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ANTI-COMPETITIVE BEHAVIOUR AS A GROUND FOR COMPULSORY LICENSING OF PHARMACEUTICAL PATENTS IN SOUTH AFRICA

by

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DECLARATION

I, Fathima Omar, 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.

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ABSTRACT

While the South African Patents Act provides for compulsory licensing in instances of an abuse of patent rights, millions of South Africans remain unable to access essential medicines because of *inter alia* the high prices charged by pharmaceutical patent holders. This research explores the idea of utilising Article 31(k) of the TRIPS agreement – which allows for compulsory licences to be issued to remedy anti-competitive behaviour – to ensure access to patented essential medicines. The central argument in the report is that compulsory licenses on Article 31(k) grounds should be granted by the competition authorities after having found anti-competitive behaviour on the part of the pharmaceutical patent holder. Moreover, this research provides solutions and recommendations to appropriately deal with the role of the competition authorities in the regulation of patented pharmaceuticals.

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I. INTRODUCTION

It is estimated that around two billion people worldwide are unable to access essential medicines.[1] The United Nations Development Programme (UNDP) and the World Health Organization (WHO) have previously highlighted that the high prices for essential medicines because of patent protection has prevented developing countries from accessing patented medicines, despite safeguards in the agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS").[2] In South Africa, the coronavirus (COVID-19) pandemic and other pandemics have resulted in an epidemiological health crisis for the country.[3] In particular, diseases such as Human Immunodeficiency Virus (HIV), Acquired Immunodeficiency Syndrome (AIDS), tuberculosis and cancer are extremely prevalent in South Africa.[4] For example, statistics for the 2021 year reveal that 8.2 million people are currently living with HIV in South Africa, which is an estimated 13,7% of the total population, and that South Africa has the highest number of persons who are enrolled in the antiretroviral therapy programme.[5] Furthermore, 84% of the South African population (forty-two million people) rely on public health for their healthcare needs.[6] However, those patients who rely on public health are usually unable to afford patented medicines and will either choose generic medicines as an alternative or skip treatment altogether.[7] Accordingly, in order to alleviate the effects of the current epidemiological health crisis in South Africa, it is imperative that patented medicines are accessible to the public.[8] Unfortunately, pharmaceutical companies who hold patents in South

[1] Behrang Kianzad 'Excessive Pharmaceutical Prices as an Anticompetitive Practice in TRIPS and European Competition Law' in Klaus Mathis & Avishalom Tor (eds) *New Developments in Competition Law and Economics* (2019) 198.
[2] Ibid at 201; Agreement on Trade-Related Aspects of Intellectual Property Rights, 15 April 1994.
[3] Shelton T Mota Makore, Patrick C Osode & Nombulelo Lubisi 'Re-configuring South African patent laws in search of an Afrocentric approach for expanding access to essential patented medicines in the Covid-19 era' (2021) 10 *Perspectives of Law and Public Administration* 267.
[4] Ibid at 268.
[5] Stats SA Statistical Release P0302 'Mid-year population estimates 2021' at 15, available at *https://www.statssa.gov.za/publications/P0302/P03022021.pdf*, accessed on 1 October 2022.
[6] Organisation for Economic Co-operation and Development (OECD) 'Excessive Pricing in Pharmaceutical Markets – Note by South Africa' 28 November 2018 at 3, available at *https://one.oecd.org/document/DAF/COMP/WD(2018)117/en/pdf*, accessed on 8 October 2022.
[7] Ibid at 5 – 6.
[8] Makore et al op cit note 3 at 268.

Africa for essential medicines often abuse their patent rights by charging significantly higher prices for medicines in South Africa compared to the price charged for the same medicines in other countries.[9]

Pharmaceutical patents confer legal monopoly rights on the patent holder.[10] This effectively allows the patent holder to control 'who may make, use, sell, offer for sale, or import the patented medicines'.[11] Pharmaceutical patent holders are therefore able to determine *inter alia* the prices for the patented medicines and the markets to which the patented medicines are supplied.[12] The exclusivity created by patent rights can lead to market power which can be abused by patent holders in certain circumstances. For instance, pharmaceutical patent holders who are dominant within a particular market are able to abuse their dominance by *inter alia* charging excessive prices for patented medicines or engaging in exclusionary conduct, such as refusing to license on reasonable commercial terms. In addition, pharmaceutical patent holders extend patent monopolies by adopting strategies such as 'evergreening' to delay and/or prevent the entry of generic medicine into the market.[13]

Compulsory licensing is an exception to the protection of Intellectual Property Rights ("IPRs") contained in the TRIPS agreement[14], and is regarded as an effective mechanism to facilitate access to patented medicines and remedy the anti-competitive practices of patent holders. In South Africa, Section 56 of the Patents Act 57 of 1978 ("the Patents Act") allows any interested person who can demonstrate that the rights in a patent are being abused to apply to the Commissioner of Patents for a compulsory license on various grounds. However, the Commissioner of Patents has failed to issue a single compulsory license under the Patents Act to date.[15] Moreover, it is common cause that the compulsory licensing system in South Africa is cumbersome and ineffective because it *inter alia* involves judicial process which can be time consuming and costly for the litigant.

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[9] Yu-Fang Wen and Thapi Matsaneng 'Patents, Pharmaceuticals and Competition: Benefiting from an effective patent examination system' at 5, 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* accessed on 8 October 2022.

[10] Burton Ong 'Compulsory Licences of Pharmaceutical Patents to Remedy Anti-Competitive Practices Under Article 31(k) of the TRIPS Agreement: Can Competition Law Facilitate Access to Essential Medicines?' in Reto M. Hilty & Kung-Chung Liu (eds) *Compulsory Licensing Practical Experiences and Ways Forward*, vol 22, (2015) 236.

[11] Ibid.

[12] Ibid.

[13] 'Compulsory licensing and the anti-competitive effects of patents for pharmaceutical products: from a developing countries' perspective' at 1, available at *https://www.idra.it/garnetpapers/C14A_Kaushik_A_Jaktar.pdf* accessed on 28 July 2022.

[14] Kianzad op cit note 1 at 202.

[15] Itumeleng Lesofe 'Forum shopping: Finding the right balance between the enforcement of competition law and the protection of intellectual property rights' (2017) 29 *SA Merc LJ* 459.

In this research report, I propose using competition policy as an alternative to promote public health and facilitate access to patented medicines. In particular, I rely on Article 31(k) of the TRIPS agreement which provides that a compulsory license can be granted to remedy a practice determined after judicial or administrative process to be 'anti-competitive'. In doing so, I will firstly outline the existing pharmaceutical regulatory landscape in South Africa. Second, I will highlight the key defects in the South African patent system and their resultant impact on public health and competition. Third, I will discuss the TRIPS framework and the benefits of relying on Article 31(k) of the TRIPS agreement to effect compulsory licensing. Fourth, I will highlight the advantages of using competition law in South Africa to facilitate access to patented medicines. Lastly, I will propose legal and structural measures that can be implemented to appropriately deal with the role of the competition authorities in the regulation of patented pharmaceuticals.

