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Management decisions regarding end of patent strategies in the South African private pharmaceutical market

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ABSTRACT

The loss of patent protection for a pharmaceutical product is a significant event for manufacturers. Although this phenomenon has been occurring in the industry for decades, it has been of increased interest during the past few years due to the much publicised “patent cliff” experienced by a number of major pharmaceutical manufacturers. Recent developments in emerging economies such as India and South Africa have brought the concept of intellectual property rights under review. The traditional approach to extend market exclusivity through the use of secondary patents is no longer valid. New product strategies are now required to transition from a patent protected market to an open market. This study adds to the current literature by investigating post-patent strategies pursued in the South African private pharmaceutical market. The primary focus was to determine the rationale behind choosing a particular strategy.

This study, exploratory in nature and structured around five propositions, investigated strategies to manage the patent expiry and potential entry from generic competitors. These included manipulating price, increasing promotion, developing value adding product extensions or launching a clone. Information was gathered through 14 interviews with product managers responsible for implementing the chosen strategy. The interviews were conducted using a structured questionnaire as well as open-ended questions. Five companies were selected for the study using purposive sampling and each company then self-selected which products would be discussed.

The most pursued strategy for the sample was to launch a clone. This allowed the manufacturer to compete with lower priced generics using the clone as well as continue to profit from the remaining brand loyal, price insensitive consumers with the original product. The price of the original product was not used to deter entry or compete with generic products. Profit-maximising behaviour was exhibited by the reduction in advertising and promotional spend after patent expiry. When available, the use of product extensions to extend market exclusivity continued to be a preferred strategy.

KEYWORDS

Pharmaceutical patent, clones, generic pharmaceuticals, entry deterring, price

DECLARATION

I declare that this research project is my own work. It is submitted in partial fulfilment of the requirements for the degree of Master of Business Administration at the Gordon Institute of Business Science, University of Pretoria. It has not been submitted before for any degree or examination in any other University. I further declare that I have obtained the necessary authorisation and consent to carry out this research.

Student Name: Paul Barron

Signature: _____

Date: 11 November 2013

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1.1 Background to the problem

The impact of patent expiry is a global phenomenon affecting all original pharmaceutical manufacturers at some time during their products' life cycles. The expiration of a pharmaceutical patent, and the subsequent opening of a drug market to potential entrants, is a significant event for pharmaceutical firms (Ellison & Ellison, 2007).

Although this phenomenon has been occurring in the industry for decades, it has been of increased interest during the past few years due to the much publicised "patent cliff" for many of the major global pharmaceutical manufacturers. This has come about through a series of products near simultaneously going off patent. Compared to previous years the rate of erosion of sales has been much higher (Jack, 2012). This attention was further heightened as Pfizer's blockbuster Lipitor, the best-selling drug in history, came off patent in the United States in December 2011 ("Cliffhanger", 2011). Pfizer's sales for Lipitor globally dropped from USD 12.9 billion in 2011 to USD 5.1 billion in 2012 due to the loss of the patent (IMS Health Incorporated, 2013).

When the patent protection of a pharmaceutical product does end, the loss of market share to competitors can be significant. A company with a successful drug will invest heavily in strategies to avoid losing market share. Charlafti (2008) suggests that the foremost strategy is to invest in drug discovery and innovation but cautions that the room for success should not be overestimated. Currently only 443 distinct molecules make up the 10,300 FDA-approved US medicinal drugs (Charlafti, 2008). Most drugs are not blockbusters, with many never achieving much commercial success. In fact many are largely supplanted by the time they lose protection (Ellison & Ellison, 2007).

Some products require little attention when patent protection lapses while others, where revenue loss will be significant, require considerably more attention. In light of these complexities a range of strategies have been deployed to manage the transition out of patent protection into a more open and competitive market. These strategies range from doing nothing, to product innovation to litigation.

The most prominent strategy is commonly called 'Evergreening.' This refers to the strategy adopted by patentees who seek to extend their period of patent protection by applying for secondary patents for related or derivative technologies. This has become

a multifaceted process which can effectively extend the patent protection for much longer than the original term, thereby keeping prices high and medicine largely inaccessible to many (Bansal, Sahu, Bakshi & Singh, 2009).

