EXCESSIVE PRICING IN THE PHARMACEUTICAL SECTOR - A BITTER PILL TO SWALLOW OR A DOSE OF THEIR OWN MEDICINE?

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LEGAL BRIEF
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INTRODUCTION
Cancer is a devastating disease with more than one hundred thousand South African’s being diagnosed with some form of cancer every year. According to the latest available statistical information1, cancer affects one in four South Africans through diagnosis of family, friends or one’s self. The effects of the disease as well as its medical treatment can be overwhelming and it is not surprising, considering the disease’s prevalence and cruelty, that the topic of cancer is a very emotive one.

COMPETITION COMMISSION INVESTIGATION
It was therefore somewhat disturbing to learn recently that the Competition Commission ("Commission") initiated an investigation into the conduct of various pharmaceutical companies including Roche, Pfizer and Aspen, in regard to the alleged excessive prices that these pharmaceutical companies had set for some of their cancer treatment medicines in South Africa. Details of the Commission’s investigation are set out in a media release which it published on 13 June 20172 and appear to be linked to damning allegations made against Aspen in an article published by The Times in the United Kingdom on 14 April 20173 with the sensational title “Drug giant’s secret plan to destroy cancer medicine”. Shortly after publication of The Times article, the Democratic Alliance indicated that it would write to the Commission to request that Aspen’s South African market conduct be investigated4. Interestingly, it seems as though the Democratic Alliance performed its own brief investigation and, post engagement with Aspen, summarily concluded that there was no evidence that Aspen was involved in the same practices it was accused of having pursued in Europe5. It is also of interest to note that Aspen recently lost an appeal against the Italian competition authority related to the pricing of its oncology medication and is expected to pay a penalty of approximately R74 million as a result thereof.

Since the Commission’s investigation is only in its infancy, exact details of its concerns are somewhat sketchy and not well articulated in its media release. For example, the Commission’s media release suggests that:

> Roche is being investigated for excessive pricing, price discrimination and/or exclusionary conduct due to the "exorbitant prices" of its breast cancer treatment medications Herceptin and Herclon, stating that a 12 month course of Herceptin costs over R500,000;

3 https://www.thetimes.co.uk/article/drug-giant-s-secret-plan-to-destroy-cancer-medicine-75rg6w2n
Pfizer is being investigated for excessive pricing of its lung cancer medication in South Africa called Xalkori, stating that there was an R80,000 price reduction for the same pack size of the medication which "suggests abusive behaviour", and

Aspen is engaging in excessive pricing as it is the only supplier in South Africa of (i) Myleran, used as a conditioning agent prior to bone marrow transplantation; (ii) Leukeran, used to treat Leukemia and Lymphoma; and (iii) Alkeran, used to treat bone marrow and ovarian cancers.

The excessive pricing allegations made against Aspen are curious as there is no actual indication of why the price for the cancer treatment medication is excessive other than to state that Aspen is the sole supplier of it. Theoretically, the absence of competition in any market place could remove competitive constraints and result in unrestrained price increases. However, the South African pharmaceutical industry is characterised by significant price regulation as contemplated in the Department of Health’s National Drug Policy which had the objective of promoting the availability of safe and effective drugs at the lowest possible cost. Following from the aims expressed in the National Drug Policy, certain amendments were made to the Medicines and Related Substances Control Act (Act No. 101 of 1965) (“Medicines and Related Substances Act”) which led to the creation of, amongst other things, a pricing committee and the introduction of a transparent, non-discriminatory pricing system in the pharmaceutical sector, the so-called single exit price.

THE SINGLE EXIT PRICE

The single exit price is calculated by combining the manufacturer’s exit price, plus a logistics fee, plus VAT. The regulations published by the Department of Health relating to a transparent pricing system for medicines and scheduled substances (“the Regulations”) stipulate that “A manufacturer, importer, distributor or wholesaler may not charge any fee or amount other than the single exit price in respect of the sale of a medicine or Scheduled substance to a person other than the State”. In addition, the Regulations set out a specific methodology for determining annual escalations of the single exit price which is administered by the pricing committee. Specifically with regard to determining what constitutes a fair manufacturer exit price, the Regulations make provision for price comparisons using international benchmarks and pharmaco-economic evaluations (which are intended to establish whether or not a medicine represents fair value for money). However, it is understood that, despite the publication of specific regulations setting out an international benchmarking methodology, price comparisons using international benchmarks are not formally part of our law as yet. In addition, section 15C of the Medicines and Related Substances Act empowers the Minister to prescribe conditions for the supply of more affordable medicines in certain circumstances so as to protect the health of the public, which conditions contemplate permitting parallel imports by third parties even where the relevant product still enjoys patent protection in South Africa. Presumably, if faced with excessively priced pharmaceuticals in South Africa in an effort to make the medication more affordable. Clearly, there are significant mechanisms already in place to deal with excessively priced pharmaceutical products.