II. THE PHARMACEUTICAL REGULATORY LANDSCAPE

a) Trips and the Doha Declaration

On 1 January 1995, South Africa became a member of the World Trade Organization ("WTO").[16] South Africa became a signatory to the TRIPS agreement in 1994 because of its membership to the WTO, and subsequently enacted the Intellectual Property Laws Amendment Act 38 of 1997, in order to give effect to the provisions of the TRIPS agreement.[17] The TRIPS agreement introduced a global intellectual property protection regime, which had a fundamental impact on access to medicines.[18] In particular, TRIPS contains certain minimum standards for the protection and enforcement of IPRs, including patent rights.[19] The TRIPS agreement contains certain public-health flexibilities that can be utilised by member states in order to achieve access to affordable medicines.[20] Despite

[16] Yousuf A Vawda 'Analysing South Africa's compulsory licensing jurisprudence: is there room for the public interest (PI) in intellectual property (IP)?' (2019) *IPLJ* 183.
[17] Ibid.
[18] Marion Motari, Jean-Baptiste Nikiema, Ossy M J Kasilo et al '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.
[19] Brook K Baker 'International Collaboration on IP/Access to Medicines: Birth of South Africa's Fix the Patent Laws Campaign' (2015/16) 60 *New York Law School Review* 311.
[20] Ibid.

the introduction of TRIPS, developed countries were able to secure an advantage over the intellectual property related industries in developing countries because of advancements in research and development.[21] Moreover, the United States threatened certain developing countries (including South Africa) that attempted to utilise the flexibilities contained in TRIPS to facilitate access to affordable medicines.[22] In the early 2000s, the HIV/AIDS pandemic worsened, and patent holders held a stronghold over life-saving medicines. Accordingly, developing countries worked together and demanded that the TRIPS Council clarify the public-health flexibilities within the TRIPS agreement. The Doha WTO Ministerial Declaration on public health ("the Doha Declaration") was subsequently adopted in 2001 and specifically recognised a member's right to utilise the flexibilities in the TRIPS agreement, to grant compulsory licenses and to specify the grounds for such licenses.[23] Despite the aforegoing, the Doha Declaration did not adequately assist developing countries with an insufficient pharmaceutical manufacturing capacity.[24] This is because Article 31(f) of the TRIPS agreement provides that the products manufactured under a compulsory license can only be used for domestic use.[25] The TRIPS Agreement was thereafter amended with the introduction of Article 31bis. Article 31bis effectively waives the obligations of Article 31(f) and allows patented medicines manufactured under a compulsory license to be exported to other developing countries with insufficient pharmaceutical manufacturing capacity.[26] Unfortunately, Article 31bis has only been used once to allow export from Canada to Rwanda and has largely been ineffective in ensuring access to patented medicines due to the administrative and procedural hurdles involved.[27]

b) The Patents Act

Section 25 read with Section 46 of the Patents Act provides that a patent will be granted for a period of twenty years for 'any new invention which involves an inventive step and which is capable of being used or applied in trade or industry or agriculture'.[28] Section 45 of the

[21] Ibid at 312.
[22] Ibid.
[23] Declaration on the TRIPS agreement and public health adopted on 14 November 2001.
[24] Baker op cit note 19 at 313.
[25] Article 31(f) of the TRIPS agreement.
[26] Ong op cit note 10 at 237.
[27] Ibid.
[28] Section 25 read with Section 46 of the Patents Act, 1978.

Patents Act provides that the patent holder for the duration of the patent, has "the right to exclude other persons from making, using, exercising, disposing or offering to dispose of, or importing the invention, so that he or she shall have and enjoy the whole profit and advantage accruing by reason of the invention".[29] Accordingly, the pharmaceutical patent holder is granted a monopoly in exchange for disclosure of the patent[30]. It must be noted that the Companies and Intellectual Property Commission (CIPC) is responsible for the registration of patent applications.[31]

c) The Medicines and Related Substances Act

Section 2 of the Medicines and Related Substances Act 101 of 1965 established the South African Health Products Regulatory Authority ("SAHPRA"). The fundamental objectives of SAHPRA are to *inter alia* monitor, evaluate, regulate, investigate, inspect, register and control medicines in the public interest.[32] SAHPRA is an entity of the National Department of Health and is mandated to report to the Minister of Health.

d) The Competition Act

The Competition Act 89 of 1998 ("the Competition Act") is further relevant to the regulation of pharmaceuticals. As mentioned earlier, the pharmaceutical patent holder is granted a legal monopoly for the duration of the patent. Accordingly, a pharmaceutical manufacturer is likely to be regarded as a dominant firm in the market for a particular medicine. In this regard, Section 8 of the Competition Act provides that it is prohibited for a firm to abuse its dominance in the relevant market by *inter alia* charging excessive prices, refusing to grant a competitor access to an essential facility or engaging in exclusionary conduct.[33]

[29] Section 45 of the Patents Act, 1978.
[30] Vawda op cit note 16 at 184.
[31] Section 34 of the Patents Act, 1978.
[32] Section 2A of the Medicines and Related Substances Act, 1965.
[33] Section 8 of the Competition Act, 1998.

The Competition Commission is mandated in terms of the Competition Act to investigate anti-competitive behaviour in South Africa, including anti-competitive conduct stemming from the exercise of IPRs. The Competition Commission will refer a matter to the Competition Tribunal for adjudication in circumstances where a firm (pharmaceutical company) has engaged in anti-competitive conduct stemming from the exercise of IPRs. In terms of Section 58 of the Competition Act, the Competition Tribunal has the power to make an appropriate order in relation to a prohibited practice under the Act.[34]

III. KEY SHORTCOMINGS OF THE PATENT REGIME

It is indisputable that South Africa's Patents Act contains certain glaring weaknesses. In particular, the legislature has failed to maximize the TRIPS public-health flexibilities to ensure access to patented medicines. The Intellectual Property Policy of the Republic of South Africa ("the IP Policy") published in 2018 by the Department of Trade and Industry[35] recognises the defects in South Africa's patent system and its impact on public health. This section will outline the defects in South Africa's patent system that are relevant to the issue of public health and competition. In particular, this section will highlight South Africa's use of a depository patent registration system, its failure to implement explicit patentability criteria, and its ineffective compulsory licensing regime.

a) Depository or non-examination patent system

The first significant defect in South Africa's patent regime is its depository or non-examination patent system.[36] This means that the CIPC does not conduct a Substantive Search and Examination (SSE) prior to the granting of a patent.[37] Therefore, the CIPC does not consider novelty, inventive step or industrial applicability when examining a patent application.[38]

[34] Section 58 of the Competition Act, 1998.
[35] The Intellectual Property Policy of the Republic of South Africa: Phase I Published under GenN 518 in GG 41870 of 31 August 2018.
[36] Baker op cit note 19 at 318.
[37] IP Policy at 17.
[38] Baker op cit note 19 at 318.

Instead, in terms of Section 34 of the Patents Act read with Regulations 40 and 41, 1978[39], the CIPC only examines the formalities of the application.[40] In this regard, the CIPC will only consider whether the application for a patent includes the prescribed forms, supporting documentation and the prescribed fee before it will grant the patent.[41] In addition, third parties who wish to challenge the patentability of a patent can only do so once the patent has already been granted.[42] Litigants are forced to approach the courts to challenge the patentability of a patent which is a costly and time-consuming process.[43] This scenario is particularly problematic in relation to challenges to the patentability of essential medicines[44].

Studies have shown that a depository system has several disadvantages.[45] In the context of medicines, South Africa's granting of patents on medicines is excessive compared to other jurisdictions around the word.[46] In addition, since the depository system does not examine the substantive merits of the patent application, several patents for a single medicine could be granted as well as secondary patents.[47] In relation to secondary patents, pharmaceutical companies are able to extend the life of a patent beyond the twenty-year period by making minor changes to the drug formulation.[48] This practice is known as evergreening and is one of the major reasons why the prices for patented medicines remain high.[49] Evergreening is particularly harmful to competition because it can *inter alia* prevent generic manufacturers from entering the market and consequently results in monopolistic prices.[50] In addition, secondary patents may deter generic manufacturers from developing more affordable medicines in fear of patent infringement.[51] For instance, Novartis held the original patent for imatinib (a cancer treatment drug) in South Africa. The original patent for imatinib expired in 2013, but a new-use patent for imatinib expired in 2022. Cipla reached an undisclosed agreement with Novartis and is the only generic manufacturer that has entered the market.[52] In

