



**UNIVERSITY of the  
WESTERN CAPE**

**The interplay between competition and patent laws in relation to access to  
medicines during future pandemics: A case study of the South African  
COVID-19 experience**

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**This mini-dissertation is in partial fulfilment of the requirements for the  
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of Law**

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## **ABSTRACT**

Competition law and its enforcement have become necessary tools in combating global health crises. This is especially true in light of the COVID-19 epidemic, which has made it imperative to increase access to emergency medications. Many nations were forced to rely on pharmaceutical companies to decide the cost and quantity of COVID-19 vaccinations to be supplied. Considering the high number of deaths and infections associated with the pandemic, with the World Health Organisation reporting over 7 million deaths, more could have been done to prevent such mortality had the issue of accessibility of vaccines been resolved at an earlier stage to ensure a balance of the enjoyment of the patents as well as the right to health.

One hand of the argument is the need for inventors to recuperate costs incurred in research and development and enjoy the monopoly granted by patents once vaccines have been developed. On the other side of the coin, competition law seeks to regulate any anti-competitive behaviour and it is undeniable that abuse of dominance which has resulted in extreme cases of exorbitant pricing of medication in the pharmaceutical industry needs to be curbed.

As a solution, this current study makes specific recommendations that are directed at promoting the access to medicines in future pandemics by balancing intellectual property rights to competition law, drawing lessons from the COVID-19 experience in South Africa.

**KEY WORDS:**

Abuse of dominance, Competition Law,

Compulsory licensing,

COVID-19,

Intellectual Property Rights,

IP waivers

Patent,

Pharmaceutical industry, Price fixing,

Vaccines

## **LIST OF ABBREVIATIONS**

<b>ARV</b>	Anti-retroviral drugs
<b>CAC</b>	Competition Appeal Court
<b>CC</b>	Constitutional Court
<b>CJEU</b>	Court of Justice of the European
<b>CIPC</b>	Companies and Intellectual Property Commission
<b>COVID-19</b>	Corona Virus Disease of 2019
<b>EEC</b>	European Economic Community and Related Instruments
<b>EU</b>	European Union
<b>GSK</b>	GlaxoSmithKline
<b>HIV</b>	Human-Immuno Deficiency Virus
<b>ICESCR</b>	International Covenant on Economic, Social, and Cultural Rights
<b>IP</b>	Intellectual Property
<b>IPRs</b>	Intellectual Property Rights
<b>J&amp;J</b>	Johnson and Johnson
<b>R&amp;D</b>	Research and Development
<b>SAA</b>	South African Airways
<b>SADC</b>	Southern African Development Community
<b>SSNIP</b>	Small but Significant Non-transitory Increase in Price
<b>SMME</b>	Small, Medium and Micro Enterprises
<b>TFEU</b>	Treaty on the Functioning of the European Union
<b>TRIPS</b>	Agreement on Trade-Related Aspects of Intellectual Property Rights

<b>US</b>	United States of America
<b>UNCTAD</b>	United Nations Conference on Trade and Development
<b>WHO</b>	World Health Organisation
<b>WIPO</b>	World Intellectual Property Organisation
<b>WTO</b>	World Trade Organisation

## DECLARATION

I, **Cathrine Ashley Makwara**, declare that ‘**The interplay between competition and patent laws in relation to access to medicines during future pandemics: A case study of the South African COVID-19 experience**, is my original work (except where acknowledgments indicate otherwise) and that neither the whole work nor any part of it has been, is being or is to be submitted for another degree or examination in any other University or academic institution. All sources and materials used are duly acknowledged and properly referenced.

Date: 10 November 2024.

Signature: *Cathrine Ashley Makwara*

## **DEDICATION**

I dedicate this dissertation to myself, for not giving up when it felt so easy to do. After all the crying, the sleepless nights, having over three versions of drafts per chapter and the writing insecurities, I am proud to say that finally I have completed my Masters dissertation. I finally did it.

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# CHAPTER 1

## 1. INTRODUCTION AND BACKGROUND TO THE STUDY

### 1.1 BACKGROUND TO THE STUDY

The Coronavirus (hereinafter referred to as COVID-19) pandemic, which began late 2019,<sup>1</sup> presented the modern world with unprecedented challenges in areas like business, healthcare, travel and tourism, and education. Regulation and enforcement of competition laws was one area that was not spared, and this was primarily observed in the pharmaceutical industry. It was now business (un)usual because competition authorities had to ease competition regulation measures to address the escalating issues, such as the demand for medical supplies.<sup>2</sup> This involved modifying enforcement priorities, permitting the exemption of specific forms of cooperation, and relaxing the efficiency defence standards.<sup>3</sup>

The acquisition of vaccinations and personal protective equipment became essential to many nations' efforts to address the public health emergency as the virus had an unparalleled fatality and infection rate. According to the World Health Organisation (WHO), at least 1.51 million deaths were recorded in Asia excluding China; 1.63 million in Europe; 259,058 deaths in Africa<sup>4</sup> with South Africa recording over 4 million cases with 102, 595 deaths.<sup>5</sup> Numerous pharmaceutical corporations, including Moderna, Pfizer, Johnson and Johnson (J&J), Novartis and GlaxoSmithKline(GSK), started the race to develop vaccines, securing patents for them, and then distributing them to other nations.<sup>6</sup> COVID-19 vaccinations, like many other medical inventions, are classified as intellectual property (IP), and as such, they should be entitled to the protection provided by the negative right.<sup>7</sup>

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<sup>1</sup> Hao YJ, Wang YL, Wang MY, Zhou L, Shi JY, Cao JM & Wang DP 'The origins of COVID-19 pandemic: A brief overview' (2022) *Transbound Emerg Dis* 1.

<sup>2</sup> Jenny F 'Competition Law Enforcement and the Corvid-19 Crisis: Business as (Un)usual?' (2020) available at SSRN: <https://ssrn.com/abstract=3606214> or <http://dx.doi.org/10.2139/ssrn.3606214> (accessed 19 December 2023).

<sup>3</sup> Jenny F 'Competition Law Enforcement and the Corvid-19 Crisis: Business as (Un)usual?' (2020) available at SSRN: <https://ssrn.com/abstract=3606214> or <http://dx.doi.org/10.2139/ssrn.3606214> (accessed 19 December 2023).

<sup>4</sup> Our World in Data 'Cumulative confirmed COVID-19 deaths by world region' available at <https://ourworldindata.org/grapher/cumulative-covid-deaths-region> (accessed 23 February 2024).

<sup>5</sup> Our World in Data 'Cumulative confirmed COVID-19 deaths by world region' available at <https://ourworldindata.org/grapher/cumulative-covid-deaths-region> (accessed 23 February 2024).

<sup>6</sup> Sagonowsky E, Liu A, Kansteiner F, Becker Z & Dunleavy K 'The top 10 vaccine companies worldwide' available at <https://www.fiercepharma.com/pharma/top-10-vaccine-companies-worldwide> (accessed 20 February 2024).

<sup>7</sup> Dean & Dyer *Introduction to Intellectual Property Law* (2014) 239.

It is undeniable that the spread of the virus caused manufacturing and transportation issues, but the main reason for developing countries' unequal access to affordable vaccines for their citizens was the ramifications of IP rights particularly patents.<sup>8</sup> The exercise of patents influenced vaccine pricing, which was exorbitant, thus, ultimately restricting access to vaccines which resulted in preventable deaths.<sup>9</sup> The COVID-19 vaccine distribution was classified by some as “pharmaceutical bullying” or “vaccine apartheid.”<sup>10</sup> In South Africa, a dose of the AstraZeneca Oxford sold for a higher price of \$5.25 per dose, which was comparatively higher as compared to \$2.15 and \$3-\$4 in Europe and in the United States of America (US) respectively,<sup>11</sup> clearly showing how the vaccines were exorbitantly priced to developing countries. Furthermore, J&J charged South Africa 15 percent more per dose of its COVID vaccine than it charged the European Union, while Pfizer-BioNTech charged South Africa nearly 33 percent more than it reportedly charged the African Union.<sup>12</sup>

This mirrored the exorbitant pricing of Anti-retroviral drugs (ARVs) during the Human Immuno-Deficiency Virus (HIV) pandemic in South Africa, which saw (GSK) and Boehringer Ingelheim – and their associated companies being taken to the Competition Commission over the exorbitant pricing of the ARVs that resulted in numerous fatalities.<sup>13</sup> The excessive pricing of ARVs was directly responsible for the premature, predictable and avoidable deaths of people living with HIV/AIDS, including both children and adults. Although noble at face value, the race to develop vaccines brought forth questions on the accessibility aspect of medicines during health emergencies as the economic implications of COVID-19 were felt through the discrepancies in drug pricing and supply between first and third-world countries.

The crux of this mini-dissertation is to examine the interplay between IP law (patent) and competition law in tackling the major problem of pricing and distribution of medicines in future

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<sup>8</sup> Park SP, Lee HJ, Yu Y, Lee EYJ and Park YS ‘Designing the global vaccine supply chain: balancing intellectual property rights with post COVID-19 vaccine equity’ (2023) *BMJ Glob Health*.

<sup>9</sup> Park, et al ‘Designing the global vaccine supply chain’.

<sup>10</sup> Prasad S, Shahid A, Edzel L, Khatri G, Cheema HA, Rocha ICN, Bardhan M & Hasan MM ‘Vaccine apartheid: the separation of the world's poorest and most vulnerable and the birth of Omicron’ (2022) *Ther Adv Vaccines Immunother* 1.

<sup>11</sup> Section 46 of the Patent Act:

(1) The duration of a patent shall be 20 years from the date of application therefore, subject to payment of the prescribed renewal fees.

<sup>12</sup> Ismail S ‘South Africa ‘held to ransom’ by big pharma, overcharged for COVID vaccines’ Aljazeera available at <https://www.aljazeera.com/news/2023/9/6/south-africa-held-to-ransom-by-big-pharma-overcharged-for-covid-vaccines> (accessed 07 March 2024).

<sup>13</sup> Health Justice Initiative ‘The Price of Life: Hazel Tau and Others vs GlaxoSmithKline and Boehringer Ingelheim: A report on the excessive pricing complaint to South Africa’s Competition Commission’ available at <https://healthjusticeinitiative.org.za/wp-content/uploads/2022/11/The-Price-of-Life.pdf> (accessed 07 March 2024).

pandemics based on the lessons drawn from the COVID-19 pandemic in South Africa. The focus will be on the role of competition law in sector-specific regulation, the functions and enforceability of IP rights, the balancing of the two competing interests – that is, competition and IP law,<sup>14</sup> the push factors in drug pricing and discrimination, the possible strategies to curb anti-competitive behaviours arising from the pharmaceutical industry; and a discussion of the role of competition law and competition authorities in tackling anti-competitive behaviours that may arise from future pandemics.

## **1.2 THE HISTORY AND LEGAL FRAMEWORK GOVERNING COMPETITION LAW IN SOUTH AFRICA**

### **1.2.1 The history of Competition law**

Competition law in South Africa is governed by the Competition Act of 89 of 1998 (Competition Act). The uniqueness of this piece of legislation is that apart from incorporating economic efficiency and consumer welfare as part of its objectives, it brings public interest concerns as part of the goals of competition law, paying homage to the history of South Africa which was characterised by unequal distribution of wealth and participation in the economy. Section 2 as a whole provides for the statutory objectives of competition law in South Africa which are: -

- “a) to promote the efficiency, adaptability and development of the economy;
- b) to provide consumers with competitive prices and product choices;
- c) to promote employment and advance the social and economic welfare of South Africans;
- d) to expand opportunities for South African participation in world markets and recognize the role of foreign competition in the Republic;
- e) to ensure that small and medium-sized enterprises have an equitable opportunity to participate in the economy; and
- f) to promote a greater spread of ownership, in particular, to increase the ownership stakes of historically disadvantaged persons.”<sup>15</sup>

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<sup>14</sup> See Chapters 2 and 3.

<sup>15</sup> Section 2 of the Competition Act 89 of 1998.

### 1.2.2 The origins of Competition law

The history of competition law which some refer to as anti-trust law, can be traced to its origin in the US. The US became concerned about the growth of corporate monopolies dominating the manufacturing and mining industries in the late 1800s.<sup>16</sup> Industries as diverse as sugar, beef, and tobacco all saw rapid growth in manufacturing and distribution businesses. As a result, there was more competition, and many businesses tried to lessen it by engaging in practices like price-fixing, monopolies, and mergers.<sup>17</sup> It is from this background that the Sherman Antitrust Act<sup>18</sup> was born. At the core of the Sherman's Act objectives was to promote economic fairness and competitiveness by prohibiting companies from colluding or merging to form a monopoly, while regulating interstate commerce.<sup>19</sup> The history and development of competition law in South Africa is discussed in part 1.2.3 below.

### 1.2.3 The role of Competition law

The central tenet of competition law is the requirement to safeguard the competitive process, consumers, and other pertinent interests in domestic markets.<sup>20</sup> Competition law addresses three types of economic practices: horizontal and vertical constraints, abuse of dominance, and merger regulation.<sup>21</sup> It seeks to promote and strengthen competition by ensuring that restrictive practices like cartels and monopolies are eliminated.<sup>22</sup> Competition law is thus desirable because it can be seen as a powerful tool for achieving significant benefits for nations and their citizens, including fostering innovation, accelerating growth, and defending the welfare and social development of nations.<sup>23</sup> It is from this background that scholars have a consensus that the main goals of competition law are; consumer welfare – which means all things that are good for consumers, such as low prices, innovation, and choice among different products;<sup>24</sup>

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<sup>16</sup> Dabber MM *International and Comparative Competition Law* (2010) 228.

<sup>17</sup> Dabber MM *International and Comparative Competition Law* (2010) 228.

<sup>18</sup> The Sherman Antitrust Act of 1890.

<sup>19</sup> Federal Trade Commission 'The Antitrust Laws' available at <https://www.ftc.gov/advice-guidance/competition-guidance/guide-antitrust-laws/antitrust-laws> (accessed 14 November 2023).

<sup>20</sup> Mehra SK 'Data Privacy and Antitrust in Comparative Perspective' (2020) *Cornell International Law Journal* 140.

<sup>21</sup> Sutherland P & Kemp K *Competition Law of South Africa* (2014) 2.2

<sup>22</sup> Van Heerden & Neethling *Unlawful Competition* (1994) 12.

<sup>23</sup> Whish & Bailey *Competition Policy and Economics* (2012) 4.

<sup>24</sup> Venkateshwaran H 'Competition Policy vis-a-vis Consumer Welfare' (2011) *International Journal for Legal Research and Analysis* 3.

economic efficiency – which is broken down into production, dynamic and allocative efficiency;<sup>25</sup> and free and fair competition.<sup>26</sup>

The Chicago School of Thought fully encapsulates the notion of consumer welfare as a goal of competition law by stating that consumer welfare consists of lowering prices, increasing output, and providing a variety of choices and quality of goods and services for the consumer, by creating an atmosphere that enhances technological advancements and innovation.<sup>27</sup> This interpretation coincides with everyday parlance as competition for the man in the street implies low prices, innovation and choice among differing products. It is from this premise that the Competition Appeal Court in *Trudon (Pty) Ltd v Directory Solutions CC and Another*<sup>28</sup> held that where a threat of harm to consumer welfare exists, competition law must intervene. The intriguing feature of the relationship between competition law and consumer welfare is that by defending the firms' rights to free market competition, the interests of consumers are indirectly safeguarded. The motivation for this is the chance to compete, which typically inspires competition and leads to a constructive allocation of resources, which in turn promotes consumer welfare.

#### 1.2.4 Competition law in South Africa

South Africa follows a blended system in measuring competition law by amalgamating both the economic and public interest factors. Unlike in most developing countries that adopted theories developed mostly in the European Union (EU) and the US,<sup>29</sup> the South African government saw it fit to interfere with the market by including public interest concerns as part of competition law objectives in sections 2(c), (e) and (f)<sup>30</sup> of the Competition Act as competition law objectives are not a one-size-fits-all approach.

The notion of the inclusion of public interest concerns was excellently highlighted in the precedence set out in *Walmart/Massmart* merger<sup>31</sup> which lucidly provides a microcosm of the macrocosm of the rationale behind including public interest as a goal in competition to be in

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<sup>25</sup> Venkateshwaran H 'Competition Policy vis-à-vis Consumer Welfare' (2011) *International Journal for Legal Research and Analysis* 3.

<sup>26</sup> Neuhoff M (ed) *A Practical Guide to the South African Competition Act* (2017) 3-19.

<sup>27</sup> United Nations Conference on Trade and Development (UNCTAD) 'Sixth United Nations Conference to Review All Aspects of the Set Principles and Rules for the Control of Restrictive Business Practices' (2010) 3.

<sup>28</sup> *Trudon (Pty) Ltd v Directory Solutions CC and Another* [2010] 2 CPLR 202 (CAC) para 38.

<sup>29</sup> Dabber MM *International and Comparative Competition Law* (2010) 290.

<sup>30</sup> Sections 2(c), (e) and (f) of the Competition Act.

<sup>31</sup> *Wal-Mart Inc/Massmart Holding Ltd*, [2011] ZACT 41.

tandem with the demands of the country's pressing economic redistributive needs and a blended competition law system. Apart from the usual economic efficiency concerns in assessing the merger, the Competition Appeals Court also relied on the impact the merger might have on employment,<sup>32</sup> and effect on Small, Medium and Micro Enterprises (SMMEs),<sup>33</sup> which fall under the branch of public interest concerns.

### 1.2.5 Anti-competitive practices

The Competition Act in Chapter 2 specifically prohibits anti-competitive practices, namely horizontal restraints, vertical restraints and abuse of dominance.<sup>34</sup> Horizontal restraints involve companies that are in a horizontal relationship that is they provide complementary goods or services which engage in conduct contrary to the objectives of fair competition.<sup>35</sup> On the other hand, vertical restraints entail companies that are in a vertical relationship with one another at different points in the distribution chain and that provide complementary goods or services that end up partaking in anti-competitive behaviour.<sup>36</sup> Abuse of dominance occurs when a company that has a large market power abuses its position by engaging in exclusionary or exploitative conduct as determined by its market share.<sup>37</sup> For the purposes of this dissertation, the focus will be on abuse of dominance as it is closely linked to price discrimination and fixing that is prevalent in the pharmaceutical industry.

## 1.3 COMPETITION LAW AND INTELLECTUAL PROPERTY RIGHTS

The clash between IP and competition law became more apparent during the COVID-19 pandemic and health crisis. Numerous academic works illustrate how closely related other legal areas, such as IP law, are to the achievement of competition law goals.<sup>38</sup> To be specific, one of the goals of competition law is to provide consumers with competitive prices and product choices;<sup>39</sup> and the desired outcomes of the quality of *goods or services* and innovation observed

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<sup>32</sup> *Wal-Mart Inc/Massmart Holding Ltd* para 137-139.

<sup>33</sup> *Wal-Mart Inc/Massmart Holding Ltd* para 2.1.4.

<sup>34</sup> Chapter 2 of the Competition Act.

<sup>35</sup> Sutherland P & Kemp K *Competition Law of South Africa* (2014) 5.3.

<sup>36</sup> Sutherland P & Kemp K *Competition Law of South Africa* (2014) 5.3.

<sup>37</sup> Section 6- section 9 of the Competition Act.

<sup>38</sup> Panda A, Patel A, Akshay D, Siddhartha K and Mathew SP 'Intellectual Property Law & Competition Law' (2010) 6 *Journal of International Commercial Law and Technology* 120-130.

<sup>39</sup> Section 2(1)(b) of the Competition Act.

in a market<sup>40</sup> directly relate to the aims of IP law (patents) encapsulated in the Patent Act 57 of 1978.<sup>41</sup>

The co-existence of these two branches of law is characterised by complexities as certain interests are at loggerheads. On one side of the debate is the necessity to take a human-rights-based approach to promote the realisation of the right to health through the availability of more affordable patented vaccinations,<sup>42</sup> which correlates to the realisation of consumer welfare goals. Article 8 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)<sup>43</sup> states that the World Trade Organisation (WTO) member countries may adopt measures necessary for the protection of public health provided that such measures are consistent with the other provisions under TRIPS.<sup>44</sup> On the other side, pharmaceutical businesses rely on the monopoly afforded by patents to recover their Research and Development (R&D) costs, marketing, and advertising expenses and incentivise innovation while making a profit and return on their investment,<sup>45</sup> a position which supports a triumph of IP rights over competition law and/or human rights.

Article 12 of the International Covenant on Economic, Social, and Cultural Rights (ICESCR),<sup>46</sup> which affirms that everyone has the right to the enjoyment of the highest achievable quality of physical and mental health, provides strong support for adopting a human-rights-based approach. The right has been interpreted to include the “prevention, treatment and control of

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<sup>40</sup> Section 43A(3)(b)(ii) of the Competition Act.

<sup>41</sup> Section 25 of the Patent Act 57 of 1978:

(1) A patent may, subject to the provisions of this section, be granted for any new invention which involves an inventive step and which is capable of being used or applied in trade, industry or agriculture.

<sup>42</sup> Hamilton C & Stokes GM ‘Patented Brand Drugs are Essential Facilities and Regulatory Compacts’ (2023) *Northwestern Journal of Technology and Intellectual Property* 18.

<sup>43</sup> The Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organisation, Annex IC, 1869 U.N.T.S 299, 33 I.L.M 1197 (1994) (hereafter, TRIPS).

<sup>44</sup> Article 7 of the TRIPS Agreement.

<sup>45</sup> Hamilton C & Stokes GM ‘Patented Brand Drugs are Essential Facilities and Regulatory Compacts’ (2023) *Northwestern Journal of Technology and Intellectual Property* 18.

<sup>46</sup> Article 12(2)(c) of the United Nations, International Covenant on Economic, Social and Cultural Rights, 1976:

1. The States Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.

2. The steps to be taken by the States Parties to the present Covenant to achieve the full realization of this right shall include those necessary for:

(a) The provision for the reduction of the stillbirth-rate and of infant mortality and for the healthy development of the child;

(b) The improvement of all aspects of environmental and industrial hygiene;

(c) The prevention, treatment and control of epidemic, endemic, occupational and other diseases;

(d) The creation of conditions which would assure to all medical service and medical attention in the event of sickness.

epidemic, endemic, occupational and other diseases” and the “creation of conditions which would assure to all medical service and medical attention in the event of sickness.”<sup>47</sup> The Constitution of South Africa, 1996 (the Constitution) also reinforces this right in section 27(1)(a),<sup>48</sup> which was further interpreted in *the Minister of Health v Treatment Action Campaign*<sup>49</sup> wherein the right to health was construed to include the right to access lifesaving drugs. It is from that bearing that, as provided in Article 102 of the Treaty on the Functioning of the European Union (TFEU)<sup>50</sup> and Section 8 of the Competition Act,<sup>51</sup> competition law may play an important role in realising the right to health as it seeks to monitor and curb excessive pricing by dominant undertakings and/or cartel activity.

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<sup>47</sup> Article 12(2)(c) of the United Nations, International Covenant on Economic, Social and Cultural Rights, 1976.

<sup>48</sup> Section 27 of the Constitution, 1996:

- (1) Everyone has the right to have access to—
  - (a) health care services, including reproductive health care.

<sup>49</sup> *Minister of Health and Others v Treatment Action Campaign and Others* 2002 (10) BCLR 1033 (CC) (5 July 2002) paras 130-131.

<sup>50</sup> Article 102 of the TFEU:

Any abuse by one or more undertakings of a dominant position within the internal market or in a substantial part of it shall be prohibited as incompatible with the internal market in so far as it may affect trade between Member States.

Such abuse may, in particular, consist in:

- (a) directly or indirectly imposing unfair purchase or selling prices or other unfair trading conditions;
- (b) limiting production, markets or technical development to the prejudice of consumers;
- (c) applying dissimilar conditions to equivalent transactions with other trading parties, thereby placing them at a competitive disadvantage;
- (d) making the conclusion of contracts subject to acceptance by the other parties of supplementary obligations which, by their nature or according to commercial usage, have no connection with the subject of such contracts.

<sup>51</sup> Section 8 of the Competition Act:

Abuse of a dominant position:

- (1) It is prohibited for a dominant *firm* to—
  - (a) charge an excessive price to the detriment of consumers or customers;
  - (b) refuse to give a competitor access to an *essential facility* when it is economically feasible to do so;
  - (c) engage in an *exclusionary act*, other than an act listed in paragraph (d), if the anti-competitive effect of that act outweighs its technological, efficiency or other pro-competitive gain; or
  - (d) engage in any of the following *exclusionary acts*, unless the *firm* concerned can show technological, efficiency or other pro-competitive gains which outweigh the anti-competitive effect of its act—
    - (i) requiring or inducing a supplier or customer to not deal with a competitor;
    - (ii) refusing to supply scarce *goods or services* to a competitor or customer when supplying those *goods or services* is economically feasible;
    - (iii) selling *goods or services* on condition that the buyer purchases separate *goods or services* unrelated to the object of a contract, or forcing a buyer to accept a condition unrelated to the object of a contract;
    - (iv) selling *goods or services* at *predatory prices*;
    - (v) buying-up a scarce supply of intermediate goods or resources required by a competitor; or
    - (vi) engaging in a *margin squeeze*.

On the other side of the debate is a movement calling for the adoption of a more IP law-based approach.<sup>52</sup> Vaccines are scientific inventions that ought to be treated as IP, particularly the ones developed for the COVID-19 pandemic. Therefore, by establishing market exclusivity—which is typically accomplished through patenting—IP rights should safeguard both existing and future inventions. Patents are an intentional government grant of monopoly power to incentivise R&D.<sup>53</sup> The TRIPS patent regime<sup>54</sup> allows the innovator to enjoy the benefits of the patent for 20 years from the date of filing which is similar to the standpoint adopted by the Patent Act.<sup>55</sup>

Thus, inventors should be able to profit from their creations for as long as the patent is valid. At the same time patents may be abused or result in unduly high costs for the intended market.<sup>56</sup> To put it another way, some IP rights protection may completely diverge from its intended goals and cause people further hardships. This played out during the distribution of COVID-19 vaccinations which was widely unequal between richer and poorer nations; by the end of April 2021, just 0.2% of the 1.3 billion doses had been administered to the latter.<sup>57</sup>

#### 1.4 PROBLEM STATEMENT

The COVID-19 pandemic brought the world to a complete stop because it offered unprecedented challenges that called for innovative answers. The virus' extraordinary rate of infection, death, and spread prompted researchers to search for a suitable vaccine to mitigate its effects. Pharmaceutical giants including GSK, Merck & Co., Sanofi Pasteur, and Pfizer, who collectively hold more than 80% of the market value,<sup>58</sup> led the race to create a COVID-19 vaccine.

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<sup>52</sup> R Gargi and R Gupta 'Intellectual Property Rights vs. Human Rights: A Need to Re-Examine the Relationship between the Two to Enhance Social Being' available at <https://ssrn.com/abstract=1887024> or <http://dx.doi.org/10.2139/ssrn.1887024> (accessed 07 March 2024).

<sup>53</sup> Dean & Dyer *Introduction to Intellectual Property Law* (2014) 259.

<sup>54</sup> Article 33 of the TRIPS:

*Term of Protection*

The term of protection available shall not end before the expiration of a period of twenty years counted from the filing date.

<sup>55</sup> Section 55 of the Patent Act.

<sup>56</sup> Storz U 'The patent maze of COVID-19 vaccines' (2021) *Expert Opinion on Therapeutic Patents* 1179.

<sup>57</sup> United Nations (UN) News 'Low-income countries have received just 0.2 per cent of all COVID-19 shots given' available at <https://news.un.org/en/story/2021/04/1089392> (accessed 07 March 2024). See also Li Z, Lu J & Lv J 'The Inefficient and Unjust Global Distribution of COVID-19 Vaccines: From a Perspective of Critical Global Justice' (2021) *The Journal of Health Care Organization, Provision, and Financing* 2.

<sup>58</sup> Jin L 'Alternative Protection of Intellectual Property Rights in Vaccine Production and Use under Covid-19' (2022) *Journal of Education, Humanities and Social Sciences* 147.

As a result of patent laws and the high cost of R&D, citizens in developed and developing nations were confronted with unequal access to affordable vaccines. An illustration of the disparities in vaccine pricing can be noted in the AstraZeneca Oxford-based vaccine which sold for a higher price of \$5.25 per dose, in South Africa as compared to \$2.15 and \$3-\$4 in Europe and in the US respectively.<sup>59</sup> In the US, a dose of Moderna was sold for \$15.25 per dose and Pfizer came at \$19.50 per dose.<sup>60</sup> These figures were quite high for most developing countries where citizens are living on less than \$3.20 per day in lower-middle income countries.<sup>61</sup> Furthermore, just 0.2% of the 1.3 billion doses of the COVID-19 vaccine had been administered to low-income countries by the end of April 2021, demonstrating the stark disparity in the vaccine's distribution between wealthy and underprivileged nations,<sup>62</sup> with countries such as Cameroon, Burundi and Namibia having fewer than 50 doses per 100 people.<sup>63</sup>

The COVID-19 pandemic has led to a renewed focus on the intersections between IP (patent) rights and competition law, with particular emphasis on the legal ramifications of market dominance, innovation, and drug pricing in the pharmaceutical sector. The pharmaceutical sector is characterised by atypical economics and a peculiar confluence of competition and patent law. Given that the pharmaceutical industry operates as an oligopoly, there are far too many discussions about the abuse of dominance,<sup>64</sup> and there has been increased debate over which of the two competing interests should come first. Some scholars have even gone so far as to label this as a situation where “profit over life” is being pursued.<sup>65</sup>

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<sup>59</sup> Jin L ‘Alternative Protection of Intellectual Property Rights in Vaccine Production and Use under Covid-19’ (2022) *Journal of Education, Humanities and Social Sciences* 147.

See also A Winning ‘South Africa to pay \$5.25 a dose for AstraZeneca vaccine from India's SII’ REUTERS available at <https://www.reuters.com/article/us-health-coronavirus-safrica-vaccines/south-africa-to-pay-5-25-a-dose-for-astrazeneca-vaccine-from-indias-sii-idUSKBN29Q0JL/> (accessed 07 March 2024).

