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"Restricting pharmaceutical patent rights to realise the right of access to healthcare under the Constitution"

by

KAMEEL PANCHAM

(Student number: 28173202)

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Prepared under supervision of Honorary Professor Chris Job of the University of Pretoria

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Chapter 1

The interaction or potential interrelationship between the Constitutional right to health and pharmaceutical patent rights

The Constitution of the Republic of South Africa[1] ("the Constitution") contains fundamental rights in Chapter 2 – the Bill of Rights. These rights are said to be the cornerstone of democracy in South Africa. They affirm the values of human dignity, equality and freedom.[2] The State is obliged to protect, promote and fulfill the rights contained in the Bill of Rights.[3] Further, the Bill of Rights is binding on all Organs of State and all natural and juristic persons within the Republic.[4]

Among these fundamental rights in Chapter 2 of the Constitution is section 27 - the right to healthcare, food, water and social security. It reads as follows:

> "*27. (1) Everyone has the right to have access to—*
>
> *(a) health care services, including reproductive health care;*
>
> *(b) sufficient food and water; and (c) social security, including, if they are unable to support themselves and their dependents, appropriate social assistance.*
>
> *(2) The state must take reasonable legislative and other measures, within its available resources, to achieve the progressive realisation of each of these rights.*
>
> *(3) No one may be refused emergency medical treatment.*"

From the above, it is easily established that the right to healthcare is a fundamental right and that the State is obliged to protect, promote and fulfill this right, as per the Bill of Rights. However, there are many external influences that deter the fulfillment of this right such as the inherent affordability of medication. The affordability of medication is itself

[1] Act 108 of 1996.
[2] Section 7(1) of the Constitution.
[3] Section 7(2) of the Constitution.
[4] Section 8(1) and 8(2) of the Constitution.

influenced by a number of factors including, but not limited to, abuse of patent regulation. The World Health Organization ("WHO") sums it up eloquently:

> "*The pharmaceutical industry underscores the importance of effective patent protection as an incentive for continued investment in the discovery and development of medicines. While it is not denied that the patent system provides incentives for pharmaceutical innovation, the market exclusivity conferred by patents leads to company profits that often outstrip the associated research, development and production costs altogether. The patent system has also not provided sufficient incentive for research and development of new medicines needed for diseases that afflict public health, including neglected diseases and orphan drugs, because forecasts deem the market too small or commercially unattractive.*"[5]

On the other side of the coin lie intellectual property rights ("IPRs"), these rights are in juxtaposition to the public interest-based rights, such as the right to healthcare. IPRs protect the private interests of the inventors of certain intellectual creations, such as medication. IPRs grant the holder the ability to prevent or exclude others from reproducing the protected creation for a limited period of time, the idea being that the monopoly the right holder obtains through the IPR would incentivize others to innovate and do the same.[6] In contrast, the fundamental rights contribute to the public interest. Exercising a private right may impact on the exercise of a fundamental right and vice versa.

IPRs are touted to be fundamental human rights in the Universal Declaration of Human Rights ("UDHR") and the International Covenant on Economic, Cultural and Social Rights ("CESCR").

Article 27(2) of the UDHR provides for:

> "*the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author*".

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[5] *Access to Medicines – Intellectual property protection: impact on public health* WHO Drug Information Vol. 19, No. 3, 2005 at page 237 https://www.who.int/medicines/areas/policy/AccesstoMedicinesIPP.pdf accessed on 10 October 2019.
[6] Klopper H *et al* (2011) *Law of Intellectual Property in South Africa* at page 433.

Article 15(1) of the CESCR, reads more or less verbatim and provides for:

> "*benefit from protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author.*"

Locally, IPRs are not specifically mentioned within the Constitution. IPRs are instead regulated through statutory enactments (the Patents Act[7], the Trademarks Act[8], the Designs Act[9] and the Copyright Act[10]) and common-law provisions. There are different types of IPRs such as patents, trademarks and copyright (for the purpose of this paper I shall focus on patents).

The Constitution, however, does recognize a property right in section 25. Section 25(1) reads as follows:

> "*25(1) No one may be deprived of property except in terms of law of general application, and no law may permit arbitrary deprivation of property.*"

It was initially the stance of the judiciary that section 25 did not extend to IPRs. The status of IPRs at that stage was debated by the Constitutional Court ("CC") in *Ex Parte Chairperson of the Constitutional Assembly: In re certification of the Constitution of the Republic of South Africa, 1996*[11] wherein the CC held:

> "*Although it is true that many international conventions recognise a right to intellectual property, it is much more rarely recognised in regional conventions protecting human rights and in the constitutions of acknowledged democracies. It is also true that some of the more recent constitutions, particularly in Eastern Europe, do contain express provisions protecting intellectual property, but this is probably due to the particular history of those countries and cannot be*

[7] Act 57 of 1978.
[8] Act 194 of 1993.
[9] Act 195 of 1993.
[10] Act 98 of 1978.
[11] *Ex Parte Chairperson of the Constitutional Assembly: In re certification of the Constitution of the Republic of South Africa* 1996 (4) SA 744.

characterised as a trend which is universally accepted. In the circumstances, the objection cannot be sustained."[12]

The CC was then of the view that IPRs were not fundamental rights even if they find such status in international instruments such as the UDHR and the CESCR and declined to impose a fundamental status on IPRs by finding them in the Bill of Rights in the Constitution.

However, that stance has changed considerably following the CC case of *Laugh It Off Promotions CC v South African Breweries International (Finance) BV t/a Sabmark International and Another*[13]. The court found that IPRs and the right to freedom of expression under section 16(1) of the Constitution enjoyed equal status. Crucially the CC did not challenge or comment on the following dictum of the Supreme Court of Appeal ("SCA"):

"*trademarks are property, albeit intangible or incorporeal. The fact that property is intangible does not make it of a lower order. Our law has always recognised incorporeals as a class of things in spite of theoretical objections thereto...*"[14]

It must be taken that in not challenging this dictum, the CC has extended judicial recognition of trademarks and other IPRs, to be considered as property under section 25 of the Constitution.

This approach was confirmed later by the SCA in the case of *Gallo Africa Ltd and Others v Sting Music (Pty) Ltd and Others*[15] wherein the court similarly found that IPRs are immovable property:

"[19] This leads ineluctably to the conclusion that IPRs, including copyright, are immovable intangibles and that, according to the principle accepted in Eilon, local courts do not have jurisdiction in respect of foreign copyright issues. In addition,

[12] *Ex Parte Chairperson of the Constitutional Assembly* (n11 above) at paragraph [75].
[13] *Laugh It Off Promotions CC v South African Breweries International (Finance) BV t/a Sabmark International and Another* (CCT42/04) [2005] ZACC 7; 2006 (1) SA 144 (CC); 2005 (8) BCLR 743 (CC).
[14] *Laugh it Off Promotions CC* (n13 above) at paragraphs [10] and [11].
[15] *Gallo Africa Ltd and Others v Sting Music (Pty) Ltd and Others* (40/2010) [2010] ZASCA 96; 2010 (6) SA 329 (SCA); [2011] 1 All SA 449 (SCA).

the fact that a work was created in this country is beside the point for present purposes."[16]

We know now that the right to health is a fundamental right under section 27 and that IPRs have the same status as they are section 25 rights. The United Nations ("UN") was of the view that the exercise of IPRs, and in particular patent rights, may affect the right to health through the limitations they impose on the ability of the State to provide affordable medication and promote medical research.[17]

It is clear that in order for our State to achieve its goal enshrined in section 27 of the Constitution it needs to achieve a balance between the exercise of section 25 IPR rights and section 27 health rights. It must be borne in mind that any limitation of either section 25 or section 27 rights must be in accordance with limitation clause of the Constitution as found in section 36.[18]

This paper seeks to achieve this balance by using the legislative mechanisms contained in the Patents Act and the Competition Act. This leads us to the research question below.

Research Question

Are the restrictive legislative mechanisms of the Patents Act and the Competition Act sufficient to enable the State to fairly regulate the exercise of pharmaceutical patent rights in trying to realise the right to healthcare under section 27 of the Constitution, without undermining such patent rights?

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[16] *Gallo Africa* (n15 above) at paragraph [19].

[17] "*The Impact of the Agreement on Trade-related Aspects of Intellectual Property Rights on Human Rights*" UN Commissioner for Human Rights, Sub-Commission on Human Rights Resolution 2000/7; the Report of the High Commissioner.

