

Under section 25 (1) of the Patents Act, inventors can obtain patent protection for any new invention that involves an inventive step, and which is capable of use in trade, industry or

agriculture.[244] The Act does not define the term 'invention' directly; instead, it specifies certain inventions that are excluded from being classified as inventions. Therefore, anything that does not fall under these listed exclusions can be considered an invention.[245]

A discovery, (which merely reveals pre-existing phenomena), scientific theories, mathematical methods, a literary, dramatic, musical or artistic work or any other aesthetic creation; a scheme, rule or method for performing a mental act, playing a game or doing business; a computer program; or the presentation of information, fall under section 25(2) which excludes them from being deemed an invention.[246] These exclusions are clarified by section 25(3), which specifies that these exclusions apply only when the invention directly pertains to that subject matter in its pure form. Section 25(4) provides other types of unpatentable inventions. These include inventions 'which would be generally expected to encourage offensive or immoral behaviour'[247], and 'for any variety of animal or plant or any essentially biological process for the production of animals or plants, not being a micro-biological process or the product of such a process.'[248]

Under section 25(11) 'An invention of a method of treatment of the human or animal body by surgery or therapy or of diagnosis practised on the human or animal body shall be deemed not to be capable of being used or applied in trade or industry or agriculture.'[249] This subsection has been interpreted to mean that, a medical technique that treats the human or animal body cannot be patented. This is to ensure that the possibility of patent infringement does not interfere with the work of physicians and veterinarians for example.[250] However, in line with Article 27 of TRIPS regarding patents for products and processes, under section 25(12) deems that while a pharmaceutical product intended for treating a disease can be patented, the method of using that product to treat the disease cannot be. This rule applies to both the initial and any subsequent medical uses of an already known substance or composition.[251]

Having established the foundational definitions and exclusions of patentable subject matter in the Patents Act, the focus now shifts to examining the core patentability criteria: novelty, inventive step and industrial applicability.

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[244] Supra note 30 at s 25 (1).
[245] Dean, O. H. (Ed.). (2014). *Dean & Dyer introduction to intellectual property law*. Oxford University Press at 5.2.2
[246] Supra note 30 at s 25 (2).
[247] Ibid at s 25 (4) (a).
[248] Ibid at s 25 (4) (b).
[249] Ibid at s 25 (11).
[250] Supra note 240 at 5.2.2.10
[251] Supra note 30 at s 25 (12).

When it comes to novelty under the Patents Act, an invention is considered novel if it is not already part of existing public knowledge or prior state of art disclosed before the priority date of that invention.[252] An invention's priority date is the day, anywhere in the world, that the first application disclosing the invention is submitted.[253] The state of art encompasses all publicly accessible information worldwide, including written and oral disclosures, publications, presentations, prior uses, and website content. Additionally, it encompasses co-pending patent applications that are not yet published but may later become publicly available, as well as inventions that remain secret but are used commercially on a significant scale, provided these uses can be reasonably discovered by the public or an examiner.[254] In *McCauley v Brickor.* 'publicly knowledge' is contextually defined, potentially referring to specialised audiences for complex technical inventions.[255] Consequently, any global disclosure that could be known to the public without breaching confidentiality can destroy an invention's novelty.[256] In determining whether an invention is disclosed, South African patent law makes the assessment a fact-specific evaluation that extends beyond domestic boundaries.[257]

Gentiruco A.G. v Firestone South Africa established a legal test for novelty in patent law. The test requires an invention to be genuinely new and not anticipated by prior art, which includes any publicly available information before the patent application's filing date. In this specific case, the court found the invention lacking novelty because it had been previously disclosed in a publication, thereby rendering it ineligible for patent protection.[258] Therefore, while the precise test for novelty may vary across jurisdictions, one thing in South Africa remains constant: for an invention to lack novelty, it must be *fully* disclosed in a single prior art source – a combination of multiple prior art sources cannot challenge novelty.[259]

The inventiveness requirement is set out in section 25(10). It states that 'an invention shall be deemed to involve an inventive step if it is not obvious to a person skilled in the art, having regard to any matter which forms, immediately before the priority date of the invention, part of the state of the art'.[260] It is important to note that assessing whether a claim lacks inventiveness typically occurs only after that the claim is novel. Note that we use *claim* instead of *invention* because as we noted in the problem statement, South Africa does not perform SSE

[252] Supra note 30 at s 25 (5).
[253] Supra note 240.
[254] Ibid.
[255] *McCauley Corporation Ltd v Brickor Precast (Pty) Ltd 1989 BP 314.*
[256] Supra note 240.
[257] Ibid.
[258] *Gentiruco AG v Firestone (SA) (Pty) Limited (66/70) [1972] ZASCA 1 (16 February 1972).*
[259] Supra note 240.
[260] Supra note 30 at s 25 (10).

for patent applications. In other countries, for example in US as indicated earlier, by means of the provision under 35 U.S. Code § 103, when one files for a patent application, the United States Patents and Trademark Office (USPTO) conducts an examination phase, where patent examiners compare the claimed invention with prior art and assess whether the differences are significant enough to involve an inventive step.[261] Such an assessment is not conducted before the grant of an application. Instead, the *assessment* for inventiveness in South Africa only occurs after the patent is granted by means of an application for revocation of a patent.[262]

The test for inventiveness for the purposes of revocation was established in *Ensign Bickford (South Africa) (Pty) Ltd. and Others v AECI Explosives and Chemicals Ltd.*[263] In *Ensign,* the court established a four-step test for assessing the inventive step: first, what is the inventive step said to be involved in the patent in suit? Second, what was, at the priority date, the state of the art (as statutorily defined) relevant to that step? Third, in what respect does the step go beyond, or differ from, that state of the art? And fourth, having regard to such development or difference, would the taking of the step be obvious to the skilled man?[264]

This test was applied in *Pharma Dynamics (Pty) (Ltd) v Bayer Pharma AG* where one of Pharma's claims was for revocation of pharmaceutical invention under Patent No. ZA2004/4083. Regarding the first step from Ensign the court focused on whether it was inventive. In this regard, the court identified an inventive step as claimed by *Bayer* in that drospirenone (DSP)—despite being poorly soluble and acid-labile—could achieve good bioavailability in an uncoated form, thus satisfying the first step.[265] Secondly, both parties' experts agreed that the known art recognized DSP as acid-labile and poorly soluble, typically requiring enteric coatings or other methods for protection and dissolution by means of the 1985 Pilbrant article. So why did inventiveness not fail on the second step? The court found that Bayer's discovery went against this established understanding. The state of the art *taught away* from using uncoated DSP because previous studies, like those in the Pilbrant article, showed that similar acid-labile compounds would degrade without enteric protection.[266] Therefore, while the state of the art was well-defined, it created a clear expectation that an uncoated form of DSP would not work. This made the discovery—that rapid dissolution of uncoated DSP still

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[261] Supra note 172.
[262] Supra note 30 at s 34 read together with Patent Regulations, 1978 at 40 and 41.
[263] *Ensign Bickford (South Africa) (Pty) Ltd. and Others v AECI Explosives and Chemicals Ltd. (4/95) [1998] ZASCA 73.*
[264] Ibid at para 24.
[265] *Pharma Dynamics (Proprietary) Limited v Bayer Pharma AG and Another (468/2013) [2014] ZASCA 123 201* at para 35.
[266] Ibid at para 36.

achieved good bioavailability—counterintuitive and, thus, inventive.[267] Regarding the third step, the key difference was that, contrary to expectations, uncoated DSP with rapid dissolution achieved effective bioavailability. The tests revealed no significant degradation, unlike prior art findings where enteric coatings were essential.[268] Finally, the court considered whether the inventive step would have been obvious to a skilled person. *Pharma* argued that in vivo tests with uncoated DSP would have been routine, but the court rejected this, noting the dangers of hindsight bias. According to Prof. Davies' testimony, conducting expensive and time-consuming in vivo tests without any expectation of success would not be logical.[269] Moreover, the court highlighted that merely being "obvious to try" is insufficient unless there is a reasonable expectation of success.[270] Based on this analysis, the court concluded that Bayer's patent involved an inventive step and was not obvious, thereby upholding its validity and dismissing Pharma's claim for revocation.[271]

Notwithstanding the above case, the key takeaway on inventiveness in South Africa is that, although a test for inventiveness exists in South Africa, it is only applied for an already granted patent.

