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PHARMACEUTICAL PATENTS AND PUBLIC HEALTH: FACILITATING ACCESS TO AFFORDABLE MEDICINES IN SOUTH AFRICA THROUGH TRIPS FLEXIBILITIES

by

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DECLARATION

I, **Ryan Bouwer** (Student number 817559, declare that this Research Report is my own unaided work. It is submitted in partial fulfillment of the requirements for the degree of Master of Laws (by Coursework and Research Report) at the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination in this or any other university.

I have submitted my final Research Report through TurnItIn and have attached the report to my submission.

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ABSTRACT

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) aims to strike a balance between the protection of creators and providing access to creative works to users of same. South Africa, as a member of the World Trade Organisation (WTO), has the flexibility to define its policy space in an internationally recognised and compliant manner to achieve an equilibrium between upholding public interest objectives and the private interests of patent holders in the field of health. South Africa has taken steps over the years to revise its medicine and intellectual property (IP) policies to address the issue of medicine access; however, implementation of reform is hampered by resource and capacity constraints, as well as economic and political pressures. As a result, the exorbitant pricing of pharmaceutical patented products continues to have an impact on the availability of essential medicines in South Africa.

This report examines the functioning of the patents system in South Africa as it relates to the granting of pharmaceutical patents. The report discusses the link between intellectual property rights (IPRs) and public health and how the patent system can create barriers to access to affordable medicines. This report contends that the current patent climate exists due to shortcomings in South Africa's Patent Act of 57 of 1978 (Patents Act) and its under-utilisation of TRIPS flexibilities. Pharmaceutical companies have exploited the current patent regime through evergreening and other abusive practises, resulting in the postponement of off-patent drugs and stifled competition, ultimately at the expense of public health. This report seeks to determine the extent to which South Africa has implemented TRIPS flexibilities in promoting access to affordable medicines in the realm of pharmaceutical patents, as well as whether South Africa can strike a balance between protecting pharmaceutical innovation and public health. It concludes by looking at how competition policy can be used to correct the imbalance and suggests that a focused and convergent approach to capacity building and transnational collaboration be employed.

KEYWORDS: TRIPS flexibilities – pharmaceutical patents – affordable access – public health

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I INTRODUCTION

South Africa is no stranger to the battlegrounds of access to medicine and IPRs and has voiced its concerns about how to strike a balance between promoting sustained and continued innovation through patents and addressing the immediate demand for access to affordable medicines. Following a protracted legal battle and growing pressure to find means to provide wider and affordable access to HIV/AIDS treatments across the globe, the Pharmaceutical Manufacturers Association withdrew its action against the South African government to have the 1997 amendments of the Medicines and Related Substances Control Amendment Act of 1997 declared unconstitutional. These amendments would seek to allow the importation of medicines at a lower cost.[1] The Pharmaceutical Manufacturers case sparked global debate on how pharmaceutical patents can create barriers to access to medicine. Twenty-five years later and despite the publication of the Intellectual Property Policy of the Republic of South Africa (IPPRSA) in 2018,[2] the issue of access to affordable medicines remains a challenge for South Africa.[3] The Covid-19 pandemic has reignited debates about the relationship between the functioning of the patent system and public health, as well as how patents can impede access to medicines.[4]

The patent system is designed to encourage innovation for the benefit of society.[5] One of the benefits of innovation to society has been the development of various medicines, which have ultimately led to the advancement and protection of public health.[6] The primary justification for the protection of non-exclusive and non-rivalrous intangible property interests is closely connected to secure economic gain for innovators and in the public health domain, a considerable amount of capital is required for the research and development (R&D) of medicines.[7] Accordingly, the pharmaceutical industry would not engage in this risky process without protection afforded to its

[1] Christa Van Wyk 'Access to affordable HIV medicines in South Africa: Patents, parallel importation, generics and medical schemes' (2006) 39(1) *De Jure* 1 at 13.
[2] Department of Trade and Industry and Competition 'Intellectual Property Policy of the Republic of South Africa Phase I' (2018) at 14, available at *https://www.gov.za/sites/default/files/gcis_document/201808/ippolicy2018-phasei.pdf*, accessed on 23 May 2023
[3] Bryan Mercurio et al 'Pharmaceutical patent law and policy in South Africa: a survey of selected SADC member states' (2023) 43 *Legal Studies* 331.
[4] Ibid at 333.
[5] Mpho Titong 'The balance between intellectual property and public health' (2021) 624 *De Rebus* 12.
[6] Yousuf Vawda et al 'Intellectual property barriers to access to COVID-19 health products in South Africa' (2021) *South African Health Review* 263 at 264.
[7] Madelein Kleyn 'Public health sector and the South African National Policy on Intellectual Property' (2014) *Without Prejudice* 28.

IP.[8] According to this premise, stronger patent protection is required for R&D to take place for the invention of medicines. As a result, the connection between IP, specifically patents, and public health is clear. It is irrefutable that an individual's health may be dependent on access to certain medicines that are patent-protected and whose manufacture is legally monopolised by the patent holder.[9]

Whilst the patent system functions as a tool to spur innovative works, it must simultaneously provide a mechanism which allows society to have access to the benefits of those inventions.[10] A proportionate balance must be struck between the rights of patent holders, who advance health care through their innovative works, and competing societal fundamental rights, such as access to health care services.[11] In the absence of such a balance, IP, and particularly the operation of the patent system, can create barriers to health, such as access to affordable medicines. Azam has noted that tension between IPRs and public health is greater in developing countries with weak public health systems and inadequate patent laws, such as South Africa.[12]

This report focuses on the intersection of IP and public health, particularly its impact on the exorbitant prices of pharmaceutical patented products. It is argued that pharmaceutical companies have exploited the patent system by extending their protection and preventing generic competition from lowering the prices of life-saving medicines. This has been aided by shortcomings in South Africa's patent granting system and delays in reforming same. This predicament is exacerbated by South Africa's failure to use TRIPS flexibilities to reduce medicine prices.

Accordingly, an investigation into those aspects of South Africa's patent legislation and regulatory framework, policy space, and international obligations is required to assist in evaluating those areas of South Africa's patent regime which require reform to facilitate access to affordable medicines. Part II of this report provides a general overview of the international public health challenge, particularly as it relates to pharmaceutical patents and excessive pricing in developing countries. Part II explores South Africa's patent granting system and how its flaws contribute to patent abuse and excessive pharmaceutical pricing. Part III of the report investigates the impact of

[8] Ibid.
[9] Titong op cit note 5 at 5-6.
[10] Kleyn op cit note 7.
[11] Ibid.
[12] Monirul Azam *Intellectual Property and Public Health in the Developing World* (2016) 139.

TRIPS flexibilities on public health and the extent to which they have been used in the South African patent regime to promote access to affordable medicines in the sphere of pharmaceutical patents. These investigations will culminate in a discussion in Part IV on whether South Africa can strike a balance between pharmaceutical innovation and public health. Part IV concludes the report, summarises its findings, and provides recommendations for the reform of South Africa's patent system.

II THE GRANTING OF PATENTS AND PHARMACEUTIAL PRICES IN SOUTH AFRICA

International organisations such as the World Health Organisation (WHO), World Intellectual Property Organisation (WIPO), and the WTO have recognised the interface of public health and other policy domains, such as IP, human rights, and international trade. While public health is regarded as a global challenge, the trilateral cooperation of these international organisations has noted that the impact of noncommunicable diseases, in addition to the existing burden of communicable diseases such as HIV/AIDS, tuberculosis, and malaria, is on the increase in low to middle-income countries.[13] As a result, there is a greater need in developing countries for improved policy making relating to the interconnection of health, trade, and IP, particularly in the development and access to medicines.[14]

A lack of access to essential medicines is hardly a result of a single influence.[15] However, it is identified that affordability of medicines plays a crucial role in access, even more so, in countries where the public health sector is fragile and a considerable portion of the population pay for health care out of pocket,[16] as is arguably the case in South Africa.[17]

(a) A brief overview of South Africa's pharmaceutical market and pricing system

[13] WTO, WHO and WIPO 'Promoting Access to Medical Technologies and Innovation: Intersections between public health, intellectual property and trade (second edition) 2020 at 17, available at *https://www.wto.org/english/res_e/publications_e/who-wipo-wto_2020_e.htm*, accessed on 22 May 2023.
[14] Ibid at 16.
[15] Vawda et al op cit note 6 at 263.
[16] WTO, WHO, WIPO op cit note 13.
[17] Varsha Bangalee & Fatima Suleman 'Pseudo-Generics in South Africa: A Price Comparison' (2019) 19 *Value in Health Regional Issues* 87.