[18] "*36. (1) The rights in the Bill of Rights may be limited only in terms of law of general application to the extent that the limitation is reasonable and justifiable in an open and democratic society based on human dignity, equality and freedom, taking into account all relevant factors, including -*

(a) the nature of the right;
(b) the importance of the purpose of the limitation;
(c) the nature and extent of the limitation;
(d) the relation between the limitation and its purpose; and
(e) less restrictive means to achieve the purpose •.

(2) Except as provided in subsection (1) or in any other provision of the Constitution, no law may limit any right entrenched in the Bill of Rights."

Chapter 2

Abuse provisions of the Patents Act

The Patents Act contains provisions aimed at restricting the abuse of monopoly patent rights in section 56. The abuses are addressed by the granting of compulsory licences to a third party who is not the patent holder. These legislative mechanisms may be of assistance to the State, in fairly restricting monopoly patent rights in order to realise the right to health in the Constitution.

Compulsory licences are most commonly granted where the patentee is found to have abused its monopoly right in a certain manner. However, in South Africa, no compulsory licences have been granted with regard to pharmaceutical related patents.[19] This may have had a detrimental effect on the prices of pharmaceuticals in South Africa.

Section 56 of the Patents Act contains four scenarios depicting the circumstances in which a compulsory licence would be granted to remedy a patent related abuse. However, one must be an 'interested person' to utilize the mechanisms of this section.

In order to invoke the provision of section 56, one must show that they are an 'interested person' as prescribed by the Patent Act. The court in *F Hoffman-La Roche & Co AG's Patent*[20] indicated that an 'interested person' would be one that could show a genuine future intention to establish an interest in the field in which the licence is sought.

Consider the following scenario; the Republic is in the midst of a health crisis, the State owns company X that could manufacture cheaper essential medication locally rather than importing it from the patent holder, company Z. The State could then show that company X has a genuine future intention to establish an interest in the field that company Z operates in. A compulsory licence could be granted to company X in such circumstances. In this instance it cannot be said that the State cannot be an 'interested person' in terms

[19] CM Correa "*Pharmaceutical innovation, incremental patenting and compulsory licensing*" South Centre Research Paper 41 (September 2011), p. 17. Available from http://citeseerx.ist.psu.edu/viewdoc/download;jsessionid=7F43CAC7AF4FFD19FE2197CA78343A43?doi=10. 1.1.357.5792&rep=rep1&type=pdf accessed 10 October 2019.
[20] *F Hoffman-La Roche & Co AG's Patent* 1971 RPC 311.

of section 56 of the Patents Act. Therefore, it can be concluded that the State is able to use the mechanisms of section 56.

I now turn to discuss the four scenarios related to the abuse of patents with respect to their function and interpretation as done by the British[21] and South African courts.

Section 56(2)(a) of the Patents Act:

"56(2) *The rights in a patent shall be deemed to be abused if—*

(a) the patented invention is not being worked in the Republic on a commercial scale or to an adequate extent, after the expiry of a period of four years subsequent to the date of the application for the patent or three years subsequent to the date on which that patent was sealed, whichever period last expires, and there is in the opinion of the commissioner no satisfactory reason for such non-working;"

There are a few key phrases that need interpretation to ascertain the working of this section. 'Patented invention' is known to include at least the invention as specifically described in the patent itself – the court in *Lake's Patent*[22] described it as "*as a general rule a patentee ought not to be called upon to manufacture any mechanism or machine which he has not specifically described and claimed in his specification*"

The phrases 'worked' and 'adequate extent' were addressed by the South African court in *Sanachem (Pty) Ltd v British Technology Group PLC*[23] ("*Sanachem*") wherein the court found that 'worked' had a meaning analogous to 'exploitation'. **'**Exploitation' was found to include exploitation by the patentee, his licensee or by infringers as well as including importation.[24] In the same matter it found that 'adequate extent' meant "*sufficient or commensurate with the needs of the Republic"*[25] This interpretation was later followed in

[21] We use the British court interpretations as the sections of the Patents Act find their root in the British statute counterparts. It assists us in interpreting the provisions as the legislature would have originally intended.
[22] *Lake's Patent* 1909 26 RPC 443.
[23] *Sanachem (Pty) Ltd v British Technology Group PLC* 1992 BP 276 (CP).
[24] *Sanachem* (n23 above) at paragraph [285].
[25] *Sanachem* (n23 above) at paragraph [286].

the case of *Delta G Scientific (Pty) Ltd v Janssen Pharmaceutics NV and Another*[26] ("*Delta G*").

Further in *Delta G*, the court held that an invention could still be worked to a greater extent or an adequate extent even if the market was found to be fully supplied. Further, regard must be had to the extent to which the invention can reasonably be expected to be worked in the circumstances to determine if the working of the invention has been adequate.[27]

The British courts had adopted a similar approach in *Re Hatschek's Patents:*[28]

> *"I have already said, the patentee is on his defence, and this being so, I do not think the extent to which the article is manufactured, or the process is carried on, can be considered adequate if it be less than it would have been but for the fact that the patentee has exercised the right conferred by his patent to the hurt of the British industry – for example the fact that he has given foreign traders a preference over British traders.*"[29]

Section 56(2)(c) of the Patents Act:

"56(2) *The rights in a patent shall be deemed to be abused if—*

> *(c)the demand for the patented article in the Republic is not being met to an adequate extent and on reasonable terms*;"

This section is probably the most applicable to the State when trying to realize the objectives of section 27 of the Constitution. 'The demand' mentioned in this section has been interpreted to mean the demand of the public rather than that of a particular person.[30] Secondly, the demand must be an actual one and not one that the applicant for a compulsory licence hopes to be in a position to create after he/she has obtained a licence and commenced operations.[31] Finally, it is established law that it is no excuse to

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[26] *Delta G Scientific (Pty) Ltd v Janssen Pharmaceutica NV and Another* 1996 BP 455 (CP) at paragraph [459].
[27] *Delta G* (n26 above) at paragraph [460].
[28] *Re Hatschek's Patents* (1909) 26 RPC 228.
[29] *Re Hatschek's Patents* (n28 above) at paragraph [241].
[30] *The Robin Electric Lamp Co Ltd's Petition* (1915) 32 RPC 202 at paragraph [214].
[31] *James Lomax Cathro's Applications* (1934) 51 RPC 75 at paragraph [82].

say there is no demand locally, whilst the patent holder is manufacturing in other countries. If the invention is being manufactured in other countries, there is a demand in those countries, and therefore the absence of any demand locally is not a valid defence. In this scenario, the patent holder must make an effort to create a demand locally. The court in *Re Boult's Patent*[32] clarified this position:

> "*The consideration of the adequacy of manufacture in this country does, no doubt, depend to some extent upon the demand existing for the article here or in neutral markets, but it does not follow that, if there is no demand existing, there is no obligation on a patentee to start an industry here. If he does in fact manufacture in foreign countries, and if there is in fact a demand for the article or process abroad, the absence of any demand here does not seem to be a valid excuse. The patentee must, in such cases, make an effort to create a demand here, and the establishment of an industry will in itself help to create in many cases a demand for the article or process in question."*

'Reasonable terms' refers mainly to the price of the protected article. This was interpreted in *James Lomax Cathro's Applications*[33] ("*James Lomax"*):

> "*Now I think in the first place that the expression 'on reasonable terms' in paragraph (c) refers mainly to the price charged for the patented article, and I am fortified in this view by a consideration of the summary of the kinds of abuses dealt with by section 27 given by Mr Justice Luxmoore in Brownie Wireless Company's Ltd's Applications (1929) 46 RPC 457 at 471 where the reference to excessive price clearly refers to an abuse covered by paragraph (c).*"

The South African court in *Sanachem* did interpret the phrase 'reasonable terms' and found it to depend on the circumstances surrounding each case and that "*if the user of the patented article is paying an excessive price then clearly the needs are not being met on reasonable terms*."[34] The court further held, citing the English decision of *Brownie*

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[32] *Re Boult's Patent* (1909) 26 RPC 383 at paragraph [387].
[33] *James Lomax* (n31 above) at paragraph [82].
[34] *Sanachem* (n23 above) at paragraphs [289] and [290].