The last criterion, in order for an invention to be patentable, it must also be capable of use or applied in trade, industry or agriculture.[272] An innovation's suitability for use or application in trade, industry or agriculture can be described as a factual matter that is typically evident from the invention itself.[273] In *Villa Crop Protection (Pty) Ltd v Bayer Intellectual Property GmbH* heard before the CCSA, the court dealt with a claim by *Villa Crop* that a patent held by Bayer must be revoked based on applicability.[274] The court found that Bayer's patent met this requirement. Specifically, it determined that the chemical compound, spirotetramat, had demonstrable utility in plant protection products, thus satisfying the criterion of industrial applicability. The evidence showed that the compound could effectively protect crops, making it relevant to trade and agriculture.[275] As a result, Villa Crop's argument was dismissed because Bayer demonstrated the practical use of the patented compound in agricultural products which

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[267] Ibid at para 35.
[268] Ibid at para 35 – 37.
[269] Ibid at para 38 – 40.
[270] Ibid at para 39.
[271] Ibid at para 41.
[272] Supra note 30 at s 25 (1).
[273] Supra note 240 at 5.2.5, Trade can be defined as any social activity in which goods or services of any type are traded for cash or other valuable items. While agriculture encompasses the science of farming, whether with crops or animals, and in its broadest meaning includes horticulture, gardening, and forestry, industry can be thought of as a specific subset of productive labour.
[274] *Villa Crop Protection (Pty) Ltd v Bayer Intellectual Property GmbH (CCT 237/21) [2022] ZACC 42*.
[275] Ibid at para 25.

were already in the market.[276] In this case, the court concluded that the patented invention was not merely theoretical but had real-world applications, reinforcing its capability to be used in industry or agriculture.

Having explored the foundational implementation of Article 27, the subsequent section will examine South Africa's approach to the Bolar exception and compulsory licensing under Articles 30 and 31 provisions respectively of the TRIPS Agreement, which provide critical mechanisms for balancing patent rights with public interest concerns.

(b) How have Articles 30 and 31 of the TRIPS Agreement been implemented into South African law?

(i) The 'Bolar' Exception/Regulatory Review

As a reminder, Article 30 of TRIPS lays out the fundamental requirements for the admissibility of the 'Bolar' exception, however, it does not aim to limit members' ability to choose the basis for the use of such an exception.

As briefly mentioned in the problem statement; to launch a generic or biosimilar medicine in South Africa, manufactures must secure registration from SAHPRA. This involves submitting efficacy, safety, and stability test results, along with a product sample for evaluation.[277] Under normal circumstances the experiments, tests etc., would constitute patent infringement because it involves using the patented product in a way that defeats the point of the patent grantee's exclusive rights in under section 45(1).[278] This was proven to be true in the U.S. case *Stauffer Chemicals v Monsanto*.[279] The court affirmed a section 45(1) line of thinking as granting the patent owner full rights to the invention's profits, while clarifying that merely possessing an infringing item without intent to use or sell does not constitute infringement.[280] The Court noted in obiter that even experimental use of a patented invention can be considered an infringement. In Stauffer, the court found that using a patented invention to prepare for marketing a similar product during the patent's term constituted an improper commercial

[276] Ibid at para 32.
[277] SAHPRA 'Licence Application Process' available at *https://www.sahpra.org.za/licence-application-process/,* accessed on 3 December 2024.
[278] Supra note 30 at s 45 (1).
[279] *Stauffer Chemical Co. v. Monsanto Co., 623 F. Supp. 148 (E.D. Mo. 1985).*
[280] Ibid.

advantage and thus was deemed an infringement.[281] In response to the outcome of this case and to facilitate generic medicine entry after patent expiration, the 'bolar' exception was implemented into the Patents Act by the Patents Amendment Act No. 58 of 2002.[282] The exception found under section 69A which reads:

> (1) 'It shall not be an act of infringement of a patent to make, use, exercise, offer to dispose of, dispose of or import the patented invention on a non-commercial scale and solely for the purposes reasonably related to the obtaining, development and submission of information required under any law that regulates the manufacture, production, distribution, use or sale of any product.
> (2) It shall not be permitted to possess the patented invention made, used, imported or acquired in terms of subsection (1) for any purpose other than for the obtaining, development or submission of information as contemplated in that subsection.'[283]

(ii) Compulsory Licensing

Similar to the conditions outlined in Article 31 of the TRIPS Agreement, South Africa has incorporated provisions for compulsory licences within sections 55 and 56 of the Patents Act.[284] Two types of compulsory licences are recognised: s 55 for dependent patents and s 56 where there has been an abuse of rights.

Dependent patents are patents which as a matter of law cannot be worked without falling within the scope of protection of another patent.[285] Under section 55, this subsequent invention necessitates authorisation from the patent holder to operate. If such authorisation is not provided willingly, the patent commissioner holds the authority to grant a licence to the subsequent inventor without requiring approval from the patent holder.[286] This type of compulsory licence is granted when there exists a crucial technical advancement that holds significant economic value relative to the original patent for which the licence is sought. Additionally, the original patent holder must offer a reciprocal licence to the owner of the

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[281] Ibid.
[282] Inserted by s 16 of the Patents Amendment Act No. 58 of 2002.
[283] Supra note 30 at s 69A.
[284] Sections 55 and 56 were amended by the addition of the proviso thereto in terms of s 44 of the Intellectual Property Laws Amendment Act 38 of 1977.
[285] Kunisawa, V. Y. M. (2015). *The TRIPS agreement implementation in Brazil: patents in the pharmaceutical area* (First edition.). Nomos Verlagsgesellschaft mbH & Co. KG.
[286] Dean supra note 240.

dependent patent under fair terms, and the granted licence cannot be transferred by the licensee of the dependent invention.[287]

Section 56 allows for an application to be made to the commissioner for patents requesting compulsory licences if it is demonstrated by another party that the patent holder has misused its patent. In instances where there are claims of patent rights being misused, any concerned individual can seek a compulsory licence from the court based on the following s 56 (2).[288] Each of the following provisions will be examined in chapter three:

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 licence 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 licence 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.'

If an applicant demonstrates an abuse of patent rights under section 56, the Commissioner of Patents has the authority to issue a compulsory licence if convinced that the patent rights are being misused and the patent holder has declined to grant a licence under reasonable terms. Upon approval, the Commissioner imposes several conditions, such as prohibiting the importation of patented goods into South Africa by the applicant, and specifying that the licence will end if, in the Commissioner's judgement, the circumstances of abuse have ended.[289]

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[287] South Africa Patents Act supra note 30 at s 55.
[288] Ibid at s 56.
[289] Supra note 30 at s 56 (1).

Having examined the technical implementation of TRIPS provisions in the Patents Act, the next section will now critically assess how these patent provisions potentially interact with and influence the constitutional right to health.

III. THE IMPACT OF THE PATENTS ACT ON THE RIGHT TO HEALTH

The term 'health safeguards' has been coined and refers to legal mechanisms within patent frameworks, primarily designed to balance patent rights with public health needs.[290] The importance of implementing public health safeguards within domestic patent systems has been repeatedly asserted in international fora.[291] For the purposes of determining whether the current patent regime impacts access to affordable medicines, we focus on SSE, opposition procedures and the above mentioned TRIPS flexibilities in their current form.