Due to its favourable marketing conditions, South Africa holds the biggest pharmaceutical products market in Africa.[18] Ranked as the fifth highest in Africa in terms of expenditure on pharmaceutical products per capita, it is reported to have a large presence of multinational pharmaceutical companies (MPCs) operating within its borders.[19] Studies show that it is a common characteristic of pharmaceutical companies to carry out patenting of their products in middle to large income countries, such as South Africa,[20] as there are a greater number of consumers with a higher disposable income per capita.[21] Equally depicted is a failure by MPCs to consider local conditions and country specific constraints,[22] which leads to aggressive patenting by these MPCs that in turn enhances barriers to access to essential medicines.[23]

South Africa continues to be afflicted by communicable and noncommunicable diseases, necessitating greater access to affordable essential medicines.[24] In an effort to restructure South Africa's public health sector, South Africa's National Drug Policy (NDP) of 1996 was implemented with the aim of reducing the cost of certain medicines.[25] Several years after the implementation of the NDP, the Medicines and Related Substances Act of 1965 was amended to allow government to action the objectives of the NDP in improving access to affordable medicines.[26] This resulted in the establishment of the pricing committee, mandated with developing a mechanism for transparent pricing and the publishing of the single exit price (SEP) medicine pricing system.[27]

In addition to the implementation of the SEP methodology for transparent medicine pricing in South Africa,[28] the Medicines and Related Substances Act provides conditions for the procurement

[18] Yu-Fang Wen & Thapi Matsaneng 'Patents, Pharmaceuticals and Competition: Benefitting from an effective patent examination system' 2013 at 1, available at *http://www.compcom.co.za/wp-content/uploads/2014/09/PatentsPharmaceuticals-and-Competition-Yu-Fang-Wen-and-Thapi-Matsaneng-Annual-CompetitionConference-2013.pdf*, accessed on 22 May 2023.
[19] Ibid.
[20] Ibid.
[21] Ibid at 6.
[22] Ibid at 2.
[23] Ibid at 1.
[24] Ibid at 5.
[25] Varsha Bangalee, & Fatima Suleman 'Has the increase in the availability of generic drugs lowered the price of cardiovascular drugs in South Africa?' (2016) 21 *Health SA Gesondheid* 60 at 61.
[26] Ibid.
[27] Ibid.
[28] Graeme Wickins 'Excessive pricing in the pharmaceutical sector – a bitter pill to swallow or a dose of their own medicine?' Legal Brief August 2017 available at *https://www.werksmans.com/wp-content/uploads/2017/08/16829-August-Legal-Brief_Pharmaceutical-Sector-FA.pdf*, accessed on 22 May 2023.

of lower priced medicines in prevailing circumstances to protect public health. This allows for the parallel import of equivalent pharmaceutical products from other jurisdictions at lower prices than existing products.[29] Interestingly and despite the SEP system and pro-generic legislation, studies indicate that implementation of these laws has not yielded competitive drug pricing in South Africa,[30] and existing policies on the pharmaceutical industry have not advanced access to affordable medicines to the extent envisioned.[31] It was further concluded that South Africans pay artificially high prices for medicines when compared to prices of other countries and which are considered to be some of the highest globally.[32] Recent investigations by the Competition Commission and the Health Justice Initiative found that other countries pay half the price for the tuberculosis drug bedaquiline than South Africa, and that South Africa was charged 15% more for the Johnson & Johnson vaccine than other European states for the Covid-19 vaccine.[33]

(b) South Africa's patent granting system

The Patents Act and its Regulations (the Regulations) governs the law of patents in South Africa. The Patents Act, along with the Regulations and, for international patents, read together with the applicable provisions of the Patent Cooperation Treaty of 1999, outline the registration procedure that must be followed when applying to South Africa's patent office to have a patent registered, which grants patent protection in South Africa.[34] South Africa's patent office is administered by the Companies and Intellectual Property Commission (CIPC) and has the responsibility to ensure compliance with the Patents Act and its Regulations in registering a patent.[35] In general, an invention is patentable if it is not excluded from patentable subject matter, achieves the purpose for which it is created, did not form part of the prior art before its filing date and the technical know-how must not be obvious to a person skilled in that area of expertise.[36] Section 25(1) of the

[29] Ibid.
[30] Bangalee & Suleman op cit note 25 at 62.
[31] Ibid at 64.
[32] Wen & Matsaneng op cit note 18 at 2.
[33] Anastasi Mokgobu 'Competition Commission to probe J&J for pricing TB drug' 14 September 2023, available at *https://www.jacarandafm.com/news/news/competition-commission-probe-jj-pricing-tb-drug/,* accessed on 17 October 2023. See also Kerry Cullinan ''Bullying' Pharma Giants Charged Suth Africa More than EU for Covid-19 Vaccines' 5 September 2023, available at *https://healthpolicy-watch.news/bullying-pharma-giants-charged-south-africa-more-than-eu-for-covid-19-vaccines/,* accessed on 17 October 2023.
[34] Wen & Matsaneng op cit note 18 at 2.
[35] Ibid.
[36]Stefanie Busch 'Promoting access to affordable generics: reforming South Africa's patent law to prevent evergreening*'* (2016) 4 *IPLJ* 101 at 105.

Patents Act requires that a new invention involves an inventive step and is capable of being used in trade, industry or agriculture.[37] In theory, should an invention meet the requirements of the Patents Act, a patent will be granted.[38]

While Section 25 of the Patents Act specifies the substantive criteria that must be met, Regulation 41, which states that the registrar shall examine the patent application to ensure compliance with the prescribed formalities, comes to the fore in the granting of patents in South Africa.[39] This means that, in practise, the registrar does not ensure complete compliance with the Patents Act, but rather whether the necessary forms are correctly completed, the prescribed fee is paid, and there is conformity with other administrative requirements such as whether the invention falls within an unpatentable category as defined in section 25(2) of the said Act.[40] It is important to note at this juncture that South Africa's current patent system is a non-examining system, also known as a 'depository system,' in which patents are only inspected for formal compliance rather than substantive validity.[41]

South Africa's patent depository system stands in stark contrast to the vast majority of countries where patents are substantively scrutinised.[42] For example, IPPRSA has reported that South Africa grants 93% of all patent applications compared to the USA, which only grants 61%.[43] South Africa's percentage is even greater when compared to other developing countries, with India and Brazil at 19% and 14% respectively.[44] Notably, South Africa is also the only country of the BRICS group of countries, which does not perform a substantive examination of its patents. In addition, South Africa's patent regime does not provide for pre- or post-grant opposition.[45] This means that third parties do not have the opportunity to participate in the patent application process before or after a patent is granted if they oppose the grant of a patent.[46] A substantive examination by the Commissioner of Patents may take place only after a patent has been granted and is challenged in