JURISDICTION

The fact that national legislation has been proclaimed to specifically deal with matters relating to pricing in the pharmaceutical sector, calls into question whether or not the Commission has the necessary authority to pursue an excessive pricing investigation into the pricing practices of Roche, Pfizer and Aspen. In the ordinary course, where the Commission and another regulatory authority share concurrent jurisdiction in respect of certain conduct, the Commission is responsible for entering into an agreement with that regulatory authority in order for the Commission to co-ordinate and harmonise its exercise of jurisdiction over competition matters within that sector. In addition, the Competition Act specifically states that “The manner in which the concurrent jurisdiction is exercised in terms of this Act and any other public regulation, must be managed, to the extent possible, in accordance with any applicable agreement concluded in terms of section 21(1)(h) and 82(1) and (2)”. At the time of writing this article, it did not appear that the Commission had entered into any memoranda of understanding with the Department of Health, the Medical Control Council or the pricing committee established in terms of the Medicines and Related Substances Act. Accordingly, it is unclear whether or not the Commission has the power to usurp the role of the bodies empowered to administer the pricing mechanisms established in terms of the Medicines and Related Substances Act. This is likely to be a bone of contention between the parties concerned if this matter proceeds to be adjudicated before the Competition Tribunal.

ORIGINATOR PHARMACEUTICAL COMPANIES VS GENERIC COMPANIES

Pharmaceutical companies have for a long time attracted the attention of competition regulators in Europe and in the United States of America, but less so in South Africa. For an insight into what the Commission is likely to be looking for during the course of its current investigation, one can take guidance from the outcomes of investigations conducted in foreign jurisdictions.

To understand why competition authorities have previously investigated pharmaceutical companies, it is important to understand the distinction between a generic pharmaceutical company and an originator pharmaceutical company. Of course, pharmaceutical companies can sell a mix of both innovative and generic medicines and the distinction between the companies is therefore not absolute but, for the purposes of this article, references will be made to “originator companies” on the one hand and “generic companies” on the other.

New medicinal innovations are created by originator companies who are involved in research and development, clinical trials, obtaining regulatory and legal authorisations, manufacturing, marketing and supply. The innovative products usually benefit from patent protection (i.e. a legally recognised exclusive right to make, use or sell a concept or invention and excludes others from doing the same for the duration of the patent) which compensates the originator for the significant costs spent on innovation. However, despite legal protection, patent...
applications are generally available for inspection in the relevant patent office. Patent protection is limited in time (usually for about 20 years), which incentivises the originator to bring the innovation to market as quickly as possible in order to maximise the benefit associated with the exclusive use right. In contrast to originator companies, manufacturers of generic products enter the market, once the duration of the patent protection has expired, with medicines that are equivalent to the original medicines. Furthermore, in many jurisdictions, when a generic company wishes to enter into the market with a product which is bioequivalent to the original it may, when seeking their own regulatory and legal approvals, rely on and refer to the originator’s previous regulatory and legal submissions which were made to the relevant authorities. This typically reduces the costs and amount of time it takes for generic products to enter the market. The effect of generic product entry on the market is significant. According to analysis conducted in Europe:

> the price of generic products that enter the market are, on average, 25% lower than the price of the originator medicines before patent expiry;

> two years after entry, prices of generic medicines were on average 40% below the former originator price; and

> prices of originator products appear to drop following generic entry.

Considering the above, it is clear to see that the ability to keep one’s competitors out of the market and retain extended and unwarranted periods of exclusivity, can give rise to a situation where excessive prices are charged.

With the above in mind, a high-level overview of some of the investigations which have been concluded in Europe and the United States of America are set out below.

**THE EUROPEAN EXPERIENCE**

The European Commission ("EC") conducted a lengthy sector inquiry into the state of competition within the European pharmaceutical sector a few years ago. It concluded that “market entry of generic drugs is delayed and there is a decline in the number of novel medicines reaching the market”. The inquiry showed that originator companies used a variety of methods to extend the commercial life of their patented products which had the effect of excluding generic medicine entry for as long as possible. Examples included using defensive patenting strategies that mainly focussed on excluding competitors without pursuing innovative efforts. In addition, settlement agreements entered into between originator and generic companies were found to delay the entry of generic drugs and were deemed to be so problematic that the EC decided to put in place annual monitoring mechanisms, specifically to review settlement agreements concluded between originator and generic companies to ensure that such settlements were not designed to harm competition.

Legal disputes between originator and generic companies can occur for a variety of reasons but usually arise from disputes linked, in some way, to a patent. Of course, the EC recognises and appreciates that parties to a legitimate legal dispute have an interest in finding a mutually acceptable compromise in order to avoid costly, time-consuming and potentially risky litigation and can do so by entering into settlement agreements. However, of particular concern for the EC are settlement agreements entered into between players in the pharmaceutical sector which result in two key outcomes: (i) they place a limitation on generic entry or a generic company’s ability to market its own medicine; and (ii) such limitation is in return for a value transfer from the originator company to the generic company (such settlements are often referred to as “pay-for-delay” settlements).