Scholars have noted that for the patentability criteria to be effective, they cannot work in isolation.[292] The 2018 IP policy affirms this by noting that the implementation of SSE in South Africa's patent regime 'will benefit patent holders by granting them rigorously assessed rights, and benefit the public at large by ensuring market exclusivity is only granted when appropriate.'[293] As a reminder, in granting a patent, South Africa only *examines* for a patent's compliance with formalities, rather than its patentability in terms of the conditions outlined under the Patents Act. In essence, the Companies and Intellectual Property Commission (CIPC) currently operates under the presumption that an invention is deserving of a patent once an application has been filed.[294] Examination regarding a patent's patentability by way of inventiveness is conducted after the fact, when an application for revocation is brought to the courts.[295]

The frailty of South Africa's current patent system, particularly its lack of substantive examination for patentability, which may have far-reaching consequences for the availability of generic medicines and by implication access to affordable healthcare. Specifically, it has created an environment conducive to evergreening by means of strategic patenting and secondary patenting. The two must not be conflated, they are related but are distinct practices,

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[290] Moyo, H., Tomlinson, C., Hu, Y. Q., Waterhouse, C., & Meyer, S. (2019). How patent law reform can improve affordability and accessibility of medicines in South Africa: four medicine case studies. *SAMJ: South African Medical Journal*, *109*(6), at p. 387.
[291] Ibid.
[292] Correa supra note 146.
[293] Supra note 79 at p. 5
[294] Supra note 59 at p. 3
[295] *Ensign* supra note 263.

both contributing to evergreening by delaying generic market entry and keeping drug prices high. Strategic patenting involves using patent strategies to maximize market control beyond protecting novel inventions, often creating complex patent landscapes that deter competition.[296] Secondary patenting focuses on obtaining patents for minor modifications to existing products, primarily to extend patent life.[297] The following essential medicines are in the current WHO essential medicines list and illustrate both concepts in action within South Africa.

(a) Patented Medicines in South Africa

(i) Bedaquiline

Bedaquiline is a medicine used to treat drug-resistant tuberculosis (DR-TB). The patent for Bedaquiline compounds in South Africa is set to expire in January 2025.[298] In anticipation of this expiry, Johnson & Johnson (Pty) Ltd (J&J) and its subsidiary Janssen Pharmaceutica (Pty) Ltd (JP) subsequently filed a secondary patent application for Bedaquiline.[299] At the time, South Africa procured Bedaquiline from J&J for approximately R5,400 per six-month treatment course. In comparison, J&J had granted a licence to Stop TB Partnership's Global Drug Facility (GDF) to procure, tender, and supply generic versions of Bedaquiline to low- and middle-income countries (LMICs) where the drug is under patent, resulting in the drug costing R2,300 per six-month treatment course.[300] Although South Africa is an LMIC, it does not buy the drug through the GDF due National Procurement policies. It is important to note that, due to the opening of an investigation into the application of the secondary patent by the Competition Commission of South Africa (CCZA) in September 2023, J&J almost immediately announced that it would no longer enforce secondary patents for Bedaquiline in

[296] WIPO Committee on Development and Intellectual Property (CDIP) 'Study On Pharmaceutical Patents In Chile' available at *https://www.wipo.int/edocs/mdocs/mdocs/en/cdip_15/cdip_15_inf_2.docx*, accessed on 3 December 2024.
[297] Ibid.
[298] South Africa Patent No. 2005/0680.
[299] Chris Dall, MA 'J&J agrees to lower price of TB drug Bedaquiline, allow production in South Africa' *CIDRAP* 9 July 2024, available at *https://www.cidrap.umn.edu/tuberculosis/jj-agrees-lower-price-tb-drug-bedaquiline-allow-production-south-africa*, accessed on 6 September 2024.
[300] Patent licensing offers patent holders a way to generate revenue by transferring patent rights to another company or individual that will use the licensor's patented technology or products.

LMICs including South Africa.[301] Thus, generic forms of the drug can now be produced locally. Furthermore, the application for the secondary patent was withdrawn by J&J in July 2024.[302] However, the lack of SSE would likely have ensured a subsequent grant. This position will be substantiated by the next medicine case study as well as in chapter four when I examine the Bedaquiline patent under India's Patents Act.

(ii) Lenalidomide

Lenalidomide is an approved treatment for multiple myeloma and certain myelodysplastic syndromes.[303] In India, where generic versions are available, a year's supply costs around R32,000.[304] Celgene's product under patent in South Africa is priced at almost R730,000 annually.[305] Lenalidomide is unavailable in South Africa's public healthcare sector. Patients requiring Lenalidomide must either pay exorbitant prices for the patented product through private insurers or forgo treatment. While the base product patents were filed internationally in 1997 and 1998,[306] they were not submitted in South Africa. However, Celgene subsequently secured secondary patents related to lenalidomide in the country.

This thesis contends that if SSE was operational in the current patent regime, secondary patents for Lenalidomide would not have been granted in South Africa. Although this is an assumption, it is substantiated by an additional flaw identified in the patent regime, the high grant rate of patents. South Africa approves patent applications at a significantly higher rate than the majority of countries, irrespective of their development and economic status. While an analysis of the WIPO IP Statistics Data Centre demonstrates the anomalies regarding South Africa's high patent grant rate, Correa also observed the same issue.[307] For example, the secondary patent application for Lenalidomide which was granted under patent no.

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[301] Medecins Sans Frontieres 'MSF and HJI Welcome J&J's Withdrawal of Patents on Lifesaving TB Drug in South Africa' available at *https://www.msf.org.za/news-and-resources/latest-news/msf-and-hji-welcome-jj-s-withdrawal-patents-lifesaving-tb-drug-south*, accessed on 6 September 2024.
[302] The Competition Commission of South Africa 'Media Statement: Commission halts TB drug investigation as intervention leads to 40% price decrease' available at *https://www.compcom.co.za/wp-content/uploads/2024/07/TUBERCULOSIS-PATENT-COMPLAINT-AGAINST-JOHNSON-JOHNSON.pdf*, accessed on 6 September 2024.
[303] Scott, L. J., & Lyseng-Williamson, K. A. (2011). Lenalidomide. *Drugs (New York, N.Y.)*, *71*(5), 625-. https://doi.org/10.2165/11206420-000000000-00000.
[304] Cancer Alliance 'Lenalidomide Valuable Patient Information From a Local Haematologist', available at *https://canceralliance.org.za/access-to-medicine/lenalidomide-access/,* accessed on 11 March 2025.
[305] ibid.
[306] PCT/US1997/013375, PCT/ US1998/010886.
[307] Correa C, (2011) 'Pharmaceutical Innovation, Incremental Patenting and Compulsory Licensing.' https://www.southcentre.int/wp-content/uploads/2013/05/RP41_Pharmaceutical-Innovation_EN.pdf at p. 7.

ZA2004/10314 in South Africa, was rejected in India under application no. 1602/MUMNP/2005 due to their strict inventiveness criteria under section 3(d) of the Indian Patents Act which will be expanded on in chapter four.

(iii) Rivaroxaban

The reason for choosing Rivaroxaban is twofold: it illustrates secondary patenting that blocks generic market entry and also demonstrates how a second public health safeguard falls short in South Africa's patent regime – pre and post grant opposition procedures.

Rivaroxaban is a medication used to treat and prevent blood clots. South Africa granted a patent to the drug's manufacturer, Bayer, in 2000.[308] The drug had an initial dosage of once a day, however, in 2007 Bayer changed this to twice a day. Bayer stated that this dosage adjustment constituted an 'inventive step' and used this to apply for a new patent. South Africa granted a new patent.[309] Thus, a patent that was meant to expire in 2020, now expires in 2026.