[39] Patent Regulations, 1978 Published under GN R2470 in GG 6247 of 15 December 1978.
[40] IP Policy at 17.
[41] Lesofe op cit note 15 at 455.
[42] Makore et al op cit note 3 at 277.
[43] Ibid
[44] Ibid.
[45] IP Policy at 17.
[46] Baker op cit note 19 at 318.
[47] Wen & Matsaneng op cit note 9 at 5.
[48] L Ndlovu 'Lessons for the SADC from the Indian case of Novartis AG v Union of India' (2015) 18 *PER/PELJ* 784.
[49] Ibid.
[50] Ibid.
[51] Julia E Hill 'Changes to intellectual property policy in South Africa: putting a stop to evergreening?' (2014) 24 *Expert Opinion on Therapeutic Patents* 840.
[52] Ibid.

comparison, there are over ten competitors that sell imatinib in India.[53] In light of the weaknesses outlined above, academics and civil society organizations have rallied for a review of the depository system.[54] The IP Policy provides that South Africa is working towards introducing SSE to its patent system.[55]

b) Patentability criteria

Article 27 of the TRIPS agreement provides that inventions are patentable provided that they are 'new', involve an 'inventive step' and are capable of 'industrial application'. The TRIPS agreement further provides that member states are at liberty to define the aforesaid terms in order to establish their patentability criteria.[56] For instance, India and Argentina have implemented strong patentability criteria in order to circumvent patent evergreening.[57] On the other hand, South Africa has failed to implement explicit patentability criteria.[58] The absence of clear criteria for patentability is particularly problematic in relation to the filing of secondary patents. The IP Policy specifically recognises the need to develop a strong patentability criterion 'to promote genuine innovation through the patent system in South Africa'. The IP Policy further recognises that an appropriate 'patentability criteria plays an important role in the growth of a domestic pharmaceutical industry'.

c) Ineffective compulsory licensing regime

The third significant defect in South Africa's patent regime is its failure to effect compulsory licensing. Compulsory licensing is regarded as an effective remedy to overcome patent monopolies and ensure access to essential medicines.[59] Although Section 55 and 56 of the Patents Act make provision for compulsory licensing, the Commissioner of Patents has failed to issue a single compulsory license under the Act.[60] In addition, there has been a limited

[53] Ibid.
[54] Lesofe op cit note 15 at 455 – 456.
[55] IP Policy at 17.
[56] C Tomlinson, C Waterhouse, Y Q Hu et al 'How patent law reform can improve affordability and accessibility of medicines in South Africa: Four medicine case studies' (2019) 109 *SAMJ* 388.
[57] Ibid.
[58] Ibid.
[59] Makore et al op cit note 3 at 277.
[60] Lesofe op cit note 15 at 459.

number of applications for compulsory licenses under the Patents Act. This is because *inter alia* the current process to obtain a compulsory license under the Patents Act is cumbersome and ineffective. In terms of Section 56 of the Patents Act, an application for a compulsory license entails an application to the Commissioner of Patents, who is a Judge of the High Court[61]. Accordingly, an application for a compulsory license involves judicial process that can be time-consuming and costly for the litigant.[62] In addition, the court processes can be further delayed because of possible appeals.[63] A report of the UNDP states that the cost to obtain a compulsory license may amount to up to R1,000,000 and that the court processes may take up to three years.[64]

In addition to the procedural hurdles of South Africa's compulsory licensing regime, the substantive grounds for compulsory licensing under the Patents Act are inadequate. In this regard, Section 56 of the Patents Act provides that an 'interested person' may apply for a compulsory license under a patent if (1) the patented article is not being worked to an adequate extent within a specific timeframe[65] (2) the demand for the patented article is not being met to an adequate extent and on reasonable terms[66] (3) refusal of the patentee to grant a licence or licences upon reasonable terms[67] (4) the price charged for the patented article is excessive compared to the price charged in countries where the patented article is manufactured.[68] There are two fundamental problems with the current formulation of Section 56 of the Patents Act. Firstly, the provision provides that an 'interested person' may only apply for a compulsory license under a patent and is likely to cover a pharmaceutical company that manufactures or imports patented medicines.[69] However, civil society organisations will probably not satisfy the 'interested person' test under the Patents Act. Second, it must be demonstrated that 'the rights in a patent are being abused', and one of the grounds for compulsory licensing must be relied on. It is submitted that the grounds for compulsory licensing under the Patents Act are

[61] Section 56 read with Section 8 of the Patents Act, 1978.
[62] IP Policy at 28.
[63] Ibid.
[64] Fix The Patent Laws submission on the Draft Intellectual Property Policy of the Republic of South Africa, Phase I, 24 October 2017, at 32, available at https://www.fixthepatentlaws.org/resources/fix-the-patent-laws-submission-on-draft-national-intellectual-property-policy-23-10-17/ accessed on 29 July 2022.
[65] Section 56(2)*(a)* of the Patents Act, 1978.
[66] Section 56(2)*(c)* of the Patents Act, 1978.
[67] Section 56(2)*(d)* of the Patents Act, 1978.
[68] Section 56(2)*(e)* of the Patents Act, 1978.
[69] L Ndlovu 'South African Patent Law and Access to Medicines' (2013) 6 *Conference: International Trade and IT Law Conference Bangkok Thailand* para 4.

narrow and incomplete.[70] Consequently, it is suggested that Section 56 of the Patents Act should be amended to include additional grounds for compulsory licensing, including *inter alia* anti-competitive behaviour as a ground for compulsory licensing.[71] The IP Policy specifically recognises that it is important for South Africa to have an effective compulsory licensing system in place 'to achieve affordability of essential goods and restrain anti-competitive practices'.[72]

IV. FACILITATING ACCESS TO PATENTED PHARMACEUTICALS

In this section of the report, I will firstly outline the TRIPS framework insofar as it relates to compulsory licensing on competition law grounds and the advantages of utilising Article 31(k) of the TRIPS agreement to facilitate access to patented pharmaceuticals. In addition, I will briefly discuss how Argentina has implemented Article 31(k) in its patent legislation. Finally, I will discuss whether the existing provisions of the Patents Act give effect to Article 31(k).

a) Anti-competitive behaviour as a ground for compulsory licensing under TRIPS

Compulsory licensing is a remedy which allows the government or other third parties authorised by the government to use the subject matter of a patent without the authorization of the right holder.[73] The term compulsory licensing can be traced back to Article 5A (2) of the Paris Convention[74] which states as follows:

> "(2) Each country of the Union shall have the right to take legislative measures providing for the grant of compulsory licenses to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work."[75]

Article 5A (2) of the Paris Convention is embodied in Article 31 of the TRIPS agreement, which defines compulsory licensing as "Other Use Without Authorization of the

[70] Baker op cit note 19 at 320.
[71] Ibid.
[72] IP Policy at 28.
[73] Article 31 of TRIPS.
[74] The Paris Convention for the Protection of Industrial Property, 20 March 1883.
[75] Article 5A (2) of the Paris Convention.

Right Holder".[76] Article 31 sets forth provisions that must be respected by member states who have enacted laws relating to compulsory licensing of patents.

Article 7 of the TRIPS agreement outlines the objectives of the agreement and states that 'the protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations'.

In addition, Article 8 of the TRIPS agreement sets forth the main principles of the agreement and is pertinent to the discussion on the abuse of IPRs (particularly patent rights) and resultant anticompetitive behaviour. In this regard, Article 8(1) provides that member states may adopt appropriate measures in their laws to protect 'public health and nutrition' on condition that such measures are consistent with the TRIPS agreement. Article 8(2) further provides that it may be necessary to implement the aforesaid measures in order to prevent the abuse of IPRs or practices which unreasonably restrain trade or adversely affect the international transfer of technology.

Article 40 of the TRIPS agreement is also noteworthy to this discussion. Article 40(1) provides that member states concur that certain licensing practices or conditions in relation to IPRs which restrain competition may adversely affect trade and may impede the transfer and dissemination of technology. Article 40(2) further provides that member states are at liberty to specify in their laws licensing practices or conditions that may constitute an abuse of IPRs and which may adversely affect competition in the market.