As indicated above, the EC’s sector enquiry identified that certain settlement agreements, aimed at resolving litigation between originator and generic manufacturers, have previously had the effect of limiting generic entry or the marketing of generic medicines. Such “limitations” have arisen in various forms including, but not limited to, the following:

> the generic company refrains from challenging the validity of the originator company’s patent and/or refrains from entering the market until the patent has expired;

> the originator company grants a licence to a generic company to establish a market presence using the originator’s product, but prevents the generic company from entering the market with its own product or restricts its ability to commercialise its product freely;

> the generic company agrees to source its supply of the active pharmaceutical ingredient for its own product from the originator company; and

> early entry of a generic medicine is allowed by the originator but delayed for a certain period of time.

The EC considered the following to constitute a “value transfer” (although this was a non-exhaustive list):

> a direct monetary transfer (e.g. payment of a lump sum) from the originator company to the generic company;

> purchasing of assets from the generic company (for example, the generic company’s stock) if the purpose of paying the generic company is to agree to discontinue the patent challenge, even in situations where stock is bought at market price;

> concluding distribution agreements or a “side deal” in which the originator company grants a commercial benefit to the generic company, for example by allowing it to enter the market before patent expiry in another geographical area or by allowing market entry with another product marketed by the originator company; and

> where the originator agrees not to enforce its patent protection against the generic company, thereby allowing the generic medicine to enter the market but imposes some other limiting provision on the generic company.

**THE AMERICAN EXPERIENCE**

In the United States of America there appears to be inconsistency in the approach adopted by the Circuit Courts in regard to whether or not
certain settlement agreements (termed reverse payment settlements), which involve a payment from the originator company (which still enjoys patent protection) to the generic company and that have the effect of keeping generic companies out of the market, contravene antitrust laws. One particular case (the Cardizem CD case\(^{11}\)) has declared this practice to constitute an illegal per se restraint on trade which was designed to eliminate competition. However, it appears from the Cardizem CD case, that the parties may have exploited a combination of poorly conceived legislation and drawn out litigation tactics to ensure that no other generic companies could enter the market for the originator company’s products until some time after the litigation had been concluded.

Other United States Circuit Courts (in the Valley Drug case\(^{12}\), the Schering-Plough Corp case\(^{13}\), the Tamoxifen Citrate case\(^{14}\) and the Ciprofloxacin Hydrochloride case\(^{15}\)) have adopted an “exclusionary zone” test, which states that there is no antitrust violation if an originator company pays a generic competitor to stay out of the market when the originator company’s product still enjoys patent protection. In short, these Courts have held that the mere presence of a patent entitles the patent holder to purchase protection from generic competition as long as the contemplated purchase of protection does not arise because the originator had perpetrated a fraud on the patent office or is not some form of sham litigation. However, this begs the question – why would the originator company agree to pay (in the Ciprofloxacin Hydrochloride case, as much as $400 million) to keep a generic competitor out of the market when it already had the legal protection of the patent. The United States antitrust watchdog, the Federal Trade Commission, has since 2009 petitioned for a change in federal legislation in order to outlaw reverse payment settlements as, in its view, such pay-for-delay settlements make consumers and the United States Federal Government pay more for much needed drugs\(^{16}\). Notwithstanding the FTC’s position on this matter, no such legislative changes have been made to address this concern.

\(^{11}\) 332 F.3d 896, 914-15 (6th Cir. 2003)
\(^{12}\) 344 F.3d 1294 (11th Cir. 2003)
\(^{13}\) 402 F.3d 1056, 1065 (11th Cir. 2005)
\(^{14}\) 466 F.3d 187, 228 (2d Cir. 2006)
\(^{15}\) 544 F.3d 1323, 1341 (Fed. Cir. 2008)

\(^{16}\) The FTC’s prepared statement to the House of Representatives can be found at the following address - https://www.ftc.gov/sites/default/files/documents/public_statements/prepared-statement-federal-trade-commission-how-pay-delay-settlements-make-consumers-and-federal/pdf/0910payfordelay.pdf

**CONCLUSION**

There are several interesting issues which are yet to unfold over the course of the Commission’s excessive pricing investigation which include the following:

- whether or not the Commission will face challenges in respect of its exercise of jurisdiction over pharmaceutical product pricing, especially considering the mechanisms in the Medicines and Related Substances Act which already appear to deal with this issue;

- if the Commission’s investigation into the conduct of pharmaceutical companies in South Africa will identify similar pay-for-delay strategies to those which have previously been executed by pharmaceutical companies in Europe and the United States of America;

- will the Commission broaden its investigation to include other players in the pharmaceutical industry in South Africa, given that more global pharmaceutical companies have been in the spotlight of other competition authorities;

- will the outcome of the Commission’s investigation result in an administrative penalty for the pharmaceutical companies; and

- if the pharmaceutical companies settle the matter or are found guilty by the Competition Tribunal, will customers including government, medical aid schemes and consumers institute civil claims against the pharmaceutical companies for damages.

Should the Commission’s excessive pricing investigation not lead to any adverse finding, the whole process may turn out to be a bitter pill to swallow for the implicated pharmaceutical companies - considering the legal costs and reputational harm involved in defending such allegations. However, should the investigation result in any administrative penalties being imposed on the pharmaceutical companies, they are likely to be significant (up to 10% of annual turnover) and could be compounded by additional civil damages claims from affected parties, which some might argue would be tantamount to a dose of their own medicine.

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