Wireless Co Ltd's Applications[35] ("*Brownie Wireless*") that "*it was not unreasonable to charge a royalty which the trade would carry*".[36]

Section 56(2)(d) of the Patents Act:

"56(2) *The rights in a patent shall be deemed to be abused if—*

> *(d)by reason of the refusal of the patentee to grant a licence or licences upon reasonable terms, the trade or industry or agriculture of the Republic or the trade of any person or class of persons trading in the Republic, or the establishment of any new trade or industry in the Republic, is being prejudiced, and it is in the public interest that a licence or licences should be granted;"*

The British courts interpreted the corresponding provision in the British Consolidated Patents and Designs Act 1907 to 1928, in *Brownie Wireless*:

> "*It is plain that in order to bring the case within that head the applicant must establish three things. To take them in the order in which they are mentioned in head (d) the applicant must prove: (1) That the patentee has refused to grant the applicant a licence on reasonable terms; (2) The trade or industry either of the United Kingdom or the establishment of any new trade or industry in the United Kingdom is prejudiced by the refusal if the grant; and (3) That it is in the public interest that a licence should be granted… The first thing to be noticed about the sub-clause is the generality of the phrases used in it.*"[37]

This approach was endorsed by the South African court in *Sanachem*; the court outlined the three components which must be satisfied namely, refusal to licence on reasonable terms; prejudice to trade, industry or agriculture; and the public interest.[38]

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[35] *Brownie Wireless Co Ltd's Applications* (1929) 46 RPC 457 at paragraphs [476] to [478].
[36] *Sanachem* (n23 above) at paragraph [290].
[37] *Brownie Wireless* (n35 above).
[38] *Sanachem* (n23 above) at paragraph [291].

'The refusal' seems to indicate that before this section can be invoked there must be a complete or definite refusal or an offer to grant a licence on terms wholly unreasonable.[39]

Again, the Patents Act, in this section, refers to reasonable terms, which has already been discussed in our analysis of section 56(2)(c) of the Patents Act. However, under section 56(2)(d) the courts have been more strict in their approach than under section 56(2)(c); in *Sanachem* the court stated: *"technically speaking without proof of an outright and definite refusal to grant a licence to the applicant, the onus cannot be discharged under subsection 56(2)(c)*".[40] The court further clarified this position by stating that the legislature intended "*to see that the patentee does not cause harm to the trade or to those who use the patented article*."[41]

The phrase 'public interest' was described in *Brownie Wireless* as: *"…in its widest meaning, namely, the interest of the community including every class which goes to constitute that body, namely, the purchasing public, the traders and the manufacturers, the patentee and the licensees, and inventors generally, (and not) be construed simply with regard to the purchasing public.*"[42]

In South Africa in the case of *Afitra (Pty) Ltd and Another v Carlton Paper of SA (Pty) Ltd*[43] the court held that unreasonable terms are not established merely on proof that the applicant can sell the same sort of article at a lower price. Other relevant considerations need to be considered when deciding whether the patentee's prices are reasonable, such as the cost of producing and marketing the patented article, the terms and conditions on which it negotiates with customers, and whether the facts show that the trade as a whole can carry the price charged.[44]

Further in the same matter, the court held that the term 'prejudice' must be interpreted widely, depending on the circumstances of each case.

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[39] *Loewe Radio Co. Ltd's Application* (1929) 46 RPC at paragraphs [489] and [490].
[40] *Sanachem* (n23 above)
[41] *Sanachem* (n23 above).
[42] *Brownie Wireless* (n35 above).
[43] *Afitra (Pty) Ltd and Another v Carlton Paper of SA (Pty)* Ltd 1992 BP 331 (CP).
[44] *Afitra* (n43 above) at paragraph [347].

Section 56(2)(e) of the Patents Act:

"56(2) *The rights in a patent shall be deemed to be abused if—*

(e) the demand in the Republic for the patented article is being met by importation and the price charged by the patentee, his licensee or agent for the patented article is excessive in relation to the price charged therefor in countries where the patented article is manufactured by or under licence from the patentee or his predecessor or successor in title."

This section applies to a scenario whereby the demand is being met by importation and the price charged is excessive in relation to the price charged in countries of manufacture. In *Sanachem*, the court held that this subsection called for a comparison between the local price for the imported article and the prices charged in countries where it was manufactured.

The majority of the expressions used in section 56(2)(e) have already been discussed above.

In *Sanachem*, the South African court interpreted section 56(2)(e) as calling for a comparison between the local price for the imported article and the prices charged in countries where it was manufactured.

This concludes my analysis and interpretation of section 56(2), it is important to remember that before invoking any of the subsections in section 56(2) it must be shown that the person invoking the section must be an 'interested person' before going into the analysis of the various subsections themselves.

Chapter 3

Abuse of dominance provisions of the Competition Act

The abuse of dominance provisions in South African competition law are to be found in sections 7, 8, and 9 of the Competition Act[45]. The abuse of dominance sections in competition law refers to 'firms'. A firm is defined in section 1(xi) of the Competition Act as: "*'firm' includes a person, partnership or a trust*".

The purpose of section 7 is to determine whether a firm is factually in a dominant position. A firm must first be established to be in a dominant position in terms of section 7 before moving on to the determination that it is in fact abusing this position prohibited by sections 8 and 9.

Section 7

Section 7 reads as follows:

> "*7. 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.*"

Section 7(a) is self-explanatory – if a firm has a market share of at least 45%, it is presumed to be dominant.

Section 7(b) creates a rebuttable presumption that a firm with a market share of between 35% and 45% is dominant. The sub-section enables the firm in question to show that it is not dominant by illustrating that it does not have market power.[46] The Competition Tribunal ("Tribunal") has interpreted this sub-section in *Nationwide Airlines and Others v*

[45] Act 89 of 1998.
[46] Section 1(xiv) of the Competition Act: 'market power' means the power of a firm to control prices, to exclude competition or to behave to an appreciable extent independently of its competitors, customers or suppliers.

South African Airways (Pty) Ltd and Others[47] wherein it provided that: "*Even if SAA's market share is below this figure of 45% the onus in terms of section 7(b) is on it to rebut the inference of market power*".[48] Here the onus rests on the respondent firm and not the Competition Commission ("Commission").

Section 7(c) provides that a firm can still be considered dominant if its market share is below 35% but can be shown to still wield market power. However, in this scenario the onus then rests on the Commission to illustrate that the firm in question has market power.

The concept of 'market power' is defined in section 1(xiv) of the Competition Act 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."*

From this it can be concluded that any firm has the potential to be dominant should they be able to wield market power despite the level of their market share.

Section 8

Section 8 of the Competition Act illustrates species of abuse a dominant firm could commit. This section describes four different potential contraventions. These contraventions can be divided into two groups:

1. Section 8(a) is an 'exploitative abuse' which to relates to circumstances wherein the firm exploits its consumers.

2. Sections 8(b), (c), and (d) are 'exclusionary abuses', which relates to circumstances wherein the firm commits an act in order to exclude its competitors. The Competition Act does in section 1(x) define an exclusionary act as: "*an act that impedes or prevents a firm entering into, or expanding within, a market.*"

Section 8 reads as:

> *"8. It is prohibited for a dominant firm to-*

[47] *Nationwide Airlines and Others v South African Airways (Pty) Ltd and Others* (92/IROct00) at page 9.
[48] *Nationwide Airlines* (n47 above).

(a) charge an excessive price to the detriment of consumers;

(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 to a competitor when supplying those goods 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 below their marginal or average variable cost; or

(v) buying-up a scarce supply of intermediate goods or resources required by a competitor."

I shall now discuss the subsections of section 8 and their meanings.

Section 8(a)

Section 8(a) relates to excessive pricing, the Competition Act itself does define 'excessive price' in section 1(ix) as:

"a price for a good or service 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 courts, in interpreting this section have had regard to what 'economic value' could mean in the context of an excessive price. This culminated in the European Court of Justice ("ECJ") formulating the *United Brands*[49] test:

"[Examine] whether the difference between the costs actually incurred and the price actually charged is excessive; and

"[I]f the answer to this question is in the affirmative, [determine] whether a price has been imposed which is either unfair in itself or when compared to competing products."[50]

In other words, an excessive price is one where there is an unreasonable relationship between the price charged for a product and the costs incurred in producing it plus a reasonable return. Excessive pricing is prohibited as a *per se* prohibition without considering competitive effects.