After the initial 2020 expiry, Dr Reddy's Laboratories (Pty) launched generic versions of Rivaroxaban sold under the name Rivaxored.[310] In response Bayer initiated a claim against Dr Reddy and Clicks who sold the generic to stop them from selling and distributing Rivaxored. They were successful in getting an interim injunction.[311] In granting the interdict, the court determined that the sale of the generic drug amounted to *prima facie* infringement of Bayer's patent. Clicks argued that the new patent was invalid as it did not meet the requirements of an 'inventive step' as 'there [was] nothing exceptional about the new dosage claim.'[312] The court held that the invention was valid under the Patents Act.[313] Additionally, the court dismissed the claim that the patentee's interest was superseded by the public interest to have access to a less expensive generic. Per Collis J., 'the protection of a patent will also serve the public interest'[314] and 'the marginal harm to a small percentage of patients […] was not considered sufficient to outweigh the negative public interest effect of failing to enforce valid patents.'[315]

This judgement in favour of Bayer emphasises the protection of patents as being aligned with public interest. However, the dismissal of public interest concerns regarding access to

[308] South Africa Patent No. 2007/006238.
[309] South Africa Patent No. 2007/06238-5.
[310] *Bayer Intellectual Property GMBH and Others v New Clicks South Africa (Pty) Ltd and Others* (CCP) unreported case unreported case no 2007/06238-5 of 15 December 2021.
[311] Ibid.
[312] Ibid.
[313] Ibid.
[314] *Bayer* supra note 310, unreported case no 2022/8099 of 7 July 2023 at para 67
[315] Ibid at para 70

affordable generics undermines the balance that intends to strike between incentivising innovation and ensuring public health. While the court was correct in adhering to the letter of the Patents Act, its reliance on the marginal harm argument disregards the broader systemic implications of evergreening practices, which disproportionately affect access to affordable essential medicines as can be seen with the above medicine case studies.

Another significant flaw in South Africa's current patent law that affects the efficacy of the patentability criteria is the absence of pre and post grant patent opposition mechanisms. These procedures are frequently employed by patent offices[316] to enable third parties to contest the validity of patent applications either before or after they are granted.[317] At present, the sole method to challenge a patent is through litigation for post-grant revocation, which typically involves a prolonged and costly process.[318] As can be seen with the above case, in instances of litigation, courts tend to adopt a conservative approach, setting a low threshold for novelty and inventiveness and often leaning towards preserving the patent holder's rights over public interests.[319]

(b) The TRIPS Flexibilities

(i) The 'bolar' exception

Although this exception allows for obtaining registration for a generic or biosimilar invention, the pitfalls of section 69A are that it imposes certain limitations on generic manufacturers. Firstly, it does not permit the use of the patented invention for purposes other than obtaining regulatory approval. Second, generic manufacturers are prohibited from mass-producing, also

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[316] See s25 of India's Patents Act 39 of 1970; European Patents Office. Guidelines for Examination, section 5. Grounds for Opposition.

[317] Pre-grant opposition allows third parties, such as public health advocates, generic manufacturers, or even government agencies, to challenge patent applications before they are granted. This is particularly important in preventing unjustified patents or cases of evergreening, where minor modifications to existing drugs are used to extend market exclusivity and delay the introduction of more affordable generics. Post-grant opposition, on the other hand, enables challenges to a patent after it has been granted, offering an additional safeguard to invalidate patents that may not meet the legal standards for novelty, inventiveness, or utility. These procedures are critical for maintaining a balance between encouraging pharmaceutical innovation and ensuring that patents do not create unnecessary barriers to affordable medicines. By allowing for the review and potential revocation of patents that restrict access to essential drugs, these opposition mechanisms help protect public health and promote the broader goal of access to medicines.

[318] South Africa Patents Act supra note 30 at s 47.

[319] *Cipla Medpro (Pty) Ltd v Aventis Pharma SA, Aventis Pharma SA and Others v Cipla Life Sciences (Pty) Ltd and Others* (139/2012) [2012] ZASCA 108; *Bayer Pharma AG v Pharma Dynamics (Pty) Ltd* (1066/2013) [2014] ZASCA 201.

known as ‘stockpiling’, the patented product prior to the expiration date of the relevant patent, even with the intention of selling the generic versions immediately after the patent expires. Thirdly, it does not extend to research exceptions which would enable broader experimentation and research activities related to the pharmaceutical patent during its patent duration. To date, it has not been used in South Africa. As such, South Africa’s failure to utilise this exception can be attributed to the issue of evergreening as previously discussed which undermine this exception, as well as a lack of legal clarity on the matter domestically. The discussion of this exception is brief because the following flexibility is more relevant to this thesis due to its nature and the South African position.

(ii) Compulsory Licensing

Atomic Energy Corporation of SA Ltd v The DuPont Merck Pharmaceutical Co is currently the only case brought forward in South Africa on the topic of compulsory licensing in respect to dependent patents.[320] In *Atomic*, the application for a dependent patent encountered a counterclaim, among others, asserting that the purported dependent patent was invalid and should be revoked. Du Plessis J acknowledged that the court would not recognise a patent as a dependent one if it was at risk of being revoked. However, the applicant's claims were considered as *prima facie* evidence that the invention was both novel and involved an inventive step. The court also noted that similar to a compulsory licence application under section 56, an applicant for a licence under section 55 had the burden to demonstrate that the offered royalty was reasonable.[321] The court found that the applicant's claims served as *prima facie* evidence of a reasonable royalty in the circumstances. Although the applicant met the requirements under section 55, the court determined that due to various factual disputes between the parties, the matter should not proceed to trial. Additionally, the court declined another counterclaim for a temporary injunction due to the balanced prospects and convenience of the parties.

With regard to section 56, the precise interpretation of section 56(2)(a) above has been the focus of examination in various legal rulings. In the case of *Sanachem (Pty) Ltd v British Technology Group PLC*,[322] the court dismissed the applicant’s argument that the patentee had not sufficiently utilised the invention. It determined that “worked” implied “exploitation,” encompassing utilisation through importation,[323] as was evident in this case. Moreover, it

[320] *Atomic Energy Corporation of South Africa v The Du Pont Merck* 1997 BIP 90 (CP).
[321] ibid, para 62.
[322] *Sanachem (Pty) Ltd v British Technology Group PLC* 1992 BP 276 (CP).
[323] ibid, para 285.

defined "adequate extent" as "sufficient or proportionate to the needs of the Republic."[324] This latter understanding was upheld in the ruling of *Delta G Scientific (Pty) Ltd v Janssen Pharmaceutics NV and Another*.[325] The court also clarified that the full saturation of the South African market did not preclude the possibility of further or adequate utilisation of the invention. Instead, each situation must be assessed to ascertain whether the invention could reasonably be expected to be utilised adequately under the prevailing circumstances. However, the applicant failed to demonstrate that the invention could be utilised more extensively in South Africa within the remaining duration of the patent.[326]

The ground in section 56(2)(d) above was considered in the case of *Afitra (Pty) Ltd and Another v Carlton Paper of SA (Pty) Ltd*,[327] where the applicant contended that it could offer the patented product at a lower price compared to the patentee. Consistent with the precedent set by *Sanachem*, Eloff JP ruled that demonstrating unreasonable terms requires more than just evidence of the applicant's ability to sell a similar product at a reduced price. Other pertinent factors must be taken into consideration to determine the reasonableness of the patentee's pricing. These factors include the expenses involved in producing and promoting the patented item, the terms and conditions of its agreements with customers, and whether the evidence indicates that the industry as a whole can sustain the pricing structure.[328]

The provisions for compulsory licensing have been active in South Africa for more than a century, however, no compulsory license has been granted.[329] This raises the question; why?