[37] Patents Act 57 of 1978 s25(1)
[38] Mikhalien Du Bois 'The Appropriate scope of property rights in patents' (2018) 6 *IPLJ* 67 at 69.
[39] Patent Regulations, 1978 in GN R2470 in *GG* 6247 of 15 December 1978.
[40] Desmond Osaretin Oriakhogba 'DABUS Gains Territory In South Africa and Australia: Revisiting the AI-Inventorship Question' (2021) 9 *South African Journal of Intellectual Property Law* 87 at 92.
[41] Du Bois op cit note 38 at 71.
[42] Busch op cit note 36 at 106.
[43] IPPRSA op cite not 2 at 7.
[44] Ibid.
[45] Busch op cit note 36 at 106.
[46] Wen & Matsaneng op cit note 18 at 4.

a South African High Court for revocation on the grounds specified in section 61 of the Patents Act, or during infringement proceedings.[47]

(c) The effects of South Africa's depository patent system on pharmaceutical patents and pricing

The intersections between trade, IP, and public health policy suggest that trade and its counterpart, competition policy, as it relates to the granting of patents in the field of public health, are at ends with the question of whether a patent is deservingly granted protection in providing an incentive for innovation and whether it fosters competition in the interests of the general public as buyers of those patented products.[48] Put differently, if a patent is unwarranted and does not promote innovation, it is accordingly not worthy of protection and can lead to the imposition of superfluous costs on the public.[49] Therefore, it stands to reason that lack of protection should enable competition policy to foster innovation and advance the public good by offering consumers beneficial products at reasonable prices, quantities, and quality.[50] It follows the commercialisation of off-patent drugs and their entry into the market stimulates competition and aids in the reduction of medicine prices.[51] The converse is equally true.[52]

In the absence of substantive evaluation, a formal examination leads to a high number of low-quality patents being granted,[53] which results in the registration of many invalid patents until such time as revocation or infringement proceedings are instituted, if at all.[54] In pursuit of financial gain, MPCs engage in the practise of evergreening and other strategic patenting methods,[55] registering multiple patents on a single medicine for a period of twenty years, which may be extended if a secondary patent is granted,[56] stifling competition and negatively impacting public health.[57]

Evergreening is a term used to describe the practice in which patent holders take advantage of the patent system through various patenting strategies.[58] A common strategy is to file new patent

[47] Du Bois op cit note 38 at 71.
[48] Wen & Matsaneng op cit note 18 at 4.
[49] Ibid.
[50] Ibid.
[51] Bangalee & Suleman op cit note 25 at 62-4.
[52] Wen & Matsaneng op cit note 18 at 5.
[53] Busch op cit note 36 at 106 & 110.
[54] Du Bois op cit note 38 at 72.
[55] Busch op cit note 36 at 112.
[56] Wen & Matsaneng op cit note 18 at 5.
[57] Ibid.
[58] Busch op cit note 36 at 110.

applications based on existing patented products, and for minor variations[59] to the original patented invention with no improved benefit, acting as an undeserved extension of the original patent.[60] These newly filed patents have a tendency to protect isometric forms, dosing instructions, and alternative modes of treatment.[61] Thus, patent holders are granted various patents on different attributes of a single existing product to avoid their products from going off-patent.[62]

Evergreening has the unwelcome side effect of increasing the patent holder's monopoly by extending the twenty-year protection already granted to their patented product.[63] This enables pharmaceutical corporates to retain their monopoly in the absence of competition and maintain the high price of medicines for longer.[64] It follows that in preserving their monopoly, the entry of generic products into the market is deferred.[65] The above-mentioned practice is abusive in that the improper award of these patents only profits the patent holder at the expense of public health interests.[66] Evergreening should be distinguished from incremental innovation. Not every patent filed based on an existing patented product is an attempt to exploit the patent system.[67] Incremental innovation details the development of medicine, either by way of enhanced health benefits or discovery of new uses of an existing patented medicine and is accordingly acceptable.[68]

South Africa's patent granting system promotes the evergreening of patented medicine because none of the patent filings are substantively examined for novelty or inventive step, resulting in the granting of additional patents for existing compounds that contain insignificant changes to the drug.[69] It is submitted that the patent system enables the pharmaceutical industry to generate large profits in instances where patent laws are lax, as is the case in South Africa.[70] This results in South Africans paying spuriously inflated prices for drugs as a direct consequence of the non-

[59] Yousuf A Vawda 'After the Novartis judgment – 'evergreening' will never be the same again!' (2014) 18 *Law, Democracy & Development* 305.
[60] Busch op cit note 36 at 110.
[61] Ibid.
[62] Busch op cit note 36 at 111.
[63] Vuyisile Hobololo 'Strategic patenting of pharmaceutical inventions and the public's right to access medicines: the South African context' (2015) 16 *The African Journal of Information and Communication* 78.
[64] Busch op cit note 36 at 111.
[65] Ibid.
[66] Ibid.
[67] Ibid
[68] Ibid.
[69] Ibid.
[70] Ibid at 111-12.

examination system.[71] It has been found that at least twenty pharmaceutical patented products being sold in South Africa are commercially available at a price that is between 9% to 35% less than other countries where biologicaly similar drugs are available.[72] Compared to other jurisdictions in which the examination system is used, secondary patents are rejected and subsequently the sale of cheaper generic products are available.[73] In some cases, the excessive cost of these drugs is deemed too high to be provided in the public sector, in contrast to other jurisdictions where generic equivalents are sold for one-tenth the price.[74] In addition to bedaquiline mentioned above, further examples of lifesaving drugs affected in South Africa include linezolid, trastuzumab and entecavir, for treating drug resistant tuberculosis, breast cancer and hepatitis B, respectively.

It is submitted that where patent terms are extended, monopolies are prolonged, and the entry of off-patent drugs could be blocked for a further term of twenty years. This has the effect of competitors abandoning R&D in the space which questionable pharmaceutical patents are granted,[75] with the result that South African's are prevented from enjoying the benefits of further innovations. A further consequence is that the barrier for entry of generic pharmaceutical products is raised, resulting in the weakened competition and the strengthening of the patent holder's monopoly.[76]

III PHARMACEUTICAL PATENTS AND THE USE OF TRIPS FLEXIBILITIES IN SOUTH AFRICA

Trilateral international cooperation between WHO, WTO and WIPO, recognise the issue of access to affordable medicines in developing countries.[77] It is through the use of the TRIPS flexibilities that a balance is sought between the intersection of IPRs and public health.[78] The TRIPS flexibilities refer to certain provisions contained in TRIPS, which provide policy space for member

[71] Ibid at 112-13.
[72] IPPRSA op cit note 2 at 15.
[73] Catherine Tomlinson et al 'Reforming South Africa's procedures for granting patents to improve medicine access' (2015) 105(9) *SAMJ* 741.
[74] Ibid.
[75] Wen & Matsaneng op cit note 18 at 5.
[76] Olga Gurgula 'Strategic Patenting by Pharmaceutical Companies Should Competition Law Intervene?' 2020 51(9) *International Review of Intellectual Property Law and Competition* 1075 at 1075-6.
[77] WTO,WHO WIPO op cit note 13 at 16.
[78] TRIPS Article 7 and 8.

countries to counteract against the effects of patents and other IPRs on various societal goals. TRIPS is considered to be the most complete international agreement on IP in existence,[79] and it obliges members of the WTO to adopt a standard level of protection for IPRs.[80] Unlike the Paris Convention which does not provide for minimum protection,[81] one of the objectives of TRIPS is to diminish the impediments to international trade and to provide for adequate protection of IPRs globally,[82] such as the compulsory patent protection in all fields of technology, which includes pharmaceutical patents, for a twenty year period.[83]

TRIPS has received much criticism for its patent protection and access to medicines, with concerns that stronger patent protection leads to higher drug prices and eliminates the potential for local production of generic drugs through the reverse engineering process,[84] on which developing countries rely.[85] It is argued further that the incentive theory has fallen short in encouraging R&D for public health interests in poorer countries with a high rate of disease.[86] This contradicts the provisions of Articles 7 and 8, which contain the TRIPS objectives and principles, which seek to achieve a balance in the rights and obligations of innovators and consumers. TRIPS provides a number of legal exceptions for signatories to take advantage of, commonly referred to as TRIPS flexibilities, to mitigate the negative effects of pharmaceutical patents on access to affordable medicines.[87] As South Africa is a member to the WTO and a signatory to TRIPS, it must accordingly comply with the minimum level of protection and mandatory provisions implemented in its local patent laws.[88] Equally true, is that South Africa may use the flexibilities afforded in implementing policies and laws aimed at increasing access to affordable medicines.

