ENHANCING ACCESS TO PHARMACEUTICALS BY REGULATING THE ANTICOMPETITIVE EFFECTS OF PATENTS IN SOUTH AFRICA.

by

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DECLARATION

I, 473559, declare that this research report is my own unaided work. It is submitted in partial fulfilment 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.

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ABSTRACT

The South African regulatory framework does not adequately address the interface between intellectual property (IP) and competition law thus rendering patents vulnerable to anti-competitive abuse and missing a critical opportunity to facilitate greater access to pharmaceuticals. This paper dissects policy and regulatory inadequacies from three perspectives. Firstly, by highlighting the slow pace in addressing necessary reform. Particularly in the context of global convergence in IP regulation and policy for nations that are party to the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). Secondly, the disuse of existing regulatory tools and policy instruments. Thirdly, the paper considers the fragmentation and disconnect between the broad set of IP regulators. There is scope to develop fields of work and guiding principles related to the interaction between competition law and intellectual property laws in South Africa to facilitate greater access to pharmaceuticals. To give true meaning to South Africa's intention to move towards universal healthcare, a collaborative working model between all healthcare, competition and IP regulators to ensure regulatory reform that is fit for purpose and quality universal access to healthcare is required.

KEYWORDS

Access to Pharmaceuticals, Competition, Intellectual Property, TRIPS, Regulatory Reform.

LIST OF ACRONYMS AND ABBREVIATIONS

AIDS	Acquired Immunodeficiency Syndrome
ARV	Anti-Retroviral drugs
BI	Boehringer Ingelheim (Pty) Ltd
CIPC	Companies and Intellectual Property Commission
CompCom	Competition Commission (South Africa)
DOH	Department of Health
DTI	Department of Trade and Industry
GSK	GlaxoSmithKline South Africa (Pty) Ltd
HIV	Human Immunodeficiency Virus
IP	Intellectual Property
IPR	Intellectual Property Right
MCC	Medicines and Control Council
MRSA	Medicines and Related Substances Act
NHREC	National Health Research Ethics Council
OECD	Organization for Economic Co-operation and Development
SAHPRA	South African Health Products Regulatory Authority
SANAS	South African National Accreditation System
SAPC	South African Pharmacy Council
SEP	Single Exit Price
TRIPS	The Agreement on Trade-Related Aspects of Intellectual Property Rights
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

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I. INTRODUCTION

The pharmaceutical industry is characterised by high production costs for new products, vulnerability to competition and high stakes in ownership.[1] Abuse of monopolies created in an area essential to public health raises a myriad of issues. Considering the separation of these regulatory and policy areas, it is necessary to ensure that the appropriate regulatory and policy response is implemented. The optimization of patent protection and fair competition aims entails the realisation that these areas co-exist and any distortions or issues concerning policy in either area influence the other.[2] The object of competition law related to Intellectual Property ('IP') law is to provide intervention and oversight on the exercise of Intellectual Property rights ('IPR') in the market.[3] An increasingly contentious issue in the competition policy-IP interface concerns patent abuse and its effect on the market, particularly access to pharmaceuticals.

The Agreement on Trade-Related Aspects of Intellectual Property Rights ('TRIPS') is an all-inclusive and far-reaching IP treaty, with implications for nations that intend to engage in global trade.[4] TRIPS aims to unify global approaches to ownership of and protection of IPRs to promote the growth of international commerce in information goods and services.[5] The effectiveness of the application and implementation of TRIPS and its flexibilities by developing nations, as a means to promoting competitive pharmaceutical markets and thereby access to pharmaceuticals is widely debated and questioned.[6] Despite the implementation of TRIPS flexibilities in IP policy, South African patent law lacks clear guidelines and directives for approaching the competition policy-IP interface. This presents a stumbling block to access.

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[1] William A.W. Neilson, Robert G. Howell, and Souichirou Kozuka 'Intellectual Property Rights and Competition Law and Policy: Attempts in Canada and Japan to Achieve a Reconciliation' (2002) *Washington University Global Studies Law Review* 333-4.

[2] William E. Kovacic 'Intellectual Property Policy and Competition Policy' (2011) 66 *NYU Annual Survey of American Law* 424.

[3] Mor Bakhoum 'Intellectual Property, Competition Law and Access to Pharmaceuticals: The Relevance of a 'Market Approach' to the Exercise of Intellectual Property Rights' available at *https://www.wto.org/english/tratop_e/trips_e/colloquium_papers_e/2013/chapter_9_2013_e.pdf,* assessed 18 November 2021.

[4] Jeremy de Beer, Jeremiah Baarbé, and Caroline B. Ncube 'Evolution of Africa's Intellectual Property Treaty Ratification Landscape' 2018 *The African Journal of Information and Communication* 74.

[5] World Trade Organisation 'Agreement on Trade-Related Aspects of Intellectual Property Rights - Preamble' available at https://www.wto.org/english/docs_e/legal_e/27-trips.pdf, assessed 14 January 2022.

[6] Marion Motari, Jean-Baptiste Nikiema, Ossy M. J. Kasilo, Stanislav Kniazkov, Andre Loua, Aissatou Sougou and Prosper Tumusiime 'The role of intellectual property rights on access to medicines in the WHO African region: 25 years after the TRIPS agreement' 2021 *BMC Public Health* 1.

IP law is a statutory mechanism that regulates and operates within various other policy mechanisms.[7] This research report places reliance on Ghosh's premise that centres on an understanding of IP as more of a system of laws regulating creative activity as opposed to solely analogous to real property rights.[8] This broader view of IP law assists in understanding more complex and contentious areas of patent policy in the pharmaceutical arena.[9]

South Africa's implementation and utilisation of various IP policy tools to promote competition, with specific reference to the pharmaceuticals market is scant and as a result, the literature addressing these aspects considered in this paper is based on developments in more experienced jurisdictions such as the United States of America, the European Union and Canada. This is a limitation to note in the scope of this analysis. The analysis is nonetheless necessary from a law reform perspective. The development of sound policy applications in the South African context is important and necessary, and a common thread throughout the writer's analysis. This research report will consider the extent to which pharmaceutical patents lend themselves to the scrutiny of competition authorities and further the extent to which the pharmaceutical industry self-regulates the potentially anticompetitive effects of patents. Regulatory and policy interventions to address the anticompetitive abuses of pharmaceutical patents in South Africa are proposed, with due regard to the flexibilities inherent in TRIPS. For improved access to pharmaceuticals, this paper proposes a way to clarify and regulate the competition policy-IP interface. This research report refers to patented pharmaceutical medicines and products as pharmaceuticals although these terms may be used interchangeably throughout the report.

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[7] Companies and Intellectual Property Commission 'Submission by South Africa: Exceptions and Limitations' available at *https://www.wipo.int/export/sites/www/scp/en/meetings/session_27/3rdparty_comments/south_africa.pdf*, assessed 1 September 2022.

[8] Ghosh S. 2008. "When property is something else: Understanding intellectual property through the lens of regulatory justice." In *Intellectual property and theories of justice*, Gosseries A, Marciano A and Strowel (eds), 106-121. Palgrave Macmillan, London 106.

[9] Ibid at 107.

II. REGULATION OF THE SOUTH AFRICAN PHARMACEUTICAL MARKET OUTSIDE OF PATENT LAW

a) The pharmaceutical sector regulatory framework and the generic drug as a means to greater access

Successful and purposeful policy direction requires not only theoretical understanding but an in-depth and practical understanding of the affected market.[10] Patent law operates within a wide regulatory context, such as competition and pharmaceuticals. Patent law, therefore, requires harmonisation with such systems.[11] The nature, role and operation of IP is interconnected to various regulatory mechanisms outside of IP. In South Africa, the pharmaceutical sector regulators may have a crucial role to play in enhancing access to pharmaceuticals.

Improvements to the affordability of drugs invariably result in increased access. The data suggests that South Africa consumes a larger volume of generic prescription medicines whereas, from a spending perspective, the spending on originator prescription medicines is higher.[12] This may indicate a significant pricing differential and possible pricing distortion in the pharmaceutical market. Where patients rely on the public healthcare system, they often cannot afford pharmaceuticals and, where possible, rely on generic treatments or, at worst, forego treatment altogether.[13] The absence of generics in the market may pose a significant threat to access to pharmaceuticals and public health that requires appropriate regulatory intervention and support.

The South African pharmaceutical sector is highly regulated.[14] Six central regulators play an essential role in the regulation of the pharmaceutical sector. These are, the Medicines and Control Council ('MCC') in regulating the pharmaceuticals sold in the country, the South African Pharmacy council ('SAPC'),governs the pharmacy profession as a whole, the South African

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[10] Robert D Anderson and William E Kovacic 'The application of competition policy vis-à-vis intellectual property rights: The evolution of thought underlying policy change - WTO Staff Working Paper, No. ERSD-2017-13, World Trade Organization (WTO), Geneva' (2017) available at *https://www.wto.org/english/res_e/reser_e/ersd201713_e.pdf*, assessed 21 July 2022.