Finally, Article 31(k) of the TRIPS agreement is an effective provision that may be used by member states to ensure access to essential medicines, using the competition law regime.[77] In particular, Article 31(k) allows for the granting of compulsory licences to remedy anti-competitive practices and states as follows:

> "(k) Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases. Competent authorities shall have the authority to refuse termination of authorization if and when the conditions which led to such authorization are likely to recur"

[76] Ibid.
[77] Ibid at 198.

Notably, Article 31(k) contains a key procedural requirement[78]: the practice must be determined to be anti-competitive through a judicial or administrative process. For example, the relevant competition authority of the member state could determine this issue in order to satisfy this requirement. In addition, it is apparent that for Article 31(k) to find application, the relevant member state would need to have existing domestic legislation prohibiting anti-competitive practices.[79] In all the circumstances, it is clear from the above that the TRIPS agreement and in particular Article 31(k) provides that a compulsory license in respect of a pharmaceutical patent can be granted in circumstances where a pharmaceutical company has engaged in anti-competitive behaviour. Furthermore, it is evident from the various articles referred to above that the TRIPS agreement provides a framework for member states to intervene in circumstances where anti-competitive practices have arisen because of the abuse of IPRs, thereby promoting competition law objectives.[80]

b) Competition-based compulsory licenses

There are several advantages to utilising the flexibilities contained in Article 31(k) of the TRIPS agreement. Firstly, the compulsory license may be issued without prior negotiation with the patent holder, as otherwise required by Article 31(b) of the TRIPS agreement. In the context of ensuring access to medicines, this flexibility is particularly advantageous because it avoids protracted negotiations with a patent holder, thereby ensuring efficiency.

Second, the products manufactured under the compulsory licence are not restricted to use by the domestic market of the member state, as otherwise required by Article 31(f) of the TRIPS agreement. In other words, the products manufactured under the compulsory license may be exported to other countries. This flexibility is significant because of South Africa's increasing manufacturing capacity.[81]

[78] Ibid.
[79] Kianzad op cit note 1 at 210.
[80] Ibid at 203.
[81] Tenu Avafia, Jonathan Berger & Trudi Hartzenberg 'The ability of select sub-Saharan African countries to utilise TRIPs Flexibilities and Competition Law to ensure a sustainable supply of essential medicines: A study of producing and importing countries' *Trade Law Centre for Southern Africa* at para 2.3.1. available at *https://unctad.org/system/files/official-document/ictsd-tralec2006d3_en.pdf* accessed on 8 October 2022.

Third, the need to correct the anti-competitive practice may result in the remuneration paid to the patent holder to be lower than the 'economical value of the authorisation', or the remuneration may be excluded altogether.[82]

c) The implementation of Article 31(k) in Argentina

In order to determine how South Africa should implement Article 31(k) of the TRIPS agreement, it is useful to discern how the provision has been implemented in other countries. Argentina is one country that has implemented Article 31(k) in its patent legislation, and its implementation of the provision is useful to this discussion because it was subsequently the subject of a WTO trade dispute between itself and the United States[83].

In relation to compulsory licensing on Article 31(k) grounds, Argentina's patent legislation delineates the types of conduct constituting 'anti-competitive practices'.[84] In this regard, the national patent legislation provides that the following types of conduct shall be regarded as 'anti-competitive practices':

> "(a) comparatively excessive pricing, compared to the average market or being discriminatory of patented products, in particular when there are offers of supplying the market at prices significantly lower than those offered by the patentee for the same product;
> (b) refusal to supply the local market on reasonable commercial terms;
> (c) interference with commercial or production activities;
> (d) any other act that enters into the behaviours considered punishable by Law No. 22.262 or its replacement or substitute."[85]

Argentina and the United States agreed that if a firm's conduct constituted any of the anti-competitive practices delineated above, then 'such a finding will not in and of itself warrant an automatic determination that a patent owner is engaging in an 'anti-competitive' practice'.[86] In

[82] Frederick Abbott 'Anti-competitive behaviours and the remedies available for redress' in Frederick Abbott, Sean Flynn & Carlos Correa et al *Using competition law to promote access to health technologies* (2014) UNDP 51.
[83] World Trade Organization WT/DS171/3 WT/DS196/4 'Notification of Mutually Agreed Solution' 20 June 2002 at 2, available at https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=Q:/IP/D/22A1.pdf&Open=True accessed on 17 January 2022.
[84] Ong op cit note 10 at 240.
[85] Ibid. Article 44 of the Patent and Utility Models Law No. 24.481, amended by Law No, 24.572 (T. O. 1996) (translated from Spanish).
[86] Ibid.

this regard, it was agreed that in order to justify the granting of a compulsory license on Article 31(k) grounds, the National Commission on the Defense of Competition must have found that the practice is anti-competitive in terms of No. 25.156 (Law of Defense of Competition), which requires 'the existence of an abuse of a dominant position in the market . . . in order for a practice to be considered 'anti-competitive''.[87] In the circumstances, in order to obtain a compulsory license in Argentina on Article 31(k) grounds, the national competition authority must have first determined that the patent holder has contravened the relevant abuse of dominance provisions in their competition legislation.[88]

d) Do the provisions of the Patents Act give effect to Article 31(k) of TRIPS?

It is apparent that Section 56 of the Patents Act does not explicitly provide that a compulsory license may be granted to remedy an 'anticompetitive practice'.

As alluded to earlier, the Doha Declaration provides that member states are entitled to specify the grounds for compulsory licensing. In this regard, civil society organisations have submitted that South Africa should introduce specific ground/s allowing for the granting of compulsory licenses in order to remedy anti-competitive behaviour, as authorised by Article 31(k).[89] Furthermore, academics in South Africa have proposed legislative amendments to Section 56 of the Patents Act including the granting of a compulsory license on the ground that the patent holder has engaged in an anti-competitive practice.[90] In addition, they have recognized the advantages of compulsory licensing on competition law grounds. In this regard, it has been submitted that competition-based compulsory licenses may result in lower royalties and allow for the products manufactured under the compulsory license to be exported to external markets.[91] Furthermore, it has been submitted that if there is sufficient detail as to what conduct will constitute an anti-competitive practice, then such licenses will be straightforward to obtain and will not involve a specialised investigation or adjudication process.[92]

[87] Ibid.
[88] Ong op cit note 10 at 240.
[89] Fix The Patent Laws submission on the Draft Intellectual Property Policy of the Republic of South Africa, Phase I, 24 October 2017, at 30, available at https://www.fixthepatentlaws.org/resources/fix-the-patent-laws-submission-on-draft-national-intellectual-property-policy-23-10-17/ accessed on 29 July 2022
[90] Baker op cit note 19 at 320; Submission by University of KwaZulu-Natal-Affiliated Academics on The Draft Intellectual Property Policy of the Republic of South Africa Phase 1 2017, 23 October 2017, at 45, available at *https://www.fixthepatentlaws.org/resources/ukzn-submission-on-south-africa-draft-national-intellectual-property-policy-23-10-17/* accessed on 29 July 2022.
[91] Ibid at 43.
[92] Ibid at 43.

South Africa can give effect to Article 31(k) of the TRIPS agreement by including a ground in Section 56 of the Patents Act which allows for the granting of a compulsory license to remedy an anti-competitive practice, including details on what conduct constitutes anti-competitive practices. However, in my opinion, the granting of a compulsory license on Article 31(k) grounds must be subject to the competition authorities in South Africa having found that the firm has violated Section 8 of the Competition Act. However, this approach may be procedurally burdensome. For instance, if the competition authorities have established that a firm has engaged in conduct constituting an anti-competitive practice and has abused its dominance under Section 8 of the Competition Act (justifying the granting of a compulsory license of a patent), then it would mean that the complainant has to still apply to the Commissioner of Patents under the Patents Act for the compulsory license itself. This process could be costly and inefficient especially in relation to patented pharmaceuticals.

