On 6 December 2012 the European Court of Justice decided the case of *AstraZeneca v Commission*. The ECJ upheld the European Commission’s finding of a novel abuse of dominance - by strategic misuse of regulatory procedures, AstraZeneca impeded the entry by marketers of generic pharmaceutical products into various European markets. The company was found to have made misleading representations to patent regulatory agencies in order to procure unwarranted extensions to existing patents, and to have strategically withdrawn the market authorisations ordinarily relied upon by generic producers to sell their products.

What is novel about this? Abuse of dominance laws are typically applied to what might be described as conduct in the market. What we mean by this is the manner in which the dominant firm provides its goods or services to the market, and engages with its suppliers, customers and competitors. The AstraZeneca case applies abuse of dominance law to ‘non-market’ conduct - in this case conduct in the course of engaging with regulatory authorities. This previously unchartered species of anti-competitive behaviour could be described as a ‘regulatory abuse’.

This case appears, therefore, to have expanded the frontiers of European abuse of dominance law. Its implications may well be profound for the enforcement activities of competition authorities around the world, and the dominant companies whose behaviour they scrutinise. If the principles laid down by the European Commission and relevant courts are capable of adoption in other competition law jurisdictions, the already burdensome duty on dominant companies not to abuse their position will intensify.

In particular, to avoid potential liability under competition law, dominant firms will have to be sure that when obtaining, extending or strengthening intellectual property rights through engagement with the relevant authorities they do not ‘distort genuine competition’, and that their conduct does not diverge from ‘competition on the merits’. The originators of proprietary pharmaceutical products will be on the front line.

In South Africa, the principles set out in the AstraZeneca case may have particularly important application. First, the promotion of generic pharmaceutical products is a key tenet of South Africa’s national healthcare policy to bring affordable access to critical medicines for all South Africans. Second, the country’s patent registration process is based on a ‘depository system’, which means that patent applications are granted without detailed review of their merits. Patents are subject to challenge only after they are granted. This creates ideal conditions for expansive applications for, and extensions by way of modification of patents, which may benefit the applicant (and harm competition) even if the resulting rights are successfully challenged and set aside in due course. The practice of ‘evergreening’ patents over branded pharmaceuticals provides a particularly interesting illustration, which we discuss below.

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2 *AstraZeneca v Commission* European Court of Justice case C-457/10 P.
In this paper we evaluate (a) whether it would be desirable for South African competition law to adopt the principles set out in the AstraZeneca case, and (b) whether South Africa’s abuse of dominance law is sufficiently robust for effective enforcement of these principles.

Section 1 explains the conduct of AstraZeneca that was impugned by the European Commission. This necessarily entails a description of the applicable regulatory rules and procedures that AstraZeneca was alleged to have contorted to its advantage. Section 2 analyses the interpretation applied by the European Commission, and upheld by the General Court and the Court of Justice, which classified the conduct within the scope of the applicable abuse of dominance law. This includes an assessment of the arguments for and against application of competition laws to non-market conduct, and engagement with regulatory agencies in particular. Section 3 gives an overview of South Africa’s intellectual property and pharmaceutical regulatory laws that would apply to conduct akin to that of AstraZeneca. Section 4 explores how that conduct might be classified under South Africa’s abuse of dominance laws. In particular, we assess whether it would be accurate to characterise the conduct as an ‘inducement abuse’ in contravention of section 8(d)(i) of the Competition Act.

Based on this analysis, we draw conclusions on whether there is scope and benefit for South African abuse of dominance law to evolve in line with this ground-breaking European precedent.

SECTION 1 – WHO IS ASTRAZENECA, AND WHAT DID THEY DO WRONG?

AstraZeneca Plc is an international producer of branded pharmaceutical products, which has head offices in the UK. It was created by a merger between Astra AB, a Swedish company, and Zeneca Group Plc, a UK company, which became effective on 6 April 1999.3

The case relates to an AstraZeneca product called Losec. Losec is what would informally be known in the pharmaceutical industry as a ‘blockbuster drug’. Astra AB launched Losec in the late 1980’s4. By the end of 1993 it had become the world’s third largest pharmaceutical, with annual sales worth approximately US$ 1.7 billion5. Sales of Losec earned US$ 4.8 billion in 1998, US$ 5.9 billion in 1999 and US$ 6.3 billion in 2000. This made Losec the most successful prescription medicine of all time6. It is therefore uncontroversial to state that Losec was an extremely lucrative product for its owner, AstraZeneca.

For purposes of our analysis it is not necessary to submerge in the rabbit-warren of details surrounding the medical conditions treated with Losec, its clinical attributes, and alternative products that can also treat the relevant ailments. This is set out primarily in paragraphs 31 to 111 of the European Commission’s decision. The essential points are:

- Losec is an anti-stomach-ulcer medicine.
- At the time of its launch, Losec was primarily sold in capsule format.
- The active ingredient in Losec is called omeprazole.

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Omeprazole reduces the production of the acid in people’s stomachs, which causes ulcers.

At the relevant time there were alternative medicines, but omeprazole-based products were the most effective way to treat stomach ulcers and related conditions. This is, of course, the version of the European Commission. AstraZeneca vigorously but unsuccessfully disputed this view before the European Courts during the course of defining the market relevant to assessing AstraZeneca’s dominance.

It is AstraZeneca’s patent over omeprazole that protected Losec’s exclusive market position, and enabled its enviable success. AstraZeneca’s conduct in relation to this patent is the focus of the European Commission’s enforcement action, which we describe below.

In order to meaningfully summarise the essence of AstraZeneca’s conduct that was impugned by the European Commission, it is necessary to first explain the process that the originator of a branded, or ethical original pharmaceutical product had to follow to bring that product to market, and the procedures for doing so in Europe. We have summarised the process under the rules as they stood at the time of the conduct, based on the European Commission’s comprehensive description.

**Introducing and marketing a proprietary pharmaceutical product in Europe**

Before a company launches a proprietary pharmaceutical product, it needs three things: (1) **valid patents**, which provide legal protection from therapeutically equivalent generic products (which are based upon the original compound) being sold in the relevant market, (2) **market authorisations** to sell the product, and (3) in countries where medicine prices are regulated, **approval of the regulated price** at which the product is to be sold.

**Patents**

Patents are typically sought and obtained over a number of aspects of the medicine at an early stage of its development. The most important patent generally relates to the product’s active ingredient. In the AstraZeneca case, the patented active ingredient is omeprazole. This is the chemical compound that is biologically active, and gives the product its main therapeutic capability.

Marketers of branded pharmaceutical products will typically also obtain patents over the product’s formulation – the format in which it is sold and ingested, such as capsules or tablets. AstraZeneca’s Losec product was first introduced into the market primarily under protection of a patent over its capsule formulation. Patents over formulations of a product confer relatively weak protection because, if it is not patented, the active ingredient may be incorporated into a different formulation and sold in the market.