[11] Ghosh op cit note 8 at 118.

[12] Organisation for Economic Co-operation and Development 'Directorate for Financial and Enterprise Affairs Competition Committee: Excessive Pricing in Pharmaceutical Markets – Note by South Africa DAF/COMP/WD(2018)117)' (2018) available at *https://one.oecd.org/document/DAF/COMP/WD(2018)117/en/pdf*, assessed 18 January 2022.

[13] Ibid.

[14] Organisation for Economic Co-operation and Development 'Directorate for Financial and Enterprise Affairs Competition Committee: Excessive Pricing in Pharmaceutical Markets – Note by South Africa DAF/COMP/WD(2018)117)' (2018) available at *https://one.oecd.org/document/DAF/COMP/WD(2018)117/en/pdf*, assessed 18 January 2022.

National Accreditation System ('SANAS') in providing accreditation to pharmaceutical laboratories, the Department of Health ('DOH') regulates the pricing of all pharmaceuticals sold in the country, the National Health Research Ethics Council ('NHREC') governs the conducting of clinical trials in South Africa, and finally, the South African Health Products Regulatory Authority ('SAHPRA') exercises broad oversight in matters concerning pharmaceuticals, scheduled substances, clinical trials, and medical devices, and replaces the MCC.[15] As South Africa moves towards universal healthcare coverage for all citizens, strong policy approaches that govern all role-players concerned are critical to ensure meaningful access to pharmaceuticals.[16]

b) Regulatory reform in the pharmaceutical regulatory sector: price control

In November 2018, the Organization for Economic Co-operation and Development ('OECD') held round table discussions on 'Excessive Pricing in Pharmaceuticals'.[17] The OECD discussions were facilitated to discuss possible competition intervention in the pharmaceutical market and how economic and legal theories might be able to support such initiatives; to consider and highlight the issues in competition cases that dealt with pharmaceutical markets and, in particular, excessive pricing; to understand the extent of price regulation in the pharmaceutical market as well as the type of the collaboration between sectoral regulators and competition authorities in regulating this aspect.[18] The South African Competition Commission's ('CompCom') submissions to the OECD detailed the structure of South Africa's healthcare system as a dual system comprising the public and private sector with unequal resources and access to pharmaceuticals.[19] At the time, the private healthcare sector catered to an estimated sixteen per cent of the population who had access to medical insurance through membership to Medical Aid Schemes and could therefore afford high-quality private healthcare.[20] The private healthcare sector accounted for 84 per cent of total

[15] Organisation for Economic Co-operation and Development 'Directorate for Financial and Enterprise Affairs Competition Committee: Excessive Pricing in Pharmaceutical Markets – Note by South Africa DAF/COMP/WD(2018)117)' (2018) available at *https://one.oecd.org/document/DAF/COMP/WD(2018)117/en/pdf*, assessed 18 January 2022.

[16] V Bangalee and F Suleman 'Is there transparency in the pricing of medicines in the South African private sector? (2018) 108(2) *South African Medical Journal* 83.

[17] Ibid.

[18] Organisation for Economic Co-operation and Development 'Directorate for Financial and Enterprise Affairs Competition Committee: Excessive Pricing in Pharmaceutical Markets – Note by South Africa DAF/COMP/WD(2018)117)' (2018) available at *https://one.oecd.org/document/DAF/COMP/WD(2018)117/en/pdf*, assessed 18 January 2022.

[19] Ibid.

[20] Organisation for Economic Co-operation and Development 'Directorate for Financial and Enterprise Affairs Competition Committee: Excessive Pricing in Pharmaceutical Markets – Note by South Africa

pharmaceutical spending in the country. In comparison, the public healthcare sector served an estimated 84 per cent of the population, accounting only for 16 per cent of pharmaceuticals expenditure.[21] In South Africa, overall spending on pharmaceuticals is driven by the private healthcare market.[22] Abuse of patent rights by pharmaceutical companies by patent holders may result in excessive pricing and reduced competition, severely prejudicing access to pharmaceuticals by the public healthcare sector, thereby affecting a large portion of the population. It is widely accepted that generics offer a significant opportunity to broaden and facilitate access to pharmaceuticals. The expansion of markets is often a direct result following the expiry of a patent.[23]

Amendments to the Medicines and Related Substances Act[24] ('MRSA') allowed for establishing a Pricing Committee with a mandate to correct pricing distortions in the market through the development of transparent pharmaceutical pricing systems.[25] The amended MRSA made *pricing and procedural* provision for the parallel importation of drugs produced by manufacturers other than the patent holder (section 15C), specific prohibition on bonus, rebate schemes and other sale incentives (section 18A), prohibitions on medicine sampling (section 18B), the introduction of mandatory generic substitution (section 22F) and the formation of a Pricing Committee (section 22G).[26] The rationale for introducing price controls was the government's belief that pharmaceuticals are essential for ensuring public health, and adequate regulation was required to provide controlled pricing and prevent inflated pricing and abuses by pharmaceutical

DAF/COMP/WD(2018)117)' (2018) available at *https://one.oecd.org/document/DAF/COMP/WD(2018)117/en/pdf*, assessed 18 January 2022.

[21] Organisation for Economic Co-operation and Development 'Directorate for Financial and Enterprise Affairs Competition Committee: Excessive Pricing in Pharmaceutical Markets – Note by South Africa DAF/COMP/WD(2018)117)' (2018) available at *https://one.oecd.org/document/DAF/COMP/WD(2018)117/en/pdf*, assessed 18 January 2022.

[22] Ibid.

[23] Yu-Fang Wen and Thapi Matsaneng 'Patents, Pharmaceuticals and Competition: Benefiting from an effective patent examination system'(2014) available at *http://www.compcom.co.za/wp-content/uploads/2014/09/Patents-Pharmaceuticals-and-Competition-Yu-Fang-Wen-and-Thapi-Matsaneng-Annual-Competition-Conference-2013.pdf* , assessed 15 May 2022.

[24] Act 101 of 1965.

[25] Organisation for Economic Co-operation and Development 'Directorate for Financial and Enterprise Affairs Competition Committee: Excessive Pricing in Pharmaceutical Markets – Note by South Africa DAF/COMP/WD(2018)117)' (2018) available at *https://one.oecd.org/document/DAF/COMP/WD(2018)117/en/pdf*, assessed 18 January 2022.

[26] Skhumbuzo Ngozwana 'Policies to Control Prices of Medicines: Does the South African Experience Have Lessons for Other Countries?' in M. Mackintosh et. al. Making Medicines in Africa (2016) 210.

manufacturers through rebates and bonus incentives to promote the dispensing of particular pharmaceuticals.[27]

The MRSA amendments have intervened by regulating price increases and pricing mechanisms along the pharmaceuticals value chain, following the manufacture of pharmaceuticals and before their sale to consumers. The MRSA amendments achieved their aims by setting dispensing fees for pharmacies and a framework for logistics fees in wholesale and distribution of pharmaceuticals.[28] The objective of the MRSA amendments is not entirely separate from the purposes of this report. The report addresses the anticompetitive abuse of patent rights that may restrict access to pharmaceuticals. Price control is a significant component of access to pharmaceuticals. Price control is largely connected to the argument expounded throughout this report, of IP as a system of regulatory components regulating the products of innovation and creativity.

In 2004, the Single Exit Price ('SEP') regulatory framework came into being; the framework was implemented to ensure that manufacturers sell pharmaceuticals at standardised prices.[29] The Minister of Health sets annual increases in the SEP, as well as any deviations from increases in terms of the SEP. [30] The framework was developed in a context where patent holder firms dominated the pharmaceuticals market with little competition from generic manufacturers and pharmaceutical prices in South Africa were unjustly inflated through bonus systems, discounts, rebates and various questionable incentives that led to the dispensing of more expensive drugs.[31] The incentives and additional measures employed by pharmaceutical firms increased the final costs of pharmaceuticals by 50 per cent.[32]

In the first year, immediately after introducing the SEP framework, a 22 per cent decrease in the price of pharmaceuticals were reported.[33] Although marginal in the larger picture of healthcare costs, the decrease is significant in showing that effective regulation contributes to the affordability of pharmaceuticals. While early data suggests success, the full impact of the SEP framework requires further investigation.[34] The pricing of pharmaceuticals in South Africa is based on the

[27] Ngozwana op cit note 27.
[28] Ibid at 211.
[29] Ngozwana op cit note 27 at 210.
[30] Ibid.
[31] Ngozwana op cit note 27 at 210.
[32] Ibid at 218-9.
[33] Ngozwana op cit note 27 at 218-9.
[34] Ibid at 219.