In South Africa, the Competition Appeal Court ("CAC") in *Mittal Steel South Africa Ltd and Others v Harmony Gold Mining Company Ltd*[51] found that the wording of section 8(a) requires four steps in order to determine whether an excessive price has been charged to the detriment of consumers:

"*1. first, the determination of the actual price charged;*

2. second, the economic value of the good or service must be ascertained;

3. third, if the actual price exceeds the economic value, it must be determined whether the difference between them is unreasonable; and if so,

[49] *United Brands Company and United Brands Continentaal BV v. Commission*, 27/76 [1978] ECR-207.
[50] *United Brands* (n49 above) at section 252.

[51] *Mittal Steel South Africa Ltd and Others v Harmony Gold Mining Company Ltd* (70/CAC/Apr07).

4. it must be determined if the charging of the excessive price is to the detriment of consumers."[52]

Section 8(b)

Section 8(b) refers to an 'essential facility', this concept is defined in 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*"[53]

The CAC in *Glaxo Wellcome (Pty) Ltd & Others and National Association of Pharmaceutical Wholesalers & Others*[54] has set out what the applicant will need to demonstrate in order to allege a contravention of section 8(b):

> "*to allege a contravention of section 8(b) a complainant will have to aver in its complaint that:*
>
> *a) the dominant firm concerned refuses to give the complainant access to an infrastructure or a resource;*
> *b) the complainant and the dominant firm are competitors;*
> *c) the infrastructure or resource concerned cannot reasonably be duplicated;*
> *d) the complainant cannot reasonably provide goods or services to its competitors without access to the infrastructure or resource; and*
> *e) it is economically feasible for the dominant firm to provide its competitors with access to the infrastructure or resource."*[55]

[52] *Mittal Steel* (n51 above).
[53] Section 1(viii).
[54] *Glaxo Wellcome (Pty) Ltd & Others and National Association of Pharmaceutical Wholesalers & Others* (15/CAC/Feb02).
[55] *Glaxo Wellcome* (n54 above) at pages 31-32.

Sections 8(c) and 8(d)

As we have mentioned above sections 8(c) and 8(d) of the Competition Act are both types of exclusionary abuses in that they are abuses that exclude competitors of a firm (see definition of 'exclusionary act' above).

However, sections 8(d) and 8(c) are related to one another. Section 8(d) lists *specific species* of 'exclusionary acts'.

Section 8(c) is the 'catch-all' provision in that if the alleged 'exclusionary act' is not listed under section 8(d) the case still be brought under section 8(c). This gives the Commission or applicant the opportunity to seek recourse for types of exclusion not specifically covered in section 8(d).

For section 8(c) to be invoked the conduct must first meet the definition of an 'exclusionary act' that has the effect of substantially lessening or preventing competition. Secondly, if the conduct of the offending firm does not lead to technological, efficiency and pro-competitive gains that outweigh the exclusionary effect of the conduct, the conduct will be found to be a contravention of section 8(c).

Section 8(c) is wide enough to incorporate exclusionary acts not contemplated by section 8(d). For example, the Tribunal, in *Competition Commission v Senwes Ltd*[56] has found that margin squeeze falls within the ambit of section 8(c) of the Competition Act.

Margin squeeze is defined as follows:

> "A margin squeeze occurs when a vertically integrated firm that is dominant in the supply of essential upstream inputs sets prices at the upstream and downstream levels such that the margin between these prices is insufficient for a downstream competitor to cover its costs."[57]

[56] *Competition Commission v Senwes Ltd* (110/CR/Dec06).
[57] CRA (Chares River Associates), 2010. *Competition memo: margin squeezes and the inefficient "equally efficient operator"*.

Further, in the case of *Competition Commission v Media 24*[58] it was found that the concept of predatory pricing may also constitute an exclusionary act for purposes of section 8(c). Predatory pricing involves the charging of lower prices by a firm, the aim being to get rid of competitors so that the firm can charge considerably higher prices later. The predator is willing to sell at a loss (below cost) for a period, in the hope that its competitors either exit the market or decide stop selling that product. When the target competitors have left the market, the predator pushes prices back up.

In terms of section 8(d), the conduct must meet the definitions set out in the sub-paragraphs. The listed prohibited acts are presumed to be exclusionary. If the conduct meets the definition, the Tribunal must then determine whether or not the exclusionary conduct has an anti-competitive effect.

The Tribunal's approach to section 8(c) and (d) appears to be two-fold in that one needs to:

1. prove the existence of an exclusionary act *and*

2. that said exclusionary act is anti-competitive.

In determining whether the exclusionary act is in fact anti-competitive, the Tribunal held in *Competition Commission v South Africa Airways (Pty) Ltd*[59] ("*SAA"*):

> "*We then enquire whether the exclusionary act has an anti-competitive effect. This question will be answered in the affirmative if there is (i) evidence of actual harm to consumer welfare or (ii) if the exclusionary act is substantial or significant in terms of its effects in foreclosing the market to rivals. This latter*

[58] *Competition Commission v Media 24* (CR154Oct11).
[59] *Competition Commission v South Africa Airways (Pty) Ltd* (18/CR/Mar01). See also *Nationwide Airlines* paragraphs [142]-[143] where the Tribunal followed the exact test laid out in *SAA*.

is partly factual and partly based on reasonable inferences drawn from proven facts."[60]

The test in *SAA* together with the wording of subsections 8(c) and 8(d), has the effect of shifting the burden of proving pre-competitive gains that outweigh the negative effects of the conduct.

As per the Competition Act, an act can be exclusionary and can have anti-competitive effects but may still not necessarily fall foul of the Competition Act, if the pro-competitive effects are shown to outweigh the negative.

In terms of section 8(c), the onus is on the complainant to show that the anti-competitive effects of the conduct outweigh the technological, efficiency and pro-competitive gains (efficiency justification or the objective justification[61]). If the complainant successfully discharges the onus, it will have proved an abuse of dominance.[62]

In terms of section 8(d), the burden of proof shifts to the respondent firm who must prove that the efficiency justifications outweigh the anti-competitive effect of the conduct. If the respondent firm fails to do so, the complainant would be seen to have proved an abuse of dominance.[63]

Section 8(c) and (d) also differ in respect of penalties. If a firm is found to have contravened section 8(c), a fine may not be imposed on the firm unless the conduct is substantially a repeat by the same firm of conduct previously found by the Tribunal to be a prohibited practice. However, the Competition Amendment Act[64] has changed the function of section 8(c) with regard to penalty, it would appear that there is no longer no fine to be imposed for first time contraventions of this subsection.

[60] *SAA* (n59 above) at paragraph [132].
[61] *Senwes Ltd* (n56 above) at paragraph [170].
[62] *SAA* (n59 above) at paragraph [134].
[63] *SAA* (n59 above) at paragraph [135].
[64] Act 18 of 2018.

We now turn to discuss the interpretations of the various species of exclusionary acts found under section 8(d).

Section 8(d)(i)

This section provides that a dominant firm may not require or induce a supplier or customer to not deal with a competitor. While the Competition Act does not impose an obligation on any firm to supply, or buy a product or service, from another business, it does prohibit a firm from imposing a condition or giving incentives or inducements to another firm to not deal with its competitors.

If a dominant firm engages in the conduct described it is presumed to have engaged in an 'exclusionary act' defined by the statute.

Section 8(d)(ii)

Refusing to supply scarce goods[65] to a competitor when supplying those goods is economically feasible, is prohibited in terms of this section. A refusal to supply is prohibited when it is aimed at eliminating actual or potential competitors. This may take the form of an outright refusal to supply, a refusal based on terms, which the supplier knows are not acceptable, or refusal on unfair conditions.

The onus rests on the complainant to show that the elements of the act have been established. Thereafter, the dominant firm may raise various defences or justifications for its behaviour.[66]

Section 8(d)(iv)

Predatory pricing involves strategic conduct where a firm deliberately incurs short-term losses in order to eliminate a competitor so as to be able to charge excessive prices in

[65] Note that *services* are excluded from the prohibition. A refusal to supply a product or service (excluding scarce goods) will be caught by the general prohibition against engaging in exclusionary acts under section 8(c).

[66] A respondent can of course show that the goods are not scarce and indeed available from other competitors; that there has been no refusal to supply or that the complainant is not a competitor. In other words that the elements of the prohibition do not exist.

the future. This provision does not, therefore, imply that when an activity is run at a loss, it is in itself an infringement of the law; neither does it mean that consumers cannot benefit from such short-term conduct. The key in assessing this conduct is whether the dominant firm is covering its cost.