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7 An ethical original product is one which gives rise to new chemical or organic compounds from original research and development. Ethical or original products are usually sold and marketed under a brand name and are therefore sometimes referred to as branded ethical products or as the original or branded ethical product.

8 World Health Organisation Technical Report Series, No. 961, Annex 10, Procedure for prequalification of pharmaceutical products (definition of an “active pharmaceutical ingredient (API): a substance used in a finished pharmaceutical product (FPP), intended to furnish pharmacological activity or to otherwise have direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease, or to have direct effect in restoring, correcting or modifying physiological functions in human beings.”).
In Europe, patents can be obtained in two ways. First, the company can apply to the European Patent Office. This results in a bundle of patents covering each country specified in the application. Second, the company can apply individually to the national patent offices in each country where it wishes to sell the product.

Patents are valid for 20 years from the date they are filed. This period was determined by balancing the degree of protection necessary to incentivise innovation and development of new products, with the benefits to consumers of exposing new products to competition.

**Market authorisations**

A market authorisation is effectively a certificate which grants the holder permission to sell the pharmaceutical product subject to certain restrictions and responsibilities. Market authorisations are obtained by satisfying the relevant health authorities of a pharmaceutical product’s clinical characteristics, such as its safety, efficacy and quality, in the treatment of disease in the interest of protecting public health.

In each EC member state, applicants for market authorisations are typically required to submit a range of documents, including results of pharmacological and toxicological tests, and clinical trials. A granted market authorisation recognises the product’s qualitative and quantitative composition, pharmacological properties, as well as its pharmaceutical form and strength.\(^9\)

The successful applicant is allowed to market the product for as long as the market authorisation remains in force. However, its exclusivity over the right to market the product is, of course, dependant on the validity of the applicable patents.

European law affords generic manufacturers a simplified procedure for obtaining market authorisation.\(^10\) They are allowed to rely in some respects on information submitted by the ‘original’ applicant in relation to a proprietary product.\(^11\) In particular, the requirements to submit a number of test results are waived.

Therefore, in the absence of an operative market authorisation for the original product, the process of obtaining the requisite permission to sell generic products becomes more expensive, time-consuming and complex. A generic producer must conduct its own extensive testing process and submit sufficient results with its application for a market authorisation.

Either the national medicinal authorities or the European Commission, based on opinions by the European Medicines Evaluation Agency, are responsible for granting market authorisations.\(^12\) There are three steps in the grant of a marketing authorisation – **first**, a technical authorisation is issued by the relevant authority, **second**, the applicant is notified, and **third**, the authorisation is published in the country’s official journal or gazette.\(^13\)

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\(^11\) Point 8(a)(ii) of the third paragraph of Article 4 of Directive 65/65/EEC.
\(^12\) Commission Decision C(2005) 1757 at paragraph 7.
Pricing approval

After a market authorisation has been obtained for the product, the final step is to obtain approval of the price at which the product is to be sold. The methods for regulating medicine prices vary between European countries, and so do the processes for obtaining approval of the applicable price. Generally, however, the approval takes place in three steps – first the relevant authority approves the regulated price, second, the company is notified of the approved price, and third, the price is published in the country’s official journal or gazette.14

Applications for pricing approval are made to the relevant national medicines regulator. Usually, firms will begin the pricing approval application process before the market authorisation has been obtained, but the approval is only granted after the market authorisation.15

Extending the exclusivity – Supplementary Protection Certificates

Pharmaceutical companies often obtain their patent some time before they are granted the market authorisation required to sell the product. This gives rise to a common problem. The ‘down time’ between when the patent is issued and when the firm begins to sell the product prevents the holder from exploiting the exclusive right for the full period of protection.

To address this situation, European law provides for something called a ‘supplementary protection certificate’ or SPC. SPC’s are granted upon application, and come into effect at expiry of the patent. Their effect is akin to extending the life of the patent over the active ingredient.16

The availability and duration of an SPC differs case by case. The patent holder is only entitled to an SPC if more than five years have passed between the date of filing the patent, and the date on which the first marketing authorisation was issued in the EEA. If an SPC is available, its duration will be determined by the time that has lapsed between filing the patent and obtaining the first market authorisation in the EEA. The later the date of the market authorisation, the more likely it is that an SPC will be available, and the longer the duration of the SPC will be.

In Europe, SPC’s are granted by national patent offices. There is no centralised Community-wide application process. There is limited discretion applied by the issuing authorities in granting SPC’s. The practice of the national patent offices is generally to rely, without verification, on the information submitted by the applicants including the dates of the relevant patent and market authorisation. Then, only after they are granted, the SPC becomes liable to potential challenge by third parties.17

Critically, the application for an SPC is supposed to reflect the date that the technical authorisation was issued by the relevant health authority (the first stage of the market authorisation process described above)18 – not the date of notification to the applicant, or publication, and not the date of pricing approval.19

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15 European Commission, DG Competition, 2009, ‘Pharmaceutical Sector Inquiry’, final report at page 118. Note that in France, Italy, the Netherlands and Sweden pharmaceutical companies may submit a pricing and reimbursement dossier before the marketing authorisation is officially granted. In these countries, the only condition is a positive CHMP (Committee for Human Medicinal Products at the EMEA) opinion.
19 It is also important that an SPC is only available if the first market authorisation in the EEA was obtained after 1 January 1985. The two exceptions to this are that the authorities in Denmark and Germany can only grant the SPC if the first market authorisation was issued after 1
The regulatory process that must be followed before launching a proprietary medicine in Europe may therefore be illustrated as follows:

Against this background, we proceed to summarise the activities of AstraZeneca that caused this dispute. The European Commission identified two related but distinct abuses. The first abuse comprised AstraZeneca misleading the relevant national patent authorities to obtain SPC’s to which it was not entitled, or to which it should only have been entitled to for a shorter duration. The second abuse involved a strategic withdrawal of the market authorisation for the capsule formulation of omeprazole, in order to disrupt the preparations of generic manufacturers who wished to introduce therapeutic equivalents of Losec immediately upon expiry of AstraZeneca’s SPC.

January 1988, and the authorities in Belgium and Italy can only grant the SPC if the first market authorisation was issued after 1 January 1982Commission Decision C(2005) 1757 at paragraph 156 and 157.
The First Abuse: Misleading to obtain SPC’s

The most effective way to simplify the cumbersome factual matrix that gave rise to the first abuse is to describe each stage of the conduct in line with the explanation above of the process for introducing and marketing a pharmaceutical product in Europe – (1) file patents, (2) obtain a market authorisation, (3) get pricing approval, and then (4) procure an SPC if available.

AstraZeneca’s patents

AstraZeneca filed applications for patents over omeprazole on 3 April 1979, 10 April 1979, 11 April 1979, 12 April 1979 and 8 August 1979. These were granted, and therefore valid for 20 years from the date of filing – until April 1999. AstraZeneca subsequently obtained patent protection over the capsule formulation of omeprazole, which was valid until April 2007.