Firstly, the hesitancy has been linked to the challenges of meeting the conditions for compulsory licensing. At times, requests for compulsory licences were denied due to the applicant's inability to meet the required burden of proof, as seen in *Syntheta (Pty) Ltd v Janssen Pharmaceutica NV & Another*,[330] where the court determined that there was 'no genuine effort made to establish the crucial jurisdictional facts.' In *Syntheta* the applicant had a burden of proof that the patented invention was not 'worked' in South Africa and to a

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[324] ibid, para 286.
[325] *Delta G Scientific (Pty) Ltd v Janssen Pharmaceutica NV and Another* 1996 BP 455 (CP), para 459.
[326] ibid, para 460.
[327] *Afitra (Pty) Ltd and Another v Carlton Paper of SA (Pty) Ltd* 1992 BP 331 (CP).
[328] ibid, para 347.
[329] Behrang Kianzad 'Compulsory Licensing as a Remedy Against Excessive Pricing of Life-Saving Medicines' *The South Centre* 28 May 2024 at p. 36, available at *https://www.southcentre.int/wp-content/uploads/2024/05/RP197_Compulsory-Licensing-as-a-Remedy-Against-Excessive-Pricing-of-Life-Saving-Medicines_EN.pdf*, accessed on 28 September 2024.
[330] *Syntheta (Pty) Ltd previously Delta G Scientific (Pty) Ltd v Janssen Pharmaceutica NV and Another* 1999 (1) SA 85 (SCA).

commercial scale or scope.[331] However, the applicant failed to satisfy the required burden of proof.

Second, the criteria for granting a compulsory license under section 56 is narrow in scope. The Patents Act in contrast to the TRIPS Agreement lacks a provision that permits the grant of a compulsory licence as remedy for anti-competitive conduct. While the Act allows for compulsory licensing in cases of excessive pricing, which can be considered a form of uncompetitive behaviour, it does not encompass other forms of anti-competitive practices. The Indian Patents Act is analysed in chapter six to demonstrate the use of such a provision. Additionally, the Act does not strictly incorporate the 'adequate remuneration' from Article 31. Rather section 56(13)(b)(ii) stipulates that the Commissioner can, when awarding costs, consider 'whether the applicant for a license ... might have been avoided by the grant, by the patentee concerned to the applicant, of a voluntary license on reasonable terms.'[332] However, adequate remuneration encompasses reasonable terms. This provision means that the applicant must have sought a voluntary licence on reasonable terms, which was denied by the patent holder; otherwise, it is difficult to comprehend how the patent holder can grant a licence on reasonable terms that have not been met.

The Bill of Rights binds the legislature. Recalling para 4 of the Doha Declaration '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.' The judiciary affirmed the constitutional right to health includes access to affordable medicines.[333] In implementing flexibilities that provide a wide berth for member states, the South African legislature has failed. Compulsory licensing is part and parcel of 'protecting' and 'promoting' the right to health.

IV. CONCLUDING REMARKS

The goal of this chapter was to answer the first part of the fundamental thesis question: Does the patent regime in South Africa in its current form negatively impact on the attainment of the fundamental right to health as enshrined in the Constitution? In answering this, I will refer to the nature of the right to health and what is the nature of the duty imposed by that right i.e., to respect (prevent interference with access to healthcare), to protect (safeguard individuals from

[331] ibid, para 6.
[332] Supra note 30 at 56 (13) (b) (ii).
[333] *Clicks* supra note 125.

violations by third parties), and to fulfill (actively promote and provide access to healthcare services).

The above analysis highlights critical weakness in the current patent regime, in relation to the 'health safeguards'. While the implementation of the patentability criteria from the TRIPS Agreement in the Patents Act is strictly adhered to, their functionality is impaired by a lack of SSE which facilitates evergreening through strategic and secondary patenting. Consequently, delaying generic drug entry and inflating prices of essential medicines, directly impeding access to affordable healthcare.

Medicine case studies such as those involving Bedaquiline, Lenalidomide and Rivaroxaban exemplify how pharmaceutical companies have taken advantage of a flawed patent regime to extend monopolies on essential medicines, raising prices and limiting availability. The above also underscores the absence of effective pre and post grant opposition mechanisms and the judiciary's conservative stance favouring patent holders, further exacerbating the issue.

These flaws conflict with the state's duty under the Constitution to respect, protect and fulfill the right to health. By failing to implement TRIPS flexibilities as such as robust compulsory licensing and a flexible 'bolar' exception, South Africa's patent regime falls short of balancing patent rights with public health needs. Therefore, the current patent regime does indeed negatively impact the attainment of the constitutional right to health, as it prioritises patent holder interests over equitable access to affordable essential medicines, undermining the state's obligation to ensure affordable healthcare for all.

CHAPTER FOUR

WHAT CAN BE DONE TO ENABLE THE REALISATION OF THE RIGHT TO HEALTH THROUGH PATENT LAW?

I. INTRODUCTION

In light of chapter three's findings, the goal of this chapter is to answer the second part of the fundamental thesis question: how can the patent system be recalibrated to balance the right to health and the rights of patent holders?

In response to the question, this chapter offers three solutions, short-term and long-term. Firstly, in the long-term, SSE should be implemented to curb evergreening. This solution is influenced by the operation of section 3(d) of India's Patent Act, 1970 regarding its 'inventiveness' criterion. For the second solution, this thesis puts forward the use of TRIPS flexibilities namely compulsory licensing and the 'bolar' exception as a crucial short-term solution due to their nature; as primarily reactive and temporary interventions.[334] The flexibilities address immediate healthcare crises but do not fundamentally restructure the underlying patent system that creates barriers to medicine accessibility. This solution is discussed through the implementation and interpretation of compulsory licensing under section 84 of India's Patent Act.

Amidst this discussion of the first two solutions, a further aim is to assess where South Africa stands in implementing the 2018 draft IP policy recommendations as it forms a long-term solution and that it has been six years since its publication.

Finally, against the backdrop of determining whether the constitutional right to health obligates private entities and by extension pharmaceutical companies to aide in its realisation, we consider the applicability of Kolawole and Ncube's recommendation as discussed in chapter one of a communitarian ethic in South Africa.[335]

II. INDIA'S PATENT REGIME AND ACCESS TO MEDICINES

[334] Khor supra note 74.
[335] Supra note 15.

(a) Inventiveness

With regard to 'inventiveness' under the patentability criteria, paramount to restricting the possibility of evergreening through secondary patenting in India lies in section 3(d) which 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.'[336]

Section 3(d) has been interpreted by the judiciary and patent offices with regard to medicines. In *Novartis A.G. v. Union of India*[337] Novartis' patent application for a beta crystalline was rejected by the Madras patent office,[338] the High Court,[339] the Intellectual Property Appellate Board (IPAB),[340] and by the Supreme Court citing that section 3(d) was intentionally designed to prevent evergreening while not completely barring incremental innovations, particularly in life-saving medications.[341] In its decision, the Supreme Court first ruled that 'efficacy' specifically meant 'therapeutic efficacy' in pharmaceutical contexts, and that improved physicochemical properties alone were insufficient for patentability[342] and determined that Novartis had not provided adequate evidence of enhanced therapeutic efficacy, despite showing 30% improved bioavailability.

Conversely when the efficacy of a patented compound for treatment of Chronic Myeloid Leukaemia (CML) in *Bristol-Myers Squibb Company & Ors vs Mr. J.D. Joshi & Anr* was challenged by the defendant, the court ruled in favour of the plaintiff. The reasoning was that firstly, the defendants' mere assertion of the patent being a derivative was insufficient. Secondly, the compound's apparent success in treating cancer raises questions about its efficacy. Third, the fact that defendants themselves were willing to launch the product suggested potential therapeutic value.[343] However, in rejecting the defendants claim for the

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[336] The Indian Patents Act 37 of 1970 at s 3 (d).
[337] *Novartis AG v. Union of India*, 2007 A.I.R. 24759 (2013).
[338] Gabble, R., Kohler, J.C. "To patent or not to patent? the case of Novartis' cancer drug Gleevec in India". *Global Health* 10, 3 (2014). https://doi.org/10.1186/1744-8603-10-3
[339] Ibid.
[340] Ibid.
[341] Ibid.
[342] *Novartis v. Union of India & Others* [2013] 13 S.C.R. 148.
[343] *Bristol-Myers Squibb Company & Ors vs Mr. J.D. Joshi & Anr. on 29 June, 2015,* para 57.

aforementioned reasons the court believed that a full trial is necessary to definitively determine the compound's efficacy.[344]

The test for 'inventiveness' in South Africa and India is sufficiently robust. However, where India may influence South Africa is through adoption of a 'therapeutic efficacy' requirement for patent applications on pharmaceutical drugs based on a prior invention. South Africa's reactive mechanism which only applies the test after the patent is granted for revocation does not explicitly prevent evergreening—particularly the patenting of minor modifications such as for Rivaroxaban which offer no real therapeutic benefit. By implementing an SSE system, this would ensure such incremental innovations are scrutinised for real therapeutic value, preventing extended monopolies for essential medicines. An added benefit lies in reduced litigation costs. Relying solely on post grant revocations there is a burden of challenging weak patents falls on generic manufacturers or public interest groups, often leading to lengthy and expensive court battles. A pre-grant inventiveness assessment similar to India's would reduce the incidence of such disputes by preventing weak patents from being granted in the first place.