The Doha Declaration on TRIPS and Public Health (Doha Declaration) was adopted in 2001 in response to criticism received over the implications of TRIPS on public health in developing

[79] Shyama V Ramani & Eduardo Urias 'Access to critical medicines: When are compulsory licenses effective in price negotiations?' (2015) 135 *Social Science and Medicine* 75.
[80] Busch op cit note 36 at 103.
[81] Ibid.
[82] TRIPS Preamble.
[83] Ramani & Urias op cit note 79.
[84] Ibid.
[85] Wen & Matsaneng op cit note 18 at 7.
[86] Motari et al 'The role of intellectual property rights on access to medicines in the WHO African region: 25 years after the TRIPS agreement' (2021) 21 *BMC Public Health* 1 at 2.
[87] Ramani & Urias op cit note 79.
[88] Wen & Matsaneng op cit note 18 at 6.

countries.[89] The Doha Declaration sought to balance the concerns between developed and developing countries through use of the TRIPS flexibilities.[90] In doing so, the Doha Declaration reaffirms that members should not be prevented from taking measures to protect public health and that TRIPS should be understood and implemented in a manner that promotes access to medicines for all.[91] Accordingly, the Doha Declaration confirms the rights of members to employ the exceptions and safeguards within TRIPS in light of public health considerations.[92] Thus, in addition to imposing the certain minimum standards of patent protection, a number of public health flexibilities may be adopted by member nations as well. The most significant of these flexibilities include exclusions and standards of patentability, compulsory licenses and government use provisions, parallel imports, opposition procedures, and competition policies.

(a) Substantive examination, patentability criteria and opposition procedures

It is argued that the cumulative effect of South Africa's inadequacies in its patent regime (depository system, lack of opposition procedures, and weak patent criteria) can lead (and has led) to the abuse of the patent system, particularly in the sphere of public health.[93] Article 7 of TRIPS acknowledges the equilibrium between protection and enforcement of IPRs and promoting social and economic welfare of its users.[94] In addition, Article 8 permits members to take necessary steps in protecting public health in preventing abuse by right holders, subject to compliance with the TRIPS standards.[95]

Article 27 of TRIPS provides that members may incorporate high standards of patentability into their national legislation and accordingly legislate strict criteria for the conditions of novelty, inventive step and industrial applicability.[96] While South Africa is said to have high patentability standards,[97] and its Patents Act requires that each patent application be examined for validity

[89] Busch op cit note 36 at 104.
[90] Ibid.
[91] Ibid.
[92] Wen & Matsaneng op cit note 18 at 7.
[93] Busch op cit note 36 at 106.
[94] Brook K. Baker 'A full description of WTO TRIPS flexibilities available to ARIPO member states and a critique of ARIPO's comparative study analyzing and making recommendations concerning those flexibilities' at 5, available at *https://www.bu.edu/gdp/files/2020/05/ARIPO-Member-States-obligations-and-flexibilities-under-the-WTO-TRIPS-Agreement-March-2019.pdf*, accessed on 22 May 2023.
[95] Ibid.
[96] Ibid at 11.
[97] Carlos M. Correa (ed) *Pharmaceutical Innovation, Incremental Patenting and Compulsory Licensing* (2013) at 17.

against the substantive requirements of the Patents Act, the unfortunate reality is that a low patent standard is applied.[98] Under section 34 of the Patents Act, the examination of patents is qualified by the words 'in the prescribed manner,' which together with Regulation 41, allows examiners to simply perform a tick box exercise,[99] negating the test for substantive validity.[100]

Implementing a substantive examination of patents would ensure that patents meet the criteria for patentability and accordingly worthy of protection.[101] The result is that only eligible patents will be registered, whilst simultaneously excluding those patent applications which are not genuine inventions,[102] or which contain frivolous changes.[103] Critics of substantive patent examination argue that such a system is simply unworkable in South Africa, as in many developing countries, due to a lack of skill and human resources.[104] A substantive search and examination system would require patent examiners to have the requisite skill and insight in a particular field of knowledge.[105] This would entail the education and training of examiners in technical areas of knowledge, which would be time-consuming and costly.[106]

The collaborative approach proposes that South Africa outsource or share the task of examination with more capable patent offices outside its jurisdiction.[107] Substantive examinations are thus redirected to countries or regional organisations with capacity until South Africa is able to carry out those tasks itself.[108] Another benefit is that South Africa could streamline the automatic rejection of patents by taking cognisance of the decisions from those patent offices in similar applications.[109] This approach would entail that South Africa work with a country or region with similar patentability standards, sufficient capacity for examination and possible comparable demographics considering social, economic and cultural factors.[110] In this regard, the African

[98] Busch op cit note 36 at 115.
[99] Vawda YA 'Country Case Study: South Africa' in Carlos M. Correa (ed) *Pharmaceutical Innovation, Incremental Patenting and Compulsory Licensing* (2013) at 237.
[100] Busch op cit note 36 at 105.
[101] Ibid at 114.
[102] Vawda op cit note 59 at 315.
[103] Julia E Hill 'Changes to intellectual property policy in South Africa: putting a stop to evergreening? (2014) 24(8) *Expert Opinion on Therapeutic Patents* 839 at 840-41.
[104] Busch op cit note 36 at 115.
[105] Ibid.
[106] Ibid.
[107] Tomlinson et al op cit note 73 at 742.
[108] Busch op cit note 36 at 115.
[109] Tomlinson et al op cit note 73 at 742.
[110] Ibid.

Regional Intellectual Property Organisation (ARIPO) and the Organisation Africaine de la Propriété Intellectuelle (OAPI) are suitable options as many of their sub-Saharan members suffer from similar constraints as a result of similar socio-economic factors.[111]

South Africa, it is argued, can work around the aforementioned constraints by first training examiners for specific trades or industries. A concern has been expressed that patents would be restricted in the field of public health, discriminating against the pharmaceutical industry and thus violating Article 27(1) of TRIPS.[112] In this regard, it has been confirmed by WIPO that in addressing a nation's capacity constraints, substantive examination may be limited to:

> '[c]ertain strategic fields of technology for the country concerned' and that: 'Applications relating to other fields of technology may be subject to formal examination only or to outsourcing either within or outside the country'.[113]

The WIPO dispute settlement body allows for the prioritisation of certain sectors based on public interest considerations, provided that this does not conflict with TRIPS.[114] Accordingly a phased-in approach to substantive examination observes the importance of distinguishing between classes of patent subject matter.[115] This approach coincides with public interest considerations and can be of particular assistance to developing nations with capacity constraints.

Article 27 of TRIPS provides additional flexibility, which India and Argentina have fully utilised, in the form of patentable subject matter and exclusions from patentability.[116] Apart from the provisions relating to discrimination of inventions in differing classes of patents and several express prohibitions on patentability, TRIPS provides Members with the flexibility to define the subject matter which may be patentable and those which are excluded.[117] Whilst the Patents Act provides an extensive account as to what may consist of an invention, it is submitted that it can do more to prevent abuse of its patent system by the pharmaceutical industry. In this regard,

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[111] Marumo Nkomo 'Regional integration in the area of intellectual property: The case for Southern African Development Community involvement' (2014) 18 Law *Democracy & Development* 317 at 324. See also Motari, et al op cit note 86 at 6.
[112] Elissa Amponsaa Duku *TRIPS flexibilities and access to essential medicines in South Africa* (LLM Thesis University of Cape Town, 2021) at 46.
[113] IPPRSA op cit note 2 at 17.
[114] Ibid at 18.
[115] Ibid.
[116] Baker op cit note 94 at 10.
[117] Ibid.