Accordingly, in my opinion, it is more appropriate for the competition authorities in South Africa to implement Article 31(k) of the TRIPS agreement. Moreover, there are several advantages to utilising competition law to facilitate access to patented medicines. These key advantages will be discussed in the chapter that follows.

V. USING COMPETITION POLICY TO FACILITATE ACCESS TO PATENTED MEDICINES

In this section of the report, I will discuss *inter alia* how South Africa has successfully used competition law in the past to facilitate access to patented medicines, the appropriateness of the competition authorities to establish anti-competitive behaviour and the provisions of the Competition Act that can be used to establish anti-competitive behaviour stemming from the exercise of IPRs.

a) South Africa's experience in using competition policy to facilitate access to patented medicines

In South Africa, competition law rules have been used in the past to compel licensing of pharmaceutical patents through reliance on the abuse of dominance provisions in Section 8 of the Competition Act.[93] The well-known case of *Hazel Tau & others v GlaxoSmithKline,*

[93] Malebakeng Agnes Forere 'The compliance of South Africa's patents compulsory licensing regime to the TRIPs Agreement' (2019) *Queen Mary Journal of Intellectual Property* 169.

Boehringer Ingelheim & others, 2002[94] ("Hazel Tau") is an example of where competition law was used to remedy the anti-competitive behaviour of pharmaceutical companies and ensure access to affordable patented medicine. In *Hazel Tau*, HIV infected persons and other civil society organisations filed a complaint with the Competition Commission against two pharmaceutical companies, GlaxoSmithKline ("GSK") and Boehringer Ingelheim ("BI") regarding the accessibility of patented antiretroviral medicines (ARVs). GSK held patents in South Africa on AZT (branded as Retrovir), Lamivudine (branded as 3TC) and AZT/Lamivudine (branded as Combivir) and BI held a patent in South Africa on Nevirapine (NVP) (branded as Viramune).[95] The complainants alleged that GSK and BI had abused their dominant positions in the relevant market by engaging in excessive pricing in respect of their patented ARVs to the detriment of consumers, in contravention of Section 8(1)(a) of the Competition Act.[96] GSK and BI had also refused to license the patented ARVs to local generic manufactures.

First, the complainants submitted that GSK and BI were dominant firms for purposes of Section 7 of the Competition Act. In this regard, the complainants submitted that South Africa is the relevant geographic market for each patented ARV. In relation to the relevant product market, the complainants argued that each ARV established its own market, and that GSK and BI were dominant in each particular market. In the alternative, the complainants argued that GSK and BI were dominant firms in relation to each therapeutic class of the ARVs.

Once dominance had been established in terms of Section 7 of the Competition Act, the complainants proceeded to prove that GSK and BI had abused their dominant positions in the market by engaging in excessive pricing. Prior to the amendments to the Competition Act in 2019, the term 'excessive price' was defined as the 'price of a good or service which bears no reasonable relation to the economic value of that good or service'. The claimants submitted that a number of factors must be taken into account in order to determine whether the price charged for the good (ARVs) is reasonable in relation to the economic value of the good[97]:

> "(a) what the price of the good would be in a competitive market (ie in the absence of patent protection) including a normal rate of profit in that context;
> (b) a reasonable allowance for the recovery of research and development costs, relevant to the production of the good concerned, which other producers and sellers of the equivalent good in a competitive market would not have incurred;

[94] *Hazel Tau & others v GlaxoSmithKline, Boehringer Ingelheim & others, 2002* South African Competition Commission, Competition Commission Case No. 2002 Sep226.
[95] Statement of complaint in terms of Section 49b(2)(B) of the Competition Act 89 of 1998 at 3.
[96] Ibid at 5.
[97] Ibid at 22.

(c) some allowance for additional profit as an incentive for innovation and any unusual entrepreneurial risk;

(d) the nature and extent of the detriment to consumers that results from the high price; and

(e) the adverse impact of the high prices on constitutionally protected and internationally recognized rights."[98]

The complainants demonstrated that the actual prices charged for the ARVs in South Africa were excessive as compared to the economic value of the ARVs and proved *prima facie* that there was a contravention of Section 8(1)(a) of the Competition Act.[99] The Competition Commission thereafter investigated the complaint and found that GSK and BI had violated not only Section 8(1)(a) of the Competition Act (prohibition against excessive pricing) but also Section 8(1)(b) (refusal to grant a competitor access to an essential facility), and Section 8(1)(c) (engaging in an exclusionary act).[100] In the circumstances, the Competition Commission referred the matter to the Competition Tribunal for hearing. However, prior to the matter reaching the Competition Tribunal, GSK and BI each entered into settlement agreements with the Competition Commission and agreed to the following:

"(1) grant licenses to generic manufacturers;

(2) permit the licensees to export the relevant ARV medicines to sub-Saharan African countries;

(3) where the licensee did not have manufacturing capability in South Africa, permit the importation of the ARV medicines for distribution in South Africa only, provided all the regulatory approvals were obtained;

(4) permit licensees to combine the relevant ARV's with other ARV medicines; and

(5) not require royalties in excess of 5% of the net sales of the relevant ARV's."[101]

The *Hazel Tau* case had a significant impact on the accessibility and affordability of ARVs. In particular, the Competition Commission completed a study based on data for the years 2000 to 2015 and found that the cost for ARVs decreased by more than 11% per annum.[102] In addition, the Competition Commission's intervention in the *Hazel Tau* case ensured better access to ARVs. For example, in 2004 only 47 500 people received ARV

[98] Ibid at 23.
[99] Ibid at 34.
[100] Hazel Tau & others v GlaxoSmithKline, Boehringer Ingelheim & others, 2002, at 4, available at *https://unctad.org/ippcaselaw/hazel-tau-others-v-glaxosmithkline-boehringer-ingelheim-others-2002-south-african-competition* accessed on 29 July 2022.
[101] Ibid.
[102] OECD note by South Africa op cit note 6 at 8.

treatment through the antiretroviral therapy programme. However, this number increased to 3 407 336 people by 2016.[103] Lastly, the settlement agreements in *Hazel Tau* had a fundamental impact on generic competition in the supply for ARVs because it resulted in the introduction of 14 new drugs into the market.[104] Furthermore, due to the settlements, there are currently 32 producers of ARVs in the South African market.[105] In all the circumstances, it is apparent that the Competition Commission's intervention in *Hazel Tau* was vital in ensuring access to affordable medicine in South Africa.

In 2008, competition law once again facilitated access to patented medicines. The Competition Commission invited interested parties to make submissions on the proposed merger between Aspen Pharmacare Holdings Limited ("Aspen") and GlaxoSmithKline South Africa (Pty) Ltd ("GSK")[106]. The submissions made by Treatment Action Campaign (TAC) and AIDS Law Project resulted in the Competition Commission approving the merger subject to certain conditions. In particular, the conditions required GSK to grant licences to several generic manufacturers for the manufacture and/or import of their patented drug Abacavir, 'on terms and conditions no less favourable than those granted to Aspen'.[107] Abacavir is a drug that is used to treat children who are infected with HIV.[108]

b) Effective implementation of competition policy by an independent competition authority

It is common cause that competition policy can be effectively implemented by a competent competition authority with broad investigative powers.[109] Patent law on the other hand requires specific parties to litigate in order to achieve a desired outcome. For example, only interested persons (such as generic manufactures) may apply for a compulsory license under Section 56 of the Patents Act. In the context of facilitating access to patented pharmaceuticals, competition law is far more attractive because the general public, including civil society organizations, (who may not necessarily have adequate resources to litigate) are able to submit

[103] Ibid at 9
[104] Ibid at 10.
[105] Ibid.
[106] Section 27 'Submission on discussion paper on compulsory licensing' 7 October 2010 at 5, available at *https://section27.org.za/wp-content/uploads/2010/10/S27submissionToDIPP.pdf* accessed on 29 July 2022.
[107] Competition Commission Press Release 'Competition Commission approves pharma merger on condition that Abacavir is out-licensed to generic manufacturers' 2 September 2009 available at http://www.compcom.co.za/wp-content/uploads/2014/09/02-Sept-09-Competition-Commission-approves-pharma-merger-on-condition-that-Abacavir-is.pdf accessed on 29 July 2022.
[108] Ibid.
[109] Avafia et al op cit note 82 para 5.

complaints to the Competition Commission. The Competition Commission is thereafter able to investigate anti-competitive behaviour stemming from the exercise of IPRs in the public interest.[110] This process avoids protracted litigation and substantial legal costs. It is significant to mention that the South African Competition Commission has been instrumental in dealing with anti-competitive behaviour since its formation.