The CAC in *Media 24 (Pty) Ltd vs Competition Commission of South Africa*[67] held that section 8(d)(iv) does not favour the interpretation that 'intention' of the wrongdoer be considered. Intention is irrelevant. Note that section 8(d)(iv) has undergone a makeover in terms of the Competition Amendment Act.

Section 9

Section 9 prohibits price discrimination by dominant firms and reads as follows:

> "*9(1) An action by a dominant firm, as the seller of goods or services is prohibited price discrimination, if –*
>
> *(a) it is likely to have the effect of substantially preventing or lessening competition;*
>
> *(b) it relates to the sale, in equivalent transactions, of goods or services of like grade and quality to different purchasers; and*
>
> *(c) it involves discriminating between those purchasers in terms of –*
>
> *(i) the price charged for the goods or services;*
>
> *(ii) any discount, allowance, rebate or credit given or allowed in relation to the supply of goods or services;*
>
> *(iii) the provision of services in respect of the goods or services; or*
>
> *(iv) payment for services provided in respect of the goods or services.*
>
> *(2) Despite subsection (1), conduct involving differential treatment of purchasers in terms of any matter listed in paragraph (c) of that subsection is not prohibited*

[67] *Media 24 (Pty) Ltd vs Competition Commission of South Africa* (146/CAC/Sep16).

price discrimination if the dominant firm establishes that the differential treatment –

(a) makes only reasonable allowance for differences in cost or likely cost of manufacture, distribution, sale, promotion or delivery resulting from the differing places to which, methods by which, or quantities in which, goods or services are supplied to different purchasers;

(b) is constituted by doing acts in good faith to meet a price or benefit offered by a competitor; or

(b) is in response to changing conditions affecting the market for the goods or services concerned, including –

(i) any action in response to the actual or imminent deterioration of perishable goods;

(ii) any action in response to the obsolescence of goods;

(iii) a sale pursuant to a liquidation or sequestration procedure; or

(iv) *a sale in good faith in discontinuance of business in the goods or services concerned*."

Price discrimination refers to a set of circumstances where customers of a dominant firm, who themselves are competitors, receive different treatment from their supplier. A pre-requisite of this section is that it must involve competitors of a firm as the customers.

In deciding whether or not there has been any discrimination, it is necessary to first determine what is similar and what is different. The Competition Act states the

requirement that the transactions be equivalent and involves products or services of like grade and quality.

Sub-section 2 lists defenses available to a firm accused of being involved in price discrimination. However, apart from the defenses listed in section 9(2) the respondents can show that i) there is not a substantial lessening or prevention of competition; and ii) the transactions are not equivalent. Again, this section has undergone changes in terms of the Competition Amendment Act.

I have not discussed the Competition Amendment Act and its effect on the abovementioned sections of the Competition Act as these sections have not yet been tested or brought to the Tribunal or CAC for interpretation.

Chapter 4

Using the legislative mechanisms of the Patents Act to restrict the ambit of pharmaceutical patent rights: abuse of rights under section 56 of the Patents Act

I have above (in Chapter 2) discussed how one would anticipate the courts interpreting the various provisions of sections 55 and 56 of the Patents Act. Within this chapter we shall discuss the application of these provisions by the courts, in limiting patent right abuses, with specific reference to pharmaceutical patents within our Constitutional framework.

I first briefly outline the process that an applicant for a compulsory licence would have to follow.

The Uniform Rules of Court provide for two forms of procedure – namely applications and actions. An application for a compulsory licence is a procedure on application. Application procedure is started by way of notice of motion supported by evidence on affidavit (founding affidavit) setting out the basis for the compulsory licence. This must be served on the patentee and any other person who appears from the Patent Register to have an interest in the patent in question.

The patentee could in these instances make a counterclaim for an interdict, but the grant of such interdict would unlikely be forthcoming for the reason that the very issue is before the court would be entitled to a compulsory licence and if that was found to be the case, the alleged infringement would inherently be unlawful.[68]

If the application is opposed, the respondent has the right to file an answering affidavit answering the allegations put forth in the founding affidavit. Thereafter the applicant is afforded the opportunity to reply on affidavit (replying affidavit). Applications are then determined on these pleadings, and in normal circumstances, oral evidence is not heard.

The procedure above is initiated before the Commissioner of Patents ("the Commissioner"), who has all the powers and jurisdiction akin to that of a single judge

[68] *Atomic Energy Corporation of SA Ltd v The Du Pont Merck Pharmaceutical Co* 1997 BIP 90 (CP) at paragraphs [94A] and [94H].

presiding over civil matters before a provincial division of the High Court having jurisdiction at the place where the proceedings before the Commissioner are held.[69] The procedure is governed by the Patent Regulations 1978 ("Patent Regulations"). Regulations 96 and 97 read as follows:

> "*96. Application for compulsory licence An application for a compulsory licence under section 55 or 56 (1) of the Act shall be brought by way of notice of motion and shall be served on the patentee and any other person who appears from the registrar to have an interest in the patent.*
>
> *97. Notice of motion In the case of proceedings initiated by way of notice of motion a party resident or incorporated outside the Republic shall have one month from the date of service of such notice on him within which to lodge and serve his notice of intention to oppose.*"

These regulations are to be read with Regulations 82 to 88:

> "*82. Procedure on opposition A notice of opposition in any matter in which opposition is allowed under the Act shall be made on Form P19 and shall be accompanied by a statement of particulars of the grounds on which the opposition is based and shall be duly filed and served.*
>
> *83. Within two months of the filing and service of the notice of opposition the applicant shall file and serve a counterstatement in the form of a plea. If such counterstatement is not lodged within the said period or within such further period as the registrar may allow the application shall be deemed to be abandoned and the opponent may apply to the commissioner for an order as to costs.*
>
> *84. Within two months of the lodging and service of the counterstatement the opponent shall file and serve his evidence in the form of an affidavit.*
>
> *85. Within two months of the filing and service of the opponent's evidence the applicant may file and serve answering evidence in the form of an affidavit.*

[69] See section 17(1) of the Patents Act.

86. Within two months of the filing and service of the applicant's answering evidence the opponent may file and serve replying evidence, in the form of an affidavit, confined to matters strictly in reply.

87. (a) No further evidence shall be filed by either party except by leave or direction of the commissioner. (b) All evidence shall be by affidavit unless otherwise directed by the commissioner.

88. Upon completion of the evidence the opponent or if he fails to do so."

It is submitted that this process is too cumbersome and burdensome on parties and this is perhaps why there are few matters involving compulsory licence applications in our jurisprudence. This may also hinder the State's ability to fulfil its constitutional obligations under section 27.

Given that there is minimal jurisprudence relating to compulsory licences, how does one begin to use the legislative mechanisms of sections 55 and 56 of the Patents Act to limit pharmaceutical patent rights? It may serve to start at the repealed section 56(1A) of the Patents Act[70], which read as follows:

"*Pending the final determination of an application for a compulsory licence the applicant shall not, except under special circumstances, be prohibited by interdict from infringing the patent*."

Before the Appellate Division *British Technology Group Ltd v Sanachem (Pty) Ltd*[71] there was an application for an interdict to restrain the continued infringement of a patent pending an appeal.

The application was refused as the patentee had failed to demonstrate 'special circumstances' entitling it to the relief of an interdict. The court distinguished between general and special circumstances being – "*something of an exceptional nature which in the exercise of a judicial discretion would be sufficient to justify the relief sought*"[72]

[70] Repealed in terms of the Intellectual Property Laws Amendment Act 38 of 1997.
[71] *British Technology Group Ltd v Sanachem* (Pty) Ltd 1993 BP 415 (CP).
[72] *British Technology Group* Ltd (nr 71 above).

After section 56(1A) was repealed the case of *Cipla Medpro v Aventis Pharma*[73] ("*Cipla*") followed wherein the court had the opportunity to interpret the Patents Act in light of the Constitution and free from the prohibition in section 56(1A).

Free from section 56(1A), the court could then test the extent of the broad constitutional principles upon the current patent regime, especially in relation to the right of access to health care services and medicines in intellectual property disputes.