SEP framework. However, manufacturer's set a price, and the SEP framework steps in thereafter to regulate increases.[35] A tendency by pharmaceutical patent holders is to set prices high, and this is evidenced by comparatively higher pricing as compared to other nations.[36] For instance, Imatinib, a cancer medicine, cost around R 867.00 per tablet in South Africa in 2013 and around R 86.00 in India.[37] In India, a patent application for this medicine was rejected since it was a new formulation of an old drug.[38] This centres patentability as a key factor to pricing and enhanced access.

Despite the amendments outlined above, patent holder companies retain carte blanche to set initial and launch prices.[39] At the same time, the pricing committee makes decisions concerning increases under the SEP framework.[40] It could be argued that any action concerning prices set by patent holders would best be left to mechanisms regulating patent rights and competition authorities. The government has proposed an international benchmarking approach to setting prices where the SEP would be set to the value of the lowest priced medicine within the basket of benchmarked countries.[41] A legislative reform of this nature would potentially reduce the costs of pharmaceuticals by an estimated 25 per cent.[42] However, the initiative has been in the works since 2006 with no material developments due to strong opposition.[43] This paper argues that there are reforms that may achieve worthwhile results with less opposition.

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[35] Organisation for Economic Co-operation and Development 'Directorate for Financial and Enterprise Affairs Competition Committee: Excessive Pricing in Pharmaceutical Markets – Note by South Africa DAF/COMP/WD(2018)117)' (2018) available at *https://one.oecd.org/document/DAF/COMP/WD(2018)117/en/pdf*, assessed 18 January 2022.

[36] Ibid.

[37] Yu-Fang Wen and Thapi Matsaneng 'Patents, Pharmaceuticals and Competition: Benefiting from an effective patent examination system'(2014) available at *http://www.compcom.co.za/wp-content/uploads/2014/09/Patents-Pharmaceuticals-and-Competition-Yu-Fang-Wen-and-Thapi-Matsaneng-Annual-Competition-Conference-2013.pdf* , assessed 15 May 2022.

[38] Ibid.

[39] V Bangalee and F Suleman 'Is there transparency in the pricing of medicines in the South African private sector? (2018) 108(2) *South African Medical Journal* 83.

[40] Ngozwana op cit note 26 at 211.

[41] Alex van den Heever 'Review of the Competition in the South African Health System' (2012) available at *http://www. compcom.co.za/wp-content/uploads/2014/09/Review-of-Competition-in-the-South-African-Health-System.pdf*, accessed 13 May 2022.

[42] Ibid.

[43] Alex van den Heever 'Review of the Competition in the South African Health System' (2012) available at *http://www. compcom.co.za/wp-content/uploads/2014/09/Review-of-Competition-in-the-South-African-Health-System.pdf*, accessed 13 May 2022.

It is submitted that the pricing controls introduced by the amendments to the MRSA dealt only with curbing rampant and unregulated price increases while creating an enabling procedural environment for the introduction of measures to potentially reduce the costs of pharmaceuticals in the form of parallel importation and mandatory generic substitution. The MRSA amendments created an enabling procedural environment to exploit TRIPS flexibilities. It is submitted that a large component of fully taking advantage of TRIPS flexibilities to enable greater access to pharmaceuticals can be done through collaborative IP and competition law regulatory reform. The MRSA amendments brought about transparent price controls along the pharmaceuticals value chain while patent holder companies retained carte blanche to set initial prices.[44] The stage has been set for primary regulatory price controls to pharmaceutical pricing increases, while the initial pricing of pharmaceuticals remains a crucial constraint to access to drugs. The importance of the pharmaceutical sector regulators cannot be gainsaid; it is evident that to facilitate access, broader regulatory collaboration is required.

III. STRATEGIC PATENTING OF PHARMACEUTICALS: THE INTERFACE BETWEEN PHARMACEUTICAL PATENTS AND COMPETITION

Rigorous academic interrogation of the competition policy-IP interface in competition advocacy is undoubtedly necessary. It has laid the foundation for the global development of policy responses in this area and what is arguably a gradual global regulatory convergence.[45] The object of competition law is to regulate the consumer market and economy whereas IP protection focuses on protecting the expression of the innovator.[46] A common goal of IP and competition laws is to promote innovation and enhance consumer welfare. Innovation is facilitated by IP laws, which provide incentives for its diffusion and commercialization.[47] Additionally, IP laws give creators of novel and useful products, more efficient processes, and enforceable property-like rights.[48]

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[44] Ngozwana op cit note 26 at 211.

[45] Robert D Anderson and William E Kovacic 'The application of competition policy vis-à-vis intellectual property rights: The evolution of thought underlying policy change - WTO Staff Working Paper, No. ERSD-2017-13, World Trade Organization (WTO), Geneva' (2017) available at *https://www.wto.org/english/res_e/reser_e/ersd201713_e.pdf*, assessed 21 July 2022.

[46] Itumeleng Lesofe 'Finding the Right Balance Between the Enforcement of Law and The Protection of Intellectual Property Rights' (2017) 29(3) *South African Mercantile Law Journal* 454.

[47] US Department of Justice and the Federal Trade Commission 'Antitrust Guidelines for the Licensing of Intellectual Property' (1995) available at *https://www.justice.gov/sites/default/files/atr/legacy/2006/04/27/0558.pdf*, assessed 21 July 2022.

[48] Ibid.

Through competition laws, innovation and consumer welfare are promoted by prohibiting actions that may harm competition whether concerning existing or emerging consumer services.[49] Learning processes have led to major developments concerning the competition policy-IP interface. Researchers have focused on licensing agreements, anti-competitive patent settlement agreements, and arrangements to eliminate patent thickets, exclusionary conduct, and abuse of dominance.[50] The point of departure of competition authorities is that IPR are acquired legitimately in a system that grants IPR for deserving creative endeavours.[51] IP is not presumed to automatically confer market power, and consequently, competition law does not concern itself with the use of IPR in the ordinary course.[52] Viewed under this light, IP does not grant a rights holder a monopoly in any economically substantial sense.[53] Essentially, IP rights generally do not harm competition in a manner that raises concerns among competition authorities. The focus of competition authorities is, therefore, anticompetitive stratagem and they're accompanying effects. Consequently, competition law enforcement must only provide corrective measures where they are warranted and where the IP protection system alone cannot prevent unlawful restrictions on competition.[54] In 2018, the Secretariat of the OECDt proposed that a thorough understanding of market dynamics and sectoral regulations is necessary to effectively apply competition law in the pharmaceutical sector.[55] This implies that regulatory approaches to foster access to

[49] US Department of Justice and the Federal Trade Commission 'Antitrust Guidelines for the Licensing of Intellectual Property' (1995) available at *https://www.justice.gov/sites/default/files/atr/legacy/2006/04/27/0558.pdf*, assessed 21 July 2022.

[50] Robert D Anderson and William E Kovacic 'The application of competition policy vis-à-vis intellectual property rights: The evolution of thought underlying policy change - WTO Staff Working Paper, No. ERSD-2017-13, World Trade Organization (WTO), Geneva' (2017) available at *https://www.wto.org/english/res_e/reser_e/ersd201713_e.pdf*, assessed 21 July 2022.

[51] World Trade Organization ('WTO'), World Health Organization ('WHO') and World Intellectual Property Organization ('WIPO') 'Promoting Access to Medical Technologies and Innovation' (2020) 2 World Trade Organization, World Health Organization and World Intellectual Property Organization 97.

[52] Ibid.

[53] Robert D Anderson and William E Kovacic 'The application of competition policy vis-à-vis intellectual property rights: The evolution of thought underlying policy change - WTO Staff Working Paper, No. ERSD-2017-13, World Trade Organization (WTO), Geneva' (2017) available at *https://www.wto.org/english/res_e/reser_e/ersd201713_e.pdf*, assessed 21 July 2022.

[54] Ibid.

[55] Organisation for Economic Co-operation and Development 'Directorate for Financial and Enterprise Affairs Competition Committee: Excessive Pricing in Pharmaceutical Markets – Background Note by Secretariat DAF/COMP (2018)12' (2018) available at *https://one.oecd.org/document/DAF/COMP/WD(2018)117/en/pdf*, assessed 21 July 2022.

pharmaceuticals require deep rooting in economic principles, their operation in the sector, and in-depth understanding of all sectoral regulation and its impact.

In the South African context, the Department of Trade and Industry ('dti') recommends a joint effort between IPR policymakers and the CompCom to clarify the ambit of the intersection of Competition Law and IPR with little clarity as to how this will translate in practice.[56] On the other hand, IPRs policy and regulation are equally unclear regarding the substantive application of the tools at its disposal should an overlap of this nature occur. By considering IP as a regulatory process, we can better assess the roles of other aspects of IP that have traditionally been viewed as distinct, such as delict, contract, competition law, and health policy and law.[57] Consequently, targeted and more precise policymaking can be conducted to remedy IP regulatory deficiencies.