Argentina's incorporation of its directives on the examination of patent applications involving 'chemical-pharmaceutical substances' and India's implementation of its 'pharmaceutical-orientated exclusions,'[118] are most notorious in attempting to curb the effects of evergreening[119] and poor quality patents in the health sector. In essence, India's Patents Act[120] and specifically section 3(d) prohibits patents on 'mere discoveries of new forms of existing substances,'[121] unless it can be proved that there has been enhanced efficacy.[122] Despite the effectiveness of the aforesaid provision having been criticised,[123] and further its compliance with TRIPS questioned altogether,[124] the provisions have received global recognition and affirmation.[125] Accordingly, it is recommended that developing nations adopt guidelines and incorporate similar provisions concerning pharmaceutical patents in light of public health considerations.[126]

Another flexibility provided for under TRIPS and which South Africa has failed to implement is pre- and post-grant opposition proceedings. The availability of these procedures, as provided for in TRIPS Articles 32 and 62, would allow interested parties to make representations regarding the granting of patents.[127] A further safeguard and which TRIPS makes express reference to is that the outcome of these procedures shall be subject to judicial review.[128] A successful implementation of these procedures would allow for interested persons to oppose filed patents on various grounds[129] substantiated by evidence and legal argument.[130] Opposition proceedings would allow parties such as generic drug manufacturers and organisations representing civil society's interest in affordable medicines to prevent the granting of weak patents, evergreening, and general patent regime

[118] Ibid at 11.
[119] Duku op cit note 112 at 48.
[120] India's Patents Act, 1970.
[121] India's Patents (Amendment) Act, 2005 s3(d).
[122] Baker op cit note 94 at 10.
[123] LTC Harms 'Tweaking patent law: Patent law policy and pharmaceutical patents' (2014) *IPLJ* 1 at 7-8.
[124] Carlos M Correa 'Is Section 3(d) Consistent with TRIPS?' (2013) 48 *Economic and Political Weekly* 49 at 49-52
[125] Busch op cit note 36 at 118.
[126] L Ndlovu 'Lessons for the SADC from the Indian Case of Novartis Ag V Union Of India' (2015) 18(4) *PELJ* 783 at 806.
[127] Baker op cit note 94 at 22.
[128] Ibid.
[129] Busch op cit note 36 at 115.
[130] Baker op cit note 94 at 22.

abuse[131] by permitting additional scrutiny of patentable subject matter, exclusions, required disclosures and patentability criteria.[132]

Whilst it is reasoned that opposition procedures are also subject to resource constraints,[133] it is submitted that it is more feasible to reject an invalid patent than suffer the economic damages of unwarranted patents,[134] particularly in the sphere of health, which has been globally identified as an area of constant abuse. The Patents Act does not provide for opposition proceedings and only allows for patent revocation on limited grounds and after a patent has been granted. As alluded to earlier in this report, revocation proceedings can be complicated, time-consuming, and costly.[135] It is submitted that an effective implementation of pre- and post-grant opposition procedures should allow for simple and speedy proceedings,[136] and which are not cost prohibitive, with the objective that stronger patents are granted.[137]

It is argued that the abovementioned measures will have only a limited impact and must be implemented in conjunction with a system of substantive examination to test their eligibility, as well as pre- and post-grant opposition procedures as an additional safeguard.[138] With the previously mentioned constraints in mind, it is clear that South Africa will struggle to implement all of the reformative measures at the same time without external assistance. It is proposed that South Africa's first port of call should be to implement substantive patent search and examination, and a strong case can be made for South Africa and other developing countries of the global south, as well as their regional IP institutions, to align their efforts to achieve such a result, which has so far been insufficient.[139]

(b) Compulsory licenses

[131] Tomlinson et al op cit note 73 at 742.
[132] Baker op cit note 94 at 22.
[133] Lakpini Clarence Sokolambe *An Examination of South Africa's Efforts at Patent System Reform: TRIPS Flexibilities Fully Appropriated For Public Health Needs* (LLM Thesis University of Cape Town, 2019) at 58.
[134] Busch op cit note 36 116.
[135] Yousuf A Vawda 'Analyzing South Africa compulsory licensing jurisprudence: Is there room for the public interest (PI) in intellectual property (IP)?' (2019) *IPLJ* 182 at 184.
[136] Baker op cit note 94 at 22.
[137] Busch op cit note 36 at 116.
[138] Hill op cit note 103 at 841.
[139] Nirmalya Syam 'Robust Patent Examination or Deep Harmonization? Cooperation and Work Sharing Between Patent Offices' in Correa & Hilty (eds) *Access to Medicines and Vaccines* (2022) 266.

TRIPS includes a provision for additional flexibility known as a compulsory licence. This provision allows for the use of a patent without the permission of the right holder. While the Doha Declaration adds that TRIPS does not limit the grounds for using a compulsory licence, member nations must follow the conditions outlined in Article 31 of TRIPS when exercising this flexibility.[140] Although compulsory licencing provisions have been included in the Patents Act for some time, the mechanism has rarely been used.[141] The CIPC has reported that only five applications for compulsory licences have been recorded, one of which is for a pharmaceutical patent and none of which have been granted.[142]

The compulsory licensing provision allows for government to reduce the effects of a patent by permitting a third party to use the invention, without consent of the patent holder, subject to making payment of reasonable remuneration to the patentee.[143] This provision finds a balance between the rights of a patentee (which spurs innovation) and public interest in benefiting from those inventions (such as access to essential medicines).[144] This exception to a patent holder's exclusive rights is regarded as a powerful tool for improving access to affordable medicines.[145]

The Patents Act allows for compulsory licensing under two conditions, namely: non-working and non-licensing of a patent and the existence of a dependent patent.[146] In the first instance, a compulsory license may be issued for a dependent patent in terms of section 55 of the Patents Act. This can arise where a patented invention, referred to as the dependent invention, cannot be worked without obtaining authorisation under a prior patented invention, referred to as the original patent. In other words, without the granting of the license under prior patent, that dependent patent is blocked or cannot be worked without infringement of the earlier patent.[147] Although not concerning a pharmaceutical product, the only apparent case for issue of a compulsory license in terms of section 55 is that of *Atomic Energy Corporation of South Africa v The Du Pont Merck.*[148]

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[140] Duku op cit note 112 at 27.
[141] Kleyn op cit note 7 at 29.
[142] CIPC Submission by South Africa 'Expectations and Limitations' 9 October 2017 para 2.3 available at *https://www.wipo.int/scp/en/meetings/session_27/3rdparty_comments/south_africa.pdf*, accessed on 14 February 2023.
[143] Hobololo op cit note 63 at 79.
[144] Du Bois op cit note 38 at 80.
[145] Hobololo op cit note 63 at 80.
[146] M du Bois 'State use provisions for patent law, and expropriations: Some comparative law guidelines for South Africa during the Covid-19 crisis and beyond' (2020) 23 *PELJ* 1 at 3.
[147] Hobololo op cit note 63 at 80.
[148] 1997 BIP 90 (CP).

Being the only known reported case, latter courts have not had much opportunity to pronounce under what circumstances these licenses may be awarded, although its interpretation is understood to mean that patent holders should be prevented from blocking fair completion and hindering development.[149] Whilst the court found that the onus of proof rests on the applicant for the license to show that a royalty was reasonable in the circumstances and the applicant's evidence constituted what a reasonable royalty could be, it ultimately found that a number of disputes of fact were apparent and that the matter had to be referred to trial.[150] This raises questions of the appropriateness of the application procedure for compulsory license, as there will undoubtedly be factual disputes of a material nature.