AstraZeneca’s market authorisations

The first market authorisation obtained by AstraZeneca in the EEA was in France. As mentioned above, the most important date related to the grant of the market authorisation is the so-called ‘technical authorisation’, which was on 15 April 1987.

AstraZeneca’s SPC applications

AstraZeneca’s SPC applications were the focal point of the first abuse. The correct date for calculating AstraZeneca’s entitlement to potential SPC’s in EEA countries, and the duration of those SPC’s was the date of the first technical authorisation for Losec in the EEA - 15 April 1987.

However, when making its SPC applications, AstraZeneca instructed its patent agents to record the date of the first market authorisation in the applications as being 21 March 1988. This was the date that the authorisation was published. The AstraZeneca internal documents obtained by the European Commission apparently demonstrated that AstraZeneca:

- Knew that the correct date should have been 15 April 1987.
- Realised that this would mean that SPC’s extending patent protection until April 2002, would only be obtainable in Belgium, the UK, Ireland, Luxembourg and the Netherlands.

20 To the European Patent Office, for protection in Belgium, Luxembourg, the Netherlands, Switzerland, Germany, France, the UK, Italy and Sweden.
21 In Norway.
22 In Denmark.
23 In Finland and Austria.
24 In Ireland.
Deliberately included later dates in its SPC applications, in order to obtain SPC’s to which it was not entitled in Germany and Denmark and extend the period of the SPC’s obtained in Belgium, the UK, Ireland, Luxembourg and the Netherlands.  

Minutes of the particular internal meetings suggest that this was done in order to maintain consistency. Other company documents indicated that AstraZeneca believed that the product could not be sold until pricing approval had been obtained, and that this is therefore (in AstraZeneca’s own view) a more fair and appropriate date for determining the duration of an SPC.

AstraZeneca’s SPC application in Luxembourg, for example, was submitted to the national patent office by a French and a Luxembourg patent agent. AstraZeneca indicated to the French patent agent that in its opinion the date of publication - 21 March 1988 - should be used. AstraZeneca further indicated that they were “of the opinion that no further argumentation is required at this stage.”

The French patent agent then conveyed the instructions to the Luxembourg patent agent, adding that “although this position is debatable we ask you to comply with these instructions.” He also contacted AstraZeneca to enquire whether he should follow the same approach in respect of all applications which he was instructed to file on behalf of AstraZeneca. AstraZeneca indicated that its instruction, to use the date of 21 March 1988, was only applicable in respect of the applications made for omeprazole and omeprazole sodium.

In the European Commission’s view, this showed that AstraZeneca did not actually believe that the later date was the correct date to use in its SPC application. By using the later date of publication as the decisive date, only for the omeprazole applications and not for the other SPC applications made on its behalf, AstraZeneca displayed a clear and calculated intention to deliberately mislead the authorities and obtain unjustified extension to its patents.

The effect was that SPC’s were obtained in three countries where no such entitlement would have arisen if the true dates had been submitted, and in four countries patent protection was unlawfully obtained for seven months to one year longer than would have been allowable if the true dates had been used.

**The second abuse - Strategic withdrawal of market authorisations**

Patents and market authorisations are public. This enables generic producers to anticipate the expiry of a patent, and begin preparing the launch of therapeutically equivalent products.

As mentioned above, generics companies typically rely on information in the existing marketing authorisation over the original product in their own applications. A generic manufacturer may, however, only take advantage of this simplified procedure if the generic version is “essentially

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34 Commission Decision C(2005) 1757 at paragraph 204.
"similar" to the reference product. This means marketing the formulation specified in the market authorisation of the original product.

As the expiry of its SPC’s approached, AstraZeneca conceived one final strategy to prolong the entry of generic producers of omeprazole-based products. AstraZeneca decided to deregister the market authorisation for Losec capsules and simultaneously launch a tablet version of Losec, called Losec MUPS (“Multi-Unit Pellet System”).

The effect of this would be that:

- Generics companies that had already prepared launch plans, marketing strategies and market authorisation applications based on the capsule formulation of Losec would have to substantially delay their product launches to make provision for a different (tablet) formulation.

- Alternatively, if generics companies wished to proceed with launching omeprazole products in an “original” capsule formulation, they would have to include more data and documents in their applications for market authorisation.

According to one AstraZeneca internal document, the withdrawal of Losec capsules and simultaneous launch of Losec MUPS would “serve the primary purpose of [inter alia] putting more resource and time pressure on companies developing omeprazole copies/generics.”

Another internal memorandum contextualised the conduct as part of a strategy intended to “delay generic introduction through technical and legal hurdles” because “[e]very day of protected sales of Losec is worthwhile considering the huge sales volume projected at patent expiry”.

The European Commission interpreted this strategy as a deliberate distortion of genuine competition, and inconsistent with normal methods of competition or ‘competition on the merits’. It imposed a fine of EUR 60 million. The General Court and the Court of Justice agreed, although the fine on AstraZeneca was reduced to EUR 52.5 million by the General Court.

SECTION 2 – APPLYING ABUSE OF DOMINANCE RULES TO NON-MARKET CONDUCT

From the description above, it should be clear that based on the European Commission’s version of the facts, AstraZeneca’s conduct was (1) deliberate (2) misleading and (3) probably foreclosed competition. The question is – was it appropriate to classify this behaviour as an abuse of dominance under competition law?

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41 Commission Decision C(2005) 1757 at paragraph 293.
44 An evaluation of the dominance and market definition analyses conducted by the European authorities is beyond the scope of this paper. We have also not delved in detail into the arguments whether AstraZeneca’s conduct constitutes ‘normal methods of competition’ or ‘competition on the merits’. Our focus is on whether competition law should apply to this type of conduct in the first place, rather than whether in such application, a contravention is established.
The nature of the two abuses differs materially. Therefore, to answer this question, we need to look at each separately – the first ‘misleading abuse’, and then the second ‘withdrawing abuse’.

**The first abuse - Misleading patent agencies to obtain undue SPC’s**

AstraZeneca’s fundamental argument as to why it was inappropriate to apply competition law to the ‘misleading abuse’ is that the laws that set out the requirements for a valid application for and grant of an SPC are sufficient. These rules comprise self-standing frameworks in support of each member state’s policy towards promoting innovation and competition. AstraZeneca argued that the authorities endowed with jurisdiction to enforce these laws, should have exclusive competence to do so. In other words, if a company makes an SPC application that includes false or misleading information, the relevant authorities and not competition law enforcers should ensure that:

- the application is either not accepted or is refused, or
- the information in the application is corrected before it is decided upon, and
- appropriate measures are taken to punish the applicant if appropriate.

If the applicable laws do not adequately provide for these solutions, it does not mean that competition laws should apply. Rather, the deficient laws should be changed. In the European context, enforcement proceedings should be brought by the European Commission against the members states concerned, for failure to give effect to the relevant European legal instruments. Similarly, if the relevant regulatory authorities are not equipped to effectively enforce the laws, then they, rather than the non-compliant applicant, are at fault.