A significant component of global competition advocacy has been ensuring the soundness of patent granting mechanisms so as not to weaken competition.[58] Kovacic also observes that IP issues raised in the competition policy realm often have their origin in the IPR-granting process.[59] Improvements in the process of granting rights would be the first-best solution to competition problems concerning IP.[60] Anderson and Kovacic argue that the prosecution of competition cases based on anticompetitive use of IP law is a second-best solution.[61] This view emphasises IP regulation as a first-line defence. Competition policy, therefore, acts as a secondary line of defence. In competition advocacy and IPR-related research, the expansion of patentable subject matter over time is a concern.[62] This may increase competition prosecution in the IP realm, thereby exerting unnecessary pressure on competition authorities.

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[56] The Department of Trade and Industry '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*, assessed 28 January 2022.
[57] Ghosh op cit note 8 at 113.
[58] Kovacic op cit note 2 at 423.
[59] Ibid.
[60] Kovacic op cit note 2 at 423.
[61] Robert D Anderson and William E Kovacic 'The application of competition policy vis-à-vis intellectual property rights: The evolution of thought underlying policy change - WTO Staff Working Paper, No. ERSD-2017-13, World Trade Organization (WTO), Geneva' (2017) available at *https://www.wto.org/english/res_e/reser_e/ersd201713_e.pdf*, assessed 21 July 2022.
[62] Robert D Anderson and William E Kovacic 'The application of competition policy vis-à-vis intellectual property rights: The evolution of thought underlying policy change - WTO Staff Working Paper, No. ERSD-2017-13, World Trade Organization (WTO), Geneva' (2017) available at *https://www.wto.org/english/res_e/reser_e/ersd201713_e.pdf*, assessed 21 July 2022.

Strategic patenting in the pharmaceutical market entails the filing of patents with the deliberate intention of preventing competitors, with the intent of creating prior art, potential or otherwise, from being granted patents, and practices to extend the span and operation of their patents in the geographical markets where their patents operate.[63] The result of such strategic patenting is the impermissible and illegal extension of otherwise legitimate right to exclude others granted by the operation of a patent.[64] It has far-reaching effects, firstly through the abuse of monopoly power by the patent right holders and, secondly, as a result of strategic patenting, raising concerns about access to pharmaceuticals.

Anticompetitive patent use remains a threat to access to pharmaceuticals, particularly in underdeveloped regulatory environments.[65] Strategic patenting operates for the sole purpose of benefitting the business position of pharmaceutical patent holder firms and favourably influencing the behaviour of competitors.[66] A number of anticompetitive practices of patents that restrict access to pharmaceuticals include restrictive licensing agreements, patent evergreening, litigation to stop competition, patent settlements, 'pay-for-delay' agreements between originators and generic companies, excessive prices, refusals to license, and unchecked market dominance.[67] Strategic patenting comes in various forms, both technical and complex. They can occur at various stages of the lifecycle of IPR from acquisition, use, and disposal. This paper considers strategic patenting broadly as an anticompetitive abuse of the patent right. This is consistent with the approach of South African competition authorities, as discussed below, as a contravention of the Act.

IV. SHORTCOMINGS IN SOUTH AFRICAN IP LAW CREATE AN ENABLING ENVIRONMENT FOR ANTICOMPETITIVE PATENT USE

South Africa is the most developed sub-Saharan African country and is home to one of the largest pharmaceutical companies in Africa, Aspen Pharmacare.[68] Through its position South Africa can

[63] Vuyisile Hobolo '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* at 78.
[64] Ibid.
[65] Yousuf A Vawda and Bonginkosi Shozi *Eighteen years after Doha: An analysis of the use of public health TRIPS flexibilities in Africa* (2020 Research Paper, No. 103, South Centre, Geneva) 5.
[66] Hobolo op cit note 63 at 78.
[67] Chan Park, Achal Prabhala and Jonathan Berger 'Using Law to Accelerate Treatment Access in South Africa: An Analysis of Patent, Competition and Medicines Law' available at *https://www.undp.org/content/dam/undp/library/hivaids/English/using_law_to_accelerate_treatment_access_in_south_africa_undp_2013.pdf*, assessed 28 January 2022.
[68] Chenxi Jiao, 'The Negative Effect of Pharmaceutical Patents on South African Industry' (2007) 5(3) *Cardozo Public Law, Policy, and Ethics Journal* 657.

benefit Africa through research and development, and potentially, distribution.[69] Competition law may act as a complementary measure to the enforcement mechanisms already existing under the TRIPS agreement in that competition law authorities may initiate proceedings and impose fines in the case of abuses that infringe competition enactment provisions.[70] However, the South African regulatory framework does not adequately address the competition policy-IP interface, thereby missing a critical opportunity to facilitate greater access to pharmaceuticals. This section highlights the various South African patent law shortcomings that allow the proliferation of anticompetitive patent use.

A common feature of competition cases involving patent licensing issues is the presumption that owning patent rights automatically creates market power based on the ownership of such rights, which is not always the case.[71] Each instance of alleged infringement is to be adjudicated on its own merits. For instance, the granting of a patent right does not always equate to market power. A further vital point to note is that large profits are not objectionable from a competition perspective. Instead, the concern is the prevention of concerted practices, practices unduly manipulating market power, and the abuse of dominant positions.[72] A finding of contravention of the Act depends on showing a net anticompetitive effect. Strategic use of patents, which unduly prevents others from innovating and competing, would amount to such an anti-competitive act in certain circumstances.[73]

There are inherent dangers to competition in awarding overly broad and invalid patents. First, questionable patents affect innovation either by making it costlier or discouraging it completely. Secondly, in incremental innovation industries that focus on minor improvements to existing innovations, questionable patents potentially increase 'defensive patenting' and may sometimes result in patent thickets that require complex licensing arrangements.[74] The key controls to address

[69] Jiao op cit note 68.
[70] Ibid.
[71] Organisation for Economic Co-operation and Development 'Directorate for Financial and Enterprise Affairs Competition Committee: Excessive Pricing in Pharmaceutical Markets – Background Note by Secretariat DAF/COMP (2018)12' (2018) available at *https://one.oecd.org/document/DAF/COMP/WD(2018)117/en/pdf*, assessed 21 July 2022.
[72] Competition Act 89 of 1998.
[73] Elna Mcleary 'The Competition Act has pierced patent law's bubble' (2013) *Pharmaceutical and Cosmetic Review* 32.
[74] Federal Trade Commission 'To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy – A Report by The Federal Trade Commission October 2003' available at

the above concerns are recognised as minimizing the issuance of questionable patents through strengthening registrations requirements, implementing more publicly accessible measures of disposing of dubious patents such as post-grant review and opposition, publicly accessible information on registered patents, and enhanced prioritization of economics in IP policymaking.[75] Notwithstanding global anticompetitive abuses of patents, various shortcomings in the South African Patent regulatory regime make it particularly vulnerable. The discussion below highlights the susceptibility of the South African patent system to the strategic and anticompetitive patent abuses described above.

a) Guidelines on the implementation of existing legislation on the competition policy-IP interface: a missed opportunity

Section 10(4) of the Competition Act[76] is the only reference to IPR in the Competition Act. The provision relates to exemption awarded to firms under chapter two of the Competition Act, concerning any agreement or practice, or category of agreements or rules, *that relates to the exercise of IPRs*. The provision's wording indicates broad application to the exercise of IPR and exemption only at the instance of a party to the admittedly infringing conduct. South African law does not provide a clear guideline or directive on approaching IP-related competition issues aside from the exemption set forth under the Act. IPRs have only come up in a single case concerning an exemption application under section 10(4) of the Act, with little specificity.[77] The exemption application concerned a new entity established in South Africa by Visa International Service Association, and Visa International Service Association Incorporated ('Visa'), Visa South Africa (Pty) Ltd ('Visa SA').[78] Visa and all South African banks would form shareholders of Visa SA and from time to time would discuss Visa business operations in South Africa including the issuing of Visa interchange rates, in contravention of the Competition Act.[79] Dingley and Knoetze are of the view that the findings of this decision are not entirely straightforward as exemption under

https://www.ftc.gov/sites/default/files/documents/reports/promote-innovation-proper-balance-competition-and-patent-law-and-policy/innovationrpt.pdf, assessed 27 July 2022.

[75] Robert D Anderson and William E Kovacic 'The application of competition policy vis-à-vis intellectual property rights: The evolution of thought underlying policy change - WTO Staff Working Paper, No. ERSD-2017-13, World Trade Organization (WTO), Geneva' (2017) available at *https://www.wto.org/english/res_e/reser_e/ersd201713_e.pdf*, assessed 21 July 2022.