<sup>60</sup> Kates J, Coc C & Michaud J ‘How Much Could COVID-19 Vaccines Cost the U.S. After Commercialization?’ available at <https://www.kff.org/coronavirus-covid-19/issue-brief/how-much-could-covid-19-vaccines-cost-the-u-s-after-commercialization/> (accessed 19 February 2024).

<sup>61</sup> World Bank ‘Nearly Half the World Lives on Less than \$5.50 a Day’ available at <https://www.worldbank.org/en/news/press-release/2018/10/17/nearly-half-the-world-lives-on-less-than-550-a-day> (accessed 11 January 2024).

<sup>62</sup> United Nations (UN) News ‘Low-income countries have received just 0.2 per cent of all COVID-19 shots given’ available at <https://news.un.org/en/story/2021/04/1089392> (accessed 07 March 2024).

<sup>63</sup> Statista ‘Number of administered coronavirus (COVID-19) vaccine doses per 100 people in Africa as of March 15, 2023, by country’ available at <https://www.statista.com/statistics/1221298/covid-19-vaccination-rate-in-african-countries/> (accessed 14 January 2024).

<sup>64</sup> Pitruzzella G & Arnaudo L ‘On Vaccines, Pharmaceutical Markets and a Role for Competition Law in Protecting (Also) Human Rights (2017) *European Competition Law Review* 350.

<sup>65</sup> de Haan E ‘Big Pharma raked in USD 90 billion in profits with COVID-19 vaccines’ available at <https://www.somo.nl/big-pharma-raked-in-usd-90-billion-in-profits-with-covid-19-vaccines/> (accessed 23 February 2024). See also Kollewe J ‘Pfizer accused of pandemic profiteering as profits double’ available at

It is an undeniable fact that IP rights also have an influence on R&D spending and its distribution among different areas and countries.<sup>66</sup> These two problems are interrelated and have raised many concerns and controversies in the industry and in the application of competition law to IP rights use and agreements. Thus, in response to the access to essential medicines in times of pandemic (present and future) the role of competition law in the accessibility, distribution and pricing of medical innovations protected by patents has thus been brought back to the surface and will be the focus of this mini-dissertation.

## 1.5 RESEARCH QUESTIONS

The mini-dissertation seeks to resolve the following main question:

In view of the COVID-19 experience in South Africa, to what extent can competition law be applied as a regulatory tool to address anti-competitive behaviours in the pharmaceutical industry in order to promote access to medicines in future pandemics in South Africa?

To answer the main question, the following sub-questions will be addressed:

- a) What are the competition concerns in the pharmaceutical industry?
- b) How effective is competition law as a tool to curb abuse of patent rights resulting in excessive pricing of medicines in the pharmaceutical industry?
- c) What is the role of competition law and competition authorities in tackling anti-competitive behaviours relating to pricing and distribution of medicine in future pandemics?
- d) What possible strategies can competition law enforcers adopt to curb anti-competitive behaviours arising from the abuse of patent rights in the pharmaceutical industry in future pandemics?

## 1.6 THE OBJECTIVES OF THE RESEARCH PROJECT

The overarching purpose of this study is to draw from the experience with access to COVID-19 vaccines in South Africa and assess the interface between competition law and patent law

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<https://www.theguardian.com/business/2022/feb/08/pfizer-covid-vaccine-pill-profits-sales> (accessed 23 February 2024).

<sup>66</sup> Sugarda P & Wicaksono M 'Balancing IP Rights and Competition Law through Patent Pools in Indonesia: A Comparative Analysis' (2021) *Journal of Central Banking Law and Institutions* 106.

in relation to the promotion of access to medicines during future pandemics. To this end, the mini-dissertation will examine the effectiveness of competition law as a regulatory tool to address anti-competitive behaviours in the pharmaceutical industry in order to promote access to medicines in future pandemics in South Africa.

The specific objectives of this study are to:

- a) examine the competition concerns in the pharmaceutical industry.
- b) analyse the effectiveness of competition law as a tool to curb abuse of patent rights resulting in excessive pricing of medicines in the pharmaceutical industry.
- c) investigate the role of competition law and competition authorities in tackling anti-competitive behaviours relating to pricing and distribution of medicines during pandemics.
- d) recommend possible strategies that competition law enforcers can adopt to curb anti-competitive behaviours arising from the abuse of patent rights in the pharmaceutical industry in future pandemics.

## **1.7 SIGNIFICANCE OF STUDY**

The patterns of worldwide pandemics, such as HIV, Zika, Ebola, COVID-19, and monkeypox, appear to be recurring. There appears to be a failure in the global response to health crises. Future vaccine development will unavoidably become increasingly necessary. In cases where lives need to be spared, the discussion on balancing the benefits to accrue to inventors as a result of patents, drug pricing and accessibility will continue after the COVID-19 pandemic. This mini-dissertation thus aims to contribute to the debate and the existing literature on the balancing of the two competing interests; that is IP rights and competition interests in the pharmaceutical industry by providing a different more nuanced perspective. The study will not only be of value to South Africa or the Southern African Development Community (SADC) region alone, but also to the African continent at large. It will shed light on the appropriate responses by assessing the role of competition law in curtailing anti-competitive conduct prevalent in the pharmaceutical industry.

## 1.8 LITERATURE REVIEW

Several remarkable studies have already been undertaken and need to be revisited to highlight the contribution of this study to the existing body of knowledge.<sup>67</sup> There has been growing consensus amongst scholars that the realisation of competition objectives is not to be done in isolation but rather through help from other branches of law.<sup>68</sup> Many scholars are agreeable to the fact that competition law should intervene to regulate anti-competitive behaviour rampant in the pharmaceutical industry.<sup>69</sup> However, there has been no consensus on the preferred method. Some scholars advocate for IP waivers,<sup>70</sup> with some supporting price control measures<sup>71</sup> and the latter group suggesting the employment of compulsory licensing.<sup>72</sup>

Liannos, Minssen and Kollmar propose that competition authorities should take a proactive approach to controlling the pharmaceutical industry's anti-competitive practices, which are typified by the presence of oligopolies that impede competition goals, particularly those related to consumer welfare.<sup>73</sup> They suggested that in sectors where competition can be limited primarily because of competing interests such as IP rights and the overall structure of the pharmaceutical industry, competition law should be applied by competition authorities as a "sword" to enable the achievement of public health goals.<sup>74</sup> Patel et al, who contend that the

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<sup>67</sup> Panda A, Patel A, Akshay D, Siddhartha K & Mathew SP 'Intellectual Property Law & Competition Law' (2010) 6 *Journal of International Commercial Law and Technology* 120-130. See also Jenny F 'Competition Law Enforcement and the Covid-19 Crisis: Business as (Un)usual?' (2020) available at SSRN: <https://ssrn.com/abstract=3606214> or <http://dx.doi.org/10.2139/ssrn.3606214> (accessed 19 December 2023).

<sup>68</sup> Venkateshwaran H 'Competition Policy vis-a-vis Consumer Welfare' (2011) *International Journal for Legal Research and Analysis* 4.

See also R Gargi and R Gupta 'Intellectual Property Rights vs. Human Rights: A Need to Re-Examine the Relationship between the Two to Enhance Social Being' available at <https://ssrn.com/abstract=1887024> or <http://dx.doi.org/10.2139/ssrn.1887024> (accessed 07 March 2024); Jin L 'Alternative Protection of Intellectual Property Rights in Vaccine Production and Use under Covid-19' (2022) *Journal of Education, Humanities and Social Sciences* 150.

<sup>69</sup> Lianos I, Minssen T & Kollmar C 'Tackling Grand Challenges with Competition Law: Lessons from the Pandemic' in Sauter W, Canoy M & Mulder J (eds) *EU Competition Law and Pharmaceuticals* (2022) 2.

See also Panda A, Patel A, Akshay D, Siddhartha K & Mathew SP 'Intellectual Property Law & Competition Law' (2010) 6 *Journal of International Commercial Law and Technology* 120-130.

<sup>70</sup> Katarina Foss-Solbrekk K, 'The IP waiver and COVID-19: reasons for unwavering support' (2021) *Journal of Intellectual Property Law & Practice* 1349.

See also Jin L 'Alternative Protection of Intellectual Property Rights in Vaccine Production and Use under Covid-19' (2022) *Journal of Education, Humanities and Social Sciences* 151.

<sup>71</sup> Danieli D 'Excessive pricing in the pharmaceutical industry: adding another string to the bow of EU competition law' (2021) *Health Econ Policy Law* 64-75.

<sup>72</sup> Hamilton C & Stokes GM 'Patented Brand Drugs are Essential Facilities and Regulatory Compacts' (2023) *Northwestern Journal of Technology and Intellectual Property* 19.

<sup>73</sup> Lianos I, Minssen T & Kollmar C 'Tackling Grand Challenges with Competition Law: Lessons from the Pandemic' in Sauter W, Canoy M & Mulder J (eds) *EU Competition Law and Pharmaceuticals* (2022) 2.

<sup>74</sup> Lianos I, Minssen T & Kollmar C 'Tackling Grand Challenges with Competition Law: Lessons from the Pandemic' in Sauter W, Canoy M & Mulder J (eds) *EU Competition Law and Pharmaceuticals* (2022) 7.

competition authorities must ensure the co-existence of IP laws and competition policy in order to promote both consumer and economic welfare, also support this position as both policies aim to foster innovation, which in turn advances a country's economy.<sup>75</sup>

Liannos et al contend that the vaccine and pharmaceutical industries' oligopolistic market structure undermines the goals of competition law because it allows a small number of players to control the market and abuse their dominance to the point where the industry becomes uncompetitive. This, in turn, affects drug prices, which has a two-fold impact on consumer welfare and the right to health. According to this viewpoint, competition authorities must monitor and prevent dominating enterprises' and/or cartel activity's excessive pricing<sup>76</sup> to realise the right to health.

Jin advances the case for the use of IP waivers to address the issues pertaining to the manufacturing and distribution of vaccines.<sup>77</sup> Vaccinations are scientific discoveries that should be safeguarded and handled like IP.<sup>78</sup> As stated earlier, patent protection for any pharmaceutical product is up to 20 years under TRIPS. According to Jin, the result of the aforementioned patent protection, particularly concerning vaccinations, is that developing nations that lack the resources to carry out independent R&D on COVID-19 vaccines are compelled to depend on nations where vaccines are manufactured, and patents are established. This is also supported by Foss-Solbrekk who states that a preferable path to universal vaccine accessibility would be to adopt the COVID-19 IP waiver, which would enable pharmaceutical companies, academic institutions, and pertinent governmental authorities to take immediate action without waiting for state IP licencing.<sup>79</sup> This is because some wealthy states retain vaccines because they can afford to do so, putting developing nations at a financial disadvantage as their vaccination costs triple those of developed nation patent holders.<sup>80</sup> One

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<sup>75</sup> Panda A, Patel A, Akshay D, Siddhartha K & Mathew SP 'Intellectual Property Law & Competition Law' (2010) 6 *Journal of International Commercial Law and Technology* 120.

<sup>76</sup> Panda A, Patel A, Akshay D, Siddhartha K & Mathew SP 'Intellectual Property Law & Competition Law' (2010) 6 *Journal of International Commercial Law and Technology* 121.

<sup>77</sup> Jin L 'Alternative Protection of Intellectual Property Rights in Vaccine Production and Use under Covid-19' (2022) *Journal of Education, Humanities and Social Sciences* 147.

<sup>78</sup> Chaudhary T & Chaudhary A 'TRIPS waiver of COVID-19 vaccines: Impact on pharmaceutical industry and what it means to developing countries' (2021) *The Journal of World Intellectual Property* 449.

<sup>79</sup> Katarina Foss-Solbrekk K, 'The IP waiver and COVID-19: reasons for unwavering support' (2021) *Journal of Intellectual Property Law & Practice* 1351.

<sup>80</sup> Jin L 'Alternative Protection of Intellectual Property Rights in Vaccine Production and Use under Covid-19' (2022) *Journal of Education, Humanities and Social Sciences* 147.

instance of this pricing disparity between wealthy and poor nations became evident during the COVID 19 pandemic with respect to the sale of vaccines.<sup>81</sup>

In light of this, Jin suggests that in order for IP waivers related to the production of COVID-19 vaccines to be performed successfully, they should be classified as “force majeure,” which refers to an unforeseen occurrence or circumstance that makes performance impossible.<sup>82</sup> Applying the general concept of force majeure to the COVID-19 pandemic benefits the public at large because the pharmaceutical industry’s current undertaking is impeding consumer welfare and competition objectives by using patent protection as a defence, making access to vaccinations difficult for many people.<sup>83</sup>

Dos Santos, Ncube and Ouma note that in October 2020, in response to the COVID-19 pandemic, India and South Africa petitioned the WTO to permit countries to waive IP rights.<sup>84</sup> For waivers to successfully apply, they must be agreed to by all WTO member states which makes it a problem as many were opposed including the COVID-19 waiver application made by South Africa and India.<sup>85</sup> It is only in June of 2022 a compromise was reached with the outcome framed as a WTO “decision” rather than a waiver.<sup>86</sup> Thambisetty, McMahon, McDonagh, Yoon Kang & Dutfield note that the decision is largely unrelated to the initial TRIPS waiver petition for South Africa and India, which was predicated on the need for inexpensive access to pharmaceuticals for the containment, prevention, and treatment of COVID-19 during the pandemic.<sup>87</sup> Support from other nations was also withheld as the EU distanced itself from the text, which defeats the purpose of the waiver.<sup>88</sup> When some

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<sup>81</sup> Jin L ‘Alternative Protection of Intellectual Property Rights in Vaccine Production and Use under Covid-19’ (2022) *Journal of Education, Humanities and Social Sciences* 150.

<sup>82</sup> Hutchison D and Pretorius C (eds) *The Law of Contract in South Africa* 3 ed (2017) 434.

<sup>83</sup> Jin L ‘Alternative Protection of Intellectual Property Rights in Vaccine Production and Use under Covid-19’ (2022) *Journal of Education, Humanities and Social Sciences* 150.

<sup>84</sup> Dos Santos F, Ncube CB & Ouma M ‘Intellectual property framework responses to health emergencies – options for Africa’ (2022) *South African Journal of Science* 3.

<sup>85</sup> Balasubramaniam T ‘TRIPS Waiver Negotiations Go Down to the Wire in the Run-Up to MC12’ International Institute for Sustainable Development available at <https://www.iisd.org/articles/policy-analysis/trips-waiver-negotiations-mc12> (accessed 14 January 2024).

<sup>86</sup> WTO Ministerial Decision on The TRIPS Agreement (Adopted on 17 June 2022) WT/MIN(22)/30 WT/L/1141 available at <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/WT/MIN22/30.pdf&Open=True> (accessed 07 March 2024).

<sup>87</sup> S Thambisetty, A McMahon, L McDonagh, H Yoon Kang & G Dutfield ‘The Covid-19 TRIPS Waiver Process in Critical Review: An Appraisal of the WTO DG Text (IP/C/W/688) and Recommendations for Minimum Modifications’ available at [https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=4124497](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4124497) (accessed 07 March 2023).

<sup>88</sup> The Telegraph Online ‘European distances itself from Biden’s waiver on patent rights’ available at <https://www.telegraphindia.com/world/european-distances-itself-from-bidens-waiver-on-patent-rights/cid/1815017> (accessed 07 March 2024).

restrictions on the COVID-19 vaccine's IP rights are waived within a reasonable range in a way that does not harm scientists' and researchers' ability to be creative and profitable, manufacturers benefit from higher sales, and the waiver could have been a desirable decision because, in Jin's opinion, IP waivers benefit both consumers and patent owners.<sup>89</sup>

On the other side of the coin are critics who favour an approach of rendering assistance to less-developed countries in facilitating their access to COVID-19 vaccines without necessarily having to rely on IP waivers.<sup>90</sup> Permitting the use of IP waivers, according to some academics, will create a negative precedent and have an impact on the profitability and enjoyment of the monopoly that patents grant.<sup>91</sup> Certain authors, such as Jecker and Atuire, contend that temporary IP waivers have no bearing because the problem of medicine shortages is permanent and the number of health emergencies is constantly increasing.<sup>92</sup>

Danieli proposes the use of price control under competition law as a tool for the governance of the prevalent high prices in the pharmaceutical industry.<sup>93</sup> Support of this method finds its reference in the European jurisdiction under the TFEU. In line with the legislative prohibition set out in Article 102(a) of the TFEU,<sup>94</sup> price regulation finds its footing in line with the goal of consumer welfare. To fully understand the concept of price regulation, Danieli refers to the precedent set out in *United Brands*<sup>95</sup> where the Court of Justice of the EU (CJEU) developed a

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<sup>89</sup> Jin L 'Alternative Protection of Intellectual Property Rights in Vaccine Production and Use under Covid-19' (2022) *Journal of Education, Humanities and Social Sciences* 151.

<sup>90</sup> Goldberg PK 'Forget the vaccine patent waiver' *Project Syndicate 13 May 2021* available at <https://www.project-syndicate.org/commentary/wto-vaccine-waiver-is-beside-the-point-by-pinelopi-koujianou-goldberg-2021-05?barrier=accesspaylog> (accessed 12 January 2024).

<sup>91</sup> Decan Herald, 'Vaccine Patent Waiver Sets Dangerous Precedent, Says Big Pharma' available at <https://www.deccanherald.com/world/vaccine-patent-waiver-sets-dangerous-precedent-says-big-pharma-983279.html> (accessed 13 October 2023).

<sup>92</sup> Jecker NS & Atuire CA 'What's yours is ours: waiving intellectual property protections for COVID-19 vaccines' (2021) *Journal of Medical Ethics* 3.

<sup>93</sup> Danieli D 'Excessive pricing in the pharmaceutical industry: adding another string to the bow of EU competition law' (2021) *Health Econ Policy Law* 73.

<sup>94</sup> Article 102 of the TFEU:

Any abuse by one or more undertakings of a dominant position within the internal market or in a substantial part of it shall be prohibited as incompatible with the internal market in so far as it may affect trade between Member States.

Such abuse may, in particular, consist in:

- (a) directly or indirectly imposing unfair purchase or selling prices or other unfair trading conditions;
- (b) limiting production, markets or technical development to the prejudice of consumers;
- (c) applying dissimilar conditions to equivalent transactions with other trading parties, thereby placing them at a competitive disadvantage;
- (d) making the conclusion of contracts subject to acceptance by the other parties of supplementary obligations which, by their nature or according to commercial usage, have no connection with the subject of such contracts.

<sup>95</sup> *United Brands Company and United Brands Continental BV v Commission of the European Communities*, 27/76, EU: C:1978:22.

two-step test to assess whether goods or services were being charged excessively. Under the first threshold, it must first be established “the difference between the costs actually incurred and the price actually charged is excessive.” If the answer is in the affirmative, then it must be determined whether such a price “is either unfair in itself or when compared to competing products.”<sup>96</sup> To bridge the gaps between national pricing and reimbursement procedures, industry regulators and courts may find it useful to apply the *United Brands* test as a tool for price control in conjunction with other methodologies, as suggested by Danieli. Antitrust enforcement against excessive price practices may in fact provide certain parameters of reference.

Hamilton and Stokes believe that one way to encourage drug accessibility and affordability is through compulsory licensing, which is a provision of the TRIPS agreement.<sup>97</sup> Section 55 of the Patents Act stipulates that where it can be demonstrated that a patentee’s prior patent serves as the foundation for subsequent patents, then compulsory licensing may also be implemented.<sup>98</sup> Compulsory licensing is permitted as “other use without authorisation of the right holder” under Article 31 of the TRIPS agreement. Under specific conditions and limitations, the clause permits WTO members who are parties to the TRIPS agreement to implement mandatory licensing.<sup>99</sup>

As noted by Urias and Ramani, compulsory licensing authorises the production of generic versions of patented medicines.<sup>100</sup> Singham opines that in instances where countries employ the use of compulsory licensing, the government usually intervenes by mandating that a patent holder release their patent right to the government institution or a licensee in return for a set fee.<sup>101</sup> In determining the set fee, Hollis proposes an “outcome-based” approach wherein patent holders would be compensated based on the rated quality of life improvement generated by the

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<sup>96</sup> *United Brands*, 27/76, para. 252.

<sup>97</sup> Hamilton C & Stokes GM ‘Patented Brand Drugs are Essential Facilities and Regulatory Compacts’ (2023) *Northwestern Journal of Technology and Intellectual Property* 19.

<sup>98</sup> Section 55 of the Patents Act:

Where the working of a patent (hereinafter referred to as dependent patent) without infringement of a prior patent is dependent upon the obtaining of a licence under that prior patent, the proprietor of the dependent patent may if agreement cannot be reached as to such licence with the proprietor of the prior patent, apply to the commissioner for a licence under the prior patent, and the commissioner may grant such a licence on such conditions as he may impose, but including a condition that such licence shall be used only to permit the dependent patent to be worked and for no other purpose.

<sup>99</sup> Article 31 of the TRIPS, WTO, 2006.

<sup>100</sup> Urias E & Ramani SV ‘Access to medicines after TRIPS: Is compulsory licensing an effective mechanism to lower drug prices? A review of the existing evidence (2020) *J Int Bus Policy* 369.

<sup>101</sup> Singham S, ‘Competition Policy and the Stimulation of Innovation: TRIPS and the Interface between Competition and Patent Protection in the Pharmaceutical Industry’ (2000) *Brooklyn Journal of International Law* 390.

drug and the extent of its use. This means that drug developers would receive an income from government payments based on the drug sales (and hence the frequency of drug use) and the usefulness rating of the drugs.<sup>102</sup> The loophole in adopting an “outcome-based” approach is that the system of assessing the drugs for ratings is characterised by complexities as it should be implemented on an ongoing basis which could result in a diversion of funds received from the government.<sup>103</sup>

Brand notes that compulsory licensing is used only as a last resort in “exceptional circumstances” supported by the essential facility doctrine wherein there is a conflict between IP rights and the principles of competition law.<sup>104</sup> The Competition Act defines an essential facility as “an infrastructure or resource that cannot be reasonably be duplicated and without access competitors cannot reasonably provide goods or services to the customer.”<sup>105</sup>

Brand further notes that the first case in which refusal to license was regarded as abusive in the exercise of an IP right was the European Case of *Radio Telefis Eireann (RTE) and Independent Television Publications Ltd (ITP) v Commission of the European Communities* (commonly referred to as the *Magill* case)<sup>106</sup> where IP rights had been trumped in favour of the aims of competition law. Sapna notes that the US opposes the use of compulsory licensing as it is of the opinion that it defeats the whole purpose of a patent which is to reward innovation and for innovators to recoup costs in R&D.<sup>107</sup> Hobololo recognises that pursuing compulsory licensing is tainted with many difficulties and these include that the remedy is not one wherein the general public can employ as the application to work the non-worked patent must be done by a legal entity and that the discharge of the burden of proof is onerous as many applicants usually have inadequate evidence as patents are not on public domains.<sup>108</sup>

The methods stated above to curb excessive pricing of medicines during pandemics have mainly focused on a Eurocentric approach with developed countries leading the discussions

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<sup>102</sup> Hollis A ‘An Efficient Reward System for Pharmaceutical Innovation’ available at <https://www.keionline.org/misc-docs/drugprizes.pdf> (accessed 17 January 2024).

<sup>103</sup> Baker A, ‘Financing Drug Research: What are the issues?’ Centre for Economic and Policy Research 21 September 2004 available at <https://cepr.net/report/financing-drug-research-what-are-the-issues/> (accessed 23 February 2024).

<sup>104</sup> Brand J ‘Intellectual Property and the abuse of a dominant position in South African Competition law’ (2005) *SALJ* 912.

<sup>105</sup> Section 1 of the Competition Act.

<sup>106</sup> *Radio Telefis Eireann (RTE) and Independent Television Publications Ltd (ITP) v Commission of the European Communities* [1995] ECR I-743.

<sup>107</sup> Sapna K, ‘Compulsory Licensing of Patents During Pandemics’ (2022) *Conn. L. Rev* 65.

<sup>108</sup> Hobololo V, ‘Strategic Patenting of Pharmaceutical Inventions and The Public’s Right to Access Medicines: The South African Context’ (2015) *The African Journal of Information and Communication (AJIC)* 80.

and implementation. This study is different in that it will provide an Afrocentric approach from a South African perspective in dissecting how in particular compulsory licensing is the most desirable method in dealing with excessive pricing. Considering that developing countries, in particular African countries, are usually the ones to suffer from the ramifications of patent enforcement, as seen from the COVID-19 and HIV pandemics, it only makes sense for an African-centred approach to be adopted.

## 1.9 THE RESEARCH PROCEDURE AND METHODOLOGY

This mini-dissertation will utilise a qualitative methodology as its preferred research method. Altheide and Johnson state that qualitative research is mainly based on interpretivism<sup>109</sup> and constructivism as stated by Guba and Lincoln.<sup>110</sup> It is from that bearing that the study will consult a range of literature both primary and secondary, with an emphasis on the role of competition law and policy, functions of IP rights as well as the nature of the pharmaceutical industry to bring light and well-researched responses to the research questions. The literature that will be consulted includes, but is not limited to, primary sources of law, that is, statutes (both domestic and international), case law, treaties and regulations as well as secondary sources of law that is, journal articles, textbooks, case law, discussion papers and internet websites. The study will also rely on laws and experiences from the EU, UK and US for comparative and persuasive reasons. The reasoning behind relying on experiences from these countries is supported by sections 39(1)(b) and (c)<sup>111</sup> read together with section 233 of the Constitution<sup>112</sup> which permits any court or tribunal to consider foreign and international law when interpreting any legislation and this automatically includes an interpretation of the Competition Act. It should also be noted that the research is desk-based.

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<sup>109</sup> Altheide DL & Johnson JM, 'Criteria for assessing interpretive validity in qualitative research' in N. K. Denzin & Y. S. Lincoln (eds.) *Handbook of qualitative research* (1994) 485–499.

<sup>110</sup> Guba EG & Lincoln YS, 'Competing paradigms in qualitative research' in N. K. Denzin & Y. S. Lincoln (eds.) *Handbook of qualitative research* (1994) 105-117.

<sup>111</sup> Section 39 (1) of the Constitution:

When interpreting the Bill of Rights, a court, tribunal or forum—  
(b) must consider international law; and  
(c) may consider foreign law.

<sup>112</sup> Section 233 of the Constitution:

When interpreting any legislation, every court must prefer any reasonable interpretation of the legislation that is consistent with international law over any alternative interpretation that is inconsistent with international law.

## 1.10 PREVIEW OF CHAPTERS

This study is divided into 5 chapters namely, including this current chapter.

Chapter 2 provides an overview of IP rights that are found in the pharmaceutical industry; that is patents, copyright and trademarks. Here the chapter gives more focus to patents as it is the crux of the mini-dissertation, highlighting the nature of the rights afforded by patents, requirements for registration as well as enforcement mechanisms available to a patent holder.

Chapter 3 examines abuse of dominance as provided for under the Competition Act. It also discusses ways in which abuse of dominance manifests itself and the implications it has on competition, particularly in the pharmaceutical sector.

Chapter 4 highlights the competition concerns in the pharmaceutical industry by stressing the interplay between patent law and competition law. Here the research highlights the nature of IP rights that exist in the pharmaceutical industry, the exercise and ramifications thereof in conjunction with the exploitative and exclusionary conduct pertinent to the pharmaceutical industry as consequences of the exercise of patents.

Chapter 5 gives an overview of the research study in the form of a conclusion. It also provides recommendations that can be followed in future pandemics in order to balance consumer welfare concerns in the form of access to affordable vaccines and patent enforcement and enjoyment.

## CHAPTER 2

# EXAMINATION OF INTELLECTUAL PROPERTY RIGHTS IN THE PHARMACEUTICAL INDUSTRY

### 2.1 INTRODUCTION

The intersection of Intellectual Property Rights (IPRs) and public health policy has become a critical area of concern, particularly in the context of access to essential medicines. The development and availability of life-saving medicines rely heavily on the protection of IPRs, particularly patents. The grant of patent protection to pharmaceutical innovators, as enshrined in international agreements, such as the TRIPS,<sup>1</sup> as well as national laws such as the Patent Act 57 of 1978 (Patent Act), aims to promote innovation and reward investment in R&D. The fundamental premise underlying the patent regime posits that the advancement of industrial technology serves the greater public good, thereby justifying the grant of exclusive rights to inventors as an incentive for innovation.<sup>2</sup> While patents incentivise innovation by granting exclusive rights to inventors, they can also create barriers to access and affordability of essential medicines. The tension between promoting innovation and ensuring public health needs has become increasingly pronounced, especially in the context of the COVID-19 pandemic.

This chapter examines the complex interplay between IPRs, specifically patents, and the availability and affordability of medicines. Through a critical analysis of relevant legal frameworks, including TRIPS and the Patent Act, this chapter explores the nature of IPRs that exist in the pharmaceutical industry; that is copyrights, trademarks and patents. The discussion goes on to highlight the intricacies relating to the requirements for patent registration supporting it with existing literature and case studies. As part of this mini-dissertation, an analysis of patent examination, with a focus on potential policy reforms that can be implemented to enhance the effectiveness of the Patent Act will also be undertaken. Enforcement mechanism available to a patent holder will be identified and discussed, aiming

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<sup>1</sup> The Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organisation, Annex IC, 1869 U.N.T.S 299, 33 I.L.M 1197 (1994).

<sup>2</sup> Burrell TD *South African Patent Law and Practice* 2 ed (1986) 1.

to strengthen the patent system and promote innovation. By investigating the legal dimensions of the IP-access to medicines nexus, this chapter aims to contribute to the ongoing discourse on striking a balance between patent protection and public health needs.