The European Commission’s response to this is both creative and convincing. Competition law is designed to prevent conduct that has an anti-competitive effect. Therefore, even if there are other laws in place that may remediate a particular aspect of the unlawful conduct, provided the activity causes (or is likely to cause) anti-competitive effects, it may give rise to liability under competition law, too. Paragraph 744 of the European Commission’s decision says:

*The fact that other laws and remedies prohibit misleading representations or provide for remedies against them is irrelevant where the objective competition enforcement is not to penalise such misconduct per se, but rather to prevent the anti-competitive effects of such misconduct in the market place.*

This line of reasoning provides strong support for the European Commission’s novel intervention in this case. As we explained in the introduction, competition laws have, until this case, applied to ‘market conduct’, as opposed to regulatory engagements. The argument set out above effectively means that the source of the conduct (engagement with other market actors, or engagement with regulators) is irrelevant – the role of competition law in this world is to deal with the conduct’s **effect in the market**.

Therefore, while other laws may prohibit the very same conduct that causes the anti-competitive effects, this should not exclude the application of competition law, which prohibits any conduct that may distort competition.
It also turns out that, in Europe there is no effective provision for imposing a penalty upon a firm that obtains undue patent protection through misleading the regulator.45 Therefore, the application of Article 102 TFEU to the conduct, along with its corresponding penalty provisions, was important to ensure an adequate deterrence.

**The second abuse – Strategically withdrawing market authorisations**

The central objection raised by AstraZeneca to the application of competition law in relation to the ‘withdrawal abuse’, was that there was no legal obligation for it to retain its market authorisation. Indeed, to have done so in the interests of assisting its potential competitors to piggy-back on its investment and innovation would not have made business sense.46 If there is no legal duty to keep the capsule market authorisation in place, then how could it possibly be an offence to withdraw it?

In AstraZeneca’s view, the application of competition law to this conduct is therefore entirely misplaced. The only time that a competition law duty could be imposed on a dominant firm to assist its potential rivals like this would be if the market authorisation constituted an essential facility, and AstraZeneca’s withdrawal of it was found to be some sort of indirect refusal to supply or provide access. AstraZeneca argues that an essential facilities case has obviously not been properly brought, and that the European Commission’s case on the second abuse is therefore unsustainable.47

The European Commission’s response to this argument too, is clear and persuasive. The fact that AstraZeneca’s conduct was compliant with the applicable laws is irrelevant. It is commonplace for competition law to apply to conduct which would be considered perfectly legal under other laws. The charging of a predatory price, for example, would be a legal, legitimate business practice if it were not for competition law. Like with the first abuse, the legality or otherwise of the conduct under other laws should not be determinative of whether it may be subjected to examination under competition law.48

On this basis, it would appear to us that there are sound theoretical reasons for applying competition law to conduct like AstraZeneca’s. The scene is therefore set to commence an analysis of the South African position. The first step is to set out the equivalent patent and pharmaceutical regulatory laws. The purpose of this is to understand what equivalent conduct, if implemented in South Africa, could potentially attract competition law scrutiny.

**SECTION 3 – SOUTH AFRICA’S IP AND PHARMACEUTICAL REGULATORY LAWS**

The South African system for protection of innovative medicines and exploitation by licensing of those medicines under the control of the national health authority is substantially similar to that adopted in Europe. Patent registrations over product compounds and formulations protect innovation for monopoly periods, while the health regulator authorises sale and exploitation of safe quality medicines. Policy review of these legislative and regulatory regimes sometimes

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46 Opinion of Advocate General Mazák delivered on 15 May 2012 at paragraph 74.
promises slow relief against the persistent demand to allow greater and more speedy access to affordable medicines in a developing country.

**Patent protection**

The South African Patent Act\(^49\) is a key component, and features prominently in the perennial debate and tension between competing policy goals providing protection to and reward for innovation in medicines on the one hand, and providing access to affordable medicines for all South Africans on the other.\(^50\)

At an early stage of research and development and when original pharmaceutical research companies file applications for patent protection in the European Union, simultaneous filings are often made in South Africa. This application is usually made well in advance of any request for authorisation to market the end medicine. South Africa, along with more than 145 others, is a signatory to the international Patent Co-operation Treaty which allows an applicant, when filing an application in one signatory state, to designate any other co-signatory state as a territory in which it seeks patent protection. This facilitates procedures for establishing a system of protection of innovation across a broad range of states.

The Patent Act allows for application to be made and letters of patent to be issued with only minimal consideration by the authority of the validity of the claims made. South Africa follows a so-called ‘depository system’, which provides for limited examination of applications. Examination is restricted to compliance with the procedural aspects of the Patents Act.

The validity of the patent (and protection granted under it) may not be opposed at the time of the application. Only once the patent has been granted any person may challenge the validity of the essential claims of novelty or inventiveness. Any challenge would have to be made by way of application for revocation of a patent before the Commissioner of Patents. An application for an interdict is not easily granted given firstly that the balance of convenience would usually weigh in favour of the patent holder, and secondly that the dispute is likely to be evidence-based and require a significant amount of technical knowledge and skill\(^51\). The holder of a disputed patent is, therefore, almost always guaranteed a few extra years of protection.

In respect of medicines, the usual application and grant of patents is protection over product invention, being the chemical compound containing the essential therapeutic Active Pharmaceutical Ingredient (API). However patents may also be sought and granted in respect of the process of manufacture or method by which the API works in the human body.

Generally in South Africa, patents may be granted within 12-18 months of a complete application. However, once granted, the life of a patent is a long 20 years, a period believed to adequately allow, incentivise and reward the exploitation of the monopoly protection granted, but not unduly exclude competition.

Unlike in Europe, there is no provision for extension of the life of the original patent by a supplementary protection certificate as discussed above.

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\(^{49}\) Act 57 of 1978.

\(^{50}\) See the policy arguments outlined in National Association of Pharmaceutical Wholesalers & Others v Glaxo Wellcome (Pty) Ltd & Others, 68/IR/Jun00 at paragraph 100 to 102; Section 4.2 of the National Drug Policy for South Africa; and Treatment Action Campaign and Doctors Without Borders, Memorandum ‘DTI must urgently “Fix the Patent Laws” to improve South Africans’ access to medicines’, dated 7 August 2013.

Marketing authorisation

Control over registration, marketing, distribution and pricing of medicines in South Africa is governed by the Medicines and Related Substances Control Act (Act)\(^{52}\). No medicine\(^{53}\) may be sold in South Africa unless registered\(^54\).

Application for registration of a medicine under the Act is not dependent upon the applicant holding existing patent protection. The test is a different one, essentially requiring the applicant for the licence to demonstrate it meets the technical requirements of quality, safety and efficacy of the product for the purpose which it is intended. Any patent over the API, formulation or process protects copying of the application and exploitation by third parties.