A compulsory license may also be permitted in terms of section 56 of the Patents Act in situations where a patent holder displays abusive behaviour of its patent rights and refused a voluntary license.[151] Abuse occurs when, after a certain period of time and without good reason, a patented invention is not being worked with on a commercial scale or to an adequate extent in South Africa; demand for the patented article in South Africa is not being met to an adequate extent and on reasonable terms; refusal to licence on reasonable terms prejudices trade, industry, or agriculture in the country and it is in the public interest that a licence be granted; and where the demand is being met by importation and the price charged is excessive in relation to the price charged in countries of manufacture.[152] Although the number of reported cases are scant and the courts have not had much opportunity to clarify with particularity what is required in the awarding of a compulsory license in instances of abuse,[153] it is submitted that a court will only grant a compulsory license in exceptional circumstances.[154]

A compulsory license can be obtained through application to the Commissioner of Patents, and which is done through the Court of the Commissioner of Patents which is endowed with the powers of a High Court judge. Accordingly, not only are compulsory licenses granted by way of judicial intervention, but the High Court is similarly the forum in which applications for interdicts are

[149] Du Bois op cit note 38 at 84.
[150] Vawda op cit note 135 at 186-7.
[151] Du Bois op cit note 38 at 84.
[152] Ibid.
[153] Ibid.
[154] Ibid at 86.

sought in instances of patent infringement. It is therefore necessary to review how the courts have discerned these applications.

The case of *Cipla Medpro v Aventis Pharma SA*[155] is relevant as it concerns a dispute regarding a pharmaceutical patented product and which first raised the issues of public health and public interest and which required the court to balance constitutional principles, such as the right of access to health against IPRs.[156] In this matter, the patent holder (Aventis) alleged that a generic manufacturer of its cancer drug (Cipla), had infringed its patent of the drug by way of selling a less expensive form of the patent holder's medicine.[157] Cipla countered the application by alleging that the patent did not meet the requirements of patentability and was invalid due to a lack of novelty and inventive step.[158]

As amicus, the Treatment Action Campaign (TAC) provided that the Patents Act must be interpreted in line with the Constitution and that the rights of the patentee must be balanced with the public who require life-saving medicines.[159] However, the court reasoned that it would not be in the public interest to deny an interdict given the facts of the case, and that no evidence suggested that Aventis could not continue to meet the demand for the drug, nor could Cipla demonstrate that its product provided improved therapeutic benefits or more than a slight decrease in the costs of its generic product compared to Aventis' generic counterpart.[160] Finally, the court determined that there is no material impediment to the supply of medicine to consumers if the interdict was granted.[161] In the aforementioned case, it appears that the court was hesitant to use a human rights-based analysis in its assessment of the IPRs dispute, finding TAC's reasoning in dismissing the interdict to be:

> '[n]o more than opposition to the monopoly that the law confers upon a patentee' and that: '[t]o refuse an interdict only so as to frustrate the patentee's lawful monopoly seems to me to be an abuse of the discretionary powers of a court'.[162]

[155] *Cipla Medpro (Pty) Ltd v Aventis Pharma SA* 2013 (4) SA 579 (SCA).
[156] Vawda op cit note 135 at 190-1.
[157] Ibid 191.
[158] Ibid.
[159] Ibid.
[160] Ibid at 192.
[161] Ibid.
[162] Ibid.

With the *Cipla Medpro v Aventis Pharma SA* case arguably having set a precedent, two related decisions were recently reported. The matter of *Bayer v Dr Reddy* concerned an application restraining Dr Reddy's from selling generic versions of Bayer's medicine at 40% less than Bayer's product.[163] Briefly, Bayer (a German MPC) obtained a patent for blood thinning medicine in 2000, which was set to expire in 2020.[164] Bayer obtained a patent in 2007 for the same medicine to be dosed once daily, as opposed to the previous patent, which required a twice daily dosing.[165] Bayer argued that the dosing change was an inventive step.[166] Bayer's claim, according to Dr Reddy's, was unlawful because it is simply an attempt to register an unpatentable dosage regime and is a clear example of patent evergreening.[167] The court, in granting the interdict, held that:

> 'It can't be denied that the protection of a patent serves the public interest. The monopoly given to the originator of a drug ensures that the public interest is served by ongoing research and development. This principle underpins the protection of patents in our law'.[168]

In a related matter of *Bayer v Clicks*, Bayer sought to restrain Clicks from disposing of the cheaper generic version of the Bayer's medicine.[169] The Court in granting the interdict and citing the latter case together with the decision in *Cipla Medpro v Aventis Pharma SA*, held that:

> '[t]he marginal harm to a small percentage of patients in the private sector (who don't have medical aid or who have to make a small co-payment) was not considered to be sufficient to outweigh the negative public interest effect of failing to enforce valid patents'.[170]

Given the foregoing, it is easy to see why compulsory licences are underutilised. The preceding cases demonstrate patentees' obstinacy in being able to thwart generic competitors and thus access to affordable medicines by patenting their own generics. It also depicts the courts' approach when faced with applications for compulsory licences, which it appears unwilling to grant.[171] In this regard, it has been argued that the High Court judges serving as the Commissioner of Patents were

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[163] *Bayer Intellectual Property GMBH v Dr Reddy's Laboratories (Pty) Ltd* 2021 ZACCP BIP 6 (CP) para 87.
[164] Ciresh Singh 'A battle between patent owners and pharmacies' (2023) 634 *De Rebus* 31.
[165] Ibid.
[166] Ibid.
[167] Tania Broughton 'Pharmaceutical giant Bayer stops Clicks selling cheaper generic blood thinning medication' Ground Up 8 June 2023 available at *https://www.groundup.org.za/article/pharmaceutical-giant-bayer-stops-clicks-selling-cheaper-generic-blood-thinning-medication/*, accessed on 23 May 2023.
[168] *Bayer* op cit note 163 para 98.
[169] *Bayer Intellectual Property GMBH v New Clicks South Africa (Pty) Ltd* 2023 ZACCP para 1.
[170] Ibid para 70.
[171] Vawda op cit note 135 at 197.

appointed without the necessary experience and expertise to deal with IPRs disputes.[172] Another contributing factor for its underusage is the cost prohibitive and protracted procedure involved in attempting to obtain such a license and by that time the parties may no longer consider it a viable option.[173] This is particularly true for small to medium enterprises in costly litigation against MPCs.[174]

A further reason put forward is that the application for a compulsory license should be applied for by juristic persons with the financial and technical resources to work a non-worked patent.[175] Accordingly, without access to such resources, compulsory licensing is reduced to an inoperable measure for civil society to exploit.[176] Another limitation revealed by an examination of the judicial decisions before the Commissioner of Patents is the failure of applicants to discharge the burden of proof.[177] In this regard, a substantially high precedential burden of proof has been set for applicants to evidence that 'competing public interest considerations should sway the balance of convenience in its favour'.[178] Lastly, it has been argued that political sanctions and economic pressures in the form of trade sanctions, legal challenges, and international complaints, as well as the imposition of embargos as a result of failed trade negotiations and agreements between developed and developing countries, act as a deterrent to developing countries' use of compulsory licencing.[179]

One way in which South Africa can address the above-mentioned concerns is to relook at its compulsory license provisions. It is submitted that our provisions are outdated and have not developed in line with other jurisdictions.[180] The Doha Declaration reaffirms the rights of member states to award compulsory licenses, specifically as it concerns medicines and excessive pricing with the purpose of avoiding litigation before WTO dispute settlement bodies.[181] The compulsory license provisions should be amended to include terms facilitating the use of compulsory licensing