## 2.2 BACKGROUND OF IPRs

The concept of IP has its roots in antiquity. However, the modern paradigm of IPRs emerged during the industrial revolution marked by the enactment of seminal international legislation.<sup>3</sup> The World Intellectual Property Organisation (WIPO) describes IPR as rights which are like any other property rights which allow creators or owners of patents, trademarks or copyrighted works to benefit from their own work or creation.<sup>4</sup> WIPO further highlights the necessity of IPRs in that, firstly the progress and well-being of humanity rests on its capacity to create and invent new works in the areas of technology and culture. Secondly, the legal protection of new creations encourages the commitment of additional resources for further innovation and also that the promotion and protection of IP spurs economic growth, creates new jobs and industries, and enhances the quality and enjoyment of life.<sup>5</sup> IPRs are founded on the principles of territoriality—which means that IPRs are bound by national legislation; temporality, which permits creators or inventors to enjoy the exclusivity granted by their IPRs for a set period of time (for example, patent protection typically lasts for twenty years); and balance, which requires IPRs to strike a balance between individual rights and the larger public interests.<sup>6</sup> The territorial principle in patents simply posits that IPRs are protected to the extent defined by IP national laws.<sup>7</sup> For instance, is a patent granted in South Africa will only enjoy monopoly to the extent defined under the Patent Act.

The IP landscape in South Africa is underpinned by various international treaties which include the Convention of Paris for the Protection of Industrial Property,<sup>8</sup> commonly referred to as the Paris Convention which deals with patents, designs and trademarks; the Berne Convention for

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<sup>3</sup> Mokyr J 'Intellectual Property Rights, Industrial Revolution, and the Beginnings of Modern Economic Growth' (2009) 99 *American Economic Review* 349.

<sup>4</sup> WIPO 'What is intellectual property' available at [www.wipo.int/about/ip/en](http://www.wipo.int/about/ip/en) (accessed 3 September 2024).

<sup>5</sup> WIPO 'What is intellectual property' available at [www.wipo.int/about/ip/en](http://www.wipo.int/about/ip/en) (accessed 3 September 2024).

<sup>6</sup> United Nations Policy Paper 'The Role of Intellectual Property Rights in Promoting Africa's Development Overview of IPR in Africa' (September 2022) 12.

<sup>7</sup> Dean & Dyer *Introduction to Intellectual Property Law* (2014) 239.

<sup>8</sup> Convention of Paris for the Protection of Industrial Property March 1883.

Protection of Literary and Artistic Works<sup>9</sup> dealing with copyright and the TRIPS<sup>10</sup> which deals with all forms of IP.<sup>11</sup> On a national level, IP law has existed in South Africa since 1916 where the composite Patents, Designs, Trademarks and Copyright Act 9 of 1916 was enacted which was subsequently repealed. Currently, IPRs in South Africa are regulated by legislation including the Patents Act, the Designs Act 195 of 1993, the Trade Marks Act 194 of 1993 and the Copyright Act 98 of 1978.

From a constitutional perspective, the present Constitution of South Africa indirectly embraces IP in section 25 (4)(b) wherein the section reads that for the purposes of this section (section 25: the property clause) property is not limited to land.<sup>12</sup> Although section 25 of the Constitution is not explicit in providing a definition of property, the phrase “not limited to land” clause (4)(b) of same has been construed in *First National Bank of SA Ltd t/a Wesbank v Commissioner, South African Revenue Service; First National Bank of SA Ltd t/a Wesbank v Minister of Finance*<sup>13</sup> to essentially include any property interests tangible or intangible which resonates with the constitutional conception of property. In *Laugh it Off Promotions CC v South African Breweries (Finance) BV t/a Sabmark International (Freedom of Expression Institute as Amicus Curiae)*,<sup>14</sup> the Constitutional Court (CC) rendered a seminal decision which established that an IP interest is of a proprietary nature for the purposes of section 25(1) of the Constitution. The court’s ruling meticulously balanced the proprietary interests safeguarded by the Trade Marks Act and the constitutional entitlement to freedom of expression as embodied in section 16 of the Constitution,<sup>15</sup> thereby ensuring a nuanced balance between IP interests

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<sup>9</sup> Berne Convention for Protection of Literary and Artistic Works September 1886.

<sup>10</sup> The Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organisation, Annex IC, 1869 U.N.T.S 299, 33 I.L.M 1197 (1994).

<sup>11</sup> South Africa has ratified and is a member of these treaties.

See Dean & Dyer *Introduction to Intellectual Property Law* (2014) xxviii.

<sup>12</sup> Section 25(4) of the Constitution of the Republic of South Africa 1996:

For the purposes of this section—

(a) the public interest includes the nation’s commitment to land reform, and to reforms to bring about equitable access to all South Africa’s natural resources; and

(b) property is not limited to land.

<sup>13</sup> *First National Bank of SA Ltd t/a Wesbank v Commissioner, South African Revenue Service; First National Bank of SA Ltd t/a Wesbank v Minister of Finance* 2002 4 SA 768 (CC) para 51.

See also Van der Walt AJ & Shay RM ‘Constitutional analysis of Intellectual Property’ (2014) 17 *PER / PELJ* 54.

<sup>14</sup> *Laugh it Off Promotions CC v South African Breweries (Finance) BV t/a Sabmark International (Freedom of Expression Institute as Amicus Curiae)* [2005] 8 BCLR 743 (CC).

<sup>15</sup> Section 16 (1) of the Constitution:

(1) Everyone has the right to freedom of expression, which includes—

(a) freedom of the press and other media;

(b) freedom to receive or impart information or ideas;

(c) freedom of artistic creativity; and

(d) academic freedom and freedom of scientific research.

while concurrently protecting the fundamental rights of expression.<sup>16</sup> The court ruled that section 34(1) of the Trade Marks Act,<sup>17</sup> which deals with dilution, did not apply in Laugh it Off's parody of SAB's Black Label beer brand as it constituted fair expression and did not tarnish the mark. On a similar footing, the Constitutional Court in *Blind SA v Minister of Trade, Industry and Competition*<sup>18</sup> also harmonised propriety rights and the constitutional principles on the basis of the principle of supremacy of the Constitution which simply states that the Constitution is the supreme law of the Republic; law or conduct inconsistent with it is invalid, and the obligations imposed by it must be fulfilled.<sup>19</sup> In line with the objects and purpose of the Constitution<sup>20</sup> the court ruled that sections 6 and 7 read together with section 23 of the Copyright Act<sup>21</sup> were unconstitutional inasmuch as they contravene fundamental rights of persons with visual and print disabilities, specifically, the right to equality and non-discrimination;<sup>22</sup> freedom of expression;<sup>23</sup> the right to human dignity;<sup>24</sup> the right to language and participation in cultural life<sup>25</sup> and the right to freedom to receive or impart information.<sup>26</sup>

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<sup>16</sup> Okorie C 'Intellectual Property and the Constitutional Court of South Africa: Lessons from the Deployment of Adjudicative Strategies' (2023) *Intellectual Property and the Constitutional Court of South Africa* 1515.

<sup>17</sup> Section 34 (1) of the Trade Marks Act:

(1) The rights acquired by registration of a trade mark shall be infringed by-

(a) the unauthorized use in the course of trade in relation to goods or services in respect of which the trade mark is registered, of an identical mark or of a mark so nearly resembling it as to be likely to deceive or cause confusion;

(b) the unauthorized use of a mark which is identical or similar to the trade 15 mark registered, in the course of trade in relation to goods or services which are so similar to the goods or services in respect of which the trade mark is registered, that in such use there exists the likelihood of deception or confusion;

(c) the unauthorized use in the course of trade in relation to any goods or 20 services of a mark which is identical or similar to a trade mark registered, if such trade mark is well known in the Republic and the use of the said mark would be likely to take unfair advantage of, or be detrimental to, the distinctive character or the repute of the registered trade mark, notwithstanding the absence of confusion or deception: Provided that 25 the provisions of this paragraph shall not apply to a trade mark referred to in section 70(2).

<sup>18</sup> *Blind SA v Minister of Trade, Industry and Competition and Others* CCT320/21 [2022] ZACC 33.

<sup>19</sup> Section 2 of the Constitution.

<sup>20</sup> Section 7 of the Constitution:

1) This Bill of Rights is a cornerstone of democracy in South Africa. It enshrines the rights of all people in our country and affirms the democratic values of human dignity, equality and freedom.

(2) The state must respect, protect, promote and fulfil the rights in the Bill of Rights.

(3) The rights in the Bill of Rights are subject to the limitations contained or referred to in section 36, or elsewhere in the Bill.

<sup>21</sup> Sections 6 and 7 of the Copyright Act provide for the nature of copyright in literary or musical works and in artistic works respectively. When read together with section 23 which provides for infringement of copyrighted works, do not cover or contain exceptions to allow people who are visually impaired to enjoy literary, musical or artistic works, without necessarily infringing on the copyright in line with section 23.

<sup>22</sup> Section 9(3) of the Constitution.

<sup>23</sup> Section 16(1) (b) of the Constitution.

<sup>24</sup> Section 10 of the Constitution.

<sup>25</sup> Section 30 of the Constitution.

<sup>26</sup> Section 32 of the Constitution.

## 2.3 IPRs IN THE PHARMACEUTICAL INDUSTRY

IPRs intersect and converge due to global advancements, market realities and legislative involvement, resulting in overlapping or parallel regimes.<sup>27</sup> IPRs are recognised in the pharmaceutical sector in three forms: patents, trademarks, and copyright. Of these, patents are the most prevalent and pertinent to this mini-dissertation. The goals of patents, as provided for by the Patents Act, is to reward inventors for their contributions to society and to promote the creation of novel and practical inventions.<sup>28</sup> The Patents Act was deemed appropriate by the legislature to address social and economic issues and offer workable solutions. It grants the owner a 20-year negative right to prevent others from creating, utilising, exercising, selling, or importing their invention.<sup>29</sup> Within the realm of patent jurisprudence, inventions are conventionally dichotomised into two categories; products and processes.<sup>30</sup> Product claims pertain to tangible subject matter, encompassing physical objects, devices and articles of manufacture.<sup>31</sup> An example of a product patent is the Epipen also known as the Automatic Injection Device used to administer epinephrine to severe allergic reactions which was initially patented by Sheldon Kaplan in 1970.<sup>32</sup> Process claims relate to methods, systems, and techniques for achieving a particular outcome.<sup>33</sup> They are commonly divided into two types namely ‘method of using’ and ‘method of making’ claims.<sup>34</sup> Process patents safeguard the proprietary procedures and techniques employed in production, distinguishing them from the product patents that protect the final output or product. Three essential requirements must be met for an invention to be eligible for patent protection in South Africa: novelty, utility, and inventiveness.<sup>35</sup>

Trademarks as IPRs also exist in the pharmaceutical industry. According to common law, a trade mark’s primary purpose is to identify its owner’s products from those manufactured by

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<sup>27</sup> *Philips Electronics BV v Remington Consumer Products* [1998] RPC 283 310.

<sup>28</sup> Section 45 (1) of the Patent Act 57 of 1978:

The effect of a patent shall be to grant to the patentee in the Republic, subject to the provisions of this Act, for the duration of the patent, 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.

<sup>29</sup> Section 46 (1) of the Patent Act.

<sup>30</sup> Thomas JR ‘Of Text, Technique and the Tangible: Drafting Patent Claims Around Patent Rules’ (1998) 17 *UIC John Marshall Journal of Information Technology & Privacy Law* 220.  
See also Burrell TD *South African Patent Law and Practice* 2 ed 58.

<sup>31</sup> Schechter RE & Thomas JR *Intellectual Property the Law of Copyrights, Patents and Trademarks* (2003) 293.

<sup>32</sup> Cui Z ‘Potential treatment for allergies and anaphylaxis’ (2023) 14 *Systematic Review Pharmacy* 249.

<sup>33</sup> Schechter RE & Thomas JR *Intellectual Property the Law of Copyrights, Patents and Trademarks* (2003) 239.

<sup>34</sup> Schechter RE & Thomas JR *Intellectual Property the Law of Copyrights, Patents and Trademarks* (2003) 239.

<sup>35</sup> Section 25 (1) of the Patent Act:

A patent may, subject to the provision of this section, be granted for any new invention which involves an inventive step and which is capable of being used or applied in trade or industry or agriculture.

others.<sup>36</sup> The definition of ‘trade mark’ in the Trade Marks Act also follows the same route in providing a connection between the goods in question and the proprietor.<sup>37</sup> This notion was supported in *LA Group (Pty) Ltd v Stable Brands (Pty) Ltd and Another*<sup>38</sup> where Ponnar JA quoted *Scandecor Developments AB v Scandecor Marketing AV & Others* where it was held that:

“A trade mark is a badge of origin or source. The function of a trade mark is to distinguish goods having one business source from goods having a different business source. It must be “distinctive”. That is to say, it must be recognisable by a buyer of goods to which it has been affixed as indicating that they are of the same origin as other goods which bear the mark and whose quality has engendered goodwill.”<sup>39</sup>

In the pharmaceutical sector, trademark registrations have been filed for the shape and colour of tablets as exemplified in *Beecham Group plc and Others v Triomed (Pty) Ltd*<sup>40</sup> wherein Beecham Group sought to enforce its registered trademark for the shape of the antibiotic Augmentin against Triomed’s importation and sale of the identical product under the name Augmaxcil. The court held that the bi-convex, regular oval shape of the tablet lacked inherent distinctiveness and failed to demonstrate acquired distinctiveness through usage.<sup>41</sup> Furthermore, the court determined that no pharmacist would reasonably perceive shape alone as an indicator of the product’s origin or association with a specific manufacturer as is the purpose of a trademark.<sup>42</sup>

Copyright as an IPR also exists in the pharmaceutical industry. Copyright is a creature of statute which is unregistrable and is presently provided for by the Copyright Act. Though at a minimum in the pharmaceutical industry in contrast to trademarks and patents, copyright can aid in the protection of artistic creations and pharmaceutical research that is supplied by a pharmaceutical business. This covers marketing materials, websites, software, product literature, and packaging designs. The creator of a work protected by copyright has the sole

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<sup>36</sup> Chowles & Webster’s *South African Law of Trade Marks, Company Names and Trading Styles* (1972) 16.

<sup>37</sup> Section 2 (1) of the Trade Marks Act 194 of 1993:

‘trade mark’ other than a certification trade mark or a collective trade mark, means a mark used or proposed to be used by a person in relation to goods or services for the purpose of distinguishing the goods or services in relation to which the mark is used or proposed to be used from the same kind of goods or services connected in the course of trade with any other person.

<sup>38</sup> *LA Group (Pty) Ltd v Stable Brands (Pty) Ltd and Another* (650/2020) [2022] ZASCA 20 para 36.

<sup>39</sup> *Scandecor Developments AB v Scandecor Marketing AV & Others* [2001] UKHL 21, [2002] FSR 122 (HL) para 16 (Cited with approval in *AM Moolla Group Ltd and Others v Gap Inc and Others* [2005] ZASCA 72; [2005] 4 All SA 245 (SCA) para 38 (AM Moolla).

<sup>40</sup> *Beecham Group plc and Others v Triomed (Pty) Ltd* [2002] 4 All SA 193 (SCA).

<sup>41</sup> *Beecham Group plc v Triomed* para 23-24.

<sup>42</sup> *Beecham Group plc v Triomed* para 15.

right to make copies, distribute them, exhibit them, and alter them.<sup>43</sup> In *Biotech Laboratories (Pty) Ltd v Beecham Group plc*,<sup>44</sup> the Appellant was accused of infringing Beecham's copyright by copying the packaging insert for Augmentin. Biotech's insert was substantially identical to the Respondent's and the court held that the Appellant's arguments were without merit and that indeed the copyright insert was clearly vested in the Respondent. The Appellant argued that the Respondent's packaging was not original and that the copyright of the package insert vested in the State in term of section 5(2) of the Copyright Act considering that Augmentin was registered under the Medicines Control Council (MCC, an organ of state) for sale.<sup>45</sup> This argument was rejected as Harms JA agreed with Swart J from the court a quo that the copyright vests in Smith-Kline Beecham as MCC's role was to approve or disapprove the package insert in line with its regulations thus not making it the owner of the copyright.<sup>46</sup>

## **2.4 LEGAL FRAMEWORK GOVERNING PATENTS: PATENTS ACT 57 of 1978**

### **2.4.1 Requirements for granting patents in South Africa**

The patent regime encompasses the protection of novel, useful inventions and discoveries in various technological domains, including biotechnology, information technology, and other applied scientific disciplines.<sup>47</sup> The grant of a monopoly pursuant to a patent incentivises the practical application and exploitation of the invention. This enables the inventor to realise a financial return through either direct exploitation of the granting of licenses to third parties in exchange for royalty payments. Burrell posits that a patent constitutes a *quid pro quo* wherein the grant of the exclusive rights (*quid*) conferred by the patent is exchanged for the disclosure and dissemination of novel knowledge (*quo*), thereby making such knowledge freely accessible for public utilisation and benefit.<sup>48</sup> However, determining whether or not any exclusive right is to be granted to an inventor, a strict application of the requirements of granting a patent are applied to ensure that patents are not granted on a charity basis where the alleged inventions

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<sup>43</sup> Termini RB & Miele A 'Copyright and Trademark Issues in the Pharmaceutical Industry: Generic Compliance or Brand Drug Imitating: 'Copycat or Compliance' (2013) *Pennsylvania Bar Association Quarterly* 35.

<sup>44</sup> *Biotech Laboratories (Pty) Ltd v Beecham Group plc and Another* 2002 (4) SA 249 (SCA).

<sup>45</sup> *Biotech Laboratories (Pty) Ltd v Beecham Group plc and Another* 2002 (4) SA 249 (SCA) para 10.

<sup>46</sup> *Biotech Laboratories (Pty) Ltd v Beecham Group plc and Another* 2002 (4) SA 249 (SCA) para 22-23.

<sup>47</sup> Burrell TD *South African Patent Law and Practice* (1986) 3.

<sup>48</sup> Burrell TD *South African Patent Law and Practice* (1986) 3.

See also *Pope Applicance Corporation v Spanish River Pulp and Paper Mills Ltd* [1929] AC 269 para 281.

are not novel or useful.<sup>49</sup> In South African patent law, an invention is required to meet three vital conditions which are novelty, usefulness, and inventiveness as espoused in section 25(1) of the Patent Act, as the substantive base.<sup>50</sup> Procedurally, the Patent Regulations provide for the form in which patent applications should take.<sup>51</sup> The substantive requirements for the registration of a patent are going to be discussed in detail below.

#### *2.4.1.1 Novelty requirement in Patents*

For a patent to be granted in South Africa and warrant the protection of exclusion and monopoly of use for 20 years, the invention should first satisfy the requirement of novelty. In patent law, novelty is part of the legal criteria for determining whether an invention is patentable. The novelty requirement is underpinned by two key policy objectives, that is; the need to prevent patentees from usurping subject matter rightfully regarded as part of the public domain<sup>52</sup> as well as encouraging innovative development by deterring inventors from engaging in duplicative development efforts.<sup>53</sup> According to Dean and Dyer,<sup>54</sup> for an invention to be considered novel, it must not have been made available to the public or part of the existing state of the art immediately preceding its priority date. The concept of ‘state of the art’ refers to all the cumulative knowledge or product or process which has been made available to the public by written description or by use or in any other way.<sup>55</sup> The reasoning behind using novelty as a criterion is not only to protect property rights as gleaned upon in section 25 of the Constitution,<sup>56</sup> but also to go on further to remove the easy option to copy patents, inertly encouraging diversity and innovation. Although novelty may never be proven absolutely, relying on patent and literature searches on the internet can provide an indication of an invention’s novelty. South Africa has an ‘absolute’ novelty criterion, which implies that identical innovations anywhere in the world will invalidate patent rights.<sup>57</sup> Meaning that, if identical innovations exist in another nation, a patent applicant will be unable to secure patent

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<sup>49</sup> Schechter RE & Thomas JR *Intellectual Property the Law of Copyrights, Patents and Trademarks* (2003) 314. See also Dean & Dyer *Introduction to Intellectual Property Law* (2014) 249.

<sup>50</sup> Patent Act 57 of 1978.

<sup>51</sup> Patent Regulations in GN R2470 G 6247 of 1 January 1979.

<sup>52</sup> Schechter RE & Thomas JR *Intellectual Property the Law of Copyrights, Patents and Trademarks* (2003) 323.

<sup>53</sup> Frischmann B ‘Innovation and Institutions: Rethinking the Economics of U.S. Science and Technology Policy’ (2000) 24 *Vermont Law Review* 347.

<sup>54</sup> Dean & Dyer *Introduction to Intellectual Property Law* (2014) 245.

See also Section 25 (5) of the Patents Act.

<sup>55</sup> *McCauley Corporation Ltd v Brickor Precast (Pty) Ltd* 1989 BP 314 (CP) para 335E.

See also Section 25 (6) of the Patents Act.

<sup>56</sup> Constitution of the Republic of South Africa.

<sup>57</sup> Dean & Dyer *Introduction to Intellectual Property Law* (2014) 245.

protection for the invention under the South African Patents Act. In *Rosaire v National Lead*<sup>58</sup> the US court reiterated that a novelty analysis is done by determining what the meaning of the claims are, what the scope of the claims are and a comparison with the prior art related to the invention in order for the alleged invention to be patentable. This position is also cemented in the local jurisdiction as highlighted in the case of *Gentiruco v Firestone*<sup>59</sup> wherein Trollop JA reiterated that the particular claim must be construed to ascertain its essential constituent elements or integers. Where the claims and prior art have been construed and are compared to each other and it is found that on comparison the two documents are essentially the same, the claim is regarded to have been anticipated and not novel.<sup>60</sup> According to Burrell<sup>61</sup> as cited with approval in *Cipla Medpro (Pty) Ltd v Aventis Pharma SA*,<sup>62</sup> the most efficient approach to assess novelty is to conduct a sequential analysis of the claim's constituent element's examining each integer individually, and correspondingly, identifying their counterparts within the purported anticipatory reference.

#### 2.4.1.2 Inventiveness requirements in Patents

Once a patent is proven to be novel, a determination of whether the patent is deemed to involve an inventive step is done.<sup>63</sup> Section 25(1) of the Patents Act provides that an invention is patentable if it involves an inventive step. This is also echoed in Article 27(1) of the TRIPS Agreement wherein it is stated that a patent shall be granted to protect inventions "which involve an inventive step."<sup>64</sup> Similarly, pursuant to article 56 of the European Patent Convention,<sup>65</sup> an invention shall be deemed to involve an inventive step if, in light of the existing state of the art, it would not be apparent to a person of ordinary skill in the relevant field. As a starting point, an in-depth analysis of what an inventive step entails need to be provided. In essence, the enquiry into inventiveness involves a four-step method. In *Ensign-*

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<sup>58</sup> *Rosaire v National Lead* 5<sup>th</sup> Circuit 1955.

<sup>59</sup> *Gentiruco v Firestone* 1972 (1) SA 589 (A) para 149.

<sup>60</sup> *Veasy v Denver Rock Drill and Machinery Co Ltd* 1930 AD 243 para 282.

<sup>61</sup> Burrell TD *South African Design and Patent Law* 3 ed (1999) para 4.22.

<sup>62</sup> *Cipla Medpro v Aventis Pharma* (139/12) *Aventis Pharma SA v Cipla Life Sciences* (138/12) [2012] ZASCA 108 (26 July 2012) para 26.

<sup>63</sup> *Cipla Medpro v Aventis Pharma* (139/12) *Aventis Pharma SA v Cipla Life Sciences* (138/12) [2012] ZASCA 108 (26 July 2012) para 27.

<sup>64</sup> Article 27 (1) of the TRIPS:

Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.

<sup>65</sup> Convention on the Grant of European Patents, Oct. 5, 1973, 13 I.L.M. 268 (1974).

*Bickford (South Africa) (Pty) Ltd and others v AECI Explosives and Chemicals Ltd*,<sup>66</sup> the court laid out the enquiry as including what the inventive step said to be involved in the patent in suit, what was, at the priority date, the state of the art relevant to that step, in what respect does the step go beyond, or differ from, that state of the art, and having regard to such development or difference, would the taking of the step be obvious to the skilled man. Section 25 (6) of the Patents Act provides that the state of the art shall comprise all matter (whether a product, a process, information about either, or: anything else) which has been made available to the public (whether in the Republic or elsewhere) by written or oral description; by use or in any other way. This section is critical in laying base in understanding the first step in the test for obviousness that is, the inventive step in the patent as for one to have a clear understanding of what inventive step is in the patent, a comparison of what was available in the public domain or state of the art needs to be done. As ruled in *Ausplow (Pty) Ltd v Northpark Trading 3 (Pty) Ltd*,<sup>67</sup> the determination of an inventive step involves a meticulous examination of patent claims to ascertain the specific inventive contribution, wherein said analysis inherently requires a comparative evaluation with the extant state of the art to assess the invention's patentability. In *Cipla Medpro v Aventis Pharma*<sup>68</sup> in the infringement case, Cipla raised that the invention claimed was not a new invention as part of its grounds of revocation under section 61 of the Patents Act.<sup>69</sup> Aventis claimed that the inventive step of the present invention which Cipla wanted revoked lies in the introduction of ethanol as an additive to the intermediate solution, effectively preventing gel formation during subsequent mixing with an aqueous medium.<sup>70</sup> The court after having considered expert evidence concluded that the description in the specification of the methods that had previously been used to overcome the difficulty was far from obvious, and that the patent is not susceptible to revocation on that ground.

After an analysis of what inventive step is the patent is done in conjunction with the analysis of the state of the art at the priority date of the patent, the inquiry follows through to assess how the invention differs from the existing state of the art.<sup>71</sup> The test of obviousness focuses on the

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<sup>66</sup> *Ensign-Bickford (South Africa) (Pty) Ltd and others v AECI Explosives and Chemicals Ltd* 1999 (1) SA 70 (SCA).

<sup>67</sup> *Ausplow (Pty) Ltd v Northpark Trading 3 (Pty) Ltd and Others* (742/10) 2011 (4) All SA 221 (SCA) (7 September 2011).

<sup>68</sup> *Cipla Medpro v Aventis Pharma (139/12) Aventis Pharma SA v Cipla Life Sciences* (138/12) [2012] ZASCA 108 (26 July 2012).

<sup>69</sup> Section 61 (1)(c) of the Patents read together with section 25 (1) puts its forward that an invention has to involve an inventive step and a lack thereof is a ground of revocation.

<sup>70</sup> *Cipla Medpro v Aventis Pharma (139/12) Aventis Pharma SA v Cipla Life Sciences* (138/12) [2012] ZASCA 108 (26 July 2012) para 28.

<sup>71</sup> Section 25 (10) of the Patents Act:

knowledge of a person of ordinary skill in the art at the time of invention, and inherency which allows later recognition of a patent.<sup>72</sup> The term person with ordinary skill in the art has been defined as an ordinary practitioner aware of what was general common knowledge in the relevant art at the relevant date.<sup>73</sup> To show non-obviousness, the inventor would have had to show that the person having ordinary skill in the art's reasonable expectation in combining the prior art references would fail from an objective standpoint because the novel property was inherently absent, but in fact not objectively present in the prior art compositions.<sup>74</sup> In *Roman Roller CC and Another v Speedmark Holdings (Pty) Ltd*<sup>75</sup> the court believed the test for obviousness must be judged by asking oneself whether, in the light of the state of the art at the time, the step forward taken by the invention would have been obvious to the skilled addressee. In *Santarus, Inc. v Par Pharms*,<sup>76</sup> the court found that the prior art rendered the formulation obvious. The court further stated that to hold otherwise would allow any formulation no matter how obvious to become patentable merely by testing and claiming an inherent property. This was also reinforced in the US Supreme Court case in *KSR International v Teleflex Inc*,<sup>77</sup> where it was held that:

“Granting patent protection to advances that would occur in the ordinary course without real innovation retards progress and may, for patents combining previously known elements, deprive prior inventions of their value or utility.”

#### 2.4.1.3 Utility

According to section 25(1) of the Patents Act, to be patentable, an invention must be capable of being utilised or used in commerce or industry. An innovation must be beneficial to be used or used in trade, industry, or agriculture. The desirability of this provision is that, it deters the filing of patents for abstract ideas or purely intellectual creations that cannot be put to any use. Under Section 61(1)(d) a lack of utility is a ground for patent revocation if the invention as depicted or exemplified in the whole specification cannot be executed or does not provide the

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Subject to the provisions of section 39 (6), an invention shall be deemed to involve to inventive step if it is not obvious to a person skilled in the art, having regard to any matter which forms, immediately before the priority date of any claim to the invention, part of the state of the art by virtue only of subsection (6) (and disregarding subsections (7) and (8)).

<sup>72</sup> *Pfizer Ltd and Another v Cipla Medpro (Pty) Ltd and Others* 2005 BIP 1 (CP) page 5.

<sup>73</sup> Correa CM (ed) *A Guide to Pharmaceutical Patents* (2012) 72.

<sup>74</sup> *Bayer Intellectual Property GMBH and Others v Dr Reddy's Laboratories (Pty) Ltd* (2021 BIP 6 (CP).para 62 wherein the court found that the expert evidence used by Dr Reddy had no specialised knowledge in the field of haematology, or actual involvement in trials aimed at determining dosage regimes for anticoagulants which essentially made his evidence irrelevant.

<sup>75</sup> *Roman Roller CC and Another v Speedmark Holdings (Pty) Ltd* 1996 (1) SA 405 (SCA).

<sup>76</sup> *Santarus, Inc. v Par Pharms* 694 F.3d 1344 (Fed. Cir. 2012).