Regulation 22 issued under the provisions of the Act sets out the basic requirement for application for registration of a medicine.

When applying for registration of so-called original or new chemical entity applications, evidence in support of the efficacy of the medicine must be provided by pre-clinical and clinical evidence or information.

However, when applying for registration of a generic or multi-source product, proof of efficacy may be derived from the test of bio-equivalence. Simply put, a generic is regarded as being bio-equivalent (or bio-similar) to the original medicine if the extent of absorption and rate of absorption of the API after the medicine is administered does not show significant differences from the original.

So for registration of a generic by the Medicines Control Council, the applicant must carry out bio-equivalent testing to show that the amount of the API absorbed of the generic is the same as the amount absorbed of the original.

Pre-clinical and clinical testing is not required for marketing authorisation of generics and they can be registered and thus marketed as soon as protection of the API of the original product expires. Under the provisions of section 69A of the Patents Act, an application for marketing authorisation which uses or refers to the original patented application dossier will not infringe that patent, but an infringement will occur if it commences with the marketing of a generic based upon the original while the patent is still valid.\(^{55}\) Thus, obviously, if the patent life is extended or a new protection granted over what is in essence the same product, this will result in delay in access to the generic, cheaper and bio-equivalent product.

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\(^{52}\) Act 101 of 1965, as amended.

\(^{53}\) Medicine is defined in the Act to mean "any substance or mixture of substances used or purporting to be suitable for use or manufactured or sold for use in—(a) the diagnosis, treatment, mitigation, modification or prevention of disease, abnormal physical or mental state or the symptoms thereof in man; or (b) restoring, correcting or modifying any somatic or psychic or organic function in man, and includes any veterinary medicine".

\(^{54}\) Section 14(1) of the Act.

\(^{55}\) Section 69A(1) provides: Acts of non-infringement— It shall not be an act of infringement of a patent to make, use, exercise, offer to dispose of, dispose of or import the patented invention on a non-commercial scale and solely for the purposes reasonably related to the obtaining, development and submission of information required under any law that regulates the manufacture, production, distribution, use or sale of any product.
Single Exit Pricing

The South African pharmaceutical industry underwent fundamental change in 2005 – a number of pricing regulations were introduced by amendment\textsuperscript{56} to the Act. The amendment prescribed a Single Exit Price (SEP) regime, which stipulates that a medicine may only be sold at a single approved price throughout the supply chain. This substantially removes product pricing as a component in competition between pharmaceuticals.

Following the introduction of the SEP, manufacturers and importers of medicines are required to submit for approval an all-inclusive price at which the products will be sold, throughout the chain, including at retail level. Pharmacists are not permitted to mark up prices, but are limited to prescribed service charges. Increases are strictly regulated and infrequent and moreover, there are further proposed limitations on the components of the price – namely the costs of logistics of warehousing and delivery. Current proposed regulation will extend the price regulation further requiring manufacturers and importers to price against international benchmarks to ensure price similarity with prices in 'equivalent' jurisdictions of Australia, Canada, New Zealand and Spain.\textsuperscript{57}

The regulatory requirements that must be complied with in introducing and marketing a proprietary medicine in South Africa can therefore be summarised as follows:

\textsuperscript{56} See the Medicines and Related Substances Control Amendment Act 90 of 1997.
\textsuperscript{57} Government Gazette 33878 dated 17 December 2010.
Extending the life of an expiring monopoly

What the so-called 'evergreening' process allows is patent protection from competition against generics, sometimes based upon frivolous or limited variation of the original patent right.

Given the current examination and registration process of patents in South Africa, there is nothing to prevent an existing holder from filing an additional or 'secondary' patent during the term of an original patent protection, which may protect a minor modification of the product itself, alternatively a modification of formulation or process of manufacture, but in so doing extend the life of the original patent by a further 20 years.

Earlier this year and following a seven year legal dispute, the Indian Supreme Court ruled\textsuperscript{58} that Novartis could not secure patent protection for its cancer medicine, Glivec, which enjoys existing patent protection in other countries, including South Africa.

As in other countries, it is understood that the Novartis product patent for Glivec in South Africa was due to expire in May 2013, but Novartis applied for and was granted a patent over a variant of the product, extending the life of the protection by another 20 years.

The main reasoning for the refusal by the courts to recognise the application was that Indian patent law will recognise and protect only those compounds which are truly new and innovative, demonstrating improved efficiency for patients and the Novartis application did not meet this standard. The law and its interpretation by the court was directly aimed at avoiding applications for evergreening of expiring patents.

The South African Department of Trade and Industry has recently proposed a long awaited reform of its patent law (note that this reform is of general application and not only applicable to medicines). The Department's Director of Intellectual Property has indicated that the proposed new bill will introduce a pre-examination system which is aimed at curtailing and preventing protection by patent, of products or inventions which are mere adaptation of the original and do not meet the standard requirements of novelty or inventiveness. This proposed innovation of a pre-grant patent examination system is in fact already permitted under section 34 of the existing Patents Act – more specific and detailed criteria and more strict patentability criteria are likely to be prescribed.

The proposed policy will be out for public comment shortly, however commentators are far from hopeful that the proposed new law will have a significant or prompt effect. It is suggested firstly that due to the delayed legislative process (and there may be further delays through the 2014 general election) the bill is unlikely to be debated before Parliament until at least 2015. Its path thereafter is also expected to be delayed. Secondly, it has been questioned whether the office will have the appropriate skills and resources to properly carry out the required examination of the technical patents. This possible difficulty may impede the grant of legitimate protection for all patent applications, throwing the baby out with the bathwater.

Other potential regulatory relief – access to affordable medicine

It should also be noted that the South African legislature already makes some provision for methods of increasing access to more affordable medicines for South Africans.

\textsuperscript{58} Novartis AG v Union of India and Others, Supreme Court of India Appeal case no. 2706 - 2716 of 2013.
So-called **generic substitution** is provided for under section 22F of the Act. In short, where a generic alternative to an original medicine is available, the pharmacist must supply that generic, unless the health care practitioner has expressly stipulated there shall be no such substitution or the patient requires the original to be supplied.

Another significant legislative intervention came about in section 15C of the Act, which introduced the right to sell parallel imports of bioequivalent products, which may be viewed to be of significant importance in treatment of the public in certain circumstances.

The effect of this is to allow competition in these products (and potentially greater access at more affordable pricing), despite the protection offered under the Patents Act to a holder of the marketing authorisation or licence.

**Importance of access to IP emphasized**

Apart from the critical and well documented need to grant access to protected IP in health circumstances as early as possible, especially in poor and developing countries, in a highly regulated environment where competitors are not easily able to actively compete by selling differentiated products or upon traditional grounds of price, access to the base IP in medicines becomes one of the few remaining critical areas of competition. Refusal to deal or refusal to grant access upon unmeritorious grounds (but relying upon dubious statutory protections) may well be considered potential for considerations of abuse.