(b) Compulsory Licensing

Section 84(1) establishes a framework for compulsory licensing, focusing on ensuring public access to patented inventions. The Act mandates that patents must be worked within India and allows for compulsory licensing after three years of patent grant under specific conditions.[345] Key grounds for compulsory licensing include situations where public requirements are not met, the patented invention is unavailable at an affordable price, or the invention is not worked within Indian territory.[346] The Act considers public requirements unsatisfied under various scenarios, such as when a patentee refuses to grant reasonable voluntary licenses, impedes trade or industry, fails to meet market demand, or prevents commercial development.[347] There are similarities with the provisions contained in South Africa's Patents Act, in particular, both acts require demonstrating that the patented invention is not reasonably available to the public on fair terms or is inadequately exploited to meet public demand. However, India's framework is more detailed and explicitly aligned with public health concerns for accessibility and

[344] Ibid.
[345] Supra note 331 at s 84 (1).
[346] Ibid.
[347] Ibid at s 146 (2).

affordability, providing a stronger basis for granting compulsory licences in cases of unmet public demand.

The above conditions for issuing a compulsory license were adjudicated in *Bayer v Natco*.[348] Natco Pharmaceuticals applied for a compulsory license to manufacture and sell Sorafenib Tosylate, a drug patented by Bayer and marketed as Nexavar® for treating kidney and liver cancer. Natco argued that Bayer's drug was not reasonably priced, did not meet public demand, and was not sufficiently 'worked' within India. Prior to the compulsory licence application, Bayer had previously rejected Natco's request for a voluntary license to manufacture and sell the drug.[349]

Using section 84 as the legal framework, The Controller of Patents granted the compulsory license, citing public interest and the fact that Natco's application met the three key conditions outlined in section 84: (1) the public's reasonable requirements were unmet, (2) the drug was not reasonably priced, and (3) the patented invention was not being adequately worked in India.[350] This decision was affirmed by the Hight Court, and agreed that the drug was not affordable or sufficiently available to the public, and Bayer had failed to meet its obligations under the Indian Patents Act.[351] The Supreme Court affirmed the lower courts' decision and the compulsory licence was maintained.[352]

In contrast, IPAB denied BDR Pharmaceuticals' request for a compulsory licence in the case of *BDR Pharmaceuticals v Bristol-Myers Squibb*.[353] The court's reasoning was that BDR had not established a sufficient basis for the grant of a compulsory licence under section 84. In particular, BDR had failed to meet two requirements; that they lacked the capacity to work the invention for the benefit of the public[354], and that they had made no legitimate effort to obtain a voluntary licence from the patent holder.[355] Consequently, the compulsory licence was rejected.

The above cases set a 'liberal approach' to compulsory licencing that balances patent rights with public health needs. On one hand they demonstrate a commitment to making essential medicines accessible to the public, on the other they show how India adheres to TRIPS obligations for patent rights. South Africa could benefit significantly from adopting such a

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[348] *Bayer Corporation v. Natco Pharma Ltd*., Order No. 45/2013.
[349] Ibid.
[350] Ibid.
[351] Ibid.
[352] Ibid.
[353] *BDR Pharmaceuticals International Pvt. Ltd v Bristol-Myers Squibb Company C.L.A. No. 1 of 2013.*
[354] Ibid at para 6.
[355] Ibid.

liberal approach. The previous analysis of South Africa's approach to compulsory licensing in chapter three highlights a restrictive judicial interpretation of the legislation, by imposing high evidentiary burderns on applicants as seen in the *Syntheta* case, and maintaining narrower grounds for granting such licenses than those available under TRIPS. While South Africa's model is well intentioned, it may be expanded. India's courts adopt a liberal approach because the legislation is more detailed and lends itself to a liberal interpretation as opposed to the South African provisions. Furthermore, India's model provides a robust framework specifically by allowing compulsory licensing when patented inventions are not reasonably priced. The obligations imposed by the constitutional right to health aligns perfectly with India's approach. By drafting legislation in a way that is aligned with the nature of the duty to realise the right to health and other rights contained in the Bill of Rights within the Constitution, South Africa could overcome its current legislative barriers and use TRIPS flexibilities for what they are intended for – access to affordable essential medicines.

III. VISION OR ILLUSION? REFLECTING ON INTELLECTUAL PROPERTY POLICY OF THE REPUBLIC OF SOUTH AFRICA PHASE I AFTER SIX YEARS

The 2018 Draft IP Policy is a comprehensive framework. However, in line with the thesis, the focus in this section is limited to its recommendations on SSE and compulsory licensing.

The policy calls for a phased approach beginning with applications for pharmaceutical patents, guided by the 2014 WIPO Policy Guide on Alternatives in Patent Search and Examination which provides that one of the ways to combat capacity constraints is by 'limiting substantive examination to certain strategic field of technology for the country concerned.'[356] To date, however, an SSE system still has not been implemented. The only change that has been introduced by the CIPC concerning examination is through Practice Notice No. 21 of 2023[357] which set out the requirements for expedited acceptance of a provisional patent application. The Note provides that evidence under section 15(1)(a) of the Patents Act, which may be given by affidavit or viva voce upon oath as determined by the registrar, shall be required for any requests for expedited acceptance of a patent application. Furthermore, the CIPC has previously states that it 'has gone to great lengths to capacitate a very able cohort of

[356] WIPO 'Alternatives in Patent Search and Examination' 2014, available at *https://www.wipo.int/edocs/pubdocs/en/wipo_pub_guide_patentsearch.pdf*, accessed on 11 March 2025.
[357] See CIPC, 7 April 2023, available at *https://www.cipc.co.za/wp-content/uploads/2023/04/Practice-Notice_21-of-2023-2.pdf,* accessed on 11 March 2025.

patent examiners.'[358] In this regard, a 'Request for Information for a capacity building program for SSE of patent application and the provision of a search tool for patent searches' was released by the CIPC in 2021.[359] However, as of November 2024, the CIPC has not provided updates on this capacity building.

In the meantime, according to the international patent filing statistics released by the WIPO, South Africa experienced a significant surge in the number of patent applications filed within its jurisdiction in 2022.[360] Notably, the figures indicate a remarkable 63.9% year-over-year increase in patent application filings compared to 2021.[361] A report from the Patent Registrar's office showed a 28% increase in the number of patent applications filed in 2022 as compared to 2021.[362] The divergence in these statistics is a resul of WIPO's data collection which includes both international (PCT) and national filings, wherears the CIPC's increase reflects only direct national applications.

With regards to compulsory licencing, the policy calls for a more efficient and effective compulsory licensing system than the current judicial process, which is slow and costly due to litigation and potential appeals.[363] Additionally, the policy indicates that the government aims to adopt a consultative approach to develop a system that effectively implements Paragraph 6 of the Doha Declaration, which deals with the problem of inadequate manufacturing capacities.[364] While these suggestions are noteworthy, to date, the process for obtaining a compulsory licence remains cumbersome, costly, and slow, often requiring court intervention.[365] Calls have been made for amendments to the legislation[366], however, these reforms have not been made operational.