<sup>77</sup> *KSR International v Teleflex Inc* 550 U.S. 398 (2007).

outcomes and benefits stated in the specifications.<sup>78</sup> Consistent with the *quid pro quo* principle underlying patent grants, an invention without practical utility in trade, industry or agriculture would be futile as it fails to meet the societal benefit threshold required for patent protection and compensation. Similarly, the Indian Patent Office Manual states that, “an invention is capable of industrial application if it satisfies three conditions, cumulatively; can be made; can be used in at least one field of activity; can be reproduced with the same characteristics as many times as necessary.”<sup>79</sup> These requirements are necessary to ensure that frivolous patents are not filed. In *Integrated Mining Systems (Pty) Ltd v Chamber of Mines of South Africa*<sup>80</sup> the court canvassed the issue of lack of utility and stated that:

“Not useful in patent law means that the invention will not work either in the sense that it will not operate at all or, more broadly, that it will not do what the specification promises that it will do. If the invention will give the result promised at all, the objection fails; the practical usefulness of the invention does not matter, nor does its commercial utility unless the specification promises commercial utility, nor does it matter whether the invention is of any real benefit to the public, or particularly suitable for the purposes suggested. Further, it is only failure to produce the results promised that will invalidate, not misstatements as to the purposes to which such results might be applied.”

In *Cipla Medpro v Aventis*,<sup>81</sup> Aventis’ patent on Taxotere which was used to treat various cancers once administered by way of drip was deemed useful in the pharmaceutical industry, in particular, the oncology department. The decision of the US Court of Customs and Patent Appeals in *In re Kirk*,<sup>82</sup> is instructive. In this case the court rejected intermediaries for steroids with no known use, in that the steroids compound’s utility cannot be presumed based on its structural similarity to a known useful compound. Instead, the compound’s utility must be demonstrated at the time of the application, and the pertinent inquiry is whether the disclosed compound possesses actual utility. Potential utility, in and of itself, is insufficient to establish actual utility. The patent that was subject in the matter between *Bayer and Dr Reddy’s*<sup>83</sup> was also useful in the pharmaceutical industry as the compound Rivaroxaban was found useful for the manufacture of a medicament in an oral dosage for use in the treatment of the identified thromboembolic disorders.

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<sup>78</sup> Jackson *Patent and Copy Right Law* (unpublished LLM-thesis, University of South Africa, 2011) 31.

<sup>79</sup> The Office of Controller General of Patents, Designs and Trademark of India *Manual of Patent Office Practice and Procedure* (2019) Chapter 2.

<sup>80</sup> *Integrated Mining Systems (Pty) Ltd v Chamber of Mines of South Africa* 1974 BP 281 CP paras 317E-F.

<sup>81</sup> *Cipla Medpro v Aventis* para 3.

<sup>82</sup> *In re Kirk* 1 376 F. 2d 936 (CCPA 1967) para 941.

<sup>83</sup> *Bayer Intellectual Property GMBH and Others v Dr Reddy’s Laboratories (Pty) Ltd* (2021 BIP 6 (CP)).

## 2.5 PATENT EXAMINATION

Once the substantive requirements of a patent are complied with as provided for in section 25 of the Patents Act, the inventor can proceed to file their formal application with the Companies and Intellectual Property Commission (CIPC) in the prescribed manner, on payment of the prescribed fee accompanied by a complete patent specification.<sup>84</sup> In line with Section 34 of the Patents Act<sup>85</sup> read together with Regulations 40 and 41 of the Patent Regulations,<sup>86</sup> South Africa follows a depository system or formal examination which essentially means that as long as the formalities prescribed in regulation 22 of the Patents Regulations are complied with, the CIPC will allow the application to be registered. This means that the substantive search and examination of patents which delves into the merits of the patents specification and integers is omitted.<sup>87</sup> According to Oriakhogba, a substantive patent examination evaluates patent applications for technical quality, sufficiency of disclosure, novelty, inventive step, utility of claims and industrial applicability.<sup>88</sup>

The desirability of the depository system is that, it places the burden of a substantive search on the patent holder or any interested party which in turn allows the already scarce technical skills and resources in the CIPC to be directed elsewhere.<sup>89</sup> However, in the same vein, this further burdens inventors with extra costs as already the costs of getting a patent attorney to draft patent specifications can exceed R15 000.00.<sup>90</sup> Moreover, the inventions are not tested prior being granted, unless there are disputes, thus one cannot fully know whether they are infringing on a patent or that the invention was anticipated.<sup>91</sup> The lack of substantive patent examinations

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<sup>84</sup> Regulation 22 (1) of the Patents Regulations.

<sup>85</sup> Section 34 of the Patents Act:

The registrar shall examine in the prescribed manner every application for a patent and every specification accompanying such application or lodged at the patent office in pursuance of such application and if it complies with the requirements of this Act, he shall accept it.

<sup>86</sup> Regulations 40 and 41 of the Patents Regulations:

40. Examination Any application accompanied by a provisional specification shall be examined to ensure that the documents lodged are legible and capable of reproduction.

41. The registrar shall examine the application accompanied by a complete specification in order to ensure that it complies with the prescribed formalities.

<sup>87</sup> Department of Trade and Industry *Intellectual Property Policy of The Republic of South Africa Phase I 2018* (2018) 17.

See also Dean & Dyer *Introduction to Intellectual Property Law* (2014) 258.

<sup>88</sup> Oriakhogba DO 'Dabus Gains Territory in South Africa and Australia: Revisiting The AI-Inventorship Question' (2021) 9 *South African Intellectual Property Law Journal* 92.

<sup>89</sup> Department of Trade and Industry *Intellectual Property Policy of The Republic of South Africa Phase I 2018* (2018) 17.

<sup>90</sup> Smit & Van Wyk 'Patent Costs Intellectual Property' available at <https://www.svw.co.za/south-africa-patent-costs/> (accessed 17 October 2024).

<sup>91</sup> De Rebus 'CIPC to introduce substantive search and examination' available at <https://www.derebus.org.za/cipc-introduce-substantive-search-examination/> (accessed 12 October 2024).

according to Ndlovu,<sup>92</sup> births a plethora of problems to the applicant as one cannot be sure as to who own the patent,<sup>93</sup> determine whether the patent in question does meet the section 25 requirements and as well assess whether indeed the applicant is infringing on an existing patent. In relation to pharmaceutical patents, substantive patent examination will aid in assessing the patentability of inventions to ensure that there is absolute novelty and that pharmaceutical companies will be prevented from filing multiple patents for the same drug thereby extending the 20-year monopoly or filing patents for minor improvements which will thus promote access to medicines and drugs.<sup>94</sup>

## 2.6 ENFORCEMENT OF IPRs

A key element in preserving innovation and creativity is the enforcement of IPRs. IPRs are respected and infringement is discouraged when there are strong enforcement measures in place. IPRs can be violated when someone who is not officially identified as the creator or owner does an act, or permits someone else to perform an act, over which the IPR owner has the sole authority. An owner of an IPR has a number of options for enforcing their IP in the event of such an infringement, including civil litigation, administrative procedures, criminal prosecution, and alternative dispute resolution. One of the seminal decisions highlighting the need to protect patents is the *Pharmaceutical Manufacturers Association and Others v The President of the Republic of South Africa*.<sup>95</sup> The case, which has been dubbed PharmaGate involved more than 40 pharmaceutical companies suing the South African government to halt the implementation of sections 15C, 22F and 22G of the Medicines and Related Substances

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<sup>92</sup> Ndlovu L ‘Why South Africa should introduce patent searched and examinations to improve access to essential medicines’ available at [https://www.wto.org/english/tratop\\_e/trips\\_e/colloquium\\_papers\\_e/2015/chapter\\_9\\_2015\\_e.pdf](https://www.wto.org/english/tratop_e/trips_e/colloquium_papers_e/2015/chapter_9_2015_e.pdf) (accessed 12 October 2024).

<sup>93</sup> See Oriakhogba DO ‘Dabus Gains Territory in South Africa and Australia: Revisiting The AI-Inventorship Question’ (2021) 9 *South African Intellectual Property Law Journal* 87-108, wherein inventions generated by Device for the Autonomous Bootstrapping of Unified Sentience (DABUS) were patented in South Africa with judicial support from *Thaler v Commissioner of Patents* [2021] FCA 879 in Australia which recognised DABUS an inventor but other jurisdictions such as US and EU which did not recognise DABUS as an inventor because of the human inventor requirement. *Thaler v Commissioner of Patents* was later overturned by the Full Court of the Federal Court of Australia in *Commissioner of Patent v Thaler* [2022] FCAFC 62, thus aligning with the position in UK, US and EU.

<sup>94</sup> Ndlovu L ‘Why South Africa should introduce patent searched and examinations to improve access to essential medicines’ available at [https://www.wto.org/english/tratop\\_e/trips\\_e/colloquium\\_papers\\_e/2015/chapter\\_9\\_2015\\_e.pdf](https://www.wto.org/english/tratop_e/trips_e/colloquium_papers_e/2015/chapter_9_2015_e.pdf) (accessed 12 October 2024).

See also TAC, MSF & RIS Policy Brief ‘Why South Africa Should Examine Pharmaceutical Patents: How legislative reform could boost the affordability and accessibility of medicines for South Africans’ (2013) 3.

<sup>95</sup> *Pharmaceutical Manufacturers Association and Others v The President of the Republic of South Africa and Others*, Case No.4183/98, High Court of South Africa.

Control Amendment Act,<sup>96</sup> which sought to ensure the supply of more affordable medicines through providing for parallel importation, generic substitution and setting up a pricing committee among other related measures a direct threat to the monopoly granted by the Patents Act over their patented medicines. The High Court referred the matter to the Constitutional Court (CC) for confirmation of the order that the decision by the President to bring the Medicines and Medical Devices Regulatory Authority Act 1998 into operation was null and void.<sup>97</sup> The CC confirmed the decision of the court a quo in stating that the decision made by the President to bring the Act into operation without following proper due process warranted intervention of the court's power of review.<sup>98</sup>

### 2.6.1 Civil Litigation

Once an IPR holder become aware that their IP has been violated, they have the option to take legal action against the unauthorised user. In terms of copyright, the Copyright Act stipulates that in cases where a copyright is violated, the successful copyright claimant may request an interdict, delivery-up of the infringing copies, or plates that are being used or planned to be used in the manufacture of infringing copies, in addition to damages.<sup>99</sup>

According to sections 34 and 35 of the Trade Marks Act, the owner of a trade mark may take legal action against third parties that use identical trademarks after the trademark has been registered. In *Cadila Healthcare Ltd. v Cadila Pharmaceutical Ltd.*,<sup>100</sup> Cadila Pharmaceutical was interdicted from using the word 'Falcitab' where Cadila Healthcare had obtained a trademark for 'FALCIGO' as both drugs were used to treat cerebral-malaria and the use of the word Falcitab was now causing confusion to consumers. In addition to an interdict, section 34(3) permits a trademark proprietor to obtain remedies during infringement proceedings in the form of damages, royalties, and delivery up of all infringing material.<sup>101</sup>

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<sup>96</sup> Medicines and Related Substances Control Amendment Act 90 of 1997.

<sup>97</sup> *Pharmaceutical Manufacturers Association of South Africa and Another: In re Ex Parte President of the Republic of South Africa and Others* 2000 (3) BCLR 241 paras 9-16.

<sup>98</sup> *Pharmaceutical Manufacturers Association of South Africa and Another: In re Ex Parte President of the Republic of South Africa and Others* 2000 (3) BCLR 241 paras 89-93.

<sup>99</sup> Section 24(1) of the Copyright Act 98 of 1978.

<sup>100</sup> *Cadila Healthcare Ltd. v/s Cadila Pharmaceutical Ltd.*, 2001(5) SCC 73.

<sup>101</sup> Section 34 (3) of the Trade Mark Act:

Where a trade mark registered in terms of this Act has been infringed, any High Court having jurisdiction may grant the proprietor the following relief, namely—

(a) an interdict;

In order to safeguard its IPRs and stop infringement, pharmaceutical companies rely heavily on patent litigation. A number of high-profile cases, such as *Bayer Intellectual Property GMBH v Dr Reddy's Laboratories (Pty) Ltd*<sup>102</sup> and *Pfizer Ltd v Cipla Medpro (Pty) Ltd*<sup>103</sup> have made headlines in South Africa, indicating an increase in patent litigation. Pharmaceutical companies use patent litigation as a crucial instrument to safeguard their IPRs and stop infringement.<sup>104</sup> In *Bayer International v Dr Reddy's Laboratories*,<sup>105</sup> Bayer brought a claim against Clicks seeking to prevent the distribution and sale of generic Rivaxored which Bayer was granted a patent for in 2000 under Rivaroxaban. Collis J unequivocally confirmed the rights of the patentee and that the argument raised by Clicks that the generic version of Rivaroxaban served public interest by providing a cheaper alternative did not diminish the monopoly granted to Bayer.<sup>106</sup> This case, read together with *Cipla Medpro (Pty) Ltd v Aventisa Pharma SA*<sup>107</sup> underscore the necessity for pharmaceutical companies to safeguard their patents and prevent infringement. It should be noted that the lack of substantive search and examinations by the CIPC of patents is one of the leading causes of patent litigation as only during litigation are the merits or integers of patents assessed.

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(b) an order for removal of the infringing mark from all material and, where the infringing mark is inseparable or incapable of being removed from the material, an order that all such material be delivered up to the proprietor;

(c) damages, including those arising from acts performed after advertisement of the acceptance of an application for registration which, if performed after registration, would amount to infringement of the rights acquired by registration;

(d) in lieu of damages, at the option of the proprietor, a reasonable royalty which would have been payable by a licensee for the use of the trade mark concerned, including any use which took place after advertisement of the acceptance of an application for registration and which, if taking place after registration, would amount to infringement of the rights acquired by registration.

<sup>102</sup> *Bayer Intellectual Property GMBH and Others v Dr Reddy's Laboratories (Pty) Ltd* (2021 BIP 6 (CP)).

<sup>103</sup> *Pfizer Ltd and Another v Cipla Medpro (Pty) Ltd and Others* 2005 BIP 1 (CP).

<sup>104</sup> Glasgow LJ 'Stretching the limits of intellectual property rights: has the pharmaceutical industry gone too far?' 41 (2001) *IDEA* 227.

<sup>105</sup> *Bayer Intellectual Property GMBH and Others v Dr Reddy's Laboratories (Pty) Ltd* 2021 BIP 6 (CP) paras 1-4.

See also *De Rebus A battle between patent owners and pharmacies* available at <https://www.derebus.org.za/a-battle-between-patent-owners-and-pharmacies> (accessed 15 October 2024).

<sup>106</sup> *Bayer Intellectual Property GMBH and Others v Dr Reddy's Laboratories (Pty) Ltd* 2021 BIP 6 (CP) para 98.

<sup>107</sup> *Cipla Medpro v Aventis Pharma* (139/12) *Aventis Pharma SA v Cipla Life Sciences* (138/12) [2012] ZASCA 108 (26 July 2012). In this case, it was found that Cipla by importing and offering the components of Aventis' patent Taxotere which is used in the treatment of various cancers, supplied the means of infringement to health workers who then made the composition: para 29.

## 2.6.2 Alternative dispute resolution

Due to the high cost of litigation, where there has been IP infringement, the parties typically choose mediation or arbitration as a faster and more cost-effective alternative to courtroom processes. For example, the Federal Trade Commission of America notes that settlement agreements are a means to avoid expensive litigation.<sup>108</sup> Settlement agreements and pay-for-delay agreements are prevalent in the pharmaceutical business, especially in patent litigation proceedings. Essentially, pay-for-delay agreements refer to agreements entered into by patent holders with generic companies, where the patent holders pay the generic companies to delay entry to markets containing a patent protected drug.<sup>109</sup> In the Glaxo Wellcome Plc-Zantac litigation, Glaxo, Zantac's manufacturer agreed to pay an undisclosed amount which is estimated to have exceeded US \$100 million to the generic company to prevent it from marketing a competition drug.<sup>110</sup> One case that clarifies alternate dispute resolution as a tool for IP enforcement is the case of *Lundbeck and the European Union General Court*<sup>111</sup> Lundbeck a patent holder for the citalopram molecule, a molecule used as for the production of antidepressant medicines started patent infringement proceedings against certain generic companies, including GenericsUK, Alpharma, Arrow and Ranbaxy. This eventually led to a variety of settlement agreements, which were more convenient to all parties, and meant that the companies did not have to enter into legal action, but could settle the matters independently, solely with their financial means. However, the settlement agreements were investigated by the European Commission for anti-competitiveness as there was suspected market sharing with the European Commission finding the agreements to be restrictive by object concluding that Lundbeck and the generic manufacturers were potential competitors.<sup>112</sup> As a result, Lundbeck and the generic companies were fined for €146 million.<sup>113</sup>

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<sup>108</sup> Federal Trade Commission (FTC) 'Then, now, and down the road: Trends in the pharmaceutical patent settlements after FTC v Actavis' available at <https://www.ftc.gov/enforcement/competition-matters/2019/05/then-now-down-road-trends-pharmaceutical-patent-settlements-after-ftc-v-actavis> (accessed 17 October 2024).

<sup>109</sup> Hemphill S 'Paying for delay: Pharmaceutical patent settlement as a regulatory design problem' (2006) 81 *New York Law Review* 1557.

<sup>110</sup> Hemphill S 'Paying for delay: Pharmaceutical patent settlement as a regulatory design problem' (2006) 81 *New York Law Review* 1568.

<sup>111</sup> *Lundbeck A/S, Lundbeck Ltd v European Commission, European Federation of Pharmaceutical Industries and Associations* (EFPIA) (Case C-591/16 P).

<sup>112</sup> Section 4(b)(ii) of South Africa's Competition Act also prohibits market sharing.

<sup>113</sup> European Commission, 'Case At.39226 – *Lundbeck*', 2013

## **2.7 CONCLUSION**

In conclusion, the trademarks, copyright and patents as forms of IPRs, have been useful in protecting various aspects of inventions in the pharmaceutical industry. The monopolies granted by each of these IPRs spurs innovation and allows for the owner or inventor of any of the above-mentioned IP to recuperate any costs from marketing to R&D associated with their IP. The implementation of enforcement mechanisms such as litigation and alternative dispute resolution processes, has proven effective in safeguarding IPRS, thus providing and acting as a deterrent against infringement as stated in numerous precedent above. Chapter 3 will examine abuse of dominance as a restrictive practice as provided for in the Competition Act. In particular, how patents as a right awarded to inventors can be a tool to exacerbate abuse of dominance resulting in unfair pricing, markets sharing, ultimately affecting the pricing and access to medicines in future pandemics.

# CHAPTER 3

## OVERVIEW OF ABUSE OF DOMINANCE AS A RESTRICTIVE PRACTICE UNDER THE COMPETITION ACT 89 OF 1998

### 3.1 INTRODUCTION

Understanding what exactly constitutes IPRs in the pharmaceutical industry as discussed in Chapter 2 is crucial in laying a foundation for the discussion on abuse of a dominant position which is the focus of this chapter, as IPRs can be used as a tool to exercise dominance in the markets. Abuse of a dominant position is a prohibited practice in Chapter 2 of the South African Competition Act.<sup>1</sup> Key aspects of this restricted practice include that there must be an existing dominant firm that then engages in anti-competitive conduct. Anti-competitive conduct encompasses a range of harmful practices, including predatory pricing, exclusive dealing and tying contracts, margin squeezing, and excessive pricing, which can unfairly restrict competition, stifle innovation, and harm consumers in the market.<sup>2</sup> This strikes a blow at the core of robust economic activity in the many marketplaces.

This chapter explores the concept of dominance in particular its implications on competition as provided for in sections 7, 8, and 9 of the Competition Act. The chapter will first discuss the concept of dominance, highlighting the different positions adopted in defining dominance. Secondly, a discussion on the assessment of dominance where briefly the statutory test on dominance espoused in section 7 of the Competition Act will be touched on. The chapter will further discuss the importance of identifying the relevant market in the assessment of dominance, namely the product and geographic market. Indicators of dominance will be touched on and for this mini-dissertation, market shares, market power, and superior technology will be the main focus under this heading. This particular section lays a foundation for this chapter as superior technology in the form of patents may be used to establish and entrench a position of dominance.<sup>3</sup> To substantiate the arguments, this chapter relies on sources

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<sup>1</sup> 89 of 1998.

<sup>2</sup> Organisation for Economic Co-operation and Development (OECD) ‘Abuse of Dominance in Digital Markets’ available at [https://one.oecd.org/document/DAF/COMP/GF\(2020\)4/en/pdf](https://one.oecd.org/document/DAF/COMP/GF(2020)4/en/pdf) (accessed 12 May 2024).

<sup>3</sup> Knudsen ES, Lien LS, Timmermans B, Belik I & Pandey S Stability in turbulent times? The effect of digitalization on the sustainability of competitive advantage *Journal of Business Research* 361-364.

including international treaties where the first concepts of competition law were established before being transplanted into the South African legal system, case law from both South Africa and other legal systems which will aid in the interpretation of provisions pertaining to dominance, and scholarly materials such as journal articles and textbooks.

### 3.2 THE CONCEPT OF DOMINANCE

One of the legal concepts that has generated a lot of controversy in the field of competition law presently is abuse of dominance. William Shakespeare in *Measure for Measure* once said, “O, it is excellent to have a giant’s strength: but it is tyrannous to use it as a giant.”<sup>4</sup> The principle in this quote was reaffirmed in *Competition Commission v Pioneer Foods (Pty) Ltd*<sup>5</sup> where it was established that a dominant firm has a special responsibility to ensure that its conduct does not distort competition after Pioneer foods engaged in price fixing and market allocation in the bread market. Simply put, a firm’s dominant position is not inherently problematic, but rather it is the exploitative and exclusionary conduct that may arise from such a position that is of concern. Similarly in the pharmaceutical industry, analysts have noted that while a company’s dom in a certain field is acceptable, it is concerning when that dominance is abused at the expense of competitors and customers.<sup>6</sup> Competition law scholars are, thus, primarily concerned with the abuse of dominance and how to curtail it.<sup>7</sup> Drawing inference from the UK, in *Napp Pharmaceutical Holdings Ltd and Subsidiaries v Director General of Fair Trading Competition Appeals Tribunal*,<sup>8</sup> the UK Competition Tribunal held that Napp’s high and persistent market share of 95% put it in a position of dominance approaching monopoly which places the firm on high alert for abuse of such dominance. A dominant firm or position can arise from a firm’s capacity to take advantage of its position of power in the market.

The CJEU addressed the idea of a dominant firm in detail in the case of *United Brands v European Commission* which concerned the controversial “green banana clause” which prevented any other firm from carrying Chiquita bananas cementing United Brands’ dominance in the EU banana market in breach of Article 86.<sup>9</sup> As used under Article 86 (formerly known

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<sup>4</sup> Bawcutt NW (ed) *The Oxford Shakespeare: Measure for Measure* (1991).

<sup>5</sup> *Competition Commission v Pioneer Foods (Pty) Ltd* (15/CR/Feb07).

<sup>6</sup> Whish R *Competition Law* 5 ed (2005) pages 189-190.

See also *Napp Pharmaceutical Holdings Ltd and Subsidiaries and Director General of Fair-trading Competition Appeals Tribunal*, January 2002, 1001/1/01. (hereinafter referred to as Napp Pharmaceuticals)

<sup>7</sup> Sutherland P & Kemp K *Competition Law of South Africa* (2014) 2.2.

<sup>8</sup> *Napp Pharmaceutical* para 219.

<sup>9</sup> *United Brands Co. v European Commission* Case 27/76 [1978] ECR 207, ECJ.

as Article 82) of the Treaty on European Economic Community and Related Instruments (EEC), the phrase “dominant position” was defined in *United Brands* as a being:

“Position of economic strength enjoyed by an undertaking which enables it to prevent effective competition being maintained on the relevant market by giving it the power to behave to an appreciable extent independently of its competitors, customers and ultimately its consumers.”<sup>10</sup>

It should be borne in mind that from the above assertion laid out in *United Brands*, the term “dominant position” was viewed as synonymous with a position of economic strength.<sup>11</sup> This position was reinforced in the *Hoffman La Roche v Commission*<sup>12</sup> ruling by the Court of Justice (CoJ), where the court went on further from the definition provided in *United Brands* to state that:

“Such a position does not preclude some competition, which it does where there is a monopoly or a quasi-monopoly, but enables the undertaking which profits by it, if not to determine, at least to have an appreciable influence on the condition under which that competition will develop, and in any case to act largely in disregard of it so long as such conduct does not operate to its detriment.”<sup>13</sup>

These two cases have led scholars of competition law to identify two crucial components that distinguish the courts’ definition of a “dominant position”: (i) the capacity to obstruct the continuation of effective competition in the relevant market, and (ii) the power to behave independently of its competitors, customers, and consumers.<sup>14</sup> The first element, which relates to the capacity to obstruct the continuation of effective competition in the relevant market, is closely related to a firm’s market power and economic strength that allows it to engage in exclusionary conduct, thereby significantly impeding or even precluding the existence of effective competition in the relevant market.<sup>15</sup> The second aspect involves evaluating a firm’s economic strength by analysing its relationships and interactions with other market players, including its competitors and customers, to determine how these interactions impact the competitive landscape and the overall dynamics of the market.<sup>16</sup> This viewpoint was also reinforced by the European Commission’s Discussion paper on the application of Article 82 of

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<sup>10</sup> *United Brands* para 65.

<sup>11</sup> Azzopardi A ‘Dominant position - a term in search of meaning’ (2016) *Global Antitrust Review* 6.

<sup>12</sup> *Hoffman La Roche v Commission* 85/76 [1979] E.C.R.-41 at para 38.

<sup>13</sup> *Hoffman La Roche v Commission* para 38-39.

<sup>14</sup> Whish R *Competition Law* 5 ed (2005) 179. See also Bishop S & Walker M *The Economics of EC Competition Law* 2 ed (2002) 6.06.

<sup>15</sup> Azzopardi A ‘Dominant position - a term in search of meaning’ (2016) *Global Antitrust Review* 11.

<sup>16</sup> Azzopardi A ‘Dominant position - a term in search of meaning’ (2016) *Global Antitrust Review* 11.

the TFEU to exclusionary abuse wherein instead of two elements the paper includes a third element which is that there must be an apposition of economic strength on a market.<sup>17</sup>

### 3.3 ASSESSMENT OF DOMINANCE

Abuse of dominance was classified as a prohibited practice by the Competition Act.<sup>18</sup> The statutory test for a firm's dominance is established in Section 7 of the South African Competition Act. According to the section:

“A firm is dominant in a market if-

- (a) it has at least 45% of that market;
- (b) it has at least 35%, but less than 45%, of that market, unless it can show that it does not have market power; or
- (c) it has less than 35% of that market, but has market power.”<sup>19</sup>

In *Trudon v Directory Solutions and Telkom*,<sup>20</sup> the Competition Appeal Court (CAC) reaffirmed that the inquiry into whether an entity is a dominant firm includes the identification of the relevant market in which it is involved; its market share within that market and whether it possesses the relevant market power.

A dominant position implies having the ability to control the terms of the market, to impose economic power on competitors, or, more broadly, to prevent healthy competition from existing.<sup>21</sup> Anti-competitive conduct can manifest itself in abuse of dominance as exclusive dealing agreements, excessive pricing, refusal to supply, predatory pricing, refusing to give competitors access to an essential facility, tying and bundling, and margin squeezing.<sup>22</sup> In comparison, the United Kingdom (UK), section 18 of the Competition Act<sup>23</sup> establishes the

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<sup>17</sup> European Commission ‘DG Competition discussion paper on the application of Article 82 of the Treaty to exclusionary abuses’ (2005).

<sup>18</sup> Section 6- Section 9 of the Competition Act.

<sup>19</sup> Section 7 of the Competition Act.

<sup>20</sup> *Trudon (Pty) Ltd v Directory Solutions CC and Another* [2010] 2 CPLR 202 (CAC).

<sup>21</sup> Ndlovu PN *Competition Law and Cartel Enforcement Regimes in The Global South: Examining the effectiveness of Co-Operation in South-South Regional Trade Agreements* (LLD thesis, University of the Western Cape, 2017) 3.

<sup>22</sup> Neuhoff M, Govender M & Dingley D *A Practical Guide to the South African Competition Act* 2 ed (2017) Chapter 5.

<sup>23</sup> Section 18 of the UK Competition Act of 1998:

- (1) Subject to section 19, any conduct on the part of one or more undertakings which amounts to the abuse of a dominant position in a market is prohibited if it may affect trade within the UK.
- (2) Conduct may, in particular, constitute such an abuse if it consists in—
  - (a) directly or indirectly imposing unfair purchase or selling prices or other unfair trading conditions;

“Chapter II” prohibition which essentially prohibits the abuse of a dominant position. Section 18 of the UK Competition Act heavily draws influence on Article 102 of the TFEU which also prohibits the abuse of a dominant position in the greater EU which states that:

“Any abuse by one or more undertakings of a dominant position within the internal market or in a substantial part of it shall be prohibited as incompatible with the internal market in so far as it may affect trade between Member States. Such abuse may, in particular, consist in:

- (a) directly or indirectly imposing unfair purchase or selling prices or other unfair trading conditions;
- (b) limiting production, markets or technical development to the prejudice of consumers;
- (c) applying dissimilar conditions to equivalent transactions with other trading parties, thereby placing them at a competitive disadvantage;
- (d) making the conclusion of contracts subject to acceptance by the other parties of supplementary obligations which, by their nature or according to commercial usage, have no connection with the subject of such contracts.”<sup>24</sup>

The South African Competition Act draws inspiration from Article 102 of the TFEU on the issue of abuse of dominance. In section 8, it is provided that:

“(1) It is prohibited for a dominant firm to—

- (a) charge an excessive price to the detriment of consumers or customers;
- (b) refuse to give a competitor access to an essential facility when it is economically feasible to do so;
- (c) engage in an exclusionary act, other than an act listed in paragraph (d), if the anti-competitive effect of that act outweighs its technological, efficiency or other pro-competitive gain; or
- (d) engage in any of the following exclusionary acts, unless the firm concerned can show technological, efficiency or other pro-competitive gains which outweigh the anti-competitive effect of its act—
  - (i) requiring or inducing a supplier or customer to not deal with a competitor;

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- (b) limiting production, markets or technical development to the prejudice of consumers;
  - (c) applying dissimilar conditions to equivalent transactions with other trading parties, thereby placing them at a competitive disadvantage;
  - d) making the conclusion of contracts subject to acceptance by the other parties of supplementary obligations which, by their nature or according to commercial usage, have no connection with the subject of the contracts.