**How could a South African firm implement an equivalent strategy to that used by AstraZeneca?**

Although SPC’s are not available under South Africa’s patent laws, the protection against competition from generics lies in a potential infringement action by the holder of the patent rights over the original medicine. If the patent was varied, for instance by a patent of addition (which varies the underlying patent right, but not the term) or if a new patent was granted in respect of a variation of compound, or formulation, but which was based upon the original (thus ‘evergreening’ the patent protection), this would effectively allow for a similar type of abuse to AstraZeneca’s first abuse. The holder of a marketing authorisation which was based upon expiry of the original patent would run the risk of infringement proceedings and contest of the validity of the new patent or patent in addition.

The second form of abuse would require a holder of a marketing authorisation to seek a strategic amendment to the provisions of the authorisation on the basis that the underlying API compound or formulation had changed, and thus any generic application which relies on the original dossier would also be required to open to scrutiny based upon efficacy, quality or safety grounds. This appears to be a more unlikely course of conduct than the first, ‘misleading abuse’.

On the basis of the descriptions in Section 3 above, our view is that:

- Access to generic versions of medicines is important in a developing country like South Africa.⁵⁹

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⁵⁹ See the Department of Health's Standard Treatment Guidelines and Essential Medicines list 2012.
– High costs in the private healthcare sector have been identified as a particular concern of the Commission.  

– There is significant scope for spurious applications for undue legal protection, making the potential for conduct akin to AstraZeneca’s a strong possibility in South Africa.

Therefore, it would be desirable for competition law intervention to restrain potential abusive behaviour by dominant firms in their engagements with patent and pharmaceutical regulators in South Africa.

SECTION 4 – APPLYING SOUTH AFRICAN ABUSE OF DOMINANCE LAWS TO ‘REGULATORY ENGAGEMENTS’

Section 3 has explained the desirability of adopting the central principle of the AstraZeneca case into South African competition law. This standpoint should not be surprising, given the severity of the potential harm to competition and consumers arising from this kind of behaviour. The European General Court expressed this point clearly:

In so far as it consisted in misleading representations made deliberately in order to obtain exclusive rights to which [AstraZeneca] was not entitled or to which it was entitled for a shorter period, the first abuse of a dominant position quite clearly constitutes a serious infringement.  

The European Court of Justice, in dismissing AstraZeneca’s appeal, held that AstraZeneca’s approach:

...is manifestly not consistent with competition on the merits and the specific responsibility on such an undertaking not to prejudice, by its conduct, effective and undistorted competition within the European Union.

The fundamental question is, could our Competition Act effectively prohibit such conduct like this? We have tried to answer this question below. We first summarise South Africa’s exclusionary abuse of dominance laws, and then examine viability of the potential enforcement avenues.

South Africa’s exclusionary abuse of dominance provisions

The central provisions prohibiting exclusionary abuse of dominance are sections 8(c) and (d) of the Competition Act. These set out the instances where a firm will be considered to abuse its dominance by committing an ‘exclusionary act’.

A. Section 8(c) – general exclusionary acts

Section 8(c) is a catch-all which ensures that potentially harmful conduct that falls outside section 8(d)’s more focused scope does not escape scrutiny. It prohibits any ‘exclusionary act’ that:

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60 See the Draft terms of the Competition Commission’s Market Inquiry into the Private Healthcare Sector.
61 General Court case T-321/05 [2010] 5 CMLR 1585 at paragraph 901.
62 AstraZeneca (supra) at paragraph 98.
– Is not listed in section 8(d), and

– Has an anti-competitive effect that is not outweighed by the act’s technological, efficiency or other pro-competitive gains.

An ‘exclusionary act’ is defined as ‘an act that impedes or prevents a firm entering into, or expanding within, a market’.63 This broad definition catches both pro-competitive and anti-competitive conduct within its ambit.64 This explains the need to balance the harmful effects of the conduct against its pro-competitive gains to determine legality.65 The onus to establish that the anti-competitive effects of the conduct outweigh any justifications put forward by the dominant firm lies with the complainant66 or the Competition Commission.67

Conduct that is similar to the acts listed in section 8(d), but does not meet the descriptions set out in that section will often fall to be assessed under section 8(c).68 Rather than constituting self-standing actions, allegations of contraventions of section 8(c) are therefore typically alleged in the alternative. Stipulated conduct prohibited by other sections usually forms the focus of the case.

B. Section 8(d) – specific exclusionary acts

Section 8(d) prohibits a number of specific exclusionary acts if they cannot be justified by countervailing pro-competitive effects.69 These are said to reflect the exclusionary strategies which international experience has shown to be most common,70 and incorporate tests based on ‘international best practice’ in dealing with these strategies.71 The following acts are prohibited by section 8(d) if they cannot be justified72:

(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

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63 Section 1(1)(x).
64 Commission v South African Airways case 18/CR/Mar01 at paragraph 108.
66 A complaint may be initiated by the Competition Commission or a third party. The Commission must then, following investigation, decide whether to refer the complaint to the Competition Tribunal for adjudication. If the Commission decides that a third-party-initiated complaint does not make out a contravention of the Act, the complainant may refer the complaint to the Tribunal for adjudication – effectively a private prosecution.
69 Section 8(d).
72 Section 8(d).
(v) buying-up a scarce supply of intermediate goods or resources required by a competitor.

At first blush, it would appear that once a dominant firm’s conduct has been found to accord with these definitions, a presumption of anti-competitive effects arises. However, in the South African Airways case the Competition Tribunal held that the complainant or Commission must also show that the conduct had an anti-competitive effect.\(^{73}\) Only then will the onus shift to the dominant firm to adduce evidence of efficiencies. This case therefore places ‘effects’ at the centre of the analysis.\(^{74}\)

Perhaps a useful analogy may therefore be that the specific acts mentioned in subsections (i) to (v) must be proved as a gateway requirement, in order to progress to an analysis of the conduct’s effects. The girth of this gateway depends on the construction of the particular rule in question.