It is further submitted that the competition authorities are the appropriate bodies to establish anti-competitive behaviour. Kianzad submits that Article 31(k) of the TRIPS agreement requires a 'competent competition authority' to establish anti-competitive behaviour.[111] Moreover, he submits that Article 31(k) requires developing countries to have national competition legislation in place.[112] In my view, Kianzad's interpretation of Article 31(k) is correct because competition law rules should be applied to establish anti-competitive practices, and the competition authorities of the relevant country are best suited to make this determination. For example, in a case of excessive pricing, it is a complicated task to determine whether the prices charged by a patent holder are excessive. However, the application of competition law rules means that established tests and rules are applied by the competition authorities to establish a case of excessive pricing.[113]

c) The provisions of the Competition Act offer flexibility

As discussed in the previous section, competition law has been used in the past in South Africa to compel pharmaceutical companies to grant licenses to generic manufactures and to permit the licensees to export the patented medicines to external markets. Ong submits that in order to establish that a pharmaceutical patent holder has contravened competition law rules and to justify the granting of an Article 31(k) compulsory license, there are two conditions that must be met.[114] First, it must be established that the patent holder is dominant in the market for the patented pharmaceutical product. Second, it must be established that the patent holder has abused its dominant position in the relevant market, therefore justifying the granting of the compulsory license.[115] This section will outline in detail the various abuse of dominance

[110]
[111] Kianzad op cit note 1 at 209.
[112]Ibid at 210.
[113] Ibid at 218.
[114] Ong op cit note 10 at 257 – 258.
[115] Ibid at 258.

provisions of the Competition Act that may be relied on by litigants to obtain a compulsory license of a pharmaceutical patent under the Competition Act.

i. Section 8(1)(a) – Excessive pricing

There are opposing views on whether competition authorities should intervene in a dominant firm's pricing of products and services.[116] Accordingly, jurisdictions around the world have adopted different approaches on the issue of excessive pricing. In the United States (US), there is no explicit prohibition against excessive pricing in US anti-trust policy because it is understood that monopoly prices may have a part to play in the dynamic competitive process.[117] In addition, the European Commission (EC) is reluctant to act as a price regulator and will only intervene in certain instances in relation to excessive pricing.[118] However, some member states of the European Union are more active than others in pursuing excessive pricing cases.[119] It is noteworthy to mention that the EC recently opened a formal inquiry into the excessive pharmaceutical prices of Aspen Pharma. It was alleged that Aspen Pharma had abused their dominant position by charging excessive prices for five life-saving cancer medicines.[120] This inquiry signifies that there may be a policy shift in the EU regarding excessive pricing especially in the context of pharmaceuticals.[121] South Africa has adopted a more liberal approach to excessive pricing. In fact, the prohibition against excessive pricing is explicitly provided for in Section 8(1)(a) of the Competition Act. In addition, the South African Competition Commission has pursued a few excessive pricing cases. Over the last decade there have been at least six excessive pricing cases in different sectors, including pharmaceuticals (antiretroviral drugs).[122]

Section 8(1)(a) of the Competition Act provides that it is prohibited for a dominant firm charge an excessive price to the detriment of consumers or customers.[123] The amendments to the Competition Act in 2019 introduced Section 8(2) and (3) of the Act which also deal

[116] Reena das Nair and Pamela Mondliwa 'Excessive pricing under the spotlight: What is a competitive price?' in Jonathan Klaaren, Simon Roberts, and Imraan Valodia (eds) *Competition Law and Economic Regulation: Addressing Market Power in Southern Africa* 1st ed (2017) 97.
[117] Ibid.
[118] Ibid.
[119] Ibid.
[120] Kianzad op cit note 1 at 215.
[121] Ibid.
[122] das Nair & Mondliwa op cit note 115 at 98.
[123] Section 8(1)(a) of the Competition Act, 1998.

specifically with excessive pricing.[124] In this regard, Section 8(2) provides that 'if there is a prima facie case of abuse of dominance because the dominant firm charged an excessive price, the dominant firm must show that the price was reasonable'. Section 8(3) includes relevant factors that must be considered when determining a case of excessive pricing and provides as follows:

> "(3) Any person determining whether a price is an excessive price must determine if that price is higher than a competitive price and whether such difference is unreasonable, determined by taking into account all relevant factors, which may include
>
> *(a)* the *respondent's* pricecost margin, internal rate of return, return on capital invested or profit history;
>
> *(b)* the *respondent's* prices for the *goods or services*
>
> (i) in markets in which there are competing products;
>
> (ii) to customers in other geographic markets;
>
> (iii) for similar products in other markets; and
>
> (iv) historically;
>
> *(c)* relevant comparator *firm's* prices and level of profits for the *goods or services* in a competitive market for those *goods or services*;
>
> *(d)* the length of time the prices have been charged at that level;
>
> *(e)* the structural characteristics of the relevant market, including the extent of the *respondent's* market share, the degree of contestability of the market, barriers to entry and past or current advantage that is not due to the *respondent's* own commercial efficiency or investment, such as direct or indirect state support for a *firm* or *firms* in the market; and
>
> *(f)* any regulations made by the *Minister*, in terms of section 78 regarding the calculation and determination of an excessive price."

In *Babelegi Workwear and Industrial Supplies CC v Competition Commission of South Africa*[125] the Competition Appeal Court (CAC) dealt with a case of excessive pricing of FFP1 masks (face masks) in the context of the Covid-19 pandemic. The CAC had the opportunity to interrogate the 2019 amendments to the Competition Act in relation to excessive pricing. The

[124] Competition Amendment Act, 18 of 2018.
[125] *Babelegi Workwear and Industrial Supplies CC v Competition Commission of South Africa* 2021 (6) SA 446 (CAC).

CAC held that once dominance has been established, the complainant must prove that the price charged was *prima facie* excessive.[126] And once the complainant has proved a *prima facie* case of excessive pricing in terms of Section 8(2), the burden shifts to the respondent to prove that the prices charged were reasonable.[127] The CAC held that the factors set out in Section 8(3) of the Act must be considered to determine whether the price was excessive and whether the price was reasonable.[128] Finally, the CAC held that once it has been proven that the prices charged were unreasonable, Section 8(1)(a) of the Act additionally requires that the prices were charged to the detriment of the consumers or customers.[129]

Section 8(1)(a), 8(2) and 8(3) of the Competition Act will be analysed by the Competition Tribunal in the coming months in the context of a patented pharmaceutical drug. On 8 February 2022, the Competition Commission announced that it had referred a Swiss healthcare company, Roche Holding AG and its subsidiaries (F Hoffman La Roche AG and Roche Products (Pty) Ltd) ("Roche") to the Competition Tribunal for prosecution, for allegedly charging excessive prices for a breast cancer treatment drug, Trastuzumab, in violation of Section 8(1)(a) of the Competition Act. The Competition Commission began investigating Roche in 2017. Roche had allegedly engaged in excessive pricing, exclusionary conduct and price discrimination in respect of the sale and supply of Trastuzumab. In relation to the complaint of exclusionary conduct, the information obtained by the Competition Commission suggested that Roche had engaged in 'evergreening' and 'patent thickening' to delay and/or prevent the entry of generic breast cancer drugs into the market. The Competition Commission's announcement in February 2022 indicates that it only intends to pursue a case of excessive pricing against Roche. If the complainant i.e. the Competition Commission, succeeds with its excessive pricing case against Roche, it will be interesting to see whether the Competition Tribunal will only impose an administrative penalty on Roche, or whether it will also compel Roche to grant licenses to generic manufacturers.

ii. Section 8(1)(b) – Access to an essential facility

[126] Ibid para 58.
[127] Ibid para 59.
[128] Ibid.
[129] Ibid para 66.