By the time of hearing this case, it was trite law that the public interest must be a consideration in intellectual property related disputes regarding compulsory licences. In *Syntheta (Pty) Ltd previously Delta G Scientific (Pty) Ltd v Janssen Pharmaceutica NV and Another*[74] the court stressed the use and need of the product in question by the South African public:

> "*This amounts, in truth, to little more than a recitation of the words of the subsection and is not a statement of facts from which the necessary legal conclusion can be drawn. The uses of and need for the product by the South African public and the desirability and feasibility of local production are not addressed. In particular what is overlooked is the fact that ss (2) is a statutory code. Importation is a topic addressed in ss 2(b) and (e) (which are not invoked). For the purpose of ss (2)(a) it will suffice if the patentee can show working (in Afrikaans "ge-eksploiteer") in any form. Non-working of the process claims is irrelevant because no licence is sought for the processes. Working of the product claims by importation is conceded in the paragraphs quoted above."*[75]

[73] *Cipla Medpro v Aventis Pharma* (139/12) *Aventis Pharma SA v Cipla Life Sciences* (138/12) [2012] ZASCA.
[74] *Syntheta (Pty) Ltd previously Delta G Scientific (Pty) Ltd v Janssen Pharmaceutica NV and Another* (449/96) [1998] ZASCA 74; 1999 (1) SA 85 (SCA); [1998] 4 All SA 445 (A).
[75] *Syntheta* (nr74 above) at paragraph [10].

In the *Cipla* matter, Aventis (as the holder of the patent) averred that Cipla (as the generic manufacturer) had infringed its patent by registering and commencing the manufacture and marketing of a cheaper version of Aventis' cancer medication.

The Treatment Action Campaign ("TAC"), as amicus curiae, argued that the provisions of the Patents Act must be interpreted in a manner consistent with the Constitution, and that the rights of the patent holder need to be balanced with those of persons requiring the life-saving medication.

It also argued that when considering the requirement of 'balance of convenience' in interdict proceedings which potentially threaten the right to access medicines, the party requesting the interdict must prove that its grant will not harm the public interest.

The court did accept the TAC's argument that the public interest must be considered when considering the balance of convenience:

> "*The TAC is on stronger ground when it advances factors to be taken account of when weighing the balance of convenience. In that respect it submitted that the broader public interest, and not only the interests of the litigating parties, must be placed in the scales when weighing where the balance of convenience lies. Apart from decisions to that effect in this country, we were referred to cases in other jurisdictions, particularly the United States, where injunctions against infringement have been refused on that ground.*"[76]

However, the court came to the conclusion that the public interest would not be served by denying an interdict on the facts of this case:

> "*The requirements for an interim interdict in this country are more flexible than those for a permanent injunction in the United States. Counsel for Aventis accepted, nonetheless, that the 'public-interest' factors identified in those cases can and ought to be taken into account in the exercise of our discretion, but amply demonstrated that none of those concerns arise on the facts of this case.*"[77]

[76] *Cipla* (nr73 above) at paragraph [46].
[77] *Cipla* (nr73 above) at paragraph [52].

The court noted that Cipla's opposition was based on commercial considerations, namely, its need to establish a presence in the generics market:

> "*There is some mention in Cipla's affidavits of prejudice to cancer sufferers if an interdict were to be granted but it is perfectly plain that in reality Cipla's resistance to an interdict is founded upon its commercial interests. It explains, quite frankly, the advantage to be had from being the first in the market for the supply of cheaper generic products once a patent expires. It says that a generic can be expected to expand the market for the medicine and that the first generic on the market can be expected permanently to capture about 70% of the expanded market within about eighteen months, leaving the remaining 30% to be shared amongst the original product and other generics that come onto the market. At the time its answering affidavit was filed Cipla was due to receive stock of Cipla Docetaxel, had already taken orders, and was in a position to immediately enter the market to secure that commercial advantage*."[78]

The court further based its decision on the following factors:

1. there was no evidence before it that Aventis could not continue to meet the demand for the medicine:

   > "*There is no suggestion that Aventis is not able to meet demand for Taxotere or Docetere, which was the disputed issue in Innogenetics, N.V. v Abbott Laboratories*."[79]

2. Cipla was unable to demonstrate that its product offered either superior medicinal benefits, or more than a marginal saving on the cost of its generic version in relation to Aventis' generic version:

[78] *Cipla* (nr73 above) at paragraph [42].
[79] *Cipla* (nr73 above) at paragraph [55].

"*Nor can it be said that Cipla's product offers superior medicinal benefits, which was the case in Bard Peripheral Vascular, Inc v W.L.Gore & Associates, Inc*."[80]

"*It will be apparent, then, that Taxotere is considerably more accessible than Cipla Docetaxel to patients who are dependent upon public health care, and there will be no prejudice at all to those patients, or to the state, if an interdict were to be granted. Patients who are dependent upon private health care will continue to have access to Taxotere (albeit at a considerably higher cost) and will have access to Docetere at only a marginally higher cost than Cipla Docetaxel (R100 more for a 20 mg dosage and R350 more for a dosage of 80 mg). Many of those patients will have access to medical insurance that will meet the additional cost, and for those who do not, the additional cost of Docetere is marginal."*[81]

3. and finally, there would be no material disruption of medicine supply to patients should the interdict be granted:

"It is also clear that there will be no material disruption to patients if an interdict were to be granted, as there would have been in Johnson & Johnson Vision Care, Inc v Ciba Vision Corporation. When the application was heard there were no users of Cipla Docetaxel. By March 2012 there were some 65-70 users, and I assume that by now there are probably more but switching to Taxotere or Docetere for future treatment involves no medicinal disruption. This is also not a case like Edwards Lifesciences, in which an interdict will have no practical effect."[82]

Even though the court had acknowledged that the public interest must be taken into account when determining the balance of convenience, it clearly did not apply a human

[80] *Cipla* (nr73 above) at paragraph [55].
[81] *Cipla* (nr73 above) at paragraph [58].
[82] *Cipla* (nr73 above) at paragraph [55].

rights-based approach to the interpretation of intellectual property disputes. It instead stated that the TAC's opposition to grant the interdict was:

> *"no more than opposition to the monopoly that the law confers upon a patentee. It submits that those who cannot afford Taxotere but are able to afford the price of Cipla Docetaxel, will be prejudiced if distribution of the latter were to be prohibited. Where the public is denied access to a generic during the lifetime of a patent that is the ordinary consequence of patent protection and it applies as much in all cases. To refuse an interdict only so as to frustrate the patentee's lawful monopoly seems to me to be an abuse of the discretionary powers of a court. But in any event, there will be no material prejudice of that kind on the facts of this case."*[83]

It is submitted that, based on the way the court interpreted this case, combined with the cumbersome procedure in applying for compulsory licences, limiting pharmaceutical patent rights by using the legislative mechanisms of the Patents Act will remain a difficult hurdle to overcome. The courts are clearly willing to consider the public interest when interpreting patent disputes. However, this is clearly not the overriding factor, and in the end, the courts appear to be reluctant to take a human rights based approach to patent disputes and in my estimation will remain to do so.

I leave this discussion with the following quote from the court in *Cipla*. It adequately and succinctly depicts the court's position on these matters:

> "*What we are to make of viewing the legislation through the prism of the Constitution was not developed by the TAC. Section 39(2) indeed calls upon a court to 'promote the spirit, purport and objects of the Bill of Rights' when interpreting legislation, as pointed out by the TAC, but that does not open the door to changing the clear meaning of a statute. If the clear meaning conflicts with the Bill of Rights then the remedy is to strike it down, but there has been no challenge to the constitutional validity of any of the provisions of the Act that are now material. There is also no suggestion that the meaning of those provisions is not clear. The disputes centre instead on the application of those provisions to the facts of this*

[83] *Cipla* (nr73 above) at paragraph [56].

case. On the assumption that the patent is not revocable for want of an inventive step I cannot see how s 39(2) or the prism of the Constitution comes into play so as to deny Aventis its right to enforce its patent."[84]

I now turn to discuss another legislative mechanism that could perhaps limit pharmaceutical patent rights in achieving the goals of section 27 of the Constitution, namely sections 7,8 and 9 of the Competition Act.

[84] *Cipla* (nr73 above) at paragraph [45].

Chapter 5

Using the legislative mechanisms of the Competition Act to restrict the ambit of pharmaceutical patent rights: abuse of dominance provisions under sections 7, 8, and 9 of the Competition Act

I have above (Chapter 3) described how the Tribunal and CAC would interpret the various provisions relating to abuse by a dominant firm. I now turn to discuss how these sections of the Competition Act would be applied in a situation where there is an abuse by a dominant firm of a pharmaceutical. Again, the jurisprudence in South Africa is scant at best on such matters. As such it may be best to look at the jurisprudence in the European Union ("EU") which is often used as a guide in tackling novel matters in South Africa.