(3) In this section— ‘dominant position’ means a dominant position within the UK; and ‘the UK’ means the UK or any part of it.

(4) The prohibition imposed by subsection (1) is referred to in this Act as 'the Chapter II prohibition'.

<sup>24</sup> Article 102 of the TFEU.

- (ii) refusing to supply scarce goods or services to a competitor or customer when supplying those goods or services is economically feasible;
- (iii) selling goods or services on condition that the buyer purchases separate goods or services unrelated to the object of a contract, or forcing a buyer to accept a condition unrelated to the object of a contract;
- (iv) selling goods or services at predatory prices;
- (v) buying-up a scarce supply of intermediate goods or resources required by a competitor; or
- (vi) engaging in a margin squeeze.”<sup>25</sup>

The CAC ruled in the *Trudon/Directory Solutions and Telkom* case<sup>26</sup> where Trudon, a directory publisher, alleged that Telkom, the state-owned telecoms provider, had abused its dominance in the telecommunications market. According to section 7, an entity that has more than 45% of the market is considered *per se* dominant, while a firm with less than 35% of the market must demonstrate that it has market power.<sup>27</sup> Similarly, the threshold set in section 7 was interpreted in the EU in *Hoffman La Roche v Commission*<sup>28</sup> where the European Commission reasoned that a firm possessing a market share of 40% and upwards coupled with entry gaps and a reasonable size gap with the next largest firm, presumptively confers dominance. In *casu*, the Commission found that Hoffman-La Roche’s 47% market share qualifies it for dominance due to the market’s structure, the company’s technological advantage over rivals (the second and third competitors had market shares of 27% and 18%, respectively), the lack of prospective competitors, and Roche’s overcapacity. The *Hoffman-La Roche* ruling that “*very large market shares are in themselves, save in exceptional circumstances, evidence of the existence of a dominant position,*”<sup>29</sup> was upheld by the court in *AKZO Chemie BV v Commission* where the Commission ruled that AKZO abused its dominant position in the flour additives market in the UK and Ireland.<sup>30</sup> This finding was based not only from AKZO’s significant market share of 52%, but also on its anti-competitive behaviour, including excessive dealing arrangements, which further solidified its market dominance and restricted competition.<sup>31</sup>

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<sup>25</sup> Section 8 (1) (a-d) of the Competition Act.

<sup>26</sup> *Trudon (Pty) Ltd v Directory Solutions CC and Another* [2010] 2 CPLR 202 (CAC).

<sup>27</sup> Neuhoff M, Govender M & Dingley D *A Practical Guide to the South African Competition Act* 2 ed (2017) 140.

<sup>28</sup> Para 93.

<sup>29</sup> *AKZO Chemie BV v Commission* Case 62/86, [1991] ECR I-3359 at para 60.

<sup>30</sup> *AKZO Chemie BV v Commission* Case 62/86, [1991] ECR I-3359.

<sup>31</sup> *AKZO Chemie BV v Commission* at I-3375.

### 3.4 IDENTIFICATION OF RELEVANT MARKET

Based on the previously mentioned cases of *United Brands* and *Hoffman*; in analysing dominance, the issue of the relevant market comes into play. The identification of a market is of key importance as it allows competition authorities to be able to isolate the product/industry or service as well as the geographical location where a dominant entity arises and where its commercial effects are felt.<sup>32</sup> The importance of the identification of relevant market has been stressed in the Commission Notice on the Definition of the Relevant Market for the purposes of [EU] Competition Law (hereinafter referred to as the Commission’s Notice):<sup>33</sup>

“Market definition is a tool to identify and define the boundaries of competition between firms. It serves to establish the framework within which competition policy is applied by the Commission. The main purpose of market definition is to identify systematically the competitive constraints that the undertakings involved face. The objective of defining a market in both its product and geographic dimension is to identify those actual competitors of the undertakings involved that are capable of constraining those undertakings’ behaviour and of preventing them from behaving independently of effective competitive pressure.”<sup>34</sup>

The phrase “relevant market” describes the line of commerce in which competition has been restrained and the geographic area involved, which is defined to include all reasonably substitutable products or services, and all nearby competitors, to which consumers could turn in the near term if the restraint or abuse raised prices by a not insignificant amount.<sup>35</sup> The Commission’s Notice splits the definition of a relevant market into two, that is product market and geographical market.<sup>36</sup>

The term “product-market” refers to all goods and/or services that consumers believe can be swapped or interchanged based on the characteristics, costs, and intended uses of the goods.<sup>37</sup>

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<sup>32</sup>Chakravarthy S ‘Relevant Market in Competition Case Analyses’ available at [https://www.circ.in/pdf/Relevant\\_Market-In-Competition-Case-Analyses.pdf](https://www.circ.in/pdf/Relevant_Market-In-Competition-Case-Analyses.pdf) (accessed 5 March 2024) at 1.

<sup>33</sup> Commission Notice on the Definition of the Relevant Market for the purposes of [EU] Competition Law available at [https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:C\\_202401645](https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:C_202401645) (accessed 7 July 2024).

<sup>34</sup> Paragraph 2 of the Notice.

<sup>35</sup> United Nations Trade Conference on Trade and Development (UNCTAD) ‘Continued work on the elaboration of a model law or laws on restrictive business practices’-UNCTAD, TD/B/RBP/81/Rev.4-Geneva (21 August 1995). See also The Common Market for Eastern and Southern Africa (COMESA) ‘Guidelines on Market Definition’ (2019) 6.

<sup>36</sup> European Union ‘The Commission Notice on the definition of relevant market for the purposes of Community Competition law (97/C 372/03)’ (1997) *Official Journal of the European Commission* 2.

<sup>37</sup> European Union ‘The Commission Notice on the definition of relevant market for the purposes of Community Competition law (97/C 372/03)’ (1997) *Official Journal of the European Commission* 2.

In the *Competition Commission v South African Airways (SAA)* case,<sup>38</sup> the Competition Tribunal determined that SAA was engaged in two distinct markets: one for domestic scheduled aircraft travel and another for SA travel agency sales of domestic travel within the country under the product market. Three key components of the product market are evident from this definition: price increases, consumer reactions, and the least size requirements.<sup>39</sup> Competition authorities across the globe appear to be in agreement that the veneer that runs through in defining product market is simply a matter of interchangeability or substitutability of goods/services by the consumers/purchasers.<sup>40</sup> That is, for example, if a consumer cannot access bread for whatever reason and they substitute bread for buns or burger rolls, thus, bread, buns, and burger rolls can be said to be in the same product market. The ruling in *Europemballage Corpn and Continental Can Co Inc v Commission*<sup>41</sup> by the CJEU affirmed that it is crucial to look into the characteristics of the products in question and evaluate their interchangeability on an individual basis when defining the market for market identification.<sup>42</sup> If the price of the product relevant to the investigation were to increase, all such substitutes would be included in the relevant product market from the perspective of the consumer. From a supply-side perspective, this would encompass all manufacturers who could transition to producing these replacement commodities using their current infrastructure.

The relevant geographical market refers to the area in which the undertakings concerned are involved in the supply and demand of products or services, in which the conditions of competition are sufficiently homogenous and which can be distinguished from neighbouring areas because the conditions of competition are appreciably different in those areas.<sup>43</sup> Relevant geographic markets can be local, national, international, or even global. In *Netcare Hospital Group (Pty) Ltd and Community Hospital Group*<sup>44</sup> the concept of geographical markets was dealt with. The Competition Tribunal held that geographical markets can be dual in nature, that is national in terms of price competition and local in terms of non-competition.<sup>45</sup> The geographic market is defined by purchasers' views of the substitutability or interchangeability

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<sup>38</sup> *Competition Commission v South African Airways (Pty) Ltd* (SAA) Case 18/CR/Mar01.

<sup>39</sup>Chakravarthy S 'Relevant Market in Competition Case Analyses' available at [https://www.circ.in/pdf/Relevant\\_Market-In-Competition-Case-Analyses.pdf](https://www.circ.in/pdf/Relevant_Market-In-Competition-Case-Analyses.pdf) (accessed 5 March 2024).

<sup>40</sup>Chakravarthy S 'Relevant Market in Competition Case Analyses' available at [https://www.circ.in/pdf/Relevant\\_Market-In-Competition-Case-Analyses.pdf](https://www.circ.in/pdf/Relevant_Market-In-Competition-Case-Analyses.pdf) (accessed 5 March 2024).

<sup>41</sup> *Europemballage Corpn and Continental Can Co Inc v Commission* Case 6/72 [1973] ECR 215, [1973] CMLR 199.

<sup>42</sup> *Europemballage Corpn and Continental Can Co Inc v Commission* para 32.

<sup>43</sup> The Common Market for Eastern and Southern Africa (COMESA) 'Guidelines on Market Definition' (2019) 6.

<sup>44</sup> *Netcare Hospital Group (Pty) Ltd and Community Hospital Group* 68/LM/Aug06.

<sup>45</sup> *Netcare Hospital Group (Pty) Ltd and Community Hospital Group* para 33-37.

of products made or sold at various locations. If a small but significant and non-transitory price increase in a product sold in one location would prompt buyers to substitute it with the same product sold in another location, then those two locations are deemed to constitute a single geographic market for that product. If not, the two locations are regarded to be in different geographic markets. An example of the interchangeability in geographic markets is how South Africa as of 2018 heavily relies on India as a major supplier of affordable essential drugs amounting to a total of US \$571,80 million as value of the imports.<sup>46</sup>

### 3.5 INDICATORS OF DOMINANCE

#### 3.5.1 Market share

In its Guidance paper,<sup>47</sup> the European Commission alludes to the fact that market shares are “a useful first indication” of dominance.<sup>48</sup> Market share usually refers to the sales revenue of the firm in relation to the turnover of the whole market.<sup>49</sup> However, this position is not cast in stone as held in the *Competition Commission v South African Airways (SAA)*<sup>50</sup> where the Competition Tribunal stated that apart from sales revenue, other figures such as the number of goods sold can be considered for the purpose of determining market share.<sup>51</sup> Dethmers and Dodoo argue that dominance refers to superior performance demonstrated by relatively high market shares and competitive advantages.<sup>52</sup> A substantial market share on face value serves as evidence of the existence of a dominant firm. In *AKZO*, the European Court of Justice considered market shares as one of the indicators of dominance, concluding that, with regard to market shares, very large market shares are in themselves, and save in exceptional circumstances, evidence of the existence of a dominant position.<sup>53</sup> Neuhoff states that a firm that has a market share of 45% and above is regarded as per se dominant.<sup>54</sup> Similarly, but without being more explicit,

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<sup>46</sup> Consulate of India, Johannesburg *Pharmaceutical Industry South Africa India Bilateral* available at <https://www.cgijoburg.gov.in/pdf/Pharmaceutical%20Report%20Approved.pdf> (accessed 13 August 2024).

<sup>47</sup> European Union ‘Guidance on the Commission's enforcement priorities in applying Article 82 of the EC Treaty to abusive exclusionary conduct by dominant undertakings (2009/C 45/02)’ (2009) *Official Journal of the European Commission*.

<sup>48</sup> Bhattacharya A, Morgan N & Rego L ‘Examining Why and When Market Share Drives Firm Profit’ (2021) *Journal of Marketing*.

<sup>49</sup> Neuhoff M, Govender M & Dingley D *A Practical Guide to the South African Competition Act 2* ed (2017) 140.

<sup>50</sup> *Competition Commission v South African Airways (Pty) Ltd (SAA)* Case 18/CR/Mar01.

<sup>51</sup> *Competition Commission v South African Airways (Pty) Ltd* para 58.

<sup>52</sup> Dethmers F and Dodoo N ‘The abuse of Hoffmann-La Roche: the meaning of dominance under EC competition law’ (2006) *ECLR* 537.

<sup>53</sup> *AKZO v Commission* [1991] E.C.R. I-3359 at para 60.

<sup>54</sup> Neuhoff M, Govender M & Dingley D *A Practical Guide to the South African Competition Act 2* ed (2017) 140.

the European Commission expressed this view in the *1998 Football World Cup opinion*,<sup>55</sup> as well as in the *Microsoft* decisions where it held that “Microsoft, with its market shares of over 90%, occupies almost the whole market. It therefore approaches a position of complete monopoly, and can be said to hold an overwhelmingly dominant position.”<sup>56</sup>

Market shares, while significant, should not be viewed as the only measure of a company’s dominance in the market; other indicators, such as the company’s strength over a prolonged period of time should be taken into account. This is due to the fact that existing obstacles to entry or growth, which obstruct competitors from satisfying demand in the event of prices that are too high for the market, can also have a significant impact on dominance.<sup>57</sup>

### 3.5.2 Market power

Section 1(1)(xiv) of the Competition Act defines market power as “the power of a firm to control prices, or to exclude competition or to behave to an appreciable extent independently of its competitors, customers or suppliers.”<sup>58</sup> It is important to remember that the wording of the Competition Act’s section 7(c) allows for effective dominance of a company even in the absence of a large market share.<sup>59</sup> The EU’s Office of Fair Trading (OFT) Guideline Assessment of Market Power<sup>60</sup> define market power as an enterprise’s profitable ability to maintain prices above levels of competition or to limit output or quality below levels of competition.<sup>61</sup> The definitions of market power in both the EU and SA share a commonality in that they acknowledge the significance of price control, where an undertaking’s market power is characterised by its ability to influence prices while maintaining profitability. Additionally, both definitions consider the undertaking’s relationships with its competitors and customers, recognising that market power enables an undertaking to act unilaterally, making decisions on pricing, as well as the quality and quantity of products and services, without being constrained

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See also section 7 (a) of the Competition Act.

<sup>55</sup> Commission decision of 20 July 1999, *1998 Football World Cup* (2000) O.J. L 5 at para 86-87.

<sup>56</sup> *Microsoft v Commission* Case T-201/04 [unreported] para 435.

<sup>57</sup> *Hoffmann-La Roche v Commission* at para 41. See also the European Commission-Working Document ‘Commission’s Memorandum on ‘Le problème de la Concentration dans le Marché Commun=The problem of concentration in the Common Market Studies’ *Competition Series 3* (1966), where it is said that market domination cannot be defined solely in terms of the market share of an enterprise or other quantitative elements of a particular market structure.

<sup>58</sup> Competition Act 89 of 1998.

<sup>59</sup> Section 7 (c) of the Competition Act- A firm is dominant in a market if it has less than 35% of that market, but has market power.

<sup>60</sup> Competition Market Authority (CMA) ‘Guidance: Assessment of market power: OFT415’ (December 2004).

<sup>61</sup> Assessment of market power, para 1.3-1.4.

by the reactions of its customers and rivals. It is assumed that market power occurs when an undertaking does not encounter effective competitive pressure. An analysis of market power is more prone to evaluating a corporation's behavioural component and performance than market share, which can be easily ascertained by counting the precise amount of shares a firm has in a market. In the precedent set out in *Albion Water v Water Services Regulation Authority*<sup>62</sup> the Competition Appeal Tribunal in the EU, perhaps concerned at the lack of findings of infringement of the Chapter II prohibition by the OFT and the sectoral regulators, said that: -

“when assessing dominance under the Competition Act, it is unnecessary for the competition authority to investigate distant or theoretical possibilities with a view to dotting every ‘i’ or crossing every ‘t’ that could conceivably be imagined. While a sensible analysis is required, there is no need to make the issue of dominance more complicated than it really is.”<sup>63</sup>

This is further supported by Part 6 of the Guidelines, which emphasizes that assessing market power involves not only examining a firm's conduct and performance, but also considering the influence wielded by buyers, thereby highlighting the importance of evaluating buyer power in the market.<sup>64</sup> In South Africa, the Competition Tribunal held that market power can be inferred from a firm's conduct after SAA disputed having a significant amount of market shares that can give rise to dominance.<sup>65</sup> The Kenyan Competition Authority defines buyer power as the ability of an enterprise or group of enterprises in a purchasing capacity to negotiate better terms from suppliers or impose long-term opportunity costs, such as harm or withheld benefits, that, if executed, would be disproportionately large in comparison to any long-term costs incurred by the enterprise or groups of enterprises.<sup>66</sup>

One way that market power manifests itself is as “power over price.” In other words, a company with power over price can raise prices and yet make a profit without suffering any major losses.<sup>67</sup> To evaluate a firm's pricing power, the Small but Significant Non-transitory Increase

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<sup>62</sup> *Albion Water v Water Services Regulation Authority* [2006] CAT 36, CompAR 328.

<sup>63</sup> *Albion Water v Water Services Regulation Authority* para 185.

<sup>64</sup> Whish & Bailey *Competition Policy and Economics* (2012) 366.

<sup>65</sup> *Competition Commission v South African Airways (Pty) Ltd (SAA)* Case 18/CR/Mar01 para 91 where it was held that:

*“But the Commission has gone even one step further than relying on legal presumptions. It has shown that SAA enjoys market power in relation to travel agents. Recall this is the market power that is relevant in this case otherwise, the abuse could not be perpetrated. The evidence in this case of the negotiations with travel agents and how SAA was able to impose a remuneration model on them against their own will, is an example of this.”*

<sup>66</sup> Competition Authority of Kenya ‘Buyer Power Guidelines’ available at [https://www.cak.go.ke/sites/default/files/Buyer\\_Power\\_Guidelines\\_2022.pdf](https://www.cak.go.ke/sites/default/files/Buyer_Power_Guidelines_2022.pdf) (accessed at 3 April 2024).

<sup>67</sup> European Union Commission Working Document on the ‘Proposed New Regulatory Framework for Electronic Communications Networks and Services: Draft Guidelines on Market Analysis and the Calculation of Significant Market Power’ (2001) 65.

in Price (SSNIP) test is utilised. The test is a conceptual tool first set out in the 1982 US Department of Justice Merger Guidelines to identify smallest market within which a hypothetical monopolist could impose a small significant non-transitory increase in price.<sup>68</sup> The idea behind the SSNIP test, also known as the “hypothetical monopolist test,”<sup>69</sup> is that if a company raises prices on a small but significant scale (usually understood to mean 5–10%),<sup>70</sup> for at least 12 months enough customers would switch to other service providers, inevitably ruining the company’s profits, or consumers would still be forced to rely on the said provider, allowing the company to continue operating. Paragraph 17 of the Commission’s Notice states that:

“The question to be asked is whether the parties’ customers would switch to readily available substitutes or to suppliers located elsewhere in response to a hypothetical small (in the range 5% to 10%) but permanent relative price increase in the products and areas being considered. If substitution were enough to make the price increase unprofitable because of the resulting loss of sales, additional substitutes and areas are included in the relevant market.”<sup>71</sup>

In addition to having direct control over prices, which benefits customers, market power also includes the “power to exclude.” The key component of the “power to exclude” is a company’s capacity to prevent or bar competitors from entering the market. The OFT argues that “[a dominant firm] can also use its market power to engage in anti-competitive conduct and exclude or deter competitors from the market.”<sup>72</sup> This type of market power is already explicitly taken into account by several competition authorities. The European Commission’s Guidance on the Commission’s Enforcement Priorities in Applying Article [102 TFEU] to Abusive Exclusionary Conduct by Dominant Undertakings (‘Guidance on Article 102 Enforcement Priorities’)<sup>73</sup> stresses that constraints imposed by the credible threat of future expansion by actual competitors or entry by potential competitors (expansion and entry) are relevant to the discussion of “power to exclude.” In tandem with the Guidance on Article 102 Enforcement Priorities, Article 81(3) EC, has recognised that:

“The creation, maintenance or strengthening of market power can [...] also result from a restriction of competition between any one of the parties and third parties [to an

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See also Geradin D, Petit N, Walker M, Hofer P & Louis F ‘The Concept of Dominance in EC Competition Law’ (2005) available at SSRN: <https://ssrn.com/abstract=770144> (accessed 4 April 2024).

<sup>68</sup> Whish & Bailey *Competition Policy and Economics* (2012) 31.

<sup>69</sup> Whish & Bailey *Competition Policy and Economics* (2012) 31.

<sup>70</sup> Guidelines of the OFT on the Assessment of Market Power, OFT 415, 1999

<sup>71</sup> Commission Notice on the Definition of the Relevant Market for the Purposes of [EU] Competition Law OJ [1997] C 372/5.

<sup>72</sup> “The Chapter II Prohibition”, OFT 402, 1999 at para. 3.9.

<sup>73</sup> OJ [2009] C 45/7.

agreement], e.g. because the agreement leads to foreclosure of competitors or because it raises competitors' costs, limiting their capacity to compete effectively with the contracting parties."<sup>74</sup>

The mere fact that a firm has the capacity to influence the state of affairs in the market, that is the number of entrants or to deter the existing competitors serves as evidence of market power. In *Competition Commission v Media24*,<sup>75</sup> Media24 was accused of using its market power by engaging in predation which saw Forum a publication of Media24 being used as a fighting brand by charging advertising rates that were below average ultimately resulting in Gold Net News exiting the market in 2009. Even though a firm's market share may not be a reliable indicator of its market power, its capacity to exclude competitors is sufficient proof of the firm's market power. When this type of market power is used, exclusionary practices including predatory pricing,<sup>76</sup> refusing to deal,<sup>77</sup> refusing to supply,<sup>78</sup> and margin squeezing<sup>79</sup> may appear in the market.

### 3.5.3 Superior technology

Although not explicitly an indicator of dominance, superior technology can be a vehicle on which dominance can be achieved. Whoever gets access to better technology or is a first-mover-to-scale in the fourth industrial revolution will unavoidably become an industry leader.<sup>80</sup> In the digital age, whoever takes advantage of the first-mover-to-scale benefits gets to enjoy a position of dominance automatically as behavioural economists suggest that consumers are more inclined to be attached to the first company to release a service or product or whoever perfects it better.<sup>81</sup> This is evident with Instagram which is the go-to picture-sharing application

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<sup>74</sup> Communication from the Commission, Notice: Guidelines on the application of Article 81(3) of the Treaty. (2004/C 101/08) pp.97–118 at para 26.

<sup>75</sup> *Competition Commission v Media24* 48/CR/Aug10 and 131CACJun14.

<sup>76</sup> Motta *Competition Policy: Theory and Practice* (2004) pp 412–454.

<sup>77</sup> Section 8 (1)(d)(i) of the Competition Act.

<sup>78</sup> Microsoft Commission decision of 24 March 2004, upheld on appeal Case T- 201/04 *Microsoft Corp v Commission* [2007] ECR II- 3601, [2007] 5 CMLR 846. See also Whish & Bailey *Competition Policy and Economics* (2012) chapter 17 'Refusal to Supply a new customer', pp 697–711.

<sup>79</sup> Whish & Bailey *Competition Policy and Economics* (2012) chapter 18 'Margin Squeezing', 754–759. See also *Deutsche Telekom v Commission* C-280/08; *TeliaSonera v Konkurrensverket* Case C-52/09, [2011] ECR I-527.

<sup>80</sup> Knudsen ES, Lien LS, Timmermans B, Belik I & Pandey S Stability in turbulent times? The effect of digitalization on the sustainability of competitive advantage *Journal of Business Research* 361-364.

<sup>81</sup> Oxera 'Behavioural economics and its impact on competition policy' available at [https://www.acm.nl/sites/default/files/old\\_publication/bijlagen/11586\\_oxera-behavioural-economics-competition-policy.pdf](https://www.acm.nl/sites/default/files/old_publication/bijlagen/11586_oxera-behavioural-economics-competition-policy.pdf) (accessed 24 March 2024).

with over 2 billion users<sup>82</sup> even though applications such as Flickr and Snapchat offer similar services but do not enjoy the same volume of traffic as compared to Instagram.

Platforms can fend off competitors and increase revenue by managing their susceptibility to multi-homing, which occurs when users establish connections with two or more rival platforms.<sup>83</sup> A scenario known as “multi-homing” occurs when individuals often use many rival platform services simultaneously.<sup>84</sup> Multihoming promotes competition by enabling consumers and business users to utilise multiple platforms. This aligns with the Competition Act’s section 2(b), which aims to give consumers access to competitive pricing and a wide range of products and services,<sup>85</sup> a sentiment also shared in the Consumer Protection Act.<sup>86</sup> However, the rise of the “first-mover-to-scale advantages” threatens the possibility of healthy multi-homing.<sup>87</sup> On the side of business user multihoming, first-mover advantages translate to the platform that already has a large customer base attracting business users to join that platform to maximise their profits. This is evident in the property listing industry where Property 24 is enjoying its first-mover-to-scale advantages as it is the go-to place for property listings in South Africa<sup>88</sup> despite other property listing sites such as Private Property and My Property being in existence.

In the pharmaceutical industry, which is relevant to this paper, superior technology in the form of patent developments can somewhat lead to a situation of dominance. The “indisputable technological lead” of the allegedly dominant undertakings has been taken into consideration in the then European Court of Justice (now CJEU) cases such as *AstraZeneca v European Commission*,<sup>89</sup> where the misuse of patent and regulatory procedures, which had the effect of

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<sup>82</sup> Statista ‘Instagram - statistics & facts’ available at <https://www.statista.com/topics/1882/instagram/#:~:text=Instagram%20boasts%20two%20billion%20monthly,has%20about%20360%20million%20users> (accessed on 14 May 2024).

<sup>83</sup> Harvard Business Review ‘Why Some Platforms Thrive and Others Don’t What Alibaba, Tencent, and Uber teach us about networks that flourish. The five characteristics that make the difference’ available at <https://hbr.org/2019/01/why-some-platforms-thrive-and-others-dont#:~:text=Multi%2Dhoming%20happens%20when%20users,an%20additional%20platform%20is%20low> (accessed 16 April 2024).

<sup>84</sup> European Commission, Directorate-General for Communications Networks, Content and Technology ‘Multi-homing – Obstacles, opportunities, facilitating factors’ available at <https://op.europa.eu/en/publication-detail/-/publication/57c7d6ed-ad52-11eb-9767-01aa75ed71a1> (accessed 16 April 2024).

<sup>85</sup> Section 2(b) of the Competition Act.

<sup>86</sup> Section 13 of the Consumer Protection Act 68 of 2008.

<sup>87</sup> Competition Commission South Africa ‘Online Intermediation Platforms Market Inquiry Provisional Report’ available at <https://www.compcom.co.za/wp-content/uploads/2022/07/OIPMI-Provisional-Summary-Report.pdf> (16 June 2024).

<sup>88</sup> Competition Commission South Africa ‘Online Intermediation Platforms Market Inquiry Provisional Report’ available at <https://www.compcom.co.za/wp-content/uploads/2022/07/OIPMI-Provisional-Summary-Report.pdf> (16 June 2024).

<sup>89</sup> *AstraZeneca AB v European Commission* (C-457/10 P) [2013] 4 C.M.L.R. 7 (06 December 2012).

stifling competition and impeding the entry of generic products in the anti-ulcer medicines market were taken into account. Pharmaceutical companies rely on the monopoly afforded by patents to recover their R&D, marketing, and advertising expenses and incentivise innovation while making a profit and return on their investment.<sup>90</sup> Patents are an intentional government grant of monopoly power to incentivise R&D.<sup>91</sup> The TRIPS patent regime,<sup>92</sup> allows the innovator to enjoy the benefits of the patent for 20 years from the date of filing which is similar to the standpoint adopted by the Patent Act.<sup>93</sup> Thus, inventors should be able to profit from their creations for as long as the patent is valid. However, patents can sometimes be misused or drive-up prices unnecessarily for the target market.<sup>94</sup> Due to the nature of the monopoly the patent grants, whoever files a patent in this way can be said to automatically enjoy a position of dominance for the 20-year patent. Stated differently, the execution of a patent may give rise to restrictive and exploitative practices that negatively impact competitors and consumers, respectively.

### 3.6 CONCLUSION

This chapter considered an overview of the concept of dominance in relation to competition law. In doing so, it studied the concept of dominance in particular how a firm is classified as dominant. The statutory test for the assessment of a dominant firm as provided for in section 7 of the Competition Act was discussed. The importance of paying heed to the statutory test was also highlighted as it is the genesis of understanding the outlook of a dominant firm at face value. In assessing the dominance of a firm, the identification of the relevant market is of primary importance as it is the premise on which the economic effects of abuse of dominance will be easily identified. A discussion into product and geographic markets where the subject of interchangeability was addressed as consumers are more inclined to opt for a more affordable product or service that can be substituted. This is noted in South Africa's pharmaceutical industry where most of the affordable essential medicines are imported from India. An overview of the indicators of dominance which is of paramount importance to this paper uncovered that although not explicitly stated by many scholars, superior technology can

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<sup>90</sup> Hamilton C & Stokes GM 'Patented Brand Drugs are Essential Facilities and Regulatory Compacts' (2023) *Northwestern Journal of Technology and Intellectual Property* 18.

<sup>91</sup> Dean & Dyer *Introduction to Intellectual Property Law* (2014) 259.

<sup>92</sup> Article 33 of the TRIPS:

*Term of Protection*

The term of protection available shall not end before the expiration of a period of twenty years counted from the filing date.

<sup>93</sup> Section 55 of the Patent Act.

<sup>94</sup> Storz U 'The patent maze of COVID-19 vaccines' (2021) *Expert Opinion on Therapeutic Patents* 1179.

aid in entrenching or establishing dominance apart from the usual market share and market power indicators. Chapter 4 will examine how the nature of rights, in particular, the monopoly granted by patents has adverse effects on access to and pricing of medicines, and will explore the potential for competition law to strike a balance between proprietary interests of inventors and the broader public health concerns. Specifically, the chapter will discuss how competition law can be utilised to ensure that patent holders receive fair compensation for their inventions while simultaneously safeguarding the public's access to essential medicines.