Section 8(1)(b) of the Competition Act is another provision that litigants can rely on to obtain a compulsory license of a patented pharmaceutical medicine. As mentioned earlier, in *Hazel Tau*, the Competition Commission's investigation revealed that GSK and BI had contravened Section 8(1)(b) of the Competition Act, which prohibits a dominant firm from refusing to give a competitor access to an essential facility when it is economically feasible to do so. 'Essential facility' is defined in Section 1of the Competition Act and means 'an infrastructure or resource that cannot reasonably be duplicated, and without access to which competitors cannot reasonably provide goods or services to their customers'.

At the outset, in order for Section 8(1)(b) to find application, it must be determined whether the firm is a dominant firm in terms of Section 7 of the Act.[130] The term 'essential facility' usually refers to network and infrastructure industries but may also cover IPRs.[131] In this regard, Lesofe submits that Section 8(1)(b) can be used to obtain a compulsory license in circumstances where the holder of an IPR has refused to grant a voluntary license.[132]

In *Glaxo Welcome (Pty) Ltd v National Association of Pharmaceutical Wholesalers*[133], the CAC held that in order for Section 8(1)(b) to find application, the complainant must make the following averments in its complaint:

> "1. the dominant firm concerned refuses to give the complainant access to an infrastructure or a resource;
> 2. the complainant and the dominant firm are competitors;
> 3. the infrastructure or resource concerned cannot reasonably be duplicated;
> 4. the complainant cannot reasonably provide goods or services to its competitors without access to the infrastructure or resource; and
> 5. it is economically feasible for the dominant firm to provide its competitors with access to the infrastructure or resource."[134]

iii. Section 8(1)(c) – Engaging in an exclusionary act

Section 8(1)(c) of the Competition Act can also be relied on to obtain a compulsory license of a patented pharmaceutical medicine. In *Hazel Tau*, the Competition Commission found that

[130] Lesofe op cit note 15 at 462 – 463.
[131] Ibid.
[132] Ibid.
[133] *Glaxo Welcome (Pty) Ltd v National Association of Pharmaceutical Wholesalers* CAC 15/CAC/Feb02.
[134] Ibid para 57.

GSK and BI had engaged in an exclusionary act, in violation of Section 8(1)(c) of the Competition Act. It was argued that GSK and BI had engaged in exclusionary conduct because they failed to grant licenses to generic manufactures on reasonable commercial terms.[135]

Section 8(1)(c) provides that it is prohibited for a dominant firm to 'engage in an *exclusionary act*, other than an act listed in paragraph *(d)*, if the anticompetitive effect of that act outweighs its technological, efficiency or other procompetitive gain'. This section is regarded as a 'catch all' provision and covers exclusionary conduct that is not specifically delineated in the Act.[136] 'Exclusionary conduct' is defined in Section 1 of the Competition Act and means 'an act that impedes or prevents a firm from entering into, participating in or expanding within a market'.

In *Competition Commission v Wesgrow Potatoes (Pty) Ltd and Another*[137], the Competition Commission investigated a complaint relating to a Plant Breeder's right which is a type of intellectual property. HZPC Holland B.V. ("HZPC") is an international company that breeds a superior potato varietal known as the Mondial seed potato varietal. A breeder who creates a new plant variety is granted exclusive rights over it for a twenty-year period in terms of the Plan Breeder's Rights Act 15 of 1976. HZPC was accordingly granted a Plan Breeder's Right in 1993 and its right expired in 2013.[138] HZPC and Wesgrow Potatoes (Pty) Ltd ("Wesgrow") concluded an exclusive license agreement in terms of which Wesgrow had the exclusive right to sell the Mondial seed potato varietal in South Africa.[139] Wesgrow also entered into exclusive agreements with its customers (commercial farmers) prohibiting them from reselling the seed potato.[140] The Competition Commission investigated the matter and found *prima facie* that: (i) HZPC and Wesgrow violated Section 5(1) of the Competition Act because of the exclusive agreement (from October 2013 onwards) between the parties. (ii) The exclusive agreements between Wesgrow and its customers, from October 2013 onwards, violated Section 8(d)(i) of the Act (requiring or inducing a supplier or customer to not deal with a competitor). (iv) The exclusive agreements between Wesgrow and its customers violated Section 8(c) of the Act, from October 2013 onwards[141]. The Competition Commission also

[135] OECD note by South Africa op cit note 6 at 8.
[136] Luke Kelly, David Unterhalter, Paula Youens, Isabel Goodman, & Patrick Smith *Principles of Competition Law in South Africa* (2017) 139.
[137] *Competition Commission v Wesgrow Potatoes (Pty) Ltd and Another* (CR249Mar17/SA130Nov19) [2020] ZACT 3 (15 January 2020).
[138] *Competition Commission v Wesgrow Potatoes (Pty) Ltd and Another* Competition Commission's principal submissions para 17.
[139] Ibid para 19.
[140] Ibid para 20.
[141] *Competition Commission v Wesgrow Potatoes (Pty) Ltd and Another* Settlement agreement para 3.

found that Wesgrow was a dominant firm in terms of the Act as it had a 99.1 % market share for the production and supply of the Mondial potato varietal in South Africa.[142] The matter was settled before the Competition Tribunal and HZPC and Wesgrow made certain undertakings. Wesgrow was required to *inter alia* supply plantlets for the Mondial seed potato varietal to potato seed growers, seed banks, laboratories and tissue culture facilities for a period of three from the date of the settlement agreement.[143] Although the aforementioned case did not deal with compulsory licensing and patent rights, it is important because it establishes that Section 8(1)(c) of the Competition Act can be effectively utilised to enhance competition in the market where firms engage in exclusionary conduct in relation to an IPR.

VI. THE IMPLEMENTATION OF ARTICLE 31(K) IN SOUTH AFRICA GOING FORWARD

In light of the considerations outlined in the chapter above, the current trend in South Africa which involves litigants (including civil society organisations) directly approaching the competition authorities to effect compulsory licensing to remedy anti-competitive practices (on Article 31(k) grounds), should continue.[144] However, there is currently no clear guidance from the relevant regulatory authorities regarding the interplay between patents (and in particular pharmaceutical patents) and competition. It has been cited in a publication by the WHO, World Intellectual Property Organization (WIPO) and WTO that studies published by the Organisation for Economic Co-operation and Development (OECD) and the World Bank on the interface between competition policy and public health provide that it is imperative that there is cooperation between the relevant competition authorities and other regulators in the health sector.[145] Accordingly, it is suggested that certain legal and structural changes should be implemented going forward:

[142] Ibid para 3.1.2.
[143] Ibid para 7.
[144] In fact, it has been recommended that it would be more appropriate for the competition authorities in developing countries to grant compulsory licenses in consultation with the patent office, and not the other way around (See note 13 'Compulsory licensing and the anti-competitive effects of patents for pharmaceutical products: from a developing countries' perspective' at 18).
[145] World Trade Organization (WTO), World Health Organization (WHO), World Intellectual Property Organization (WIPO) *Promoting Access to Medical Technologies and Innovation* 2 ed (2020) 96.