While the 2018 Draft IP Policy laid a solid foundation, the lack of tangible progress on SSE and compulsory licensing reform raises a critical question: Is South Africa's IP vision still a promise, or has it become an elusive illusion?

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[358] ibid.
[359] CIPC, available at *https://www.gov.za/sites/default/files/gcis_document/202101/44084gen10.pdf*, accessed on 11 March 2025.
[360] WIPO 'Intellectual Property Statistics' available at *https://www.wipo.int/web/ip-statistics*, accessed on 25 September 2024.
[361] WIPO 'IP Facts and Figures' available at *https://www.wipo.int/en/ipfactsandfigures/patents*, accessed on 11 March 2025.
[362] CIPC, available at *https://www.cipc.co.za/?p=17839*, accessed on 11 March 2025.
[363] ibid.
[364] ibid.
[365] See cases in chapter three.
[366] See Fix The Patent Laws campaign, available at *https://www.fixthepatentlaws.org/,* accessed on 3 December 2024; UKZN 'Academics call for Amendments to the Patent Law in response to COVID-19' available at https://ww1.clms.ukzn.ac.za/academics-call-for-amendments-to-the-patent-law-in-response-to-covid-19/, accessed on 3 December 2024.

IV. THE COMMUNITARIAN ETHIC OR 'UBUNTU' AS A PATH TO EQUITABLE ACCESS

In proposing this solution, we must first determine whether the Bill of Rights under section 8 (2) of the Constitution is binding on private entities for the realisation of the right to health under section 27.

Section 8(2) explicitly binds private entities to uphold certain rights in the Bill of Rights, including the right to health under section 27.[367] In the context of the right to access affordable medicines, private pharmaceutical companies such as Bayer and J&J, which control the availability and pricing of essential medications through patent monopolies, play a significant role in either facilitating or hindering this constitutional right as seen in previous chapters. While evergreening is facilitated by the patent regime in its current form, pharmaceutical companies' participation in enforcing monopolies and creating barriers to affordable medicines, infringes the right to health.

Furthermore, in considering international law, the UN Guiding Principles on Business and Human Rights also suggest that private entities have a responsibility to respect human rights, including the right to health, by ensuring that their business practices do not undermine individuals' access to essential health services.[368] Thus, while section 8(2) imposes a duty on pharmaceutical companies to align their business practices with the Constitution's guarantee of equitable access to healthcare, an international human rights obligation persists.

With the above in mind, a communitarian ethic approach is embodied in the principles of *Ubuntu* which are encapsulated in the expression 'A person is a person through other persons'. Although *ubuntu* is not specifically mentioned in the Constitution, it has emerged in courts as '*ubuntu*-based jurisprudence'[369] In *S v Makwanyane*, Makwanyane Langa J underscored a key characteristic of *Ubuntu*. In his judgement he echoed that 'An outstanding feature of *ubuntu* in a community sense is the value it puts on life and human dignity […]'[370].

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[367] Constitution of South Africa supra note 12 at section 8 (2)
[368] OHCHR 'Guiding Principles on Business and Human Rights' *UN* 2011 at p. 9, available at *https://www.ohchr.org/sites/default/files/documents/publications/guidingprinciplesbusinesshr_en.pdf*, accessed on 11 March 2025.
[369] Malan, K. (2014). The suitability and unsuitability of ubuntu in constitutional law - inter-communal relations versus public office-bearing. *De Jure*, *47*(2), at p. 234.
[370] *S v Makwanyane and Another (CCT3/94) [1995] ZACC 3* at para 225.

In the same judgement he observed that *ubuntu* advocated for balancing the interests of society against those of an individual.[371]

According to Kolawole and Ncube, 'a communitarian approach to patents on pharmaceutical drugs would have to be applied to our rethinking of creation and innovation upon which recognition of ownership is based.' [372]

In order to investigate how this rethinking might result in equitable access to affordable medicines, this thesis applies it to the development of Trastuzumab and how its development was funded. During the development of the drug, public and private funding played an important role in the research and development of the drug.[373] Public funding, especially from institutions like the National Cancer Institute (NCI) and the National Institutes of Health (NIH) in the U.S., supported foundational research on HER2 oncogenes. In the early 1980s, scientists like Dr. Dennis Slamon at UCLA, who was pivotal in identifying the role of HER2 in breast cancer, received critical grants from these agencies.[374] This significant public input in the development of an essential medicine, makes the case that, while not currently understood as such, the communitarian approach is already being applied, without the commensurate benefits i.e., accessibility and affordability. Applying the communitarian ethic here means recognising the the collective contributions to medical advancements and ensuring that life-saving medicines are not treated as commodities but as shared resources that benefit the broader society.

Patent rights derive from intellectual and material contributions. Intellectual knowledge much of which is available publicly and encompasses a vast range of information, ideas, and innovations that contribute to scientific, technological and cultural advancements.[375] Given substantial public funding in cases like Trastuzumab, a communitarian approach questions private monopolies. Public investment implies a broader societal claim to the exclusive rights patent protection affords, challenging the profit-centred ownership model. This aligns with *Ubuntu's* emphasis on shared humanity, suggesting that companies holding pharmaceutical patents in South Africa should adopt fairer pricing models, explore patent pooling, and engage in voluntary licensing to ensure wider access to essential medicines. Applying the Ubuntu ethic

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[371] Ibid at para 250
[372] Kolawole supra note 15 at p. 4.
[373] Shepard, H. M. (2019). Biomarker-Driven Drug Discovery in Cancer—Trastuzumab Development: 2019 Lasker-DeBakey Clinical Medical Research Award. *JAMA: The Journal of the American Medical Association*, *322*(13), at p. 1249.
[374] Printz, C. (2020). First person profile: Dennis J. Slamon, MD, PhD. Cancer, 126(5), 919–920. https://doi.org/10.1002/cncr.32745
[375] Supra note 15 at p. 9.

not only challenges profit-centred models but also proposes a transformative framework where public contributions yield public benefits. In practice, this could mean prioritising partnerships with local manufacturers, desisting from evergreening practices to support generic drug production, and reinforcing corporate social responsibility to balance innovation incentives with public health needs. This approach could pave the way for collaborative models of drug development, ensuring that essential medicines are accessible to all, irrespective of economic status.[376]

V. CONCLUDING REMARKS

This chapter outlined practical steps to align South Africa's patent system with the constitutional right to health. Drawing from India's experience, implementing a robust Standard Substantive Examination (SSE) framework and a more flexible compulsory licensing system can prevent evergreening and improve access to affordable medicines.

While South Africa's 2018 Draft IP Policy provides a strong foundation, its lack of implementation raises concerns about whether its vision will materialise. Effective legislative action is urgently needed to bridge this gap.

Finally, a communitarian approach, rooted in *Ubuntu*, challenges profit-driven models by highlighting public contributions to pharmaceutical innovation. This ethical framework ensures that patent law serves societal interests, balancing innovation incentives with equitable healthcare access.

[376] Ibid.

CHAPTER FIVE

SUMMARY, RECOMMENDATIONS AND CONCLUSIONS

I. SUMMARY

This thesis was completed by utilising doctrinal legal research methodology through desktop research, analysing primary and secondary legal sources including legislation, case law, academic literature, and policy documents. The fundamental question this thesis sought to answer was: "Does the patent regime in South Africa in its current form negatively impact on the attainment of the fundamental right to health as enshrined in the Constitution? If so, how can the patent system be recalibrated to balance the right to health and the rights of patent holders?"

In answering this question, the following sub-questions were considered:

1. In light of section 27 of the Constitution and international human rights treaties, does the right to health inherently include the right to affordable essential medicines?
2. What is the nature of the constitutional right to health and what is the nature of the obligations imposed by that right?
3. What is the impact of the current patent regime on access to affordable medicine, and therefore the right to health?
4. What can be done to enable the realisation of the right to health through patent law?

A summary of the answers to these questions this thesis revealed are below:

1. In light of section 27 of the Constitution and international human rights treaties, does the right to health inherently include the right to affordable essential medicines?