# CHAPTER 4

## ANTI-COMPETITIVE CONCERNS IN THE PHARMACEUTICAL INDUSTRY AND THEIR RAMIFICATIONS ON ACCESS AND AFFORDABILITY OF MEDICINES

### 4.1 INTRODUCTION

The interplay between IPRs and competition law has become a bone of contention as the strategic use of patents in particular oftentimes undermines the very principles which competition law seeks to achieve. Patents which are intended to incentivise innovation and progress by granting temporary monopolies,<sup>1</sup> unfortunately have been exploited especially in the pharmaceutical industry where competition has thus been stifled and market access restricted ultimately harming consumers. The abuse of patents as highlighted through the COVID-19 pandemic, particularly through anti-competitive practices such as patent trolling, evergreening, and patent thickets, raises significant concerns regarding the balance between promoting innovation and preserving competition.<sup>2</sup>

This chapter thus examines the tension between patent and competition law, with a clear focus on how patents are misused to restrict competition. Specifically, the chapter explores exploitative and exclusionary conduct that exists in the pharmaceutical industry which includes evergreening which is the strategic extension of patent lifetimes through minor modifications or incremental innovations,<sup>3</sup> patent thickets which is the accumulation of overlapping patents,

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<sup>1</sup> Section 45 (1) of the Patent Act.

<sup>2</sup> Ido VHP 'Designing Pro-Health Competition Policies in Developing Countries' Research Paper 125 South Centre (2020) 1.

See also Danzon P 'Competition and Antitrust Issues in the Pharmaceutical Industry' University of Pennsylvania Final Report (2014) 32.

<sup>3</sup> Ido VHP 'Designing Pro-Health Competition Policies in Developing Countries' Research Paper 125 South Centre (2020) 10-18.

hindering innovation and limiting market access, reverse settlement agreements,<sup>4</sup> excessive and/or predatory pricing, unfair trading conditions and refusal to give access to an essential facility. Chapter 4 further highlights how patent holders abuse their rights to stifle competition and the effects of patent abuse on market competition, innovation, and access to necessary medications through a thorough examination of case law, national and international competition law legislation, and economic literature. By examining these issues, this chapter advances knowledge of the intricate relationship between patents and competition law, which will ultimately influence policy suggestions that will be covered in chapter 5 to curb patent abuse and promote a competitive environment.

## 4.2 THE NEXUS BETWEEN IPRs AND COMPETITION LAW

The growth and strengthening of IPRs globally, along with the enormous disruptions caused by the COVID-19 epidemic, have led to increased scrutiny of the relationship between IP and competition law. IP and competition law have a particularly polarised relationship because IP law grants rights holders exclusive control over IPRs,<sup>5</sup> while competition law aims to protect consumers and eliminate market barriers by allowing a wide range of suppliers of goods, services, and technologies, thus creating a dynamic competitive environment.<sup>6</sup> In promoting consumer welfare and a competitive market, the preamble<sup>7</sup> and purpose of the Competition Act<sup>8</sup> both recognise the need for innovation as a driving factor for the realisation of competition goals although not explicitly provided by the Act. This is the reason why IPRs are regarded as pro-competitive as according to the EU Horizontal Competition Guidelines,<sup>9</sup> IPRs “promote

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<sup>4</sup> Gurgula O, ‘Strategic Accumulation of Patents in the Pharmaceutical Industry and Patent Thickets in Complex Technologies – Two Different Concepts Sharing Similar Features’ (2017) 48 *IIC - International Review of Intellectual Property and Competition Law* 385.

<sup>5</sup> OECD ‘Recommendation of the Council on Intellectual Property Rights and Competition’ OECD/LEGAL/0495 4.

See also Schechter RE & Thomas JR *Intellectual Property the Law of Copyrights, Patents and Trademarks* (2003).

<sup>6</sup> Whish & Bailey *Competition Policy and Economics* (2012) 769.

<sup>7</sup> Preamble of the Competition Act, where it says in order to achieve a more effective and efficient economy in South Africa; provide for markets in which consumers have access to, and can freely select, the quality and variety of goods and services they desire.

<sup>8</sup> Section 2 (1) of the Competition Act: -

The purpose of this Act is to promote and maintain competition in the Republic in order-

(a) to promote the efficiency, adaptability and development of the economy;

(b) to provide consumers with competitive prices and product choices.

See also Brassey M, Campbell J, Legh R, Simkins C, Unterhalter D & Wilson J *Competition Law* (2002) 2.

<sup>9</sup> Guidelines on the Applicability of Article 101 of the Treaty on the Functioning of the European Union to Horizontal Co-operation Agreements 2011/c 11/01 (hereinafter referred to as Horizontal Cooperation Guidelines) para 269.

dynamic competition by encouraging undertakings to invest in developing either new or improved products and processes.” Both IPRs and competition law can thus be said to share a dual fundamental objective which is to promote consumer welfare by fostering innovation.<sup>10</sup>

Innovation constitutes a vital and dynamic cornerstone of a vibrant, open, and competitive market economy, driving progress and growth. The protection afforded by IPRs incentivises undertakings to invest in R&D, culminating in novel or enhanced products and processes, thereby encouraging dynamic competition.<sup>11</sup> Competition law serves as the key catalyst for innovation, putting pressure on businesses to develop and differentiate themselves in the marketplace. However, because IPRs impose exclusive rights onto their owners on the one hand, and competition law aims to keep markets open on the other, some scholars have argued that there is a fundamental conflict between these two areas of law.<sup>12</sup> This tension is exacerbated by the fact that IPRs grant negative rights to owners that are monopolistic in nature, which appears anti-competitive on the surface because the means of producing a product or service are within the means and control of one individual for a period of years depending on the specific IPR.<sup>13</sup> The conferral of exclusive rights via IP protection may result in market power and maybe even monopoly status, depending on the unavailability of viable substitutes within the relevant market.<sup>14</sup>

In the case of *Hazel Tau v GlaxoSmithKline, Boehringer Ingelheim, and others*,<sup>15</sup> the lack of ARV replacements resulted in GSK and Boehringer Ingelheim gaining monopoly status as the pharmaceutical industry’s ARV inventors. The same can be said about COVID-19 vaccine

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<sup>10</sup> Ghidini G, ‘On the intersection between IP and Competition law(s): Balancing Conflicts of Interest in the Constitutional Paradigm’ in *Rethinking Intellectual Property* (2018) 334.

<sup>11</sup> Zevgolis NE, ‘The Interaction Between Intellectual Property Law and Competition Law in the EU: Necessity of Convergent Interpretation with Principles Established by the Relevant Case Law’ in Bharadwaj A, Devaiah VH & Gupta I (eds) *Multi-dimensional Approaches Towards New Technology: Insights on Innovation, Patents and Competition* (2018) 31.

<sup>12</sup> Whish & Bailey *Competition Policy and Economics* (2012) 769.

See also Zevgolis NE, ‘The Interaction Between Intellectual Property Law and Competition Law in the EU: Necessity of Convergent Interpretation with Principles Established by the Relevant Case Law’ in Bharadwaj A, Devaiah VH & Gupta I (eds) *Multi-dimensional Approaches Towards New Technology: Insights on Innovation, Patents and Competition* (2018) 21.

<sup>13</sup> Panda A, Patel A, Akshay D, Siddhartha K & Mathew SP ‘Intellectual Property Law & Competition Law’ (2010) 6 *Journal of International Commercial Law and Technology* 120.

<sup>14</sup> Dube D ‘Intellectual Property Rights and Competition Law’ CUTS Centre for Competition, Investment & Economics Regulation (2008) 1.

<sup>15</sup> *Hazel Tau & others v GlaxoSmithKline, Boehringer Ingelheim & others* Competition Commission Case Number: 2002Sep226 whereby patients and civil society organizations complained to the Competition Commission about the pharmaceutical companies' high price, refusal to license a necessary facility, and exploitation of their dominating position in the ARV market. The Commission ruled against the corporations and asked the Competition Tribunal to impose compulsory licenses. As indicated, the dispute was settled prior to this hearing, with the businesses agreeing to grant several voluntary licenses for the drugs in question.

producers such as J&J, Pfizer, Moderna, BioNTech, Sinovac, GSK, and AstraZeneca, whose patents for their various vaccines inevitably granted them monopoly status, allowing them to dictate who to supply, at what price, and in what quantity.<sup>16</sup> The statutory grant of exclusivity gives the IPR holder a significant advantage over other industry participants, potentially resulting in a dominant market position.<sup>17</sup> However, when the rights holder leverages this favourable position in an abusive manner, a conflict emerges between IP law and competition law necessitating careful reconciliation of these intersecting legal regimes.

### 4.3 ANTI-COMPETITIVE PRACTICES IN THE PHARMACEUTICAL INDUSTRY

#### 4.3.1 Exclusionary Conduct

The Competition Act of South Africa defines exclusionary conduct as ‘an act that impedes or prevents a firm from entering into, participating in or expanding within a market.’<sup>18</sup> According to Fumagali, Motta, and Calcagno, exclusionary practices are contracts, pricing strategies, and other actions taken by dominant firms to deter new competitors from entering the markets, to force rivals to exit, to confine them to market niches or to prevent them from expanding ultimately harming consumers.<sup>19</sup> Exclusionary behaviour can present itself vertically or horizontally.<sup>20</sup> Horizontal foreclosure occurs when a dominant undertaking engages in conduct designed to eliminate a competitor with whom it has a horizontal relationship,<sup>21</sup> so limiting competition at the same level of the market. Vertical foreclosure occurs when a dominant business uses restrictive strategies to prevent a competitor from participating in the downstream, limiting access to critical inputs, goods, or services.<sup>22</sup> It is pertinent to observe

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<sup>16</sup> Oxfarm ‘Monopolies causing "artificial rationing " in COVID-19 crisis as 3 biggest global vaccine giants sit on sidelines’ available at <https://www.oxfarm.org/en/press-releases/monopolies-causing-artificial-rationing-covid-19-crisis-3-biggest-global-vaccines> (accessed 12 October 2024).

See also FiercePharma ‘The top 10 vaccine companies worldwide’ available at <https://www.fiercepharma.com/pharma/top-10-vaccine-companies-worldwide> (accessed 07 March 2024).

<sup>17</sup> Filho SC & Ido VHP, ‘Courts and Pharmaceutical Patents: From Formalist Positivism to the Emergence of a Global Law’ Correa CM & Hilty RM (eds) in *Access to Medicines and Vaccines: Implementing Flexibilities Under Intellectual Property Law* (2022) 205.

<sup>18</sup> Section 1 (xiii) of the Competition Act.

<sup>19</sup> Fumagalli C, Motta M & Calcagno C, ‘Introduction’ in *Exclusionary Practices: The Economics of Monopolisation and Abuse of Dominance* (Cambridge University Press 2018)1-13.

<sup>20</sup> Whish & Bailey *Competition Policy and Economics* (2012) 204.

<sup>21</sup> Section 1 xv of the Competition Act defines horizontal relationship as a relationship between competitors.

See also Whish & Bailey *Competition Policy and Economics* (2012) 204.

<sup>22</sup> Whish & Bailey *Competition Policy and Economics* (2012) 205.

that numerous exclusionary abuses are concerned with horizontal foreclosure, wherein a dominant undertaking seeks to restrict competition at the same level of the market through mechanisms such as exclusive purchasing agreements, rebates, and predatory pricing.<sup>23</sup> On the other hand, exclusionary abuses including refusal to supply and margin squeezing, primarily cause harm to competition in the downstream market by denying access to essential inputs and goods.<sup>24</sup> Notwithstanding the absence of explicit recognition in pertinent policy documents, the exercise of patent rights can have a profound exclusionary effect on competitors, a phenomenon that warrants closer examination, particularly at the intersection of IPRs and competition law as will be discussed below.

### **4.3.2 Types of Exclusionary Conduct in the Pharmaceutical Industry**

#### *4.3.2.1 Patent Evergreening*

Patent evergreening constitutes a strategic practice whereby patent holders submit successive patent applications, oftentimes of questionable validity or applicability, proximate to the expiry of the statutory monopoly period, thereby forestalling the entry of generic competitors in the market.<sup>25</sup> This practice enables pharmaceutical companies to extend their exclusive rights over highly profitable drugs (sometimes referred to as blockbuster drugs such as Keytruda manufactured by Merck with an estimated revenue close to US \$24 billion)<sup>26</sup> beyond the periods normally prescribed by law by employing patent laws.<sup>27</sup> Pharmaceutical corporations usually use a multifaceted patent strategy, which includes filing many patent applications for a single drug that cover the production process, formulations, dosage regimes, derivative forms, and combination therapies, in order to extend their monopoly.<sup>28</sup> This means that rather than a single drug having a 20-year monopoly, each unique feature of the drug can obtain a 20-year monopoly on its own when it is patented, or the 20-year monopoly can be prolonged by a few years. By leveraging patent laws in this manner, pharmaceutical companies effectively prolong their market exclusivity, potentially stifling competition and limiting access to affordable

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<sup>23</sup> Section 8(1)(d) of the Competition Act.

<sup>24</sup> Whish & Bailey *Competition Policy and Economics* (2012) 205.

<sup>25</sup> Ido VHP ‘Designing Pro-Health Competition Policies in Developing Countries’ Research Paper 125 South Centre (2020) 4.

<sup>26</sup> LiveWire ‘What will be the biggest selling drug of all-time?’ available at <https://livewiremarkets.com/wires/what-will-be-the-biggest-selling-drug-of-all-time> (accessed 22 October 2024).

<sup>27</sup> Dwivedi D, Hallihosur S & Rangan L ‘Evergreening: A deceptive device in patent rights’ (2010) 3 *Technology in Society* 324-330.

<sup>28</sup> TAC, MSF & RIS Policy Brief ‘Why South Africa Should Examine Pharmaceutical Patents: How legislative reform could boost the affordability and accessibility of medicines for South Africans’ (2013) 3.

medicines. The propensity for patent evergreening in South Africa is further compounded by the jurisdiction's reliance on a formal examination regime in patent registration wherein solely the procedural requirements of patent applications are scrutinised rather than their substantive merit.<sup>29</sup> Consequently, evergreening practices although potentially detrimental to competition and public health aspirations, it technically conforms to the letter of the law.

Darunavir, an ARV medicine used in the treatment of HIV, is a prime example of this type of conduct. Darunavir was first patented in 1993, and its effective protection has been extended until 2028 through the strategic filing of further patents covering various elements of the medicine, including a combination with Ritonavir.<sup>30</sup> For major pharmaceutical corporations, the necessity to remain profitable is a strong driver for evergreening, as the expiration of patents allows generic companies to enter the market, drastically reducing revenue. The expiry of patent protection for Capoten, a pharmaceutical medicine produced and marketed by Bristol-Myers Squibb, exemplifies the profound commercial repercussions of patent expiration, which is the impetus for evergreening. Capoten's sales revenues fell from US \$146 million to US \$25 million in a single year when its patent expired.<sup>31</sup> Evergreening thus serves as a barrier to entry for generic firms in that as long as the branded medicine company has sufficient resources to constantly patent the various aspects of a patented drug, generic companies' entry into the market is delayed. The expiration of patents for a pharmaceutical product often presents generic manufacturers with a daunting dilemma; either await the lapse of all applicable patents or initiate litigation, thereby incurring substantial costs and delays.<sup>32</sup> This situation is especially dire for smaller generic medication manufacturers, who are often unprepared to engage in lengthy legal disputes with international pharmaceutical multinationals.<sup>33</sup> Given this, the significant disparity in resources and legal expertise between generic manufacturers and branded pharmaceutical companies creates an insurmountable barrier to market entry, perpetuating anti-competitive conditions that severely limit generic manufacturers' options.

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<sup>29</sup> Ducimetière C 'Second Medical Use Patents – Legal Treatment and Public Health Issues' Research Paper 101 South Centre (2019) 47.

See also Gurgula O 'The 'obvious to try' method of addressing strategic patenting: How developing countries can utilise patent law to facilitate access to medicines' (2019) *Policy Brief* 59.

<sup>30</sup> TAC, MSF & RIS Policy Brief 'Why South Africa Should Examine Pharmaceutical Patents: How legislative reform could boost the affordability and accessibility of medicines for South Africans' (2013) 3.

<sup>31</sup> Vasanthakumar NB 'Patent term extension strategies in the pharmaceutical industry' *Pharmaceuticals Policy and Law* (2005) 6 109-122.

<sup>32</sup> Dwivedi D, Hallihosur S & Rangan L 'Evergreening: A deceptive device in patent rights' (2010) 3 *Technology in Society* 329.

<sup>33</sup> Goode R & Chao B 'Biological patent thickets and delayed access to biosimilars, An American problem' (2022) 9 *Journal of Law and Biosciences* 19, where Goode reports that on average it costs a small generic drug manufacturer approximately US \$774 000.00 to litigate a single patent on a brand-name drug.

When many patents are obtained for the same medicine, they frequently result in patent thickets, or overlapping patent rights, which extend patent monopolies beyond 20 years and make it difficult to discern when the monopolies genuinely end. For example, the ARV medicine ritonavir has almost 800 related patents that cover a wide range of topics, including the active ingredient, its derivatives, dosages, formulations, potential uses for treating certain diseases, and production procedures.<sup>34</sup> These patents are largely meant to make generic businesses less confident in their ability to enter the marketplace.

As a result, the inventor obtains these secondary patents in order to protect its successful current product against generic competition, even if many of them are small and potentially invalid. This is because the entrance of generics into the market often results in an 80% loss of market share and a 20% to 30% decrease in medicine price. As additional generics join the market, prices continue to fall, often by up to 90%.<sup>35</sup> For example, when the patent for the antidepressant Prozac expired in 2001, Eli Lilly lost around 70% of their market share and US \$2.4 billion in annual sales in the United States market.<sup>36</sup>

Evergreening practices employed by branded pharmaceutical companies are highly contentious with numerous critics asserting that such a practice unlawfully restrains competition, impeding access to affordable medication and ultimately harming consumer welfare.<sup>37</sup> Continued reliance on ‘evergreening’ practices by major pharmaceutical companies is thus in direct violation of sections 2(1)(c), (d) and (e) of the Competition Act<sup>38</sup> as well as the public interest considerations espoused in the Competition Act in that evergreening excludes generic companies from participating in the market. These two provisions require the Competition

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<sup>34</sup> WIPO ‘Patent Landscape Report on Ritonavir’ available at <https://www.wipo.int/publications/en/details.jsp?id=230&plang=EN> (accessed 5 September 2024).

<sup>35</sup> OFT Decision in Case No. CE/8931/08 (12 April 2011) (Gaviscon); Before losing their exclusivity, generic medications in the EU usually cost around 25% less than the original product’s price when they first hit the market. Another effect of generic entrance is that it lowers the price of the original product. One year following the loss of exclusivity, average prices in markets where generic entry occurs decrease by nearly 20%, and two years later, they decrease by roughly 25%. In certain instances, the reduction may reach 80–90%.

<sup>36</sup> Gurgula, O ‘Strategic Patenting by Pharmaceutical Companies – Should Competition Law Intervene’ (2020) *IIC - International Review of Intellectual Property and Competition Law* 1066.

<sup>37</sup> Said ME ‘The Impact of ‘TRIPS-Plus’ Rules on the Use of TRIPS Flexibilities: Dealing with the Implementation Challenges’ in Correa CM & Hilty RM (eds) *Access to Medicines and Vaccines* (2022) 305.

See also Paine CS ‘Brand-Name Drug Manufacturers Risk Antitrust Violations by Slowing Generic Production Through Patent Layering’ (2003) 33 *Seton Hall Law Review* 479.

<sup>38</sup>Section 2 of the Competition Act:

- (1) The purpose of this Act is to promote and maintain competition in the Republic in order-
  - (c) to promote employment and advance the social and economic welfare of South Africans;
  - (d) to expand opportunities for South African participation in world markets and recognise the role of foreign competition in the Republic;
  - (e) to ensure that small and medium-sized enterprises have an equitable opportunity to participate in the economy.

Commission in line with its obligations under section 21 (1)(c) of the Competition Act to monitor the markets to ensure a level playing field for all market players big or small and further identify and eliminate unreasonable barriers that might hinder the entry of Small, Medium and Micro Enterprises (SMMEs) and Historically Disadvantaged Individuals (HDI) firms.<sup>39</sup> Evergreening's effects of exclusion include limiting generic manufacturers' access to the pharmaceutical industry, limiting job possibilities, and impeding the expansion of smaller pharmaceutical enterprises. Critics believe that evergreening hinders innovation and perpetuate monopolistic pricing, while branded pharmaceutical companies maintain that it helps them recover R&D expenditures which they are entitled to and preserve IPRs.<sup>40</sup>

#### 4.3.2.2 Reverse settlement agreements/ Pay-For-Delay Agreements

Reverse settlement agreements, also referred to as pay-for-delay agreements, constitute an additional form of exclusionary conduct pertinent in the pharmaceutical industry. Pursuant to such agreements, brand-name pharmaceutical companies and generic companies resolve patent litigation through a pecuniary transfer from the former to the latter, contingent upon the generic company's consent to delay market entry for a predetermined period.<sup>41</sup> The financial transfer included in reverse payment patent settlements can take the form of direct cash payments or indirect consideration, such as the brand-name company's pledge to forgo releasing its own approved generic product onto the market in order to prevent competition with the first-filing generic manufacturer.<sup>42</sup> In jurisdictions lacking patent search and examination regimes,<sup>43</sup> such as South Africa, generic manufacturers opt to challenge the validity of registered patents through litigation, asserting grounds such as lack of novelty, insufficient utility or the absence of an inventive step.<sup>44</sup> In the event that legal proceedings are instituted against the generic manufacturer for patent infringement, the generic manufacturer can challenge the infringement claim by showing that their product does not infringe on the brand-name's drug. Generic manufacturers thus use such litigation to invalidate or circumvent incorrectly awarded patents,

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<sup>39</sup> Competition Commission 'Background Note to the Public Interest Guideline' available at <https://www.compcom.co.za/wp-content/uploads/2015/01/Final-Background-Note-to-Public-Interest-Guideline-210115.pdf> (accessed 17 October 2024).

<sup>40</sup> Gongola JA 'Prescriptions for Change: The Hatch-Waxman Act and the New Legislation to Increase the Availability of Generic Drugs to Consumers' (2003) 36 *Indiana Law Journal* 787.

<sup>41</sup> Hutt PB, Merrill RA & Grossman LA *Food and Drug Law: Cases and Materials* 4 ed (2013) 1016. See also Hemphill CS, 'Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem' (2006) 81 *N.Y.U. L. Rev.* 1556.

<sup>42</sup> Karas L, Anderson GF & Feldman R 'Pharmaceutical "Pay-for-Delay" Reexamined: A Dwindling Practice or a Persistent Problem?' (2020) 71 *Hastings Law Journal* 961.

<sup>43</sup> South Africa being one of them.

<sup>44</sup> Section 61 (c) of the Patent Act.

thereby allowing market access and increasing competition in the pharmaceutical industry. Where the generic company is successful or shows high success rate in litigation, the brand-name drug company for fear of losing profits due to the entry of generic drugs elects the reverse settlement option to delay entry of the generic drug. Thus, the brand-name manufacturer avoids the risk of competition by paying the generic manufacturer to keep its product off the market, often for the remainder of the brand-name drug's patent term.

Pay-for-delay settlements present a general conundrum on how to strike the right balance between innovation and consumer access, in addition to being a matter of great practical importance in competition enforcement. Even though reverse settlements give generic producers financial or other benefits, they also reduce competition because there will only be one supplier of the particular patented drug, resulting in a quasi-monopoly. Furthermore, the use of the agreements acts as a deterrent to generic companies as any act of litigation which is already expensive for small generic manufacturers can be met with reverse settlements option. A notable example of pre-expiration challenges is the litigation surrounding the anti-ulcer medication Zantac, which was only settled on the eve of the trial.<sup>45</sup> Concerns about reverse settlement agreements are becoming more prevalent, as evidenced by the landmark ruling in *FTC v Actavis*<sup>46</sup> by the US Supreme Court. To keep generic versions of its medication, AndroGel, off the market until 2015—nine years after the settlement but before Solvay's patent expired—Solvay Pharmaceuticals agreed to pay the generic manufacturers tens of millions of US dollars in the Actavis case.<sup>47</sup> The Supreme Court ruled that although reverse settlement agreements are not inherently unlawful, anticompetitive consequences are certain to occur where the payment is substantial and unwarranted in comparison to the costs of the action and unrelated to the services for which it may be paid.<sup>48</sup> Drawing from Actavis that reverse settlement agreements are not *per se* illegal, allows for big pharmaceutical companies to exploit generic drug companies and keep them out of business as long as their pockets allow. This again is exclusionary in nature as it limits market participation of generic firms.

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<sup>45</sup> *Glaxo Inc. v Novopharm Ltd* 931 F. Supp. 1280 (E.D.N.C 1996).

See also Hemphill CS 'Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem' (2006) 81 *N.Y.U. L. Rev.* 1568.

<sup>46</sup> *FTC v Actavis* 570 U.S. 136, (2013).

<sup>47</sup> *FTC v Actavis* para 145.

<sup>48</sup> *FTC v Actavis* para 158

See also Karas L, Anderson GF & Feldman R 'Pharmaceutical "Pay-for-Delay" Reexamined: A Dwindling Practice or a Persistent Problem?' (2020) 71 *Hastings Law Journal* 963.

#### 4.3.2.3 Refusal of Access to an Essential Facility

The essential facilities doctrine simply states that a dominant firm is compelled to grant access to an “essential facility”, a facility presumed to be indispensable to competition on the merits, to its competitors.<sup>49</sup> The doctrine’s basic tenet is that denying competitors access to such a facility would prevent them from effectively competing with the dominant enterprise that controls the necessary infrastructure.<sup>50</sup> Section 8(1)(b) of the Competition Act explicitly prohibits dominant undertakings from refusing to give access to an essential facility when it is economically feasible to do so.<sup>51</sup> By directly addressing the problem of dominant enterprises denying access to necessary facilities, this clause was purposefully included in the legislation to fill a perceived gap in the regulatory framework and advance consumer welfare and competition. The term essential facility is defined in section 1(xi) of the Competition Act as “an infrastructure or resource that cannot reasonably be duplicated, and without access to which competitors cannot reasonably provide goods or services to their customers.”<sup>52</sup>

Of significance to this section is section 8(d)(ii) which qualifies the refusal to give access to an essential facility as exclusionary conduct subject to the ‘rule of reason’ test which simply can allow a dominant firm to escape liability if it can prove pro-competitive gains in its act. In *Glaxo Wellcome (Pty) Ltd & others v National Association of Pharmaceutical Wholesalers & others*<sup>53</sup> the CAC held that for a firm to allege that there has been a contravention of section 8(b), the complainant has to prove that:

- “(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

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<sup>49</sup> Pitofsky R, Patterson D & Hooks J ‘The Essential Facilities Doctrine Under U.S. Antitrust Law’ (2002) 71 *Antitrust Law Journal* 443-462.

See also OECD, ‘The Essential Facilities Concept’ (Organisation for Economic Co-Operation and Development 1996) 91.

<sup>50</sup> Bergman MA ‘The Role of the Essential Facilities Doctrine’ (2001) 46 *The Antitrust Bulletin* 433.

<sup>51</sup> Section 8(1)(b) of the Competition Act.

See also Brand J ‘Intellectual Property and the abuse of a dominant position in South African Competition law’ (2005) *SALJ* 910.

<sup>52</sup> Section 1(xi) of the Competition Act.

<sup>53</sup> *Glaxo Wellcome (Pty) Ltd & others v National Association of Pharmaceutical Wholesalers & others* (15/CAC/Feb02) [2002] ZACAC 3 (21 October 2002).

(5) it is economically feasible for the dominant firm to provide its competitors with access to the infrastructure or resource.”<sup>54</sup>

The same position has been adopted in EU cases such as *Magill*,<sup>55</sup> *Oscar Bronner*,<sup>56</sup> *IMS Health*,<sup>57</sup> and *Microsoft*.<sup>58</sup> Collectively, these cases held that to coerce an undertaking to provide access to an essential facility, the service or product to which access is being denied must be indispensable to be able to compete in the downstream market,<sup>59</sup> the refusal would lead to the elimination of effective competition in the downstream market,<sup>60</sup> the refusal would lead to the prevention of the introduction of a new product,<sup>61</sup> and that there is no objective justification for the refusal.<sup>62</sup> The common denominator in the EU cases is that IP was classified as an essential facility. In *Microsoft* the IP concerned was copyright over the Windows operating system which Microsoft refused to part with.<sup>63</sup> In *IMS Health*, it was the refusal to give access to the ‘1860 brick structure’, over which IMS Health had copyright.<sup>64</sup> In *Magill* it was the refusal to license to reproduce the three weekly television listings in one comprehensive television guide that was of concern.<sup>65</sup>

For the purpose of this min-dissertation, particular attention is given to patents which fall under essential facility. Drawing from the COVID-19 experience, the components of the COVID-19 vaccine from formulation which were held by different pharmaceutical companies under patents could not be easily duplicated. The monopoly of the vaccine components ultimately gave these companies a dominant position where the whole world depended on these

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<sup>54</sup> *Glaxo Wellcome (Pty) Ltd & others v National Association of Pharmaceutical Wholesalers & others* (15/CAC/Feb02) [2002] ZACAC 3 (21 October 2002) para 57.

<sup>55</sup> *Joined Cases Radio Telefis Eireann (RTE) and Independent Television Publications Ltd (ITP) v Commission of the European Communities* C-241/91 P and C-242/91 P [1995] ECR I-743.

<sup>56</sup> *Oscar Bronner GmbH & Co KG v Mediaprint Zeitungs- und Zeitschriftenverlag GmbH & Co KG* Case C-7/97 [1998] ECR I-7791.

<sup>57</sup> *IMS Health GmbH & Co OHG v NDC Health GmbH & Co KG* Case C-418/01 [2004] 4 CMLR 28.

<sup>58</sup> *Microsoft v Commission* Case T-313/05 C-257 of 15 August 2005.

<sup>59</sup> Brand J ‘Intellectual Property and the abuse of a dominant position in South African Competition law’ (2005) *SALJ* 916.