a) Guidelines on the interface between patent law and competition law

Firstly, in terms of Section 79(1) of the Competition Act, the Competition Commission has the power to 'prepare, amend, replace and issue guidelines to indicate the Commission's policy approach to any matter within its jurisdiction in terms of this Act'. Therefore, the Competition Commission should publish guidelines on the interplay between patent law and competition law. These guidelines should further deal with the issue of compulsory licensing of pharmaceutical patents and should delineate the type of conduct that will attract competition law scrutiny. Although these guidelines will not have a binding effect, they will provide much needed direction to both pharmaceutical patent holders and consumers.[146] Importantly, the Competition Commission should consult other role-players in the pharmaceutical regulatory sector including the Department of Health, SAHPRA and the CIPC, when drafting the relevant guidelines.

b) Memoranda of understanding between the Competition Commission and other regulators in the pharmaceutical sector

The pharmaceutical sector is regulated by various regulatory bodies. It is therefore imperative that there is cooperation between the Competition Commission and these regulatory bodies. For instance, although there is no official Memorandum of Understanding (MoU) between the Competition Commission and the Department of Health, the latter assisted the Competition Commission with its investigation against Roche for allegedly charging excessive prices for a breast cancer treatment drug.[147]

In terms of Section 82 of the Competition Act, a regulatory body which has jurisdiction regarding conduct regulated in terms of Chapter 2 (prohibited practices) or 3 (mergers) or on matters outlined in Chapter 4A (market inquiries) may enter into an agreement with the Competition Commission to *inter alia* promote cooperation between itself and the Competition Commission. For instance, both the Commissioner of Patents and the Competition Authorities have jurisdiction to deal with an abuse of patent rights.[148] It is therefore suggested that the

[146] Avafia et al op cit note 82 para 5.3.
[147] OECD note by South Africa op cit note 6 at 16.
[148] Luz Helena Hanauer, Isaac Quinton Ramaphala 'IP regulation in South Africa – evolution, current status,

Competition Commission enter into an official MoU with the Commissioner of Patents and/or the CIPC regarding the Competition Commission's role in the regulation of patent rights, particularly pharmaceutical patent rights.

c) Amendment to Section 58 of the Competition Act

The Competition Act does not explicitly provide that the competition authorities can order compulsory licensing of IPRs (in this case patents). In the context of pharmaceutical patents, it is crucial that the legislature amend the Competition Act to include such a provision, in line with Article 31(k) of the TRIPS agreement. For instance, in Canada, Section 32 of the Canadian Competition Act[149] allows the Federal Court to issue compulsory licenses under any patent where the patent has been used to *inter alia* unduly prevent or lessen competition in the relevant market.[150]

Section 58(1)(a) of the Competition Act provides that the Competition Tribunal has the power to 'make an appropriate order' in relation to a prohibited practice (such as a contravention of the abuse of dominance provisions under Section 8 of the Act), including *inter alia* the following:

(a) An order interdicting (stopping) the prohibited practice[151];
(b) An order that a party supply the goods to another party on terms reasonably required to end a prohibited practice[152];
(c) An order imposing an administrative penalty[153];
(d) An order for divestiture[154];
(e) An order declaring the conduct to be a prohibited practice for purposes of a damages claim[155];

and comparison with SADC region countries' (2020) 30 *Revista la Propiedad Inmaterial; Bogotá* 23.
[149] Section 32 of the Competition Act (R.S.C., 1985, c. C-34).
[150] Ibid.
[151] Section 58(1)(a)(i).
[152] Section 58(1)(a)(ii).
[153] Section 58(1)(a)(iii).
[154] Section 58(1)(a)(iv).
[155] Section 58(1)(a)(v).

(f) An order for access to an essential facility on terms reasonably required.[156]

It is apparent that Section 58(1)(a) of the Competition Act does not specifically mention 'compulsory licensing' as an appropriate remedy. Therefore, in order for a compulsory licensing order to be granted, the Competition Tribunal and the CAC will first be required to interpret Section 58(1)(a) to determine whether it is empowered to make such an order in circumstances where a pharmaceutical patent holder has abused its dominance under Section 8 of the Act.[157] In particular, the Competition Tribunal and the CAC will be required to interpret the words 'appropriate order' and determine whether or not Section 58(1)(a) should be viewed as a closed list of permitted orders.[158] Accordingly, although strong arguments can be made for a broad interpretation of Section 58(1)(a), it is problematic that an order for compulsory licensing is not expressly included in the subsection.

In order to avoid legal argument on the meaning of Section 58(1)(a) and unnecessary protracted litigation, it is suggested that the legislature amend Section 58(1) to permit the Competition Tribunal to order compulsory licensing in line with Article 31(k) of the TRIPS Agreement. The following issues should be expressly dealt with in the amendments to Section 58(1):

i. A provision that explicitly provides that the Competition Tribunal is empowered to order compulsory licensing in circumstances where a pharmaceutical patent holder has abused its dominance in the relevant market;
ii. A provision/s that deal with the royalty rate to be paid to the patent holder. In particular, the provision should explicitly provide that the need to correct anti-competitive practice is a factor that may be taken into account to determine the amount of remuneration that must be paid to the patent holder, in line with Article 31(k) of the TRIPS agreement; and
iii. In line with Article 31(k) of the TRIPS agreement, a provision that explicitly provides that the products manufactured under the compulsory license may be exported to other countries.

[156] Section 58(1)(a)(vii).
[157] Avafia et al op cit note 82 para 5.3.
[158] Ibid.

VII. CONCLUSION

It is apparent that the TRIPS framework and in particular Article 31(k) allows for compulsory licensing of pharmaceutical patents in circumstances where a pharmaceutical company has engaged in anti-competitive behaviour. In addition, it has been established that there are several advantages to utilising the flexibilities contained in Article 31(k) of the TRIPS agreement. Firstly, the compulsory license may be issued without prior negotiation with the patent holder, as otherwise required by Article 31(b) of the TRIPS agreement. Second, the products manufactured under the compulsory licence are not restricted to use by the domestic market of the member state, as otherwise required by Article 31(f) of the TRIPS agreement. In other words, the products manufactured under the compulsory license may be exported to other countries. Third, the need to correct the anti-competitive practice may result in the remuneration paid to the patent holder to be lower than the 'economical value of the authorisation', or the remuneration may be excluded altogether.[159]

Section 56 of the Patents Act does not explicitly allow for the granting of a compulsory license under a patent to remedy an 'anti-competitive practice' in line with Article 31(k) of TRIPS, despite South Africa's entitlement to do so under TRIPS and the Doha Declaration. However, instead of amending Section 56 of the Patents Act and relying on an ineffective compulsory licensing regime, it has been shown that it is more appropriate and efficient for Article 31(k) of the TRIPS agreement to be implemented by the competition authorities using competition policy as a regulatory tool for various reasons. Firstly, South Africa has effectively utilised competition policy in the past to facilitate access to patented medicines. Second, the Competition Commission is an independent investigative authority that can effectively implement competition policy. In particular, the Competition Commission is able to investigate anti-competitive behaviour stemming from the exercise of IPRs in the public interest. Third, the competition authorities are best suited to apply competition policy and establish anti-competitive behaviour. Finally, there are various provisions under Section 8 of the Competition Act that can be relied on to establish anti-competitive behaviour stemming from IPRs.

In order to effectively implement Article 31(k) of the TRIPS agreement going forward, this research proposes certain legal and structural changes that can be implemented to appropriately deal with the role of competition authorities in the regulation of pharmaceuticals.

[159] Abbott op cit note 82 at 51.

In this regard, it is proposed that the Competition Commission, in consultation with other role-players in the pharmaceutical regulatory sector, should publish guidelines on compulsory licensing of pharmaceutical patents and should delineate the type of conduct that will attract competition law scrutiny. Where appropriate, the Competition Commission should enter into agreements with other regulators in the pharmaceutical sector. Finally, there is room for the legislature to amend Section 58 of the Competition Act, to include provision/s which explicitly allow the Competition Tribunal to grant compulsory licenses in line with Article 31(k) of the TRIPS agreement.

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