In chapter two, I analysed international human rights treaties pertaining to the right to health and examined the CCSA's decisions that interpreted the meaning of the right under section 27. Through this analysis, I established that the right to health is not only an international obligation by way of various treaties including the ICESCR, UDHR etc, but also highlighted that it is a constitutional mandate. That constitutional mandate revealed that the right to health inherently encompasses equitable access to affordable medicines which was the primary focus of this thesis.

Within the Constitutional analysis, it was determined that IP rights fall within the scope of property under section 25. Given the nature of both rights, they must be balanced to serve the public interest. Additonally, property rights do not confer na absolute entitlement to ownership – as previously discussed they may be deprived or regulated in accordance with the public interest.

2. What is the nature of the constitutional right to health and what is the nature of the obligations imposed by that right?

South Africa's Constitution establishes a distinctive and progressive approach to the right to health through section 27, which creates a comprehensive framework of state obligations. Unlike traditional constitutional rights that primarily impose limitations on state action, this provision imposes both negative and positive obligations on the government. Its distinctiveness lies in its explicit recognition of socio-economic rights as enforceable, requiring the state not only refrain from unuust intereference but also to take proactive measures to progressively realise access to healthcare. Thus, the right to healthcare is fundamentally enshrined as a justiciable human right, ensuring that every individual is entitled to access healthcare services.

The constitutional provision creates a nuanced set of responsibilities for the state. These obligations are not absolute but are defined by the principle of "progressive realisation" – meaning the state must take reasonable legislative and other measures within its available resources to gradually improve healthcare accessibility. This approach recognises the practical challenges of immediately providing comprehensive healthcare while still maintaining a clear constitutional mandate for the government to work towards improving health services.

The positive obligations require the state to actively develop and implement healthcare infrastructure, create comprehensive healthcare policies, allocate resources strategically, and continuously work to enhance healthcare accessibility. Simultaneously, the state has a negative obligation to refrain from actions that would impede individuals' access to healthcare services. Furthermore, under section 8(2), the Bill of Rights can also be binding on private parties. In this context, private parties such as pharmaceutical patent holders, may have an obligation to ensure their practices do not undermine the realisation of the right to health. This dual nature of the right creates a dynamic constitutional framework that balances aspirational goals with practical implementation, acknowledging both the fundamental importance of healthcare and the economic constraints that might limit immediate full realisation of the right.

Importantly, the constitutional right is not a guarantee of immediate, comprehensive healthcare for all, but rather a commitment to progressive improvement. Courts have interpreted this to mean not only that the state must demonstrate ongoing, reasonable efforts to

expand and improve healthcare services, considering available resources and the most pressing health needs of the population but that access to healthcare must be affordable.

3. What is the impact of the current patent regime on access to affordable medicine, and therefore the right to health?

Based on the chapter three analysis, the current patent regime significantly undermines access to affordable medicine and the right to health through multiple systemic weaknesses. The patent system operates with a fundamentally flawed approach, where patents are granted almost automatically without SSE of their true inventiveness or merit. The CIPC presumes an invention deserves a patent once an application is filed, only allowing challenges through costly and prolonged litigation after the fact.

This approach has dire consequences for healthcare affordability. The case studies in chapter one and chapter three illustrate this. For instance, Bedaquiline, a drug for drug-resistant tuberculosis, was priced at R5,400 per treatment course by Johnson & Johnson in South Africa, compared to R2,300 through a global facility for low-income countries. Similarly, Lenalidomide, a cancer treatment, costs approximately R730,000 annually in South Africa, versus R32,000 in India where generic versions are available. In the case of Rivaroxaban, a blood clot medication, a minor dosage change was used to extend patent protection from 2020 to 2026, effectively blocking generic market entry.

The patent regime's weaknesses are further compounded by limited safeguards. Pre- and post-grant opposition mechanisms are absent, meaning challenges to patents are extremely difficult and expensive. When challenges do occur, courts tend to favour patent holders' rights over public health interests. Moreover, potential flexibilities like compulsory licensing remain virtually unused, with no compulsory licenses ever being granted despite being a legal option for over a century. The reasons for this, presented by the cases in chapter three, is a combination of factors, including the costs of bringing an application for a compulsory licence to the courts and the judiciary’s narrow interpretation of compulsory licensing provisions in the Patents Act, which appear to not prioritise public health of IP rights.

These systemic issues directly contradict the nature of the constitutional right to health and nature of the obligations imposed by that right, creating significant barriers to accessing affordable medicines. The patent system effectively prioritises pharmaceutical companies' commercial interests over public health needs, resulting in exorbitant drug prices that make essential treatments inaccessible to many South Africans.

II. RECOMMENDATIONS

The answers to sub question 4 are contained within the below recommendations. This thesis has highlighted the necessity for reforming patent law in South Africa, along with an analysis of the proposed policy recommendations. These policy recommendations will serve as the foundation for recommendations in this section that would ensure that the constitutional right to health is fulfilled.

South Africa can enable the realisation of the right to health through patent law by implementing three key approaches. First, the country should adopt a robust SSE system similar to India's, which would introduce a pre-grant ‘inventiveness’ test for pharmaceutical patents. This approach would specifically focus on ‘therapeutic efficacy’ as a key criterion, preventing evergreening by carefully scrutinizing incremental innovations that offer no real therapeutic benefit. By implementing such a system, South Africa could reduce litigation costs and prevent weak patents from being granted initially, thereby improving access to essential medicines.

Second, the country should reform its compulsory licensing mechanism, taking inspiration from India's more flexible approach. The current South African system is cumbersome, costly, and slow, often requiring court intervention. By adopting a more liberal framework that allows compulsory licensing when patented inventions are not reasonably priced or fail to meet public health needs, South Africa could more effectively use TRIPS flexibilities to ensure access to affordable essential medicines.

The third approach involves embracing a communitarian ethic rooted in Ubuntu, which challenges profit-driven patent models by highlighting the significant public contributions to pharmaceutical innovation. This approach recognizes that many essential medicines are developed with substantial public funding and argues that patent rights should balance innovation incentives with equitable healthcare access. By applying this ethical framework, South Africa could reframe its approach to patent law, ensuring that pharmaceutical companies' practices align with the constitutional right to health and international human rights principles.

This thesis further emphasises that while the 2018 Draft IP Policy provides a strong foundation for reform, there has been a lack of tangible implementation. Urgent legislative action is needed to transform these proposed solutions from a vision into reality, ultimately creating a patent system that prioritises public health and equitable access to essential medicines.

III. CONCLUSION

Having examined the existing patent regime in South Africa, it is evident that it undoubtedly constitutes an infringement of the constitutional right to health. For those denied this right however, there is remedy which may include legal challenges through the courts, invoking section 27 to demand access. However, the effectiveness of this remedy is limited by the absence of robust mechanisms, , such as pre- and post-grant opposition or the application of compulsory licensing, which have not been fully utilised.

What is more apparent is that the need for reform is urgent in light of access to patented medicines. The implementations of the TRIPS Agreement into domestic legislation must be reconsidered and the IP policy recommendations while admirable must be made practical. The WTO provided member states the policy space to implement the TRIPS Agreement how they see fit. The constitutional obligation to implement international agreements means South Africa must reconsider its current regime, there is a disconnect in the intentions of patent legislation and what has been implemented.

The analysis of the TRIPS Agreement indicates that effectively implementing the recommendations of the IP policy will align with the goals of the Doha Declaration. However, the actual implementation of the policy recommendations remains to be seen. While it is encouraging, action is stronger than words. The phased approach the policy recommends rather than sweeping change is a prudent strategy for long term reform.

Considering foreign law will also aide in the realisation of the right to health. Policies, regulations, legislation and decisions from other jurisdictions play a critical role in reform. India is just a drop in the bucket of what is possible. South Africa must remain on this path that encourages reform as it will lead to a better patent regime that does not infringe the right to health.

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