<sup>60</sup> Case C-418/01, *IMS Health GmbH & Co. OHG v. NDC Health GmbH & Co. KG*, 2004 E.C.R. I-5069, I-5082 (citing Case C-7/97, *Oscar Bronner GmbH & Co. KG v. Mediaprint Zeitungs- und Zeitschriftenverlag GmbH & Co. KG*, 1998 E.C.R. I-7817, I-7830–31).

<sup>61</sup> *Radio Telefis Eireann (RTE) and Independent Television Publications Ltd (ITP) v Commission of the European Communities* para 53.

<sup>62</sup> *Radio Telefis Eireann (RTE) and Independent Television Publications Ltd (ITP) v Commission of the European Communities* para 55.

<sup>63</sup> Xiang JY ‘Intellectual Property, Antitrust, and Access to Essential Technologies’ (2023) 26 *Lewis & Clark Law Review* 1142.

<sup>64</sup> Brand J ‘Intellectual Property and the abuse of a dominant position in South African Competition law’ (2005) *SALJ* 921.

<sup>65</sup> Brand J ‘Intellectual Property and the abuse of a dominant position in South African Competition law’ (2005) *SALJ* 916.

companies to manufacture and supply the vaccines. For developing countries mainly in Africa, despite the fact that they had access to facilities to manufacture the vaccines as in the case of South Africa,<sup>66</sup> refusal by the big pharmaceutical companies to license and eventually give formulations of the vaccines at a fee made it impossible to have local manufacturers and suppliers of drugs. Dos Santos, Ncube and Ouma report that South Africa and India asked for a waiver of IP rights to allow them to manufacture the drugs on their own which was met with resistance.<sup>67</sup> The R&D and know-how of manufacturing a vaccine cannot be easily duplicated hence the requirements of novelty in registration of a patent. The drug companies which led the race to the COVID-19 vaccine were economically capable of sharing the information and were to gain financially from it through licensing. However, the refusal as highly noted during the pandemic meant that generic drug manufacturers were effectively excluded from competing with the patent holders who essentially held the keys to the formulations of the vaccines.

### 4.3.3 Exploitative Conduct

Exploitative practices refer to anti-competitive conduct directed to consumers by undertakings wherein consumers are exposed to excessive prices or unfair terms.<sup>68</sup> This conduct is in direct contravention of section 2 (1)(b) of the Competition Act which states that one of the goals of the Competition Act is to provide consumers with competitive prices and product choices. In the EU, the mandate to protect consumers from exploitative practices is covered in Article 102 of the TFEU. A dominant firm that charges excessive prices risks being in contravention of Article 102 of the TFEU.<sup>69</sup> The *locus classicus* in dealing with what constitutes excessive prices is the *United Brands* case<sup>70</sup> which was thoroughly dealt with in Chapter 3<sup>71</sup>. In summation excessive pricing was determined to be a price that has no reasonable relation to the economic value of the product,<sup>72</sup> a position also supported in the then European Court of Justice decision in *AKKA/LAA*,<sup>73</sup> where the court held that it was possible to establish abusive excessive prices

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<sup>66</sup> Brown S & Rosier M 'COVID-19 vaccine apartheid and the failure of global cooperation' (2023) 3 *Br J Polit Int Relat* 535-554.

<sup>67</sup> Dos Santos F, Ncube CB & Ouma M 'Intellectual property framework responses to health emergencies – options for Africa' (2022) *South African Journal of Science* 3.

<sup>68</sup> UNCTAD 'The effects of anti-competitive business practices on developing countries and their development prospects' available at [https://unctad.org/system/files/official-document/ditcclp20082\\_en.pdf](https://unctad.org/system/files/official-document/ditcclp20082_en.pdf) (accessed 17 October 2024).

<sup>69</sup> See 3.3 of Chapter 3.

<sup>70</sup> *United Brands Co. v European Commission* Case 27/76 [1978] ECR 207, ECJ.

<sup>71</sup> See 3.2 of Chapter 3.

<sup>72</sup> *United Brands Co. v European Commission* para 250.

<sup>73</sup> *AKKA/LAA* Case C-177/16 ECLI:EU:C:2017:689.

only on the basis of a comparison between the dominant undertaking's prices and other relevant price benchmarks, without necessarily having to assess the difference between its prices and costs.

In South Africa, section 8(1)(a) of the Competition Act prohibits exploitative conduct in the form of excessive pricing. The legislature in South Africa was of the view that such an intervention in the free market was necessary to protect competition. Previously, an excessive price was defined in section 1 of the Competition Act as a price which bears no reasonable relation to the value of that good or service. This reference has since been deleted by section 1(b) of Act 18 of 2018 which amended the Competition Act. Section 8(2) of the Competition Act now 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) of the Competition Act provides that:

"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 price-cost 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."<sup>74</sup>

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<sup>74</sup> Section 8(3) (a-f) of the Competition Act.

Guidance on the application of sections 8(2) and 8(3) of the Competition Act can be found in *Harmony Gold Mining Company Ltd v Mittal Steel South Africa*<sup>75</sup> wherein the Competition Tribunal held that the assessment of excessive pricing involves a determination of the actual price; economic value; the reasonableness of a price and the detriment to consumers. Exploitative practices in the form of excessive pricing and limited access as an unfair trading condition are thus dealt with below under the heading Ramifications of the exercise of patents.

#### 4.4 RAMIFICATIONS OF THE EXERCISE OF IPRs

In the pharmaceutical sector, the use of IPRs carries substantial consequences. The availability and cost of medications can be significantly impacted by the use of IPRs.<sup>76</sup> For example, Lipitor a drug used to treat high cholesterol goes for about US \$11.13 whilst the generic version named Atorvastatin costs approximately US \$0.26. The same can be said for Norvasc a brand name medicine used to treat heart disease which is priced at US \$9.55, whereas Amlodipine costs US \$0.27.<sup>77</sup> Pharmaceutical companies' capacity to recover their R&D expenditures is one of the implications of the exercise of IPRs. This makes it possible for businesses to earn from their inventions, which is crucial for promoting innovation and spending on R&D.<sup>78</sup> However, the use of IPRs can also result in patent trolls and thickets, which can hinder innovation and restrict access to medical care.<sup>79</sup> Countries also have to strike a balance between the demands of public health and innovation, which can be a difficult and complex undertaking.<sup>80</sup> It is impossible to overestimate the role that IPRs play in promoting innovation and funding for R&D. WIPO has stated that IPRs offer exclusivity and stimulate R&D spending, enabling businesses to recover their costs and benefit from their inventions.<sup>81</sup>

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<sup>75</sup> *Mittal Steel South Africa Limited and Others v Harmony Gold Mining Company Limited and Another* (70/CAC/Apr07) [2009] ZACAC 1 (29 May 2009).

<sup>76</sup> Lanjouw JO 'Intellectual property and the availability of pharmaceuticals in poor countries' (2003) 3 *Innovation Policy and the Economy* 112.

<sup>77</sup> CenterWell 'Costs of generic and alternative drugs' available at [https://www.bing.com/search?pglt=2083&q=CenterWell+'Costs+of+generic+and+alternative&cvid=557d3f871a1f4c6aa2bb0c85eb697f3a&gs\\_lcrp=EgZjaHJvbWUyBggAEEUYOdIBCzU1NDkxNzFqMGo0qAIAAIA&F ORM=ANNTA1&PC=U531](https://www.bing.com/search?pglt=2083&q=CenterWell+'Costs+of+generic+and+alternative&cvid=557d3f871a1f4c6aa2bb0c85eb697f3a&gs_lcrp=EgZjaHJvbWUyBggAEEUYOdIBCzU1NDkxNzFqMGo0qAIAAIA&F ORM=ANNTA1&PC=U531) (accessed 17 September 2024).

<sup>78</sup> Lanjouw JO 'Intellectual property and the availability of pharmaceuticals in poor countries' (2003) 3 *Innovation Policy and the Economy* 95.

<sup>79</sup> Filho CS & Ido VHP 'Courts and Pharmaceutical Patents: From Formalist Positivism to the Emergence of a Global Law' in Correa CM & Hilty RM (eds) *Access to Medicines and Vaccines* (2022) 210.

<sup>80</sup> Lanjouw JO 'Intellectual property and the availability of pharmaceuticals in poor countries' (2003) 3 *Innovation Policy and the Economy* 96.

<sup>81</sup> WIPO 'What is intellectual property' available at [www.wipo.int/about/ip/en](http://www.wipo.int/about/ip/en) (accessed 3 September 2024).

IPRs in the pharmaceutical sector, however, have turned into a double-edged sword as, while they safeguard inventors, they have also adversely impacted drug accessibility and cost. R&D is the engine that drives advancement in the pharmaceutical sector. Money is poured into R&D for the new product to assess its feasibility, efficiency, and effectiveness before any drug or medical equipment is developed. For instance, it is possible that this R&D will take decades. For ARVs it took nearly 15 years from the advent of HIV/AIDS virus to the invention of effective antiretroviral therapy (ART) in 1996 to come to the market,<sup>82</sup> or a shorter period of less than a year as in the case of the various COVID-19 vaccines.

Unfortunately, R&D is expensive and this is made worse by the length of time it can take to produce a product, the product's complexity, the expertise required, and any other compliance-related concerns. Although the exact cost of developing a medicine is rarely disclosed, it is generally estimated to be between US \$800 and US \$1.8 billion.<sup>83</sup> The right to exclusivity provided by IPRs in the form of patents, trademarks, and copyright are protected in an effort to recoup R&D expenses and maintain pharmaceutical companies' profitability. Pharmaceutical firms benefit from their inventions through patent, which offer protection by granting exclusive right with the goal of compensating for their investment in innovation. The following discussion focus on the specific impact of patent in the pharmaceutical sector.

#### 4.4.1 Influence of patents on pricing

Both the Competition Act<sup>84</sup> and the Constitution<sup>85</sup> seek to provide access to innovative and reasonably priced medicines while preserving a competitive structure in the relevant industry; nevertheless, the exercise of patents is impeding this goal's realisation. Since companies in the pharmaceutical industry create medicines, their operations depend heavily on R&D which makes them essential to society's well-being. There cannot be innovation or the creation of new products without R&D. Nevertheless, R & D especially in this sector, may be highly costly for a business and requires years, often even decades, of labour before a medication is ready for market. This explains the significance of IPRs, especially patents, in the pharmaceutical sector. Businesses must be certain that they will hold exclusive rights to the product's sale

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<sup>82</sup> Beyrer C 'A pandemic anniversary: 40 years of HIV/AIDS' (2021) 397 *The Lancet* 2142-2143.

<sup>83</sup> Waye A, Jacobs P, Schryvers AB 'Vaccine development costs: a review' (2013) 12 *Expert Rev Vaccines* 1495-1501.

<sup>84</sup> Section 2 (1) (b) of the Competition Act:

The purpose of this Act is to promote and maintain competition in the Republic in order-  
(b) to provide consumers with competitive prices and product choices.

<sup>85</sup> Section 27(1) (a) of the Constitution:

(1) Everyone has the right to have access to—  
(a) health care services, including reproductive health care.

when it is ready to be put on the market since they invest a significant amount of money in R&D for new items.

Large pharmaceutical businesses often focus on developing two types of medicines: patent-protected items that are sold at a premium to offset investment expenses, and basic drugs that are subject to intense competition and offered at a low price.<sup>86</sup> In order to offset growing R&D expenses and the medicine's progressively dwindling patent life, manufacturers mark up the prices at which they sell their goods. The length of the patent's validity and the degree to which generic businesses are prepared to use the protected ingredient to join the market for that medication are the first factors that are evident and directly impact the price of medications. Pharmaceutical corporations offer a number of explanations for the high cost of drugs and the increasing emphasis on incremental innovation, including the difficulty of drug development and discovery and the costly and time-consuming regulatory processes involved.<sup>87</sup> To offset the costs at which the medications are eventually marketed, the R&D expenses are typically not made public. The COVID-19 pandemic highlighted the concern that patents may restrict access to future treatments and vaccinations, driving up costs to unaffordable levels.<sup>88</sup>

Section 8 of the Competition Act in paragraph a prohibits a dominant firm from charging an excessive price to the detriment of the consumers.<sup>89</sup> Excessive price was previously defined by the Competition Act although deleted by section 1(b) of Act 18 of 2018 as a price which:

“(aa) bears no reasonable relation to the economic value of that good or service; and  
(bb) is higher than the value referred to in subparagraph (aa).”

The CAC in *Mittal Steel South Africa Limited and Others v Harmony Gold Mining Company Limited*<sup>90</sup> stated that while determining a good or service's fair relationship to its economic value, it is necessary to determine whether or not the price is the outcome of “cognisable competition considerations.” The price established using the previous technique represents the product's economic worth. However, if “the price appears to have no explanation other than the pure exercise of monopoly power,” it is not reasonable in regard to economic value. This

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<sup>86</sup> Capo F, Brunetta F, Boccardelli P ‘Innovative Business Models in the Pharmaceutical Industry: A Case on Exploiting Value Networks to Stay Competitive’ (2014) *International Journal of Engineering Business Management* 1-11.

<sup>87</sup> Berman A, Lee T, Pan A, Rizvi Z, Thomas A ‘Curbing unfair drug prices, a primer for states’ (2017) Yale Global Health Justice Partnership Policy Paper 12.

<sup>88</sup> Gurgula, O ‘Strategic Patenting by Pharmaceutical Companies – Should Competition Law Intervene’ (2020) *IIC - International Review of Intellectual Property and Competition Law* 1063.

<sup>89</sup> Competition Act 89 of 1998.

<sup>90</sup> *Mittal Steel South Africa Limited and Others v Harmony Gold Mining Company Limited* 70/CAC/Apr07.

approach was also utilised in *Hazel Tau & others v GlaxoSmithKline, Boehringer Ingelheim & others*<sup>91</sup> where the Competition Commission determined that both these corporations exploited their dominant positions in the market by charging exorbitant prices for their patented ARV drugs

To ascertain if there was a reasonable relationship between the price and the economic worth of the in question ARVs, a cost-based technique was used to arrive at this conclusion. Thus, the complainants took into account in their submissions the following: the nature and extent of the harm to consumers resulting from the high price; the impact of the high prices on internationally recognised and constitutionally protected rights, that is, the right to life,<sup>92</sup> dignity,<sup>93</sup> and access to health care services;<sup>94</sup> and the hypothetical price of the good in a competitive market in the absence of patent protection, including a normal rate of profit, a reasonable allowance for the recovery of R&D, some allowance for additional profit as an incentive for innovation and any unusual entrepreneurial risk. When all these factors were considered GSK and Boehringer Ingelheim were said to be charging 1.72 to 4.01 times higher than the estimated economic value of the ARVs.<sup>95</sup>

In determining what constitutes an excessive price, it was remarked in *Napp Pharmaceutical Holdings Ltd & Others v General General of Fair Trading*<sup>96</sup> as cited in *Mittal Steel*<sup>97</sup> that:

“Measuring whether a price is above the level that would exist in a competitive market is rarely an easy task. The fact that the exercise may be difficult is not, however, a reason for not attempting it. In the present case, the methods used by the Director are various comparisons of (i) Napp’s prices with Napp’s costs, (ii) Napp’s prices with the costs of its next most profitable competitor, (iii) Napp’s prices with those of its competitors and (iv) Napp’s prices with prices charged by Napp in other markets. Those methods seem to us to be among the approaches that may reasonably be used to establish excessive prices, although there are, no doubt, other methods.”<sup>98</sup>

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<sup>91</sup> *Hazel Tau & others v GlaxoSmithKline, Boehringer Ingelheim & others* Competition Commission Case Number: 2002Sep 226.

<sup>92</sup> Section 11 of the Constitution.

<sup>93</sup> Section 10 of the Constitution.

<sup>94</sup> Section 27(1)(a) of the Constitution.

<sup>95</sup> UNCTAD *Hazel Tau & others v. GlaxoSmithKline, Boehringer Ingelheim & others*, 2002 (South African Competition Commission, Competition Commission Case No. 2002Sep226) available at <https://unctad.org/ipccaselaw/hazel-tau-others-v-glaxosmithkline-boehringer-ingelheim-others-2002-south-african-competition> (accessed 11 September 2024).

<sup>96</sup> *Napp Pharmaceutical Holdings Ltd & Others v General General of Fair Trading* [2002] CAT 1.

<sup>97</sup> *Mittal Steel South Africa Limited and Others v Harmony Gold Mining Company Limited and Another* (70/CAC/Apr07) [2009] ZACAC 1 (29 May 2009).

<sup>98</sup> *Napp Pharmaceutical* para 392.

The initial comparison between price and expenses, however, presents a challenge for competition authorities because there is a lot of secrecy surrounding the costs connected with patent R&D, as pharmaceutical companies either over-inflate their R&D costs or do not report them at all. An example of this is the Bedaquiline drug used to treat tuberculosis (TB) made by J&J, which, according to Médecins Sans Frontières (MSF), is the most expensive component of the multi-drug regimen for people with drug-resistant TB with costs of R&D a key factor.<sup>99</sup> It was, however, later revealed that the drug was developed with public funding, which was five times more than private funding due to a lack of transparency.<sup>100</sup> Light and Lexchin<sup>101</sup> argue that a 100 million doses of the COVID-19 vaccine in two large, fully equipped, state of the art facilities in the USA and EU would approximately cost US \$0.20 a dose to manufacture, staffing to oversee extensive testing for purity, safety, and consistency would be close to US \$0.30, the vaccine substance itself as reported by New York Times on the J&J vaccine was at US \$0.30 with the fill and finish costs ranging between US \$0.15 and US\$ 0.30. This would put the cost of developing one dose of vaccine below US\$ 2.00. The rates that Moderna and Pfizer were charging for vaccines in the EU and more affluent countries, according to Dyer,<sup>102</sup> ranged from US\$ 14.70 to US\$ 23.50 per dosage, which essentially does not seem to be covering the expenses related to vaccine development and production.

Due to alleged excessive pricing of the breast cancer treatment drug trastuzumab in violation of sections 8(a) and 8(1)(a) of the Competition Act, the Competition Commission in South Africa filed a referral to the Competition Tribunal against Roche Holding AG ("Roche AG"), and its subsidiaries, F Hoffman La Roche AG ("Roche Basel") and Roche Products (Pty) Ltd ("Roche SA").<sup>103</sup> Despite the Commission using every legal avenue, including diplomatic channels, Roche refused to give the Commission its cost data hindering a proper analysis of the excessive price margins charged by Roche. When compared to the cost of the COVID-19

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<sup>99</sup> The Guardian 'Cost of developing new drugs may be far lower than industry claims, trial reveals' available at <https://blindly-liberal-gobbler.edgecompute.app/global-development/2024/apr/25/cost-of-developing-new-drugs-may-be-far-lower-than-industry-claims-trial-reveals> (accessed 11 September 2024).

<sup>100</sup> The Guardian 'Cost of developing new drugs may be far lower than industry claims, trial reveals' available at <https://blindly-liberal-gobbler.edgecompute.app/global-development/2024/apr/25/cost-of-developing-new-drugs-may-be-far-lower-than-industry-claims-trial-reveals> (accessed 11 September 2024).

<sup>101</sup> Light DW and Lexchin J 'The costs of coronavirus vaccines and their pricing' (2021) *Journal of the Royal Society of Medicine* 503.

<sup>102</sup> Dyer O 'COVID-19: Countries are learning what other paid for vaccines' (2021) 372 *BMJ* 1-2.

<sup>103</sup> Competition Commission South Africa 'Competition Commission Prosecutes A Multinational Healthcare Company, Roche, for Excessive Pricing of A Breast Cancer Treatment Drug' 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> (accessed 7 September 2024).

vaccine, many concerns are brought up regarding the second and third thresholds for comparing prices with competitors as established by Napp. Large pharmaceutical companies including Moderna, Pfizer, J&J, Novartis, and GSK led the race to develop a COVID-19 vaccine, obtaining the necessary patents before exporting the vaccines to other countries.<sup>104</sup> AstraZeneca Oxford doses were sold for \$5.25 in South Africa, a relatively higher price than the \$2.15 and \$3–\$4 that they were selling for in Europe and the US, respectively.<sup>105</sup>

On the second and third threshold on comparison of prices with competitors as developed in Napp, when juxtaposed to the pricing of the COVID-19 vaccines, a lot of questions are raised. In South Africa, a dose of the AstraZeneca Oxford sold for a higher price of US \$5.25 per dose,<sup>106</sup> the J&J vaccine costed the South African government approximately US \$10.00 a dose,<sup>107</sup> and Pfizer-BioNTech charged South Africa nearly 33 percent more than it reportedly charged the African Union.<sup>108</sup> With each company simply justifying its dosage price it makes it difficult to compare and try to set a reasonable price for a dose just on price comparison.

As stated in the Napp case, a comparison of a company's price in other marketplaces should be done in order to assess whether a price is excessive. The COVID-19 pandemic resulted in significant pricing discrimination, especially against developing nations. The fact that wealthier nations produced the vaccines and held the patents did not help the problem. Patents provided pharmaceutical firms the authority to choose who they would supply, when, how much they would supply, and on what price. To fully elaborate on this, Moderna and Pfizer were charging more affluent nations and EU their vaccines with prices ranging from US\$ 14.70 to US\$ 23.50 a dose.<sup>109</sup> Furthermore, low-income countries received less than 50 doses of the COVID-19 vaccine per 100 people by the end of April 2021—that is, roughly 0.2% of the 1.3

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<sup>104</sup> Sagonowsky E, Liu A, Kansteiner F, Becker Z& Dunleavy K 'The top 10 vaccine companies worldwide' available at <https://www.fiercepharma.com/pharma/top-10-vaccine-companies-worldwide> (accessed 20 August 2024).

<sup>105</sup> Dyer O 'COVID-19: Countries are learning what others paid for vaccines' (2021) 372 *BMJ* 1-2.

<sup>106</sup> Section 46 (1) of the Patent Act:

The duration of a patent shall be 20 years from the date of application therefore, subject to payment of the prescribed renewal fees.

<sup>107</sup> Daily Maverick 'COVID-19 contracts reveal that Big Pharma 'bullied' SA while securing vaccines worth \$734m – NGO' available at <https://www.dailymaverick.co.za/article/2023-09-05-COVID-19-contracts-reveal-that-pharma-bullied-sa-while-securing-vaccines-worth-734m/> (accessed 2 September 2024).

<sup>108</sup> Ismail S 'South Africa 'held to ransom' by big pharma, overcharged for COVID vaccines' Aljazeera available at <https://www.aljazeera.com/news/2023/9/6/south-africa-held-to-ransom-by-big-pharma-overcharged-for-covid-vaccines> (accessed 07 September 2024).

<sup>109</sup> Dyer O 'COVID-19: Countries are learning what others paid for vaccines' (2021) 372 *BMJ* 1-2.

billion doses of the vaccine distributed worldwide.<sup>110</sup> There is no explanation for why the same vaccination, manufactured by the same pharmaceutical company, would be offered at three different prices depending on the buyer, and to make matters worse, these rates did not include the cost of importation. The fact that many African countries do not have the capacity be it financially or otherwise to manufacture their own drugs<sup>111</sup> exacerbates the dependency syndrome on developed countries who for seeing the desperation that African countries have justify the exorbitant prices they charge for drugs, which thus calls for a regional approach to capacitate African countries to manufacture their own drugs. As indicted earlier, Dos Santos, Ncube, and Ouma highlight that in October 2020, in reaction to the COVID-19 pandemic, South Africa and India petitioned the WTO to allow governments to waive IPRs in an effort to lower the cost of vaccines.<sup>112</sup> Oke<sup>113</sup> reports that WTO members at the 12<sup>th</sup> Ministerial conference agreed on a TRIPS waiver for COVID-19 vaccines which was a step in the right direction as the waiver allows for an eligible member (defined as all developing countries) to produce and supply COVID-19 vaccines without the consent of the patent holder.<sup>114</sup>

#### 4.4.2 Influence of patents on access to medicines

Access to medicines is crucial in the realisation of the right to health as espoused in section 27 (1) (a) of the Constitution<sup>115</sup> as well as other international instruments such as the Universal Declaration of Human Rights (UDHR) in Article 25,<sup>116</sup> Article 12 of the ICESCR,<sup>117</sup> and the

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<sup>110</sup> Louden EM ‘Scaling Up the Global COVID-19 Vaccination Program: Production, Allocation, and Distribution with an Emphasis on Equity’ (2022) 95 *Yale J Biol Med* 380.

<sup>111</sup> Oke E ‘The TRIPS COVID ‘Waiver’ Decision: Rhetorical Action or Realistic Solution?’ available at <https://emmanueloke.com/2022/06/18/the-trips-covid-waiver-decision-rhetoriac1-action-or-realistic-solution/> (accessed 28 September 2024).

<sup>112</sup> Dos Santos F, Ncube CB & Ouma M ‘Intellectual property framework responses to health emergencies – options for Africa’ (2022) *South African Journal of Science* 3.

<sup>113</sup> Oke E ‘The TRIPS COVID ‘Waiver’ Decision: Rhetorical Action or Realistic Solution?’ available at <https://emmanueloke.com/2022/06/18/the-trips-covid-waiver-decision-rhetoriac1-action-or-realistic-solution/> (accessed 28 September 2024).

<sup>114</sup> WTO ‘Draft Ministerial Decision on the TRIPS Agreement’ WT/MIN(22)/W/15/Rev.2.

See also John Hopkins Bloomberg School of Health ‘Why we’re still waiting for a pandemic treaty’ available at <https://publichealth.jhu.edu/2024/is-a-pandemic-treaty-still-possible> (accessed 12 October 2024), wherein the World Health Organisation proposal for a pandemic treaty to address pandemic prevention, preparedness and response which unfortunately has failed to be passed due to countries not coming to an agreement, however the negotiation process has been extended to 2025.

<sup>115</sup> Section 27 (1) (a) of the Constitution.

<sup>116</sup> Article 25 (1) of the (UDHR) 1948:

Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control.

<sup>117</sup> Article 12 of the (ICESCR) 1966:

African Charter on Human and Peoples' Rights.<sup>118</sup> Patents on their own are affecting access to medicines in that whoever has the monopoly over a patented medicine over the 20 years determines its supply quantity and price. In short they get to play "god" as pharmaceutical companies basically chose between who lives and who dies.<sup>119</sup> The UN report on Access to Medicines agrees that despite there being many technological advancements and innovation in the pharmaceutical industry, many have been left without access to such notable advances due to multiple barriers to access with the exercise of patents being one of them.<sup>120</sup> It is because of the existence of patents that many people in South Africa died because of HIV/AIDS as there was no access to the generic versions of the ARV owing to their absence on the market as alternative to the branded ARVs of GSK and BI.<sup>121</sup> The lack of access which is perpetuated by the exercise of patents goes against Sustainable Development Goal 3 (SDG 3) which seeks to promote the well-being of all people and ensure healthy lives.<sup>122</sup> Due to the inhibition of generic competition, the strict interpretation of patent regulations is going to prolong the periods of high prices for the novel medications required to treat these illnesses. This will put these drugs beyond reach for the government, reducing poor communities' access to them significantly.

In 2001, Oxfam reported that Ciprofloxacin, patented by Bayer in South Africa, an important anti-bacterial treatment for sexually transmitted diseases, childhood shigellosis (bloody diarrhoea), and chest infections costed R5.60/500mg tablet, which was twelve times the cost

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1. The States Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.
  2. The steps to be taken by the States Parties to the present Covenant to achieve the full realization of this right shall include those necessary for:
    - (a) The provision for the reduction of the stillbirth-rate and of infant mortality and for the healthy development of the child;
    - (b) The improvement of all aspects of environmental and industrial hygiene;
    - (c) The prevention, treatment and control of epidemic, endemic, occupational and other diseases;
    - (d) The creation of conditions which would assure to all medical service and medical attention in the event of sickness.

<sup>118</sup> Article 16 of the African Charter on Human and Peoples' Rights (Adopted 27 June 1981, OAU Doc. CAB/LEG/67/3 rev. 5, 21 I.L.M. 58 (1982), entered into force 21 October 1986):

1. Every individual shall have the right to enjoy the best attainable state of physical and mental health.
2. States parties to the present Charter shall take the necessary measures to protect the health of their people and to ensure that they receive medical attention when they are sick.

<sup>119</sup> Daily Maverick 'COVID-19 contracts reveal that Big Pharma 'bullied' SA while securing vaccines worth \$734m – NGO' available at <https://www.dailymaverick.co.za/article/2023-09-05-COVID-19-contracts-reveal-that-pharma-bullied-sa-while-securing-vaccines-worth-734m/> (accessed 2 September 2024).

<sup>120</sup> UN Secretary-General's High-Level Panel on Access to Medicines available at <https://static1.squarespace.com/static/562094dee4b0d00c1a3ef761/t/57d9c6ebf5e231b2f02cd3d4/1473890031320/UNSG+HLP+Report+FINAL+12+Sept+2016.pdf> (accessed 4 November 2024).

<sup>121</sup> *Hazel Tau & others v GlaxoSmithKline, Boehringer Ingelheim & others* Competition Commission Case Number: 2002Sep226.

<sup>122</sup> UN Secretary-General's High-Level Panel on Access to Medicines available at <https://static1.squarespace.com/static/562094dee4b0d00c1a3ef761/t/57d9c6ebf5e231b2f02cd3d4/1473890031320/UNSG+HLP+Report+FINAL+12+Sept+2016.pdf> (accessed 4 November 2024).

of the generic equivalent in India.<sup>123</sup> Pfizer patented fluconazole in South Africa at US \$9.34 a unit, but Thailand only charged US \$0.60 for the medication, which is essential in treating cryptococcal meningitis and oesophageal thrush.<sup>124</sup>

Access to medications has become more difficult due to the advent of strategic patenting, commonly known as “evergreening” as discussed above. Pharmaceutical corporations use strategic patenting, which involves submitting secondary patents when the primary patents are about to expire, as a means of preventing the arrival of generic medications.<sup>125</sup> The General Court of the EU upheld the decision of the Commission in *AstraZeneca v European Commission*<sup>126</sup> where AstraZeneca was fined €52.5 million after it was found that the company intended to file a “patent-cloud of mixtures, uses, formulations, new indications, and chemistry” in relation to its blockbuster drug omeprazole in order to delay the entry of generics at a predetermined time, which was close to the basic patent’s expiration.<sup>127</sup> Pharmaceutical corporations frequently submit numerous patent applications pertaining to a specific medication, with the goal of preventing the sale of identical generic versions as well as discouraging other businesses from attempting to develop a similar remedy.