[76] Act 89 of 1998.

[77] Visa SA (a branch of Visa International Service Association Incorporated) Case number 2001 JUL 4.

[78] Visa International Service Association 'Visa International Service Association - Response to the South African Banking Enquiry' (2010) available at *https://info.publicintelligence.net/VisaSouthAfrica.pdf*, assessed 15 May 2022.

[79] Ibid.

section 10(4) did not intend to deal with agreements of this nature.[80] It may be that the wide ambit of the provision allowed for the consideration of such an agreement despite this not necessarily being the legislative intention. In the pharmaceutical context, the provision creates a burdensome threshold for patent holders as it necessitates an admission of anticompetitive conduct without certainty as to the effect of an admission outside the exemption procedure.[81] The absence of guidelines for its application and import is likely to be directly correlated with the lack of the provision's use.

Forum shopping is the inevitable result of litigants seeking out adjudicative forums that may produce the most beneficial outcomes.[82] The outcome as opposed to the suitability of the forum to hear the dispute becomes the central focus. The decision to prosecute disputes in the most favourable forum is not unethical.[83] It may arguably be in the best interest of a client concerning litigation costs.[84] Secondly, it may result in efficiency gains where the substantive law of chosen forum may produce the best remedies.[85] On the other hand, forum shopping may result in inefficiencies where the forum decision is based on the favourability of outcomes as opposed to the relevance of the forum.[86] Invariably, resources may be allocated to resolving disputes that are irrelevant.[87] In *Chirwa v Transnet Limited*[88], the court stated that increased concerns on the issue of forum shopping are genuine and litigants should not cherry-pick forums in search of a better outcome.[89] Although the judgment expresses disapproval towards the practice, it can be argued that such disapproval is based on the available forums being sound and equipped to deal with the disputes of litigants. The spread of the practice of forum shopping in the protection and enforcement of pharmaceutical patents raises a critical issue concerning the adequacy of the forums provided by existing IP legislation in adjudicating issues of anticompetitive patent use. A further issue that arises is the expertise of a chosen forum to deal with technical issues raised,

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[80] Daryl Dingley and Jarrad Knoetze 'Could Competition Law and Patent Law successfully tie the knot?' June 2017 *Without Prejudice* 15.
[81] Dingley and Knoetze op cit note 80.
[82] Lesofe op cit note 46.
[83] Ibid.
[84] Note (No Author) ''Forum Shopping Reconsidered' (1990) 103(7) *Harvard Law Review* 1678.
[85] Alisha K Taylor, 'What does forum shopping in the Eastern District of Texas mean for patent reform?' (2007) 6 *The John Marshall Review of Intellectual Property Law* 579.
[86] Lesofe op cit note 46.
[87] Ibid.
[88] 2008 (4) SA 367 (CC).
[89] 2008 (4) SA 367 (CC) para 117.

specifically where issues cut across fields of law.[90] The issue of forum shopping is likely as it pertains to anticompetitive patent use complaints.

b) Depository patent registration and an absence of opposition proceedings in patent applications

In May 2017, the CompCom undertook a scoping study concerning the price of pharmaceutical products.[91] A notable result of the study concerns the impact of the SEP regulatory framework in stifling rampant prices increases by pharmaceutical patent holders and pharmacies.[92] Finally, the most notable finding of the exercise is that it indicated a significant shortcoming in the depository system of patent registration currently implemented in South Africa in that it could facilitate an environment that allows for the abuse of pharmaceutical patents.[93]

The DTI, notes that a particular shortcoming of South African IP policy is the depository system of IP registration.[94] Accordingly, the Registrar must examine, in the prescribed way, every patent application and accompanying specification.[95] The Registrar accepts a patent application for registration if it complies with the Patent Act.[96] Simply put, the South African Patent Office does not examine the patentability of patent applications.

A patent filing starts with an application filed with the Companies and Intellectual Property Commission ('CIPC'). Provisional specifications accompany applications and are reviewed to ensure that they are legible and reproducible. This is done, most importantly, to ensure compliance with prescribed formalities under regulation 41.[97] Yu-Fang Wen and Thapi Matsaneng argue that regulation 41 creates confusion as to the nature of the examination in that the Registrar does not ensure compliance with the Patents Act and operates on the presumption that the submission of an acceptable application and claim ought to be protected for what it claims to be, through the granting

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[90] Lesofe op cit note 46.

[91] Chan Park, Achal Prabhala and Jonathan Berger 'Using Law to Accelerate Treatment Access in South Africa: An Analysis of Patent, Competition and Medicines Law' available at *https://www.undp.org/publications/using-law-accelerate-treatment-access-south-africa*, assessed 28 January 2022.

[92] South African Competition Commission 'Health Market Inquiry: Final Findings and Recommendations Report' (2019) available at *https://www.compcom.co.za/wp-content/uploads/2020/01/Final-Findings-and-recommendations-report-Health-Market-Inquiry.pdf*, assessed 22 July 2022.

[93] Ibid.

[94] The Department of Trade and Industry 'Intellectual Property Policy of The Republic Of South Africa Phase I' is available at *https://www.gov.za/sites/default/files/gcis_document/201808/ippolicy2018-phasei.pdf*, assessed 28 January 2022.

[95] Regulation 40-3, Patent Regulations, Patents Act 57 of 1978.

[96] Regulation 40-3, Patent Regulations, Patents Act 57 of 1978.

[97] Regulations 34, 40-3, Patent Regulations, Patents Act 57 of 1978.

of a patent.[98] Upon acceptance of an application, the patent is granted. Formal compliance with requirements almost certainly results in the issuance of a written notice of acceptance of the application within approximately 18 months of the date of filing, which is thereafter published in the monthly Patent Journal.[99] Once an acceptance is published in the Patent Journal, the publication date is considered as the date of grant of the patent.[100] It can be argued that the filing process already allows for substantive examination in line with what is provided by the Patents Act.

The absence of a substantive search and examination procedure leads to a comparatively high percentage of patents being granted by the Registrar of Patents, thereby reducing the security of registered patents and the granting of patents in inappropriate circumstances. South Africa's depository system of registration places it at a disadvantage. In 2018, the DTI noted with concern that data indicated that the CIPC granted an average of 93 per cent of the patent applications received, compared to in the United States of America and the European Union where 61 per cent and 51 per cent of patents applied for were granted.[101] The figures in India and Brazil are even lower, where only 19 and 14 per cent of all patent applications were granted.[102] The disproportionately high figures for patent registration as compared to other nations may indicate various problems with the quality of registered patents. The problem is further compounded by the absence of appropriate and expressly legislated opposition proceedings.[103] Recourse exists only through costly applications to the High Court of South Africa.[104] In many cases, particularly where disputes of fact exist, application proceedings may need to be converted to action proceedings which are likely to be more costly.[105] The cost of such proceedings is likely to be driven by the

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[98] Yu-Fang Wen and Thapi Matsaneng 'Patents, Pharmaceuticals and Competition: Benefiting from an effective patent examination system'(2014) available at *http://www.compcom.co.za/wp-content/uploads/2014/09/Patents-Pharmaceuticals-and-Competition-Yu-Fang-Wen-and-Thapi-Matsaneng-Annual-Competition-Conference-2013.pdf* , assessed 15 May 2022.

[99] Regulations 44, 45, 46 and 47, Patent Regulations, Patents Act 57 of 1978.

[100] Ibid.

[101] The Department of Trade and Industry '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*, assessed 28 January 2022.

[102] The Department of Trade and Industry '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*, assessed 28 January 2022.

[103] Lesofe op cit note 46 at 457

[104] Yu-Fang Wen and Thapi Matsaneng 'Patents, Pharmaceuticals and Competition: Benefiting from an effective patent examination system'(2014) available at *http://www.compcom.co.za/wp-content/uploads/2014/09/Patents-Pharmaceuticals-and-Competition-Yu-Fang-Wen-and-Thapi-Matsaneng-Annual-Competition-Conference-2013.pdf* , assessed 15 May 2022.

[105] Ibid.

technical nature of such proceedings and the expert evidence that is likely to be led. A further issue becomes the expertise of such courts to hear such matters.

Although section 25 of the Patent Act stipulates that a patent cannot be granted in certain situations, neither the Patent Act nor the Patent Regulations provide that the Registrar can refuse a patent registration based on merits such as lack of novelty, lack of inventive step, or lack of industrial applicability if the description and claims do not contain sufficient content.[106] There is little or no room for third parties to participate in the registration process, either before or after the granting of the patent.