C. Crucial shortcoming in section 8(c)

One difference between sections 8(c) and 8(d) is critical. Both prohibit ‘exclusionary acts’. However, contraventions of section 8(d) may result in an administrative penalty of up to 10% of the firm’s turnover for the previous financial year.\(^ {75}\) By contrast, a first offence under section 8(c) does not carry an administrative penalty.\(^ {76}\) It is submitted that section 8(c) therefore suffers from an insurmountable practical problem. Once a firm’s conduct has been found to contravene section 8(c), only that firm is deterred from replicating that conduct. If another dominant firm was to imitate the exclusionary strategy, after a complex investigation and protracted adjudication proceedings (possibly involving a number of appeals) the most likely remedy would be an order that the firm simply cease the impugned behaviour.\(^ {77}\)

In addition, there is little unanimity between the Tribunal, Competition Appeal Court, Supreme Court of Appeal and Constitutional Court regarding how the section should be interpreted. This can be exploited by respondent firms in order to obfuscate enforcement proceedings.\(^ {78}\)

As a result, section 8(c) has a weak deterrent value, and is therefore itself prone to under-inclusion. As Roberts eloquently puts it:

> The construction of the... Act to specify certain conduct under 8(d) and provide a 'catch-all' effects-based test under 8(c), instead appears to have had a 'catch-none' outcome.\(^ {79}\)

For example, after eight years since initiation of the complaint against Senwes, a dominant supplier of grain storage facilities, the Constitutional Court upheld the Tribunal’s finding that margin squeeze by Senwes contravened section 8(c).\(^ {80}\) If Senwes was to continue or repeat this behaviour, it could be liable for an administrative penalty. However, if any other firm were to

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\(^{73}\) South African Airways (supra), paragraphs 110-111 and 132. The rationale for this interpretation, as set out in paragraph 110 of the tribunal’s decision, is that by allowing for a weighing of technological, efficiency or pro-competitive benefits, the legislature must have contemplated that an anti-competitive effect must first be established, else how could a proper balancing exercise be conducted?

\(^{74}\) Roberts (2012) at page 297.

\(^{75}\) Section 59(1)(a).

\(^{76}\) Section 59(1)(b).


\(^{78}\) Roberts (2012) at page 295.

\(^{79}\) Ibid.

\(^{80}\) Commission v Senwes (supra). Note that the Constitutional Court did not approve of the Tribunal ascribing the name, ‘margin squeeze’ to the conduct, but it nevertheless found that conduct to be unlawful.
engage in a margin squeeze following the Constitutional Court’s ruling, it would probably simply be ordered to stop.

In theory, a first-time lawbreaker could be sued for damages in a civil court by affected parties or subjected to an order of divestiture. In practice, the prospect of a successful damages claim is remote. There has only been one such claim following a finding of exclusionary abuse of dominance since the Act’s inception, which was settled by the parties early on in the proceedings. Although divestiture remains a legitimate and significant threat in particular circumstances, it is a severe and seldom-used intervention, and is not warranted in the majority of cases.

Furthermore, investigating and litigating cases under section 8(c) is costly, and yields more limited tangible outcomes than other prohibited practice findings (which incur administrative penalties). It is therefore also possible that the primary enforcement authority, the Commission, may be disincentivised from bringing cases under this section, choosing rather to focus resources on cases that, if successful, will act as a stronger deterrent. Section 8(c) may therefore suffer under-enforcement.

D Section 8(b)

For completeness, we examine briefly the potential for section 8(b) to assist in catching regulatory abuse. The section relies upon an interpretation of what constitutes an essential facility.

In discussing features of an essential facility in the Dorbyl case, the Tribunal quotes Motta as follows:

Any input which is deemed necessary for all industry participants to operate in a given industry and which is not easily duplicated might be seen as an essential facility . . . There are many examples that might satisfy this very loose definition of essential inputs. In the airline industry, slots at an airport; for maritime transportations, a port’s installations.

There is no South African decision on access to intellectual property as an essential facility (although the Competition Appeal Court has found access to products is not covered and mentions that resource does not cover services). The literature tends to refer to essential facilities in terms of infrastructure rather than movable property or intellectual property as a resource. The Competition Appeal Court has further cautioned that section 8(b) should not be used as ‘some more general species of refusal to deal’.

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81 Section 65.
82 Section 60.
83 Nationwide Airlines v South African Airways. The terms of the settlement are confidential, and there was no judgment or corresponding case number.
84 It is prohibited for a dominant firm to-(b) refuse to give a competitor access to an essential facility when it is economically feasible to do so;
85 Essential facility is defined to be an infrastructure or resource that cannot reasonably be duplicated, and without access to which competitors cannot reasonably provide goods or services to their customers.
86 DCD Dorbyl (Pty) Ltd / Globe Engineering Works (Pty) Ltd [2009] 1 CPLR 122 (CT) at paragraph 74.
88 Glaxo Wellcome (Pty) Ltd vs National Association of Pharmaceutical Wholesalers 15/CAC/Feb02 at paragraphs 51 -53.
89 Ibid paragraph 53.
90 Ibid at para 57.
In 2002 the Commission investigated a complaint by Hazel Tau, the Treatment Action Campaign and others in which it was argued inter alia that denial to competitors of access to patents which were ‘non-duplicable resources' constituted a contravention of section 8(b). The Commission found from its investigation that there had been such a contravention of section 8(b) but prior to the referral stage and before any determination by the Tribunal on the issue, the respondent pharmaceutical companies entered into far reaching settlement agreements for voluntary licensing of the patents.

So the potential for this argument remains open, but it seems an unlikely path for the Tribunal to travel. In addition, as explained above, the potential for the second abuse to qualify for analysis under the essential facilities doctrine was rejected by the European General Court.

Applying section 8 to regulatory abuse like AstraZeneca’s

As explained above, the ‘South African equivalent’ of AstraZeneca’s first contravention – the misleading abuse - would comprise knowingly submitting false information to the Registrar of Patents in order to procure an unwarranted further (‘evergreen’) patent. In our view, this would fall squarely within the definition of an ‘exclusionary act’. Therefore, if the other requisite elements of an abuse could be established (dominance, anti-competitive effects, and insufficient technological, efficiency or other pro-competitive gains), the conduct would fall for prohibition under the toothless provisions of section 8(c).

An equivalent of the second type of abuse might involve the holder of a marketing authorisation seek a strategic amendment to the provisions of the authorisation upon which a generic application may rely, leaving the generic application open to question or challenge on grounds of efficacy, quality or safety grounds.

The question is whether this behaviour may also be squashed into one of the boxes provided by section 8(d)? It seems quite clear to us that sections 8(d)(ii) to (v) do not provide viable avenues. Our analysis below is therefore focused on whether this conduct could be caught by section 8(d)(i).

Section 8(d)(i)

What it means to ‘require or induce a supplier or customer not to deal with a competitor’ is not clarified by the Act. Section 8(d)(i) has previously been held to apply to a wide range of conduct:

- In *Patensie Sitrus Beherend Beperk*\(^90\), the articles of association of a dominant company that provides packing and marketing facilities to its members (who are farmers), contravened section 8(d)(i) because it required its members to deliver their entire output to the company for packing and marketing.

- In *SA Raisins*\(^91\), a similar clause in a shareholders agreement requiring shareholders to supply all of their produce to the dominant company induced customers not to deal with competitors.

\(^90\) *Patensie Sitrus Beherend Beperk* v Commission case 16/CAC/Apr02.
\(^91\) *South African Raisins* v *SAD Holdings* case 04/IR/Oct/1999.
In the two South African Airways cases,\(^2\) effective loyalty inducing rebate schemes and incentive payments were held to induce travel agents not to deal with South African Airways’ competitors.