As a side note it is important to remember that these provisions (sections 7,8 and 9 of the Competition Act) are to be invoked in competition matters, where the Tribunal and CAC have exclusive jurisdiction over such matters. This is not to say that the abuse provisions in the Patents Act and the Competition Act may not be exclusive of each other, there may be potential interactions that shall be discussed in Chapter 6, below.

I begin by looking at the analogous dominance provisions in the EU. Article 102 of the Treaty on the Functioning of the European Union ("TFEU") is where the abuse provisions are to be found and it reads as follows:

> "*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."

It is clear that Article 102 prohibits the abuse of a dominant position by a firm (or undertaking as described in TFEU).

It must be kept in mind that much like in South Africa it is not illegal for an undertaking/firm to be in or have obtained a dominant position and such undertaking/firm is free to compete in the relevant markets on merit.

Article 102 thus operates in the same way as sections 7, 8 and 9 of the Competition Act in that it first needs to be shown that a firm is dominant. This in itself is not a contravention.

Further, Article 102 makes distinctions between exploitative as well as exclusionary abuses much like the South African Competition Act, this is made clear in the Commission's *Guidance on the Commission's Enforcement Priorities in Applying Article [102] to abusive exclusionary conduct by dominant undertakings*[85] which reads as follows:

"*5. In applying Article [102] to exclusionary conduct by dominant undertakings, the Commission will focus on those types of conduct that are most harmful to consumers. Consumers benefit from competition through lower prices, better quality and a wider choice of new or improved goods and services. The Commission, therefore, will direct its enforcement to ensuring that markets function properly and that consumers benefit from the efficiency and productivity which result from effective competition between undertakings.*

7. Conduct which is directly exploitative of consumers, for example charging excessively high prices or certain behaviour that undermines the efforts to achieve an integrated internal market, is also liable to infringe Article [102]. The Commission may decide to intervene in relation to such conduct, in particular where the protection of consumers and the proper functioning of the internal market

[85] *Guidance on the Commission's Enforcement Priorities in Applying Article [102] to abusive exclusionary conduct by dominant undertakings* OJ [2009] C45/7 available at www.ec.europa.eu accessed on 28 October 2019.

cannot otherwise be adequately ensured. For the purpose of providing guidance on its enforcement priorities the Commission at this stage limits itself to exclusionary conduct and in, particular, certain specific types of exclusionary conduct which, based on its experience, appear to be the most common."[86]

Finally, as proof that Article 102 is analogous the abuse provisions of the Competition Act is that it also takes into account necessity, efficiencies and pro-competitive technological gains of dominant firms in assessing potential abuses as well as placing the burden on the dominant undertaking/firm to show or demonstrate such gains in justifying their conduct:

"*28. In the enforcement of Article [102], the Commission will also examine claims put forward by a dominant undertaking that its conduct is justified. A dominant undertaking may do so either by demonstrating that its conduct is objectively necessary or by demonstrating that its conduct produces substantial efficiencies which outweigh any anticompetitive effects on consumers. In this context, the Commission will assess whether the conduct in question is indispensable and proportionate to the goal allegedly pursued by the dominant undertaking.*

29. The question of whether conduct is objectively necessary and proportionate must be determined on the basis of factors external to the dominant undertaking. Exclusionary conduct may, for example, be considered objectively necessary for health or safety reasons related to the nature of the product in question. However, proof of whether conduct of this kind is objectively necessary must take into account that it is normally the task of public authorities to set and enforce public health and safety standards. It is not the task of a dominant undertaking to take steps on its own initiative to exclude products which it regards, rightly or wrongly, as dangerous or inferior to its own product.

30. The Commission considers that a dominant undertaking may also justify conduct leading to foreclosure of competitors on the ground of efficiencies that are

[86] *Guidance on the Commission's Enforcement Priorities in Applying Article [102] to abusive exclusionary conduct by dominant undertakings* at paragraphs [5] and [7].

sufficient to guarantee that no net harm to consumers is likely to arise. In this context, the dominant undertaking will generally be expected to demonstrate, with a sufficient degree of probability, and on the basis of verifiable evidence, that the following cumulative conditions are fulfilled:

> *— the efficiencies have been, or are likely to be, realised as a result of the conduct. They may, for example, include technical improvements in the quality of goods, or a reduction in the cost of production or distribution,*
>
> *— the conduct is indispensable to the realisation of those efficiencies: there must be no less anti-competitive alternatives to the conduct that are capable of producing the same efficiencies,*
>
> *— the likely efficiencies brought about by the conduct outweigh any likely negative effects on competition and consumer welfare in the affected markets,*
>
> *— the conduct does not eliminate effective competition, by removing all or most existing sources of actual or potential competition. Rivalry between undertakings is an essential driver of economic efficiency, including dynamic efficiencies in the form of innovation. In its absence the dominant undertaking will lack adequate incentives to continue to create and pass on efficiency gains. Where there is no residual competition and no foreseeable threat of entry, the protection of rivalry and the competitive process outweighs possible efficiency gains. In the Commission's view, exclusionary conduct which maintains, creates or strengthens a market position approaching that of a monopoly can normally not be justified on the grounds that it also creates efficiency gains.*

31. It is incumbent upon the dominant undertaking to provide all the evidence necessary to demonstrate that the conduct concerned is objectively justified. It then falls to the Commission to make the ultimate assessment of whether the conduct concerned is not objectively necessary and, based on a weighing-up of any

apparent anti-competitive effects against any advanced and substantiated efficiencies, is likely to result in consumer harm."[87]

We now turn to the jurisprudence of the application of Article 102 with specific reference to compulsory licences as a remedy to alleviate contraventions of Article 102 involving IPRs. These cases don't specifically reference pharmaceutical patents or may not specifically be patent cases but are landmark IPR cases that illustrate how the court would approach the other types of matters should they arise.

The questions are (i) whether the dominance provision of competition law can be used to limit the exclusive rights of intellectual property law and (ii) can the owner of an intellectual property right be compelled to grant a licence of it to a third party under the abuse provision of competition laws.

As a starting point, the Court of Justice in the *AB Volvo v Erik Veng*[88] case took an orthodox approach to the licensing of car manufacturers IPRs in order for third parties to produce spare parts. The third parties averred that the refusal to grant such licences was an abuse of the car manufacturers dominant position and thus constituted a contravention of Article 102:

"*It must also be emphasized that the right of the proprietor of a protected design to prevent third parties from manufacturing and selling or importing, without its consent, products incorporating the design constitutes the very subject-matter of his exclusive right. It follows that an obligation imposed upon the proprietor of a protected design to grant to third parties, even in return for a reasonable royalty, a licence for the supply of products incorporating the design would lead to the proprietor thereof being deprived of the substance of his exclusive right, and that a refusal to grant such a licence cannot in itself constitute an abuse of a dominant position."*[89]

[87] *Guidance on the Commission's Enforcement Priorities in Applying Article [102] to abusive exclusionary conduct by dominant undertakings* OJ [2009] C45/7 at paragraphs [28] to [31].
[88] *AB Volvo v Erik Veng (UK) Ltd* Case 238/87.
[89] *Volvo* (nr89 above) at paragraph [8].

The Court adopted a more liberal approach to this type of issue in the case of *Magill TV Guide/ITP, BBC and RTE*.[90] In this matter, the TV companies (ITP, BBC and RTE) had refused to make their weekly programme listings available to Magill in advance. Magill wished to release the information in a single weekly publication, of which there were no similar publications. There was a found to be an obvious public demand for such a type of publication.

Magill required a licence as copyright protection over the programme listings subsisted in the three TV companies, this licence was refused. The Commission concluded that the refusal to grant Magill the licence constituted an abuse of dominance. This decision was appealed to the General Court and then to the Court of Justice[91] which stated:

> "*54 The appellants' refusal to provide basic information by relying on national copyright provisions thus prevented the appearance of a new product, a comprehensive weekly guide to television programmes, which the appellants did not offer and for which there was a potential consumer demand. Such refusal constitutes an abuse under heading (b) of the second paragraph of Article 86 of the Treaty.*
>
> *55 Second, there was no justification for such refusal either in the activity of television broadcasting or in that of publishing television magazines (RTE judgment, paragraph 73, and ITP judgment, paragraph 58).*
>
> *56 Third, and finally, as the Court of First Instance also held, the appellants, by their conduct, reserved to themselves the secondary market of weekly television guides by excluding all competition on that market (see the judgment in Joined Cases 6/73 and 7/73 Commercial Solvents v Commission [1974] ECR 223, paragraph 25) since they denied access to the basic information which is the raw material indispensable for the compilation of such a guide."*[92]

[90] *Magill TV Guide/ITP, BBC and RTE* OJ [1989] L 78/43.
[91] *RTE and ITP v Commission* EU:C:1995:98 C-241/91.
[92] *RTE* (nr91 above) at paragraphs [54] to [56].