The CIPC as the body that receives, and processes patent applications lack the relevant technical expertise to meaningfully attend to substantive patent examination.[107] Any reform toward substantive patent search and examination will likely require enormous efforts at equipping the CIPC or any examining body with the technical expertise necessary. The CIPC plays an important primary function in the patent life cycle. Reforms ought to also make provision for an effective and complementary body empowered to investigate patent issues and refer such issues to an adjudicative body, akin to the process followed by the CompCom in referring matters to the competition tribunal.[108] The technical nature and complexity of patent disputes and issues require sound registration and adjudicative bodies if a move towards substantive examination and pre- and post-grant opposition is to be effective. Despite the acknowledgement of the problematic patent landscape, change is slow and almost non-existent.[109]

In summary, various policy options are available to relieve the South African patent system of the abovementioned issues. It is understood that an immediate move towards a substantive search and examination patent system may not be possible or feasible in the near or short term.[110] At its optimum functionality, a substantive search and examination system would be bolstered by implementing pre-and post-patent registration opposition measures.[111] The measures proposed herein assist or build foundations towards such an approach. The inclusion of several broadly applicable and easily applied exclusions from patentability would make the task of examination

[106] Act 57 of 1978, as amended.
[107] Lesofe op cit note 46 at 470.
[108] Ibid.
[109] Lesofe op cit note 46 at 457.
[110] Chan Park, Achal Prabhala and Jonathan Berger 'Using Law to Accelerate Treatment Access in South Africa: An Analysis of Patent, Competition and Medicines Law' (2013) *United Nations Development Programme* 54.
[111] Ibid.

significantly easier. Secondly, mandatory disclosures in patent applications may assist in assessing the merit of applications. Patent applications may, for example, require specificity concerning the disease that its invention may treat. Improved and streamlined patent registration methodologies will facilitate substantive searches and examinations of registered patents.[112]

c) Compulsory licensing

Compulsory licensing refers to the authority granted by the state for the exploitation of a patent either by the state or a third party.[113] Compulsory licensing compels patent holders to allow or accept such rights by a third party or the state. It is widely accepted that compulsory licensing may ameliorate the anticompetitive uses of patents, particularly in the pharmaceutical industry.[114] Compulsory licensing has the potential to discourage innovative behaviour in the market as it may have the effect of eliminating an IP owner's control over their innovation.[115]

Article 31 of the TRIPS agreement empowers compulsory licensing for use by the government or third parties authorised by the government, provided that due regard is given to the considerations as set out in the TRIPS agreement such as reasonable considerations of applications based on individual merit, non-assignability, adequate remuneration in line with the economic value of authorization, authorization would be subject to judicial review or another independent review by a higher authority, among others.[116] Section 56 of the Patent Act allows for compulsory licensing on application to the registrar where it can be shown that the patent right has been abused through underutilization and non-commercialization of the patent right within a prescribed period, prevention or hindering of commercialization of an invention in the Republic by the importation of the patented item, demand for the patented article being inadequate or on reasonable terms, refusal of the patentee to grant a license on reasonable terms to the prejudice of trade or industry or agriculture, and lastly, where the demand of the patented article is being met by the importation and the price charged by the patentee is comparatively excessive.[117]

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[112] Park, Prabhala and Berger op cit note 110 at 55.
[113] Dingley Knoetze op cit note 80 at 15.
[114] Ibid.
[115] Lesofe op cit note 46 at 457.
[116] World Trade Organisation 'Agreement on Trade-Related Aspects of Intellectual Property Rights' available at https://www.wto.org/english/docs_e/legal_e/27-trips.pdf, assessed 14 January 2022.
[117] Act 57 of 1978, as amended.

According to Du Bois national health crises such as the COVID-19 pandemic necessitate reconsideration of the section in that it ought to cater for three scenarios, each capable of providing remuneration to the right holder at different stages and in compliance with the TRIPS agreement.[118] First, emergency patent use by the state without prior negotiation and notification as soon as reasonably possible.[119] Secondly, non-commercial public use without prior negotiation with the right holder.[120] Lastly, commercial state use that requires prior negotiation before use commences.[121] In June 2022, the WTO took decisive action to authorise the use of a patent required for the production of and supply of covid-19 vaccines without the consent of the right holder to address the covid-19 pandemic in exchange for reasonable remuneration for the right holder(s).[122] The payment of a reasonable remuneration would be based upon consideration of the humanitarian and non-profit nature of use and good practice in circumstances of national emergency.[123] It is submitted that the approach by the WTO will go a long way in assisting to combat health crises by assisting to eliminate IPR disputes that may prevent access to essential pharmaceuticals.

Arguments in opposition to compulsory licensing are based mainly on the position that it undermines patent protection and reduces incentives for research and innovation.[124]An argument on this basis is mainly centred on the premise that pharmaceutical firms have developed pharmaceuticals and treatments at considerable costs and the IPR is a means of recouping such expenses. This is true for some treatments but not all. For instance, many HIV/AIDS treatments have been developed through financing from public funds and research fellowships. In this sense, such treatments ought to be accessible to the public. In any event, compulsory licensing is a potentially effective tool in facilitating access to pharmaceuticals.[125]

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[118] 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 *Potchefstroom Electronic Law Journal* 26-9.
[119] Ibid.
[120] Du Bois op cit note 120.
[121] Ibid.
[122] World Trade Organization 'Ministerial Decision the TRIPS Agreement: Adopted on 17 June 2022 – Ministerial Conference, Twelfth Session, Geneva, 12 – 15 June 2022 WT/MIN(22)/W/15/Rev.1' available at *https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/WT/MIN22/W15R1.pdf&Open=True,* accessed 23 July 2022.
[123] Ibid.
[124] Lonias Ndlovu 'Theories of Intellectual Property and Access to Medicines in the Southern African Development Community (SADC)' 2016 *Obiter* 614.
[125] Ibid.

Although compulsory licensing as a policy tool is available, no indication of its use concerning pharmaceutical products exists at all. A justification raised for its non-use, particularly in instances of abuse, is the difficulty required to prove the abuse of a patent.[126] On the same reasoning, it could be argued that issues of this nature are best left to institutions empowered to deal with abuses of market power and dominance who possess sufficient capacity to conduct the necessary inquiries. In this regard, regulatory reform ought to be geared towards collaborative efforts between regulators and, at the very least, capacity and information sharing that enable the use of essential policy instruments such as compulsory licensing. The reform in IP policy may be analogous to sectors such as the financial services industry in South Africa, characterised by information sharing and collaboration among all sectoral regulators.

d) Risks inherent in competition policy-IP interface litigation

A landmark complaint lodged before the CompCom that deals with some of the critical issues addressed in this paper is a complaint against GlaxoSmithKline South Africa (Pty) Ltd ('GSK') & Boehringer Ingelheim (Pty) Ltd ('BI'), (the GSK/BI complaint) based on an allegation of excessive pricing in terms of Section 8(1)(a) of the Competition Act and later extended to include an allegation referring to the essential facilities doctrine and exclusionary conduct under sections 8(1)(b) and (c) of the Competition Act.[127] The complaint emphasises the potential to use competition law as a public law policy tool to address potentially undesirable ancillary competition effects that may arise through patenting. However, the bounds of the use of competition law require careful consideration. A crystalised approach to the current and proposed roles of IP and competition laws is required to avoid issues of forum shopping in resolving disputes and to ensure the efficient use of regulatory expertise.

The complaint was initially based on an allegation of excessive pricing in terms of Section 8(1)(a) of the Competition Act.[128] It was later extended to include an allegation referring to the essential facilities doctrine and exclusionary conduct under sections 8(1)(b) and (c) of the Competition Act.[129] In the GSK/BI complaint, the anticompetitive conduct complained of included abuse by

[126] Dingley and Knoetze op cit note 80 at 15.
[127] South African Competition Commission 'GSK and BI issue anti-retroviral licenses' (2004) 15 *Competition News* 1-2.
[128] Act 89 of 1998.
[129] Organisation for Economic Co-operation and Development 'Directorate for Financial and Enterprise Affairs Competition Committee: Excessive Pricing in Pharmaceutical Markets – Background Note by Secretariat DAF/COMP

GSK of its dominant position in the anti-retroviral drugs (ARVs) market for through excessive charges; effectively excluding access to the general public through pricing practices; refusal to allow competitors access to essential facilities; marked differences in pricing on ARV's locally as compared to generic alternatives sold internationally, and perhaps most importantly patent protection preventing the sale of generic substitutes locally and not entitling pharmaceuticals to charge excessive prices. The parties settled the case before the Competition Tribunal could adjudicate it.[130] The result is that the issues raised by the complaint did not find ventilation through a final finding of the Competition Tribunal, which may have been beneficial for precedent-setting purposes. However, the CompCom found that GSK/BI had abused their dominant position by charging excessive prices, part-taking in exclusionary conduct, and refusing to grant access to essential facilities to a competitor.[131] Before the agreed settlement, the CompCom had recommended that the Competition Tribunal authorise compulsory licenses to competitors.[132] It would have been interesting to see how the Competition Tribunal would have approached the issue of authorizing compulsory licenses, in the absence of input from IP regulatory authorities. The regulation of patent settlement agreements in litigious matters related to the competition policy-IP interface is scant in many jurisdictions. In the United States, this area has been flagged as patent settlements in some instances have raised anticompetitive concerns.[133] Settlements in these types of matters pose a significant risk to competition.[134] Regulatory reform will need to clarify the extent to which Competition authorities can partake in patent infringement litigation and settlements.