In Senwes,\(^3\) representations to farmers that they would lose the benefit of a cap on the daily storage tariff offered by Senwes (the dominant supplier of grain storage services in the relevant market) if they sold their grain to rivals of Senwes’ downstream grain trading division was an inducement.

In the Telkom SA case,\(^4\) the monopoly provider of fixed line telecommunications infrastructure (Telkom) prevented downstream Value Added Network Service providers (VANS) from connecting to its network in their own name. Instead, it required that access lines must be transferred into the names of end-customers and that VANS should act as agents for end customers. It also approached customers of independent VANS and suggested that they should migrate to Telkom’s own VANS provider. This course of conduct was designed to induce customers not to deal with Telkom’s competitors in the VANS market.

Sutherland and Kemp have suggested a further array of behaviour that could be caught.\(^5\) This may include express contractual requirements, express inducement, pricing inducement or other practical inducement.

In British American Tobacco case (Batsa),\(^6\) strategies designed to crowd out a number of ‘points of sale’ with Batsa’s cigarettes (Batsa is the overwhelmingly dominant cigarette manufacturer in South Africa) were found not to induce or require retailers not to deal with its competitors. This included incentive payments to cigarette retailers in exchange for preferential placement of Batsa products at the expense of rival brands.

What the cases therefore illustrate is that, unlike the other subsections of section 8(d), section 8(d)(i) does not specify particular conduct at all. Based on the subsection’s extraordinary breadth, it could be said that section 8(d)(i) is more akin to a second category of ‘exclusionary act’.

More cases have been brought before the Tribunal under this subsection than under the narrower and more prescriptive subsections of section 8(d)(ii) to (v). Most cases brought under section 8(d)(i) have either been dismissed because the complainant or Commission has failed to establish an anti-competitive effect, or have been successful. It has been uncommon for complaints to be dismissed because the complainant or Commission is unable to prove that an ‘inducement or requirement not to deal with a competitor’ has occurred. In Patensie Sitrus Beherend Beperk, both South African Airways cases and Telkom, a ‘requirement or inducement’ was found and the respondent firm was ruled to have contravened the Act. In the Senwes ‘inducement complaint’, an inducement was found to have been committed, but it was held not to have had an anti-competitive effect (although the Commission’s case succeeded on the basis of a margin squeeze). It is only in Batsa that the complainant has failed to establish an inducement.

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\(^2\) Commission v South African Airways (supra) and Nationwide Airlines (Pty) Ltd v South African Airways (Pty) Ltd case 80/CR/Sep06.

\(^3\) Commission v Senwes (supra), Tribunal decision at paragraph 116.


\(^5\) Sutherland and Kemp (2010) at page 7-77.

\(^6\) Commission v British American Tobacco South Africa (Pty) Ltd case 05/CR/Feb05.
Application of section 8(d)(i) to AstraZeneca-like conduct

The words of the section 8(d)(i) itself do not tell dominant companies what conduct they should avoid to ensure compliance. This job has been left to the Tribunal and the courts. The Tribunal’s articulation in its particular decisions of what conduct meets the section’s initial threshold, and should therefore proceed to an effects analysis, appears to have provided more certainty than section 8(d)(i) itself.

In our view, this inherent flexibility endowed upon the Tribunal by section 8(d)(i) creates greater potential for application to regulatory abuse than the other subsections of section 8(d). It is likely that the difficulty that the Commission or a complainant would face in a case like this would be the indirect nature of the impact on the dominant company’s customers or competitors.

In all of the Tribunal case law to date, the dominant company has engaged directly with its customers in seeking to ‘induce or require’ them not to deal with competitors. Communication by AstraZeneca to its customers or suppliers did not form part of its impugned conduct at all.

There appears to be nothing in the wording of section 8(d)(i) which explicitly precludes its application to ‘indirect inducement’. However, a broad interpretation of this nature by the Tribunal would significantly stretch the application of section 8(d)(i). Practically any conceivable ‘exclusionary act’ would have an indirect effect of inducing customers not to deal with competitors – if the dominant company prevents or impedes the entry or expansion of those competitors in the market, what choice do customers of the dominant company have?

The implications of an interpretation like this for the overall scheme of South Africa’s exclusionary abuse rules would be significant. The effect may be to discard section 8(c) for practical purposes, applying a broad construction of section 8(d)(i) in its place to any general exclusionary act. It is submitted that this would be a very welcome development in our abuse of dominance jurisprudence, but may not be true to the intention of the legislature, which deliberately crafted section 8(c) and 8(d)(i) separately. An in-depth analysis of the likely impact of this potential development is beyond the scope of this paper.

It is important to note that while sections 8(c) and 8(d)(i) could, in our view, apply to this conduct, a contravention of either section could only be established following analysis of the effect of the conduct on competition. This would be conducted on a case by case basis.

SUMMARY AND CONCLUSION

We have explained above why South Africa’s intellectual property and pharmaceutical regulatory laws lend themselves to potential misuse by medicine originators. By deliberately seeking patent protection for unoriginal tweaks to existing products, firms may obtain or extend monopoly rights to which they are not entitled. The effect of this misuse may well be to harm competition in South Africa, deny access to affordable medicines and inflate healthcare costs, despite the presence of price regulation.

There would appear to be two remedies available. First, the patent and pharmaceutical regulatory laws could be changed, to provide for more rigorous evaluation of patent applications and marketing behaviour. As set out, certain initiatives are proposed or under way, particularly
to deal with so-called evergreening of patent rights. But this is likely to take some time, and have some negative side-effects, such as lengthy reviews of patent applications, which might chill the very incentives that drive innovation.

The second option would be for competition law to step into the gap left by the deficient sector regulation. This could occur through two vehicles. First, the catch-all prohibition of ‘exclusionary acts’ contained in section 8(c) could apply. We see the definition of ‘exclusionary act’ to have a natural fit with the type of conduct under consideration, which clearly impedes or prevents potential competitors (generics companies) from entering the relevant product market. Section 8(c) would, however, not be an ideal means through which to address this conduct, because no administrative penalty is payable for a first offence, and its deterrent effect is therefore weak. This would be despite the conduct having been described in Europe as ‘deliberate’, ‘serious’ and ‘manifestly not consistent with competition on the merits’.

Alternatively, with some elastic or purposive interpretation of section 8(d)(i), the conduct could be found to constitute an indirect inducement of customers not to deal with competitors of the dominant firm. This would certainly be a more effective enforcement tool than section 8(c) – an administrative penalty befitting of the anti-competitive effect could be imposed for a first offence, and firms may be deterred from similar exclusionary strategies.

Conduct of the kind complained of requires vigilant monitoring by public interest groups in order that it may be challenged in the appropriate forum. Our competition authorities have not shied away from intervention in the past and encouraged by the AstraZeneca case, may be willing to pursue non-market conduct.

For dominant firms there is a salutary warning, when engaging with a regulatory authority to obtain a permission or license that may impact competition, the firm would have to be sure that the engagement does not distort genuine competition, or diverge from ‘competition on the merits’.
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