[172] CIPC op cit note 142 para 2.1.
[173] Harms op cit note 123 at 10.
[174] Vawda op cit note 135 at 197.
[175] Hobololo op cit note 63 at 80.
[176] Ibid.
[177] Motari et al op cit note 86 at 10.
[178] *Bayer* op cit note 163 para 87.
[179] Vawda op cit note 99 at 232.
[180] Vawda op cit note 59 at 316.
[181] Solomon Frank Sacco 'A comparative study of the implementation in Zimbabwe and South Africa of the international law rules that allow compulsory licensing and parallel importation for HIV/AIDS drugs' (2005) 5 *African Human Rights Law Journal* 105 at 113-14.

for public health emergencies.[182] Reform could also provide the legislature the opportunity to define clear parameters for what is reasonable and in the public interest, and what constitutes sufficient proof to discharge the onus of successfully applying for a compulsory licence.[183] On a reworking of the compulsory license provisions, an expeditious procedure should be contemplated as opposed to the current complex and costly judicial proceedings.[184]

Although there is much that can be done to improve the functioning of the existing compulsory licence provisions, research suggests that their use is questionable, particularly in developing countries.[185] MPCs wield significant power in threatening to withdraw their patented products from developing-country markets or causing their host countries to act unfavourably towards vulnerable nations.[186] Whilst there is also research to suggest that developing nations can use the threat of issuing a compulsory license to negotiate a reduction in medicine prices, this would appear to hinge on the import ability, manufacturing, and capacity constraints of the issuing country; not to mention political pressures and complex compulsory licensing procedures on limited grounds.[187] It is suggested that the compulsory licensing mechanism be effectively utilised in situations of public health emergencies, such as those mentioned in the Doha Declaration, alternatively in instances where life-saving medicines are immediately required, such as the Covid-19 pandemic. Accordingly, the compulsory licensing flexibility may not be a viable solution for long-term sustainable access to affordable medicines, but rather for short-term use or as a last resort.[188]

(c) Competition policy

A less recognised flexibility, but in no way less significant, is subtly embedded in Article 8 of TRIPS. Through Article 8, members are permitted to take measures in preventing abuse of IPRs which unreasonably restrain trade and this has been understood as the right of members to regulate anti-competitive practices of patents through competition law and policy.[189] In addition, Article 31(k) makes mention that compulsory licenses may be used to prevent anti-competitive practices

[182] Vawda op cit note 99 at 239.
[183] Duku op cit note 112 at 40 and 65.
[184] Gray &Vawda 'Health Policy and Legislation' (2017) SAHR 13 at 20.
[185] Ramani & Urias op cit note 79 at 75-6.
[186] Ibid.
[187] Ibid at 76.
[188] Ibid at 82-3.
[189] Baker op cit note 94 at 36.

and is augmented in Article 40 in relation to voluntary licenses. Accordingly, TRIPS promotes the use of competition law and policy to prevent anti-competitive practices which prevent restraints to trade and the abuse of patents.[190] TRIPS does not define 'anti-competitive practices' and members are provided with substantial flexibility in defining the term and in implementing policies and laws best suited for their needs.[191]

South Africa's competition framework includes the enactment of the Competition Act of 1998, which established and empowers the Competition Commission (CC) to investigate anti-competitive behaviour in all sectors of South Africa's economy.[192] If after its investigations the CC finds that a prohibited act has occurred, the matter is referred to the Competition Tribunal for hearing.[193] While it is true that the mere exploitation of the exclusive rights and dominant market position conferred by a patent is not considered an unfair trade restraint, it is argued that the previously discussed patent regime abuses are anti-competitive and can be adequately dealt with under the relevant provisions of South Africa's Competition Act.[194]

It is argued that, unlike the current patent regime, civil society groups and members of the public can use competition law to challenge large pharmaceutical companies for alleged anti-competitive behaviour such as price fixing, excessive pricing, refusal to licence, abuse of dominance, and other prohibited acts.[195] The matter of *Hazel Tau v GlaxoSmithKline and Boehringer Ingelheim*[196] and Treatment Action Campaign's threatened action of excessive pricing against Bristol-Myers Squib demonstrates this.[197] In *Hazel Tau* it was found that the respondent had abused its dominance and prohibited competition to an essential resource[198] by failing to provide licenses for generic manufacturers and charging excessive prices in the absence of reasonable commercial grounds.[199] To avoid involuntary disclosure of their production costs and pricing strategies, the pharmaceutical

[190] Ibid.
[191] Moses Nkomo 'The underutilization of TRIPS flexibilities by Developing Countries' (2010) at 132 WIPO-WTO Colloquium For Teachers Of Intellectual Property (2010) at 132, available at *https://www.wto.org/english/tratop_e/trips_e/colloquium_papers_e/2010/chapter_11_2010_e.pdf*, accessed on 22 May 2023.
[192] OECD 'Excessive Pricing in Pharmaceutical Markets – Note by South Africa' 28 November 2018 at 6, available at h*ttps://one.oecd.org/document/DAF/COMP/WD(2018)117/en/pdf*, accessed on 5 August 2023.
[193] Duku op cit note 112 at 41-2.
[194] Hobololo op cit note 63 at 80.
[195] Ibid.
[196] *Hazel Tau v GlaxoSmithKline and Boehringer Ingelheim*, Competition Commission Case No. 2002 Sep 226.
[197] Nkomo op cit note 191 at 133.
[198] Hobololo op cit note 63 at 80.
[199] OECD op cit note 192 at 8.

duopoly chose to settle the matter outside of the proceedings and by entering into various licencing agreements, which eventually led to the entry of generic competitors and, as a result, price reductions.[200] Similarly, in the matter of Bristol-Myers Squibb, the threat of filing excessive pricing complaints against the pharmaceutical monopoly resulted in an out-of-court settlement and a significant price reduction for the patented drug.[201]

Similar to the scarcity of applications for compulsory licencing, the CC, Competition Tribunal, and its Courts have not had much opportunity to adjudicate on matters of excessive pricing and abuse of dominant position in the pharmaceutical market. The most recent of its investigations is into the alleged excessive pricing and other violations of the Competition Act by local subsidiary Roche Products (Pty) Ltd and its Swiss parent company Roche Holding AG in relation to its life-saving cancer treatment drug.[202] Roche is also accused of obstructing generic drug entry through evergreening and patent thicketing.[203] The matter has been referred to the Competition Tribunal for prosecution. Notably, the Swiss MPC refused to provide the CC with its pricing and cost analytics, despite the CC exhausting all attempts through legal and diplomatic channels.[204] This matter is ongoing.

The above successes demonstrate how competition law and policy can be an effective mechanism in curbing abuses of the patent system and facilitating access to affordable medicines. However, a few challenges are notable. The depository patent system results in a vast number of patents which would need to be individually investigated to determine whether a secondary patent was awarded for inconsequential changes.[205] Furthermore, in identifying patent thickets, it becomes necessary to unravel an entanglement of patents concerning the invention which can include, active ingredients and method of use, which prolongs the investigations.[206] An apparent issue is also found in the investigations and enforcement against the MPCs opposed to their locally based

[200] Ibid.
[201] Nkomo op cit note 191 at 133.
[202] OECD op cit note 192 at 11.
[203] Ibid at 14.
[204] Competition Commission South Africa Press Release 'Competition Commission prosecutes a multinational healthcare company, Roche, for excessive pricing of a breast cancer treatment drug' 8 February 2022 at 1, available at *https://www.compcom.co.za/2022-media-releases/*, accessed on 22 May 2023.
[205] Intergovernmental Group of Experts on Competition Law and Policy 'Competition in Healthcare Markets: Access and Affordability Contribution by The Competition Commission – South Africa' 12 July 2019 at 6, available at *https://unctad.org/system/files/non-official-document/ciclp18th_cont_South_Africa_II.pdf*, accessed on 22 May 2023.
[206] Ibid.