The terms of the settlement included the granting of licenses to generic manufacturers, export by licensees to sub-Saharan African countries, import approvals to licensees in the absence of local manufacturing capability, permissions to licensees to manufacture GSK/BI's ARVs as

(2018)12' (2018) available at *https://one.oecd.org/document/DAF/COMP/WD(2018)117/en/pdf*, assessed 21 July 2022.

[130] South African Competition Commission op cit note 128.

[131] Ibid.

[132] Organisation for Economic Co-operation and Development 'Directorate for Financial and Enterprise Affairs Competition Committee: Excessive Pricing in Pharmaceutical Markets – Background Note by Secretariat DAF/COMP (2018)12' (2018) available at *https://one.oecd.org/document/DAF/COMP/WD(2018)117/en/pdf*, assessed 21 July 2022.

[133] Ghosh op cit note 8 at 119.

[134] Kovacic op cit note 2 at 424.

combinations of other treatments, and finally capped royalties at 5 per cent of the relevant ARVs.[135]

The GSK/BI complaint is significant for using competition law as a public law policy tool to address potentially undesirable ancillary competition effects that may arise using IP. A noteworthy aspect of the GSK/BI complaint is that it highlights the difficulty that may have arisen in attempting to tackle the complaint using only patent law remedies such as voluntary and compulsory licensing in the absence of an enforcement mechanism empowering patent regulators to enforce such remedies. One of the CompCom findings entailed the refusal of GSK and BI to license patents to generic manufacturers in return for 'reasonable' royalties.[136] It is worth noting that license conditions agreed between a patentee and licensee are not without restriction. A license condition that extends beyond the rights provided by the patent is prohibited by section 90 of the Patents Act.[137] At the time of the initiation of the GSK/BI complaint, voluntary licenses had already been granted to Aspen Pharmacare with terms such as royalty returns of up to 40 per cent and in some instances, limitations of sale to the South African public sector only, which the CompCom found to be unacceptable.[138] Notwithstanding that not a single compulsory license has been issued under the Patents Act despite the provision for the granting of a compulsory license by the commissioner of patents in circumstances of abuse of a patent right based on excessive pricing.[139]The GSK/BI case had a profound effect on access to ARV medication in various ways, a result that may not have been possible in the absence of effective competition regulation and enforcement.[140] The GSK/BI complaint and subsequent settlement highlighted that a critical issue is licensing costs in the compulsory licensing context. A further noteworthy aspect of the

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[135] Organisation for Economic Co-operation and Development 'Directorate for Financial and Enterprise Affairs Competition Committee: Excessive Pricing in Pharmaceutical Markets – Note by South Africa DAF/COMP/WD(2018)117)' (2018) available at *https://one.oecd.org/document/DAF/COMP/WD(2018)117/en/pdf*, assessed 18 January 2022.

[136] South African Competition Commission 'Media release No. 29 of 2003, 16 October 2003' available at *http://www.cptech.org/ip/health/sa/cc10162003.html* assessed 22 July 2022.

[137] Patents Act 57 of 1978.

[138] Duncan Matthews and Olga Gurgula *Patent Strategies and Competition Law in the Pharmaceutical Sector: Implications for Access to Medicines* (Legal Studies Research Paper No. 233/2016. Queen Mary University of London, School of Law) 6.

[139] Organisation for Economic Co-operation and Development 'Directorate for Financial and Enterprise Affairs Competition Committee: Excessive Pricing in Pharmaceutical Markets – Background Note by Secretariat DAF/COMP (2018)12' (2018) available at *https://one.oecd.org/document/DAF/COMP/WD(2018)117/en/pdf*, assessed 21 July 2022.

[140] Ibid.

settlement terms is that they mirror the development in the Doha framework as it pertains to pharmaceuticals and licensing for export where countries have insufficient manufacturing capability.[141] Quite notably, this mechanism was not achieved through IP Law and was a direct beneficiary of competition law as a policy tool.

e) The Roche AG excessive pricing referral: a role for competition authorities before patent litigation

A further noteworthy CompCom referral to consider is the complaint initiated by the CompCom Commissioner against Roche Holding AG ('Roche AG') and Genentech Incorporated (a wholly owned subsidiary of Roche AG) ('Genentech') for excessive pricing to the detriment of consumers of customers.[142] The Roche AG referral concerned an allegation of excessive pricing that took place between January 2011 and November 2020 in the South African private healthcare sector and during the period 9 November 2015 to July 2020 in the South African public healthcare sector in the sale and supply of a patented breast cancer drug, Trastuzumab.[143] The complaint culminated in a referral to the Competition Tribunal for the prosecution of Roche AG and its subsidiaries on the allegation of excessive pricing in terms of section 8(1)(a) of the Competition Act.[144]

About 50 per cent of breast cancer patients were unable to receive treatment between 2011 and 2019 due to excessive pricing.[145] Trastuzumab sold under Roche AG brand names, Herceptin and Herclon, are the only versions of the pharmaceutical available in South African.[146] At a point, the

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[141] Organisation for Economic Co-operation and Development 'Directorate for Financial and Enterprise Affairs Competition Committee: Excessive Pricing in Pharmaceutical Markets – Note by South Africa' available at *https://one.oecd.org/document/DAF/COMP/WD(2018)117/en/pdf*, assessed 18 January 2022.

[142] Competition Commission 'Competition Commission Prosecutes a Multinational Healthcare Company, Roche, For Excessive Pricing of a Breast Cancer Treatment Drug' (2022) available at *https://www.compcom.co.za/wp-content/uploads/2022/02/COMPETITION-COMMISSION-PROSECUTES-A-MULTINATIONAL-HEALTHCARE-COMPANY-ROCHE-FOR-EXCESSIVE-PRICING-OF-A-BREAST-CANCER-TREATMENT-DRUG.pdf*, assessed 18 May 2022.

[143] Ibid

[144] Competition Commission 'Competition Commission Prosecutes A Multinational Healthcare Company, Roche, For Excessive Pricing of a Breast Cancer Treatment Drug' (2022) available at *https://www.compcom.co.za/wp-content/uploads/2022/02/COMPETITION-COMMISSION-PROSECUTES-A-MULTINATIONAL-HEALTHCARE-COMPANY-ROCHE-FOR-EXCESSIVE-PRICING-OF-A-BREAST-CANCER-TREATMENT-DRUG.pdf*, assessed 18 May 2022.

[145] Ibid.

[146] Competition Commission 'Competition Commission on Investigation into Cancer Drugs Manufacturers - Media Statement by The Commissioner on The Investigation into Manufacturers of Cancer Drugs' (2017) available at *https://www.gov.za/speeches/media-statement-commissioner-investigation-manufacturers-cancer-drugs-13-jun-2017-0000*, assessed 18 May 2022.

price of Trastuzumab in the private healthcare sector during the abovementioned periods was unsupported by medical schemes due to its high cost (approx. R 500 000 per 12-month course).[147] A deeper look into the patent rights at play reveals an intricate and involved structuring of patent rights. The Trastuzumab composition patent for Roche's Herceptin product expired in 2020.[148] Genentech, which supplies Roche with exclusive marketing rights, also has patents covering combinations of the drug with other chemotherapeutic agents which could prevent pre-clinical research on a biosimilar product until 2033.[149] Roche AG and Genentech appear to be engaging in strategic patenting strategies to shield Trastuzumab from competition from biosimilar products as well as to extend its period of protection. This is expressly acknowledged by the CompCom.

A concerning aspect of the CompCom investigation is the refusal of Roche AG to provide its cost data on the alleged basis that such data was housed in Switzerland.[150] The CompCom made use of three competitive benchmarks assessments such as reliance on biosimilar manufacturing costs estimates, pricing of biosimilar drugs supplied in South Africa, and value-based price benchmarks to estimate the value attributable to the pharmaceutical.[151] If such a complaint were to be dealt with by way of the framework in the Patents Act, it is doubtful that an extensive investigation of this nature would ensue, if at all.

V. REGULATORY REFORM: OVERCOMING THE DIFFICULTIES OF USING TRIPS FLEXIBILITIES IN SOUTH AFRICA

a) The Trips Flexibilities as A Remedy Against the Anticompetitive Effects of Pharmaceutical Patents: An Insurmountable Challenge or Golden Opportunity?