This effectively goes against Section 2 of the Competition Act which aims at giving consumers a wide array of choice as the patents themselves and how they are being utilised by pharmaceutical companies through patent thickets or evergreening leaves consumers with one drug provider thus limiting access to essential medicines and also affecting their right to health. MSF reported that between 2015 and 2016, due to stock outs of the ARV medication many South Africans defaulted with some dying due to the limitations in access caused by brand-name drug manufacturers as about 20-25% of local clinics did not have access to the drugs juxtaposed to an estimate of about 160,000 people in South Africa who were taking LPV/r in November 2015.<sup>128</sup>

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<sup>123</sup> Oxfarm Briefing Paper ‘South Africa vs. the Drug Giants A Challenge to Affordable Medicines’ (2001) 3.

<sup>124</sup> Oxfarm Briefing Paper ‘South Africa vs. the Drug Giants A Challenge to Affordable Medicines’ (2001) 2.

<sup>125</sup> Gurgula, O. Strategic Patenting by Pharmaceutical Companies – Should Competition Law Intervene’ (2020) *IIC - International Review of Intellectual Property and Competition Law* 1067.

<sup>126</sup> T-321/05 *AstraZeneca v Commission* [2010] ECR II-2805.

<sup>127</sup> COMP/A. 37.507/F3 – *AstraZeneca* [2005], para. 274.

<sup>128</sup> Medecins Sans Frontieres (MSF) ‘HIV: Antiretroviral drugs fail to consistently reach patients in countries most affected by HIV/AIDS’ available at <https://www.msf.org/hiv-antiretroviral-drugs-fail-consistently-reach-patients-countries-most-affected-hivaids> (accessed 12 October 2024).

## 4.5 CONCLUSION

From the above analysis, it is clear that both IP and competition law are interdependent for the realisation of each area of law's goals. However, this intersectionality has put these two areas of law at loggerheads as one seeks to protect individual rights of the inventor, whilst the other is more concerned about creating a fair market space for everyone, which directly threatens the realisation of the monopoly rights vested on the patent holder. This chapter investigated the anti-competitive concerns that exist in the pharmaceutical industry as perpetuated by patents as a form of IP.

Dichotomised into exploitative and exclusionary conduct, Chapter 4 investigated anti-competitive conduct such as evergreening, refusal to access of an essential facility, unfair trading conditions, predatory pricing and reverse settlement agreements. The effect of such conduct was highlighted through examples from the COVID-19 pandemic where some scholars<sup>129</sup> stated that patent holders exercised some form of 'apartheid' as they determined who to supply, when, at what price and quantity without considerations as to the value of life. Private concerns triumphed over public health as some authors<sup>130</sup> contend that had it not been for the red tape surrounding access to vaccines and a lack of compromise on the part of patent holders through waivers or licensing, some deaths could have been avoided. Overall, if the lessons drawn from the COVID-19 pandemic are not learnt and the same patent regime with no compromise where pandemic arise is not met, the same problems regarding access and pricing of vaccines and other emergency medicines encountered during the HIV/AIDS pandemic, TB, Cancer and COVID-19 will continue to happen with the only difference being the number of deaths.

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<sup>129</sup> Prasad S, Shahid A, L Edzel, Khatri G, Cheema HA, Rocha ICN, Bardhan M & Hasan MM 'Vaccine apartheid: the separation of the world's poorest and most vulnerable and the birth of Omicron' (2022) *Ther Adv Vaccines Immunother* 1-5.

See also Brown S & Rosier M 'COVID-19 vaccine apartheid and the failure of global cooperation' (2023) 3 *Br J Polit Int Relat* 535-554.

<sup>130</sup> Dos Santos F, Ncube CB & Ouma M 'Intellectual property framework responses to health emergencies – options for Africa' (2022) *South African Journal of Science* 3.

See also Katarina Foss-Solbrekk K, 'The IP waiver and COVID-19: reasons for unwavering support' (2021) *Journal of Intellectual Property Law & Practice* 1349.

## CHAPTER 5

### CONCLUSION AND RECOMMENDATIONS

#### 5.1 INTRODUCTION

The main crux of this mini-dissertation was to determine the interplay between IP law (patent) and competition law in tackling the major problem of pricing and distribution of medicines in future pandemics based on the lessons drawn from the COVID-19 pandemic in South Africa.<sup>1</sup> The dissertation went on to highlight the nature of IP rights that exist in the pharmaceutical industry,<sup>2</sup> in particular patents, as they directly correlate to the problem of pricing and access to vaccines. The mini-dissertation also went on to highlight ways in which the problem of pricing and access to medicines has been tackled over the years, in particular during the COVID-19 pandemic.<sup>3</sup> The present chapter summarises the key findings of this study and further proposes some recommendations in relation to how to make medicines accessible and affordable in future pandemics whilst ensuring that the patent holder is incentivised and that fair competition exists.

The chapter is divided into two sections. The first section summarises the findings of the study. The findings mainly relate to results for the four research objectives defined for the study in chapter one. These objectives are reiterated as follows: -

- a) examine the competition concerns in the pharmaceutical industry.
- b) analyse the effectiveness of competition law as a tool to curb abuse of patent rights resulting in excessive pricing of medicines in the pharmaceutical industry.
- c) investigate the role of competition law and competition authorities in tackling anti-competitive behaviours relating to pricing and distribution of medicines during pandemics.
- d) recommend possible strategies that competition law enforcers can adopt to curb anti-competitive behaviours arising from the abuse of patent rights in the pharmaceutical industry in future pandemics.<sup>4</sup>

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<sup>1</sup> See 1.1 of Chapter 1.

<sup>2</sup> See 2.3 of Chapter 2.

<sup>3</sup> See 1.8 of Chapter 1.

<sup>4</sup> See 1.6 of Chapter 1.

The second part provides the study's recommendations. The suggested recommendations are meant to offer a balance between patent law and competition law which in turn will ensure that public health concerns are met adequately. Recommendations provided in this chapter are meant to be a guide to mainly African states to ensure that the effects of the vaccine 'apartheid' felt during the COVID-19 pandemic are minimized or better yet, eradicated.

## 5.2 SUMMARY OF FINDINGS

**Chapter 1** comprised of the introduction and background to the study, which illuminated the intersectionality between IP law in particular patents and competition law.<sup>5</sup> Both areas of law as discussed in chapter 1 work hand in glove, with one area dependent on the other for the realization of respective goals.<sup>6</sup> The main aim of the mini-dissertation, which was to examine the effectiveness of competition law as a regulatory tool to address anti-competitive behaviours in the pharmaceutical industry in order to promote access to medicines in future pandemics in South Africa<sup>7</sup> was also discussed in chapter 1 alongside the research questions,<sup>8</sup> objectives<sup>9</sup> and problem statement.<sup>10</sup>

**Chapter 2** incorporated an inquiry into the nature of IPRs that exist in the pharmaceutical industry, that is, copyright, trademarks and patents.<sup>11</sup> A particular focus was given to patents as they are the main IPR of focus to this mini-dissertation where pricing and accessibility of medicines is concerned. The requirements of registration for a patent in South Africa was discussed and this includes sections on novelty, utility and inventiveness as requirements for registration of patent in terms of section 25 of the Patent Act.<sup>12</sup> Gaps in the patent regime were also highlighted wherein the form of patent examination in South Africa was stated to be an anathema to patent regulation and enforcement. South Africa follows a formal/depository patent system where, as long as the formalities prescribed in Regulation 22 of the Patents Regulations are complied with, then the patent is registered.<sup>13</sup> Ways to deal with the lacunae made by a lack of a substantive search and examination system were proffered in paragraph

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<sup>5</sup> See 1.1 of Chapter 1.

<sup>6</sup> See 1.3 of Chapter 1.

<sup>7</sup> See 1.6 of Chapter 1.

<sup>8</sup> See 1.5 of Chapter 1.

<sup>9</sup> See 1.6 of Chapter 1.

<sup>10</sup> See 1.4 of Chapter 1.

<sup>11</sup> See 2.3 of Chapter 2.

<sup>12</sup> See 2.4.1 of Chapter 2.

<sup>13</sup> See 2.5 of Chapter 2.

2.7 above and these included the introduction of a substantive search and examination system of patents by the CIPC as well as third-party pre-grant opposition system.

**Chapter 3** dealt with the concept of abuse of dominance under the Competition Act. As provided for in section 7 of the Competition Act, which lays down the statutory test for dominance, a firm is regarded as dominant if it has at least 45% of that market; it has at least 35%, but less than 45%, of that market, unless it can show that it does not have market power; or it has less than 35% of that market, but has market power.<sup>14</sup> It should be noted that, there is nothing wrong with a firm being dominant, a firm's capability to stand out should be rewarded. However, it is the abuse of that dominance to the detriment of other competitors and consumers that the Competition Act seeks to prevent. In order to fully assess where the negative effects of the abuse of dominance are felt, it is necessary to identify the relevant market. Chapter 3 does that by categorising the market under competition law as the geographic area involved, which is defined to include all reasonably substitutable products or services, and all nearby competitors, to which consumers could turn in the near term if the restraint or abuse raised prices by a not insignificant amount as well as the product market which refers to all goods and/or services that consumers believe can be swapped or interchanged based on the characteristics, costs, and intended uses of the goods.<sup>15</sup>

To assess whether a firm is indeed dominant, indicators of dominance such as market share, market power, and superior technology are crucial as these will provide the basis for competition authorities to determine as to whether the firm in question is indeed dominant.<sup>16</sup> The significance of this chapter is that it lays the background to chapter 4 by linking chapter 2 in that patents as a form of IP can be a tool in which dominance is achieved and eventually abused to the detriment of fair competition practices.

**Chapter 4** of this mini-dissertation examined anti-competitive exercise of patents arising in the pharmaceutical industry. It was therein shown that competition concerns in the pharmaceutical industry are dichotomised into two broader categories, that exploitative conduct which simply relates to any conduct done by firms that has direct impact on customers or consumers who depend on the firm's products and or services<sup>17</sup> as well as exclusionary conduct which relates to conduct done by firms with reasonable market share or power to

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<sup>14</sup> See 3.3 of Chapter 3.

<sup>15</sup> See 3.4 of Chapter 3

<sup>16</sup> See 3.5 of Chapter 3.

<sup>17</sup> See 4.3.3 of Chapter 4.

exclude other competitors from participating in the markets.<sup>18</sup> For the purpose of this mini-dissertation, both exclusionary and exploitative conduct were dealt with within the lens of the pharmaceutical industry and anti-competitive conduct discussed include patent evergreening,<sup>19</sup> reverse settlement agreements,<sup>20</sup> refusal to access essential facilities,<sup>21</sup> excessive pricing<sup>22</sup> and unfair trading conditions.

Much of chapter 4 provided examples of the health scares that were greatly affected by anti-competitive conduct done in pharmaceutical industry as a result of the exploitation of patents. These included the HIV/AIDS pandemic where evergreening and drug stock-outs were rampant,<sup>23</sup> COVID-19 pandemic where vaccine-producing companies priced their vaccines exorbitantly out of reach of many developing countries and also limited supply based on the country,<sup>24</sup> and the excessive pricing of the breast cancer treatment drug trastuzumab by Roche,<sup>25</sup> just to mention but a few. A growing concern was highlighted in chapter 4 that, if lessons on balancing patent and competition laws are not learned from the COVID-19 pandemic, abuse of patents will result in the exclusion of other competitors from participating in the manufacturing of medicines. Ultimately consumer harm will be imminent not only from an economic point of view where predatory pricing will occur but also from a public health perspective where lives will actually be lost for the sake of profit.

### 5.3 RECOMMENDATIONS

Given the above findings, the study makes the following recommendations in order to ensure that anti-competitive conduct pertinent in the pharmaceutical industry driven by patents is minimised. This will lead to more developed and thriving pharmaceutical companies that are not dominated by a handful of companies to the exclusion of other players. A fair market will ensure that competition goals such as consumer welfare and promoting the participation of smaller firms is realised. In the same vein, a realisation of competition goals in the pharmaceutical industry will not only incentivise and promote innovation, a direct goal of IPRs,

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<sup>18</sup> See 4.3.1 of Chapter 4.

<sup>19</sup> See 4.3.2.1 of Chapter 4.

<sup>20</sup> See 4.3.2.2 of Chapter 4.

<sup>21</sup> See 4.3.2.3 of Chapter 4

<sup>22</sup> See 4.4.1 of Chapter 4.

<sup>23</sup> See 4.3.2.1 of Chapter 4.

<sup>24</sup> See 4.4.1 of Chapter 4.

<sup>25</sup> See 4.4.1 of Chapter 4.

but also have a spillover effect to ensure that public health concerns pertaining to the access and affordability of medicines are met.

### **5.3.1 Employing the ‘effects doctrine’ to bring international pharmaceutical companies to book**

In line with the principle of territoriality discussed in chapter 2<sup>26</sup> patents enjoy their monopoly and protection within the extent defined by the national IP laws under which they are registered. However, the enjoyment of the benefits attached to the patents can be enjoyed where the product in question reaches territories outside the area where the patent was registered. This now gives rise to anti-competitive effects being felt in jurisdictions other than the one where the patent is registered. In as much as the pharmaceutical companies responsible for the anti-competitive conduct are not within the jurisdiction of South Africa, the Competition Act in section 3(1) provides specifically for the application of South African competition law “to all economic activity within, or having an effect within, the Republic.”<sup>27</sup> This provision can simply be equated to the principle of extra-territorial application which refers to the jurisdiction of a state to apply its competition laws to foreign entities if their conduct affects its economic activity.

The pith of section 3 of the Competition Act is based on what is commonly known as the ‘effects test’ which empowers regulators to extend jurisdiction beyond the ‘principle of territoriality.’ The section lays down two instances where jurisdiction can be exercised. The first one is territorial application supported by the wording “all economic activity within the Republic.”<sup>28</sup> The second one is the extra-territorial application commonly referred to as the effects doctrine which empowers a country to extend the reach of competition laws to activity and parties located anywhere so long as there is some effect within that country.<sup>29</sup>

In *ANSAC*, the CAC reiterated that the question to be answered is whether the conduct complained of has direct and foreseeable substantial consequences within the regulating country as the inquiry was not based on positive or negative effects on competition in the regulating country but merely whether there are sufficient jurisdictional links between the

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<sup>26</sup> See 2.2 of Chapter 2.

<sup>27</sup> Section 3(1) of the Competition Act.

<sup>28</sup> Section 3(1) of the Competition Act.

<sup>29</sup> Section 3(1) of the Competition Act.

conduct and the consequences. This position was reaffirmed by the SCA where it was held that the Competition Act allows for extraterritorial application.<sup>30</sup>

It is undeniable that the conduct of pharmaceutical companies based outside the jurisdiction of South Africa, has direct and foreseeable consequences in South Africa as seen through the HIV/AIDS pandemic as well as COVID-19 in that competition goals were unfortunately contravened to the detriment of consumers and local players. Thus, bringing these international companies to book and fining them can act as a deterrent for future abuses.

### **5.3.2 Examining the possibility of a Competition Commission Market Inquiry for the Pharmaceutical Industry**

Enforcement under the Competition Act is at most restricted to the Competition Commission, Competition Tribunal and Competition Appeal Court. The Competition Commission is established under section 19 of the Act and plays an investigatory role as stated in *Norvatis SA (Pty) Ltd v The Competition Commission*.<sup>31</sup> In *Sappi Fine Paper (Pty) Ltd v Competition Commissioner*, the CAC found that the Commission is empowered to investigate a complaint alleging contraventions of specific provisions of the Act.<sup>32</sup>

As discussed in chapter 4, the abuse of patents by pharmaceutical companies has brought forth contraventions of the Competition Act both from an exclusionary and exploitative point of view.<sup>33</sup> However, the Commission has not taken a proactive role in investigating these offences and much of the literature being used has gaps or is from sources outside of South Africa speaking about the South African experience of the COVID-19 pandemic from an external point of view. It will thus be desirable for the Commission to have an inquiry into the anti-competitive conduct in the pharmaceutical industry. As seen from the *Glaxo Wellcome* case,<sup>34</sup> Roche breast cancer treatment case,<sup>35</sup> the Competition Commission is often called to action and with the high number of litigation cases involving pharmaceutical companies, intervention of the Commission will be welcome. The information acquired from such proceedings as well as the resources available to the Commission will allow the general public to have a holistic

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<sup>30</sup> *American Natural Soda Ash Corporation v Competition Commission of South Africa* (554/2003) [2005] ZASCA 42; [2005] 1 CPLR 1 (SCA); [2005] 3 All SA 1 (SCA) (13 May 2005).

<sup>31</sup> *Norvatis SA (Pty) Ltd v The Competition Commission* (22/CRB/Jun01).

<sup>32</sup> *Sappi Fine Papers and Competition Commission* (62/CR/Nov01) [2002] ZACT 26 (17 April 2002).

<sup>33</sup> See 4.3.1; 4.3.3 of Chapter 4.

<sup>34</sup> See 2.6.2 of Chapter 2.

<sup>35</sup> See 4.4.1 of Chapter 4.

view of the effects of the abuse of patents by pharmaceutical companies which is evidence based and from a trusted source.

The Competition Commission had made reports such as Online Intermediation Platforms,<sup>36</sup> where investigations on the anti-competitive conduct in digital platforms such as Takealot, Property 24 were done, essential food price report,<sup>37</sup> as well as the health market inquiry.<sup>38</sup> This proves that the Commission has the capacity to have an inquiry into the pharmaceutical industry with a specific focus on patents and their impact on drug pricing, as it has done so for other sectors.

### **5.3.3 Utilising the African Continental Free Trade Agreement (AfCFTA)**

The COVID-19 pandemic highlighted that any contentions about patent disputes or trade were dealt with on a continental level through the WTO. Unfortunately, because of the power dynamics, developed countries wield a lot of influence in the decision-making process in the WTO. The patent holders for the different vaccines are from developed countries. This simply means that the scales are unevenly tipped, with the biggest losers in this equation being developing countries as seen during the WTO IP waiver negotiations which were greatly opposed by developed countries such as the EU distanced itself from the text.<sup>39</sup> For waivers to successfully apply, they must be agreed to by all WTO member states which makes it a problem as many were opposed including the COVID-19 waiver application made by South Africa and India only. A continental approach will thus be desirable where instead of one country applying for a waiver, a joint effort through the AfCFTA which aims to promote development of medicines and vaccines on the African continent.<sup>40</sup> In particular, Articles 4(3) and (4) of the AfCFTA are relevant to this mini-dissertation in that, as long as the biggest losers in terms of pharmaceutical companies are concerned, (in this case African countries as seen in Cameroon,

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<sup>36</sup> See Competition Commission South Africa, 'Competition in the digital economy Version 2' available at <http://www.compcom.co.za/wp-content/uploads/2021/03/Digital-Markets-Paper-2021-002-1.pdf> (accessed 16 June 2024) and Competition Commission South Africa, 'Online Intermediation Platforms Market Inquiry Provisional Report' available at <https://www.compcom.co.za/wp-content/uploads/2022/07/OIPMI-Provisional-Summary-Report.pdf> (accessed 16 June 2024).

<sup>37</sup> Competition Commission South Africa 'Essential Food Price Monitoring Report' available at [EFPM-Report\\_Sept-2024.pdf \(compcom.co.za\)](https://www.compcom.co.za/wp-content/uploads/2022/07/OIPMI-Provisional-Summary-Report.pdf) (accessed 21 October 2024).

<sup>38</sup> Competition Commission South Africa 'Health Market Inquiry' available at [Final-Findings-and-recommendations-report-Health-Market-Inquiry.pdf \(compcom.co.za\)](https://www.compcom.co.za/wp-content/uploads/2022/07/OIPMI-Provisional-Summary-Report.pdf) (accessed 21 October 2024).

<sup>39</sup> See 1.5 of Chapter 1.

<sup>40</sup> African Union, Article 3 of the Agreement Establishing the African Continental Free Trade Area (2018).

Burundi and Namibia having fewer than 50 doses per 100 people),<sup>41</sup> do not cooperate and have a united front at the WTO, any talk of a waiver will face great resistance.

### 5.3.4 Recommendations on Possible Reforms on Patent Law

#### 5.3.4.1 Introduction of Substantive Search and Examination

As alluded to in Chapter 2, section 34 of the Patents Act<sup>42</sup> read together with Regulations 40 and 41 of the Patent Regulations,<sup>43</sup> authorises the CIPC to only do a formal examination of the patent to be registered and not deal with the merits of the application in question. The problem with this stance is that, there is no certainty whether the invention in question is indeed novel, involves an inventive step and also can be utilised in industry or trade. This defeats the whole purpose of the *quid pro quo* principle as the CIPC is simply granting monopoly rights to inventions which might not fall under the scope of protection envisaged by the Patents Act. The implications in the health sector are quite disastrous as the Treatment Action Campaign (TAC) reports that the lack of patent searches allows for major pharmaceutical companies to file several patent applications for the same drug; that can include the process, the dosage, the combination or even the raw materials used.<sup>44</sup> This conduct was seen in *Bayer v Dr Reddy's Laboratories*<sup>45</sup> wherein Bayer included dosage as part of features of its patent claim. A substantive search policy will ensure that only patents which comply with section 25 are registered thus curbing the registration of patents on a charity basis weeding out patents on new use and new formulations of existing drugs.

#### 5.3.4.2 Third-party Opposition

Section 30 of the Patents Act read together with Regulation 44 of the Patents Regulation,<sup>46</sup> allow the Registrar to immediately accept a patent once it complies with the prescribed

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<sup>41</sup> See 1.4 of Chapter 1.

<sup>42</sup> Section 34 of the Patents Act:

The registrar shall examine in the prescribed manner every application for a patent and every specification accompanying such application or lodged at the patent office in pursuance of such application and if it complies with the requirements of this Act, he shall accept it.

<sup>43</sup> Regulations 40 and 41 of the Patents Regulations:

40. Examination Any application accompanied by a provisional specification shall be examined to ensure that the documents lodged are legible and capable of reproduction.

41. The registrar shall examine the application accompanied by a complete specification in order to ensure that it complies with the prescribed formalities.

<sup>44</sup> TAC, MSF & RIS Policy Brief 'Why South Africa Should Examine Pharmaceutical Patents: How legislative reform could boost the affordability and accessibility of medicines for South Africans' (2013) 3.

<sup>45</sup> *Bayer Intellectual Property GMBH and Others v Dr Reddy's Laboratories (Pty) Ltd* para 19.

<sup>46</sup> Regulation 44 of the Patents Regulations:

As soon as the registrar is satisfied that an application accompanied by a complete specification complies with the requirements of the Act, and unless there has been a request to delay acceptance, he may accept the application and give written notice thereof which shall be accompanied by form P 8.

formalities. The problem with this approach is that already, the CIPC is strained when it comes to technical skills and resources<sup>47</sup> meaning that the capacity to fully understand the repercussions of a patent on public health might not be there. To address this problem, allowing for third-party pre-grant oppositions wherein interested parties be it doctors, academics or non-governmental organisations to share their input before a patent is accepted might help reduce filling of patents which may affect access to medicines.<sup>48</sup> This will be beneficial in that; it will reduce costs associated with patent revocation as in most cases it is only during litigation that a substantive search of the patent is done and it will provide certainty as to the validity of the patent.<sup>49</sup>

#### 5.3.4.3 Compulsory Licensing

Compulsory licensing refers to the act of using a patent without the owner's consent. In particular, when a government grants a compulsory license for a pharmaceutical treatment, it permits the importation or local production of generic versions of medicines without the patent holder's permission.<sup>50</sup> According to Section 55 of the Patents Act<sup>51</sup> compulsory licensing may be used when the patent holder does not agree to voluntarily license his patent to the dependent patent holder, in which case the CIPC Commissioner may be asked to grant a license. The TRIPS, in particular, the Doha Declaration on the TRIPS Agreement and Public Health,<sup>52</sup> provides for mechanisms to counter abuses of patents by including a provision on compulsory licensing as part of its checks and balances. Article 31 of the TRIPS Agreement provides a long list of conditions that the use of compulsory licenses at national level must comply with, including that "the right holder shall be paid adequate remuneration in the circumstances of

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<sup>47</sup> Ndlovu L 'Why South Africa should introduce patent searched and examinations to improve access to essential medicines' available at [https://www.wto.org/english/tratop\\_e/trips\\_e/colloquium\\_papers\\_e/2015/chapter\\_9\\_2015\\_e.pdf](https://www.wto.org/english/tratop_e/trips_e/colloquium_papers_e/2015/chapter_9_2015_e.pdf) (accessed 12 October 2024).

<sup>48</sup> Pre-grant opposition is discussed in-depth in Oriakhogba DO & Fenemigho AI 'Making the Nigerian patent system more efficient through pre-grant opposition mechanisms: Lessons from India and Botswana' (2016) 4 *South African Intellectual Property Law Journal*.

<sup>49</sup> Department of Trade and Industry Intellectual Property Policy of The Republic of South Africa Phase I 2018 (2018) 19.

<sup>50</sup> Wong H 'The case for compulsory licensing during COVID-19' (2020) 10 *J Glob Health* 2.

<sup>51</sup> Section 55 of the Patents Act:

Where the working of a patent (hereinafter referred to as a dependent patent) without infringement of a prior patent is dependent upon the obtaining of a licence under that prior patent, the proprietor of the dependent patent may, if agreement cannot be reached as to such licence with the proprietor of the prior patent, apply to the commissioner for a licence under the prior patent, and the commissioner may grant such a licence on such conditions as he may impose, but including a condition that such licence shall be used only for the purpose of permitting the dependent patent to be worked and for no other purpose.

<sup>52</sup> WTO Ministerial Conference, Fourth Session, Doha, 9 - 14 Nov. 2001, WT/MIN(01)/DEC/2, 20 Nov. 2001 (hereinafter referred to as the Doha Declaration).

each case, taking into account the economic value of the authorisation.”<sup>53</sup> This flexibility allows members of the WTO to manufacture medicines without facing the red tape around patent enforcement and voluntary licensing in a manner supportive of public health and access to medicines for all. In particular, paragraph 5 (b) of the Doha Declaration reaffirms the position in Article 31 of the TRIPS by essentially permitting member states to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted in order to protect public health and access to medicines for all.<sup>54</sup>

Essentially, compulsory licensing permits the manufacture of generic medications for public health purposes when the government steps in and requires a patent holder to cede their patent rights to the government or a licensee in exchange for a predetermined amount of money.<sup>55</sup> Compulsory licensing has been adopted by several countries to address public health concerns as seen in the case of Zimbabwe where in 2002, the government authorised Varichem Pharmaceuticals (Pvt) Ltd, a third party, to use the patented inventions and manufacture a generic version of ARVs following the HIV/AIDS pandemic.<sup>56</sup> The result was that instead of ARV dependent individual paying between US \$197.00- US \$237.00 for the brand-name ARV, they only got to pay US \$15.00 for Combivir the generic version that was being manufactured by Varichem Pharmaceuticals (Pvt) Ltd.<sup>57</sup> During the COVID-19 pandemic, countries such as Canada, Chile, and Ecuador spearheaded the need for compulsory licensing to manufacture vaccines. Canada amended their Patent Act<sup>58</sup> to allow for government to issue licenses and negotiate remuneration later which made the process for obtaining a license more expedient.<sup>59</sup> However, it should be noted that, compulsory licensing stands against everything that the monopoly granted by patents seeks to uphold.<sup>60</sup> The *quid pro quo* principle is unfortunately trampled upon as the incentive for the inventor to innovate as well as recuperate any R&D cost is usurped. In the case of Canada where they adopted a ‘license now, pay later’ regime, any

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<sup>53</sup> Article 31(h) of the TRIPS.

<sup>54</sup> Paragraph 5(b) of the Doha Declaration.

<sup>55</sup> Singham S, ‘Competition Policy and the Stimulation of Innovation: TRIPS and the Interface between Competition and Patent Protection in the Pharmaceutical Industry’ (2000) *Brooklyn Journal of International Law* 390.

<sup>56</sup> Lalitha N ‘Doha Declaration and Compulsory License for Access to Medicines’ Working Papers (2009) 9.

<sup>57</sup> Beall R & Kuhn R ‘Trends in compulsory licensing of pharmaceuticals since the Doha Declaration: a database analysis’ (2012) 9 *PLoS medicine* 3.

<sup>58</sup> COVID-19 Emergency Response Act, S.C. 2020, C-13 (Canada).

<sup>59</sup> Wong H ‘The case for compulsory licensing during COVID-19’ (2020) 10 *J Glob Health* 4.

<sup>60</sup> Sapna K, ‘Compulsory Licensing of Patents During Pandemics’ (2022) *Conn. L. Rev* 65.

room to negotiate the licensing fee as provided for in Article 31 (h) of the TRIPS is taken away from the inventor.<sup>61</sup>

## 5.4 FINAL WORD

In the final analysis, it is clear that pandemics are continuously going to be an ever-existing threat to humankind. The need to manufacture vaccines and procure them will always be there. However, if problems that existed in previous pandemics, that is the exploitative and exclusionary conduct perpetuated by the abuse of patents is not addressed, this problem will remain extant. Competition law should thus be utilised to curb the pricing and accessibility of medicines associated with the pandemic. As seen from the above, the “effects doctrine” can be applied, which gives competition authorities the power to investigate and fine firms outside South Africa but with conduct felt within the South African borders. An investigation into excessive pricing, and abuse of dominance should also be done. Lastly, an inquiry into the pharmaceutical industry will be of great help not only to academics but to the general public by providing evidence-based information on the South African experience of the abuse of patents by pharmaceutical companies.

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<sup>61</sup> Article 31(h) of the TRIPS Agreement:

Where the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization.

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