subsidiaries.[207] In these instances, pertinent data is often withheld by the overseas parent companies and access to such information becomes problematic and requires international cooperation,[208] which in the area of transnational competition law appears to be limited.[209] Furthermore, some argue that the CC lacks the authority to prosecute such claims because it oversteps the regulatory authority of the Medicines Control Council and the Pricing Committee, which oversees pharmaceutical product pricing and can use the provisions of section 15C of the Medicines and Related Substances Act to achieve affordable medicines in an effort to protect South African public health.[210]

Despite the limitations identified in the application of competition law and policy in the pharmaceutical sector, it is argued that it can play a complementary role in facilitating affordable pharmaceutical access, particularly in developing countries.[211] Unlike the minimum standards of IPRs protection imposed by TRIPS on developing countries, TRIPS does not create binding obligations on member nations to apply competition law.[212] This allows policy space for signatories to develop and implement their own domestic competition framework in order to foster access to affordable medicines.[213] South Africa's advances in the enforcement of competition law in pharmaceuticals serve as a model for developing countries seeking to balance innovation and access to medicines.[214] The IP regime grants a right holder an exclusive opportunity to exploit its creative work from a market.[215] The competition regulatory regime delineates the ambit for commercialisation.[216] A balance issue arises, and it is proposed that the intersection of competition law and IP law be carefully considered, and that the implementation of such a counterbalanced system be done in a way that fosters healthy competition and spurs innovation for socioeconomic gain.[217] It is submitted that the relationship between IPRs and competition law in South Africa is

[207] Ibid at 7.
[208] Ibid.
[209] Bakhoum, M. 'Intellectual Property Rights, Competition Law and Excessive Pricing of Medicines' in Correa & Hilty (eds) *Access to Medicines and Vaccines* (2022) 280.
[210] Wickins op cit note 28.
[211] Bakhoum op cit note 209 at 280.
[212] Ibid.
[213] Ibid.
[214] Ibid at 281.
[215] Ibid at 279.
[216] Ibid at 293.
[217] IPPRSA op cit note 2 at 30.

still in its embryonic stages, and there is much room for growth in developing workable solutions.[218]

IV CONCLUSION

The purpose of this report was to investigate those aspects of South Africa's patent regime that are relevant to the granting of patents in the field of public health to determine the extent to which South Africa has used the available flexibilities under TRIPS in its domestic law. The use of TRIPS flexibilities is critical to overcoming the limitations that are posed by pharmaceutical patents to facilitating access to affordable medicines, and this report sought to elaborate on those areas that require reform and development.

Based on the research conducted in this report, the issue of affordable pharmaceutical patented products remains a source of concern in developing countries.[219] As a result, there is a pressing need for developing countries, such as South Africa, to address the barriers to achieving and maintaining public health that the IP rights system can create. TRIPS gives its members flexibility in striking a balance between pharmaceutical innovation and public health,[220] including the implementation of strict patentability criteria, patent opposition proceedings, and compulsory licences. The use of anti-competitive practises and competition law is a less discussed flexibility in academic literature.

The report finds that South Africa has fallen short in implementing the TRIPS flexibilities. South Africa, like many other developing countries, faces local capacity constraints as well as economic and political pressure from MPCs and their developed host countries when attempting to implement the TRIPS flexibilities. This report has identified a need for increased capacity and transnational collaboration to achieve the proposed balance envisioned by TRIPS.[221]

The report finds that several areas of South Africa's patent regime are insufficient in their existing form, and this necessitates the need for urgent reform of same. Although an overhaul of the Patents Act is long overdue, it is submitted that a blanket approach to South Africa's patent reform would

[218] Ibid.
[219] Mercurio, et al op cit note 3 at 1-2.
[220] Du Bois op cit note 38 at 80.
[221] Nkomo op cit note 191 at 135.

be ill-advised. Without cooperation from its own government departments and other developing countries, South Africa would almost certainly struggle to implement the proposed reforms.

The report also finds that, while domestic competition law can effectively address instances of IPR's abuse, it is rarely used. [222] This could be due to the seeming conflict between the application of competition law policies and the demands of IPR systems, as well as a lack of development in competition law to address the imbalance.[223] It is argued that IP laws should not be used in isolation, but rather in conjunction with competition laws to facilitate access to affordable medicines.[224] The *Hazel Tau* case demonstrates how competition law can be used as a supplement to correct anti-competitive practises when pharmaceutical patents are abused.

It is posited that a focused and convergent approach be pursued in implementing the various flexibilities to address the issue of providing wider access to affordable medicines. Taking a focused approach would ensure that South Africa concentrates on those aspects of its patent regime that will have an immediate impact while laying the groundwork for future reforms to be implemented in the near future, rather than making unsustainable changes across the board.[225] To this end, the report finds that whilst the threat of issuing a compulsory license may assist South Africa in negotiating lower prices for medicines, the international repercussions may do more harm than good.[226] Whilst reform may render the use of compulsory licensing more effective, it is apparent that this mechanism may be best suited for public health emergencies and is a quick fix for temporarily redressing an imbalance.[227] As a result, a focused approach would seek to implement a substantive search and examination of patents in the first event. A patent reform will largely eliminate many unnecessary patents and unnecessary costs on the public in pharmaceutical innovation. The next step at reform would be to consider legislating for stricter patentability criteria akin to those found in other developing countries such as Argentina and India, and to implement pre- and then post-grant opposition procedures.[228]

[222] Tu Thanh Nguyen 'Competition law and access to pharmaceutical technology in the developing world' (2009) 28(6) *Biotechnology Law Report* 693.
[223] Ibid.
[224] Ibid at 698.
[225] Sokolambe op cit not 133 at 38-9.
[226] Ramani & Urias op cit note 79 at 75-6.
[227] Ibid at 82-3.
[228] Hill op cit note 103 at 841.

In addressing the need for strengthened capacity, it is suggested that at a local level, those government departments which find themselves at the crossroads of innovation and public health operate in tandem rather than in isolation. A convergent approach would see departments such as the DTI work with the Department of Health (DoH) to avoid duplicating and thus wasting efforts in achieving the same or similar mandated objectives. A practical example could see the DTI and DoH sign an official memorandum of understanding regarding their respective roles in pharmaceutical pricing and conducting investigations, assisting one another, and increasing cooperation.[229] This would lead to greater harmony in exercising their regulatory powers.

In addition to measures taken at the national level, a regional convergent approach would entail South-South cooperation in the Southern African Development Community region.[230] South Africa should consider joining organisations such as ARIPO or OAPI with the aim of pooling resources and build bargaining power to overcome capacity constraints and political pressures.[231] This is especially true when many of the same diseases are present in the African region. On an international level, South Africa may seek assistance from BRICS partners such as India and Brazil, which have successfully implemented reforms and effectively used TRIPS flexibilities.[232] BRICS could also form a powerful lobby and increase their bargaining power in negotiations and economic sanctions against Western pharmaceutical giants and their developed host countries.[233]

In conclusion, while the multilateral agreement on IP may not be the best system for developing countries, it does provide significant flexibility in implementing the TRIPS framework.[234] It cannot be gainsaid that IPRs do not operate in a vacuum, and in cases where the functioning of the IP system fails and their flexibilities are not operational, competition law can be used as a complementary tool in providing the necessary balance between access and innovation.[235] Such an approach is TRIPS compliant[236] and conducive to developing long-term access to affordable

[229] OECD op cit note 192 at 16.
[230] Nkomo op cit note 191 at 136. See also Yousuf A. Vawda 'Compulsory Licenses and Government Use: Challenges and Opportunities' in Correa & Hilty (eds) *Access to Medicines and Vaccines* at 97.
[231] Syam op cit note 139 at 244 & 267.
[232] Hill op cit note 103 at 842.
[233] Ramani & Urias op cit note 79 at 75-6 & 82.
[234] Nkomo op cit note 191 at 137.
[235] Bakhoum op cit note 209 at 293.
[236] Azam op cit note 12 at 142.

medicine, as well as an equitable patenting system that promotes pharmaceutical innovation in a competitive market in the public interest.

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