TRIPS affords members various flexibilities in how they formulate their patent laws; these include the setting of patentability criteria, the definition of limited exceptions to patent rights, providing

[147] Competition Commission 'Competition Commission on Investigation into Cancer Drugs Manufacturers - Media Statement by The Commissioner on The Investigation into Manufacturers of Cancer Drugs' (2017) available at *https://www.gov.za/speeches/media-statement-commissioner-investigation-manufacturers-cancer-drugs-13-jun-2017-0000*, assessed 18 May 2022.

[148] Competition Commission 'Competition Commission on Investigation into Cancer Drugs Manufacturers - Media Statement by The Commissioner on The Investigation into Manufacturers of Cancer Drugs' (2017) available at *https://www.gov.za/speeches/media-statement-commissioner-investigation-manufacturers-cancer-drugs-13-jun-2017-0000*, assessed 18 May 2022.

[149] Ibid.

[150] Competition Commission 'Competition Commission on Investigation into Cancer Drugs Manufacturers - Media Statement by The Commissioner on The Investigation into Manufacturers of Cancer Drugs' (2017) available at *https://www.gov.za/speeches/media-statement-commissioner-investigation-manufacturers-cancer-drugs-13-jun-2017-0000*, assessed 18 May 2022.

[151] Ibid.

for the exclusion of specific subject matter, the location of requirements for information disclosure in patent applications, imposing requirements for patent examination and registration opposition, the authorisation of parallel importation of pharmaceuticals, allowing a limited range of right patent exceptions, and the establishment of enforcement mechanisms.[152] The term 'flexibilities' broadly refers to a set of norms, rules and standards that allow variations in implementing the TRIPS Agreement obligations, including limits on exercising IPR.[153] The agreement is explicit on the importance of a member nation's flexibility in adopting measures to protect public health provided they are in line with the framework provided by the agreement.[154] The TRIPS and its subsequent development in the Doha Declaration have had profound effects on IP and access to pharmaceuticals.[155] The Doha Declaration clarifies the position concerning the stance of TRIPS as supportive of independent measures by governments to protect public health.[156]

As a market regulatory mechanism, competition law may prove to be a valuable tool for combating anticompetitive practices in the pharmaceutical industry since it provides a systemic approach beyond the technology transfer approach of the TRIPS competition provisions.[157] The object of competition law related to IPR is traditionally viewed to provide intervention and oversight on the exercise of IPR in the market.[158] The analytic framework provided in this paper contributes to the broader debate concerning adequate development to support regulatory reform beneficial to South Africans and South Africa's development goals.

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[152] WTO, WHO and WIPO op cit note 51 at 13.

[153] United Nations Secretary-General High-Level Panel on Access to Health Technologies 'Promoting innovation and access to health technologies' (2015) available *https://static1.squarespace.com/static/562094dee4b0d00c1a3ef761/t/57d9c6ebf5e231b2f02cd3d4/1473890031320/UNSG+HLP+Report+FINAL+12+Sept+2016.pdf*, assessed 21 July 2022.

[154] World Trade Organisation 'Agreement on Trade-Related Aspects of Intellectual Property Rights' available at *https://www.wto.org/english/docs_e/legal_e/27-trips.pdf*, assessed 14 January 2022.

[155] Mor Bakhoum 'Intellectual Property, Competition Law and Access to Pharmaceuticals: The Relevance of a 'Market Approach' to the Exercise of Intellectual Property Rights' available at *https://www.wto.org/english/tratop_e/trips_e/colloquium_papers_e/2013/chapter_9_2013_e.pdf, assessed* 18 November 2021.

[156] Ibid.

[157] Mor Bakhoum 'Intellectual Property, Competition Law and Access to Pharmaceuticals: The Relevance of a 'Market Approach' to the Exercise of Intellectual Property Rights' available at *https://www.wto.org/english/tratop_e/trips_e/colloquium_papers_e/2013/chapter_9_2013_e.pdf, assessed* 18 November 2021.

[158] Ibid.

The jurisdiction of the South African Competition Act[159] concerning IP matters is founded in Article 40 of the TRIPS agreement, which allows member states to enforce their domestic competition legislation to the extent that it concerns the abuse of a patent.[160] Article 40 acknowledges the potential adverse effects of patents on markets. It empowers member nations to specify in *their legislation licensing practices or conditions that may constitute an abuse of IPR hurting competition in the relevant market*.[161]

b) Socio-Economic Advancement as a Policy Goal

In its paper on the first phase of its IP policy reform, titled IP Policy of The Republic of South Africa Phase I 2018, the DTI acknowledges that South Africa's IP laws do not support South Africa's socio-economic advancement.[162] The Department of Trade and Industry is of the view that a comprehensive IP approach that is geared towards the promotion of the local manufacturing sector, protecting and making the best use of South Africa's natural resources, and supporting domestic industries and citizens to obtain benefits from the framework[163] The DTI takes cognisance of the importance of IP towards the realization of public health goals.

To give true meaning to South Africa's intention to move towards universal healthcare, collaboration between all healthcare sector regulators to ensure quality universal access to healthcare is required. Several Memoranda of Understanding (MOUs) have been reached between the CompCom and different sector regulators in response to the Competition Act, which enables the commission to manage areas of concurrent jurisdiction over prohibited practices, facilitate joint education programmes, provide input on complaints and applications before regulators, and to set up joint working committees.[164] An MOU between competition and IP regulators does not exist. It is therefore likely that these sectors operate in silos despite their concurrent jurisdiction in matters involving anticompetitive abuse of patents. Promoting a collaborative effort between

[159] Act 89 of 1998.

[160] World Trade Organisation 'Agreement on Trade-Related Aspects of Intellectual Property Rights' available at *https://www.wto.org/english/docs_e/legal_e/27-trips.pdf*, assessed 14 January 2022.

[161] World Trade Organisation 'Agreement on Trade-Related Aspects of Intellectual Property Rights' available at https://www.wto.org/english/docs_e/legal_e/27-trips.pdf, assessed 14 January 2022.

[162] The Department of Trade and Industry '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*, assessed 28 January 2022.

[163] Organisation for Economic Co-operation and Development 'Directorate for Financial and Enterprise Affairs Competition Committee: Excessive Pricing in Pharmaceutical Markets – Note by South Africa' (2018) available at *https://one.oecd.org/document/DAF/COMP/WD(2018)117/en/pdf*, assessed 18 January 2022.

[164] Lesofe op cit note 46 at 476-7.

competition, IP, and other healthcare sector regulators allows for information sharing and referral of anticompetitive behaviour to the correct forum depending on the nature of transgressions.

c) Reformatory direction

Precise and unambiguous IP and Competition Law reform are urgently required. First, to expressly delineate the content and extent of patent rights through clinical means of assessment to ensure that they are worthy of such protections.

Secondly, reform ought to definitively provide for TRIPS flexibilities under competition legislation and guidelines around the use of competition and IP policy tools should a competition infringement occur. Well-defined and consistent regulatory and policy approaches between the IP and competition law systems require strengthening to ensure certainty and the extent and breadth of rights as well as uniformity and common purpose in resolving disputes.[165]

VI. CONCLUSION

Appropriate regulation and policy development concerning the intersection between IP and competition law is slow thus creating an obstacle to facilitating maximal access to pharmaceuticals due to the pricing effects likely to accompany an abuse of the patent right. South Africa has enacted legislation incorporating TRIPs and the Doha Declaration in large measure, but tools such as compulsory licensing have not been applied and supported in practice. Adopting globally accepted policy and regulatory instruments will strengthen the South African patent system. As discussed above, this follows the trend of global convergence in IP regulation and policy reform. To ensure that true innovations are granted rights, it is necessary to establish a sound mechanism for granting rights. It also includes accessible opposition measures, readily available information on existing rights and a clear delineation of the role of all related regulators involved.

As a market regulatory mechanism, competition law may prove to be a valuable tool for combating anticompetitive practices in the pharmaceutical industry since it provides a systemic approach to tackling issues of this nature. Competition Law takes on a broader purpose and broadly questions the use of patents from their acquisition to their disposal to prevent anticompetitive abuses of these fundamental patent rights and abuses of the flexibility inherent in the IPR governance framework.

There should be no underestimation of the importance of sectoral regulators in the pharmaceutical sector. To maximise access to pharmaceuticals and ensure reform tailored to suit South Africa and

[165] Matthews and Gurgula op cit note 140 at 12.

enhance access to those who need it most, collaboration among all pharmaceutical sectoral regulators is essential. This can ensure that a fit-for-purpose approach that can be effectively implemented and takes full advantage of the uniquely South African public health needs is adopted. In conclusion, the paper proposes that truly effective reform and enhanced access to pharmaceuticals will only be possible if all regulators take a coordinated, symbiotic approach to patent regulation and policy.

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