This case introduced the concept of compulsory licensing or the refusal thereof as being an abuse under Article 102 of the TFEU. Further, it introduced the concept of 'essential facilities' in so far as the licence could have created a new downstream market.

In the *Microsoft v Commission*[93] case, the General Court acknowledged the possibility if a claim to a licence under Article 102 but in exceptional circumstances as held in *Magill*. This could include a scenario where the licencee intended to produce a new product for which there was consumer demand. In this matter the Commission found that Microsoft was dominant in two different markets – (i) personal computer operating systems and (ii) work group server operating systems.

Microsoft's refusal to give its competitors the requisite interoperability information of its two operating system platforms was deemed to be an abuse of its dominant position by the Commission. The Commission found that without such information, Microsoft's competitors could not develop and distribute product's that would be capable of competing with Microsoft's. The matter was taken on appeal by Microsoft to the General Court in *Microsoft v the Commission*[94] who then succinctly summarized the applicable case law and approach regarding IPRs, licensing and abuse of dominance:

> "*331 It follows from the case-law cited above that the refusal by an undertaking holding a dominant position to licence a third party to use a product covered by an intellectual property right cannot in itself constitute an abuse of a dominant position within the meaning of Article 82 [102] EC. It is only in exceptional circumstances that the exercise of the exclusive right by the owner of the intellectual property right may give rise to such an abuse.*
>
> *332 It also follows from that case-law that the following circumstances, in particular, must be considered to be exceptional:*
>
> > *— in the first place, the refusal relates to a product or service indispensable to the exercise of a particular activity on a neighboring market;*

[93] *Microsoft v Commission* OJ [2007] L 32/23.
[94] *Microsoft v the Commission* EU:T:2007:289 Case T-201/04.

— in the second place, the refusal is of such a kind as to exclude any effective competition on that neighboring market;

— in the third place, the refusal prevents the appearance of a new product for which there is potential consumer demand.

333 Once it is established that such circumstances are present, the refusal by the holder of a dominant position to grant a licence may infringe Article 82 [102] EC unless the refusal is objectively justified.

334 The Court notes that the circumstance that the refusal prevents the appearance of a new product for which there is potential consumer demand is found only in the case-law on the exercise of an intellectual property right."[95]

It is submitted that should an abuse case regarding IPRs or even pharmaceutical patents, the only way that the patent right could be limited by competition abuse provisions is in the same circumstances as described by the *Microsoft* matter. The Tribunal and the CAC would, in a pharmaceutical patent case, have to answer (i) if it was an exceptional circumstance that gave rise to the patent abuse (ii) consider what an exceptional circumstance is (it seems to be a scenario where the refusal to licence would give rise to a secondary/neighboring market); and is the refusal to licence justified (i.e. are their efficiencies, defenses pro-competitive gains by refusing to licence).

[95] *Microsoft* (nr94 above) at paragraphs [331] to [334].

Chapter 6

Interactions between licensing of intellectual property rights and competition policy

I have throughout this paper ascertained that the conferring of an IPR upon the holder does not automatically confer market power on them or establish the ability to exercise market power. This much is confirmed through the jurisprudence and a succinct paragraph from *Antitrust Law, An Economic Perspective* wherein it is written:

> "*a patent is actually a poor proxy for monopoly power, since most patents confer too little monopoly power to be a proper object of antitrust concern. Some patents confer no monopoly power at all. A patent may simply enable a firm to reduce the cost advantage of a competing firm; in such a case the patent might actually reduce the amount of monopoly power in the market*."[96]

However, there are multiple benefits and risks to competition policy through licensing of IPRs, through interactions between the two, some of which we discuss briefly here.

Benefits to competition

1. Maximizing profits

It may seem a bit perverse and at odds with competition policy, but if the IPR holder could perform the ideal price discrimination between its customers, it could theoretically gain the maximum amount of profit out of the innovation. This is because the IPR holder could charge its customers different prices based on the value they place on the innovation, in this way the IPR holder maximizes its profit and its output by perfectly satisfying its consumer demand. This concept is adequately recorded in the report of the Mergers and Monopolies Commission, Indirect Electrostatic Reprographic Equipment:

> "*We do not think that the forms of price discrimination practiced by Rank Xerox, as described above, are or have been against the public interest. If Rank Xerox had charged the same fixed rent to all customers, together with a small variable charge to*

[96] R.A. Posner, *Antitrust Law, An Economic Perspective*, 172 note 3 (1976).

cover the costs of servicing and supplies, the fixed rent would almost certainly have been pitched at a level which would have made Rank Xerox machines too expensive for less intensive users. The spread of the use of plain paper copiers would have been slower and the competitive impact of the technological innovation on the market for copying would have been reduced. Similarly, under a scheme of charging that did not discriminate according to the different uses of a machine but prescribed a uniform charge per copy, users of hired machines would not so effectively have exploited the versatility of the machines as under the system actually used.

The discrimination resulting from the rental system might be objectionable if it served to inhibit competition. The standard rental terms relate to single machines, and we are satisfied that they do not inhibit competition. For example, an efficient competitor producing a machine similar to a Rank Xerox machine could match the company's standard rental scheme even if it produced far fewer machines and a more limited range of models than Rank Xerox. Further there is no evidence that under the Standard Commercial Terms any category of user or of use of rented machines has been unprofitable to Rank Xerox; that is, there is no evidence that any category of user or of use has been subsidised, thereby undermining the competition of other suppliers. We conclude that Rank Xerox's pricing policy, in so far as it relates to individual machines, does not operate against the public interest. This conclusion relates both to the gradation of charges with a monthly copy volume per machine and also to the modal system of charging."[97]

2. Reputation of quality

Licensing agreements may include provisions that ensure that the patent holder can ensure his reputation for quality even though the article in question is being manufactured or produced by a third party. The most effective way to ensure this is for the patent holder to tie in the use of a specific protected product or process that affects essential factors such as the efficiency of the process of manufacture or the product's actual operation.

[97] Mergers and Monopolies Commission, *Indirect Electrostatic Reprographic Equipment* page 97 (1976).

One is to tie the use of a protected product or process to the purchase of some other input affecting the product's operation or the efficiency of the process.

Risks to competition

1. Formation of cartels

Licensing agreements could be detrimental to competition policy in that they could be a vehicle for cartel arrangements. The main concern here is that licensing agreements between competitors or even potential competitors could lessen or prevent competition in that the agreements could lead to the parties fixing prices, limiting outputs and/or dividing markets. Competition authorities and courts should be aware that the market that could possibly be cartelized is not always necessarily the market which is the subject of the licensing agreement.

Further, tie-in agreements may also facilitate cartel activity, even though we described them above as being potentially pro-competitive. This is because the agreements to tie in specific things to the product may be easily used as a method to detect cheating in a cartel arrangement.

2. Exclusionary effects

Finally, it is acknowledged that licensing agreements can operate to exclude other firms from any given market. These problems can arise if there is an exclusivity or "tie-out" arrangement with licensees, that is, that the licensees employ only the licensor's technology, freezing out other potential licensors.

This concern is similar to the concerns raised above in this document, about a licensor gaining a dominant position in the market for a tied good; the possible anticompetitive effect depends upon the conditions of entry in the second market. To the extent that entry there is relatively easy, the licensor will not have gained market power even if he has acquired a large market share.

Conclusion

In conclusion, it is submitted that the State faces an uphill battle in fulfilling its obligations in terms of section 27 of the Constitution. The legislative mechanisms described above are burdensome and time consuming and have very little South African jurisprudence to assist the State in running such matters before the courts or Tribunal and CAC.

It is possible, it would seem, to limit pharmaceutical patent rights using these legislative mechanisms, but it is submitted that the State would only be successful if the courts adopt a more human rights based approach to interpreting these matters, currently it would seem that the courts are reluctant to do so.

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