1.2 Motivation for research

Recently this preferred approach of patent extension or 'Evergreening' has been challenged by regulators, especially in emerging markets. India has been particularly active in this regard with news headlines frequently reporting the revoking of major pharmaceutical companies' intellectual property rights (Staton, 2013). This type of policy action raises concerns as to the validity of the most successful strategy for pharmaceutical companies, that of patent extension. Pharmaceutical companies therefore have had to begin reconsidering other alternatives which do not require legal protection.

Recent comments by Novartis AG CEO Joseph Jimenez (2012) in the Harvard Business Review highlight the lack of a consistently good model in the industry to handle this transition from a patent protected market to an off-patent market. In another interview he comments that the emerging markets are the future of the industry but that the uncertainty around patent protection makes it a difficult balancing act if innovation is not rewarded (Nisen, 2013).

This balance between innovation and the socially optimal or acceptable degree of patent protection has been continuously debated. Through the years a number of structural and policy changes across markets and countries have been implemented to better regulate or manage this balance (Caves, Whinston, Hurwitz, Pakes, & Temin, 1991).

The implementation of patents however may result in monopoly type prices for many leading pharmaceutical products. This negatively impacts access to medicine for many developing countries. These developing countries have two primary needs regarding access to medicine. Firstly, access to medicines that target diseases prevalent in both high and low income countries at affordable prices is needed. Secondly, development of new medicines to target diseases impacting primarily developing countries is required (Danzon & Towse, 2003). For this reason developing countries need to carefully consider the balance between protection of intellectual property rights and access to medicine.

Following recent intellectual property rulings in India regarding the patent protection of a cancer drug by Novartis AG, South Africa's department of trade and industry has affirmed that it will be reforming the intellectual property rules to limit the opportunity for pharmaceutical companies to extend patent protection through the process of 'Evergreening' (Reuters, 2013).

The pharmaceutical industry in South Africa is relatively well developed, although mostly focused on the production of generic products. Some multinational companies have a direct presence in the country as it is increasingly targeted by foreign companies looking for a stable base from which to penetrate sub-Saharan Africa. ("Competitive Landscape", 2013)

This paradox of changing legislative dynamics regarding patent protection in emerging markets as well as the belief that emerging markets are the future growth markets for pharmaceutical industry challenges the traditional business and product strategies for innovative pharmaceutical companies. As such there is a need to consider the product strategies available to be pursued in the absence of patent extension through legal channels.

Current literature suggests a finite number of strategies that can be pursued for original patent protected products (Barak & Wilson, 2003; Kvesic, 2008).

These include the following:

1. Maintain sales price (or even increase) and operate at lower sales volume.
2. Lower prices to meet generic competition head on.
3. Launch a clone to compete with generic competition.
4. Launch a fighter brand, product extensions or a new product to convert consumers to a superior product.
5. Withdraw the product from the market.

The choice of strategy may depend on a number of product-specific, company-specific or market related factors. No one strategy is shown to be the preferred choice.

1.3 Research objectives

This research is focused on the decisions made regarding the product strategy pursued once patent protection has expired. These decisions will be assessed from a micro economic perspective with focus on the economics of market entry. The variables of

price and product quality will be used within the constructs of an analytical framework to categorise decisions made. The research aims to investigate what factors were considered to assess the impact of patent expiry.

Further to assessing the variables considered to choose the product strategy, the research will also consider what strategy was chosen and the underlying reasoning behind the choice pursued to maximise revenue once patent protection has lapsed. The objective is to better understand what choices were taken and why these were chosen and not to assess the success or failure of the strategy.

The key objectives for selected products are therefore:

- Determine the product strategy chosen
- Understand the underlying decisions which resulted in this strategy
- Identify which factors or variables were considered in choosing the product strategy

This research attempts to add to the body of knowledge regarding product strategy decisions around patent expiry by considering what decisions were previously taken by companies as a product lost patent protection. It will further seek to understand what factors were assessed to arrive at this decision.

The findings will be of interest to pharmaceutical companies to better assess what strategies to follow in South Africa as products reach the end of their patent. The analysis will also be valuable to policy development in South Africa to assist in finding the balance between innovation and access.

1.4 Research scope

The research scope is limited to a sample of specific products which have lost patent protection in the South African private pharmaceutical market. Patent protection must have lapsed and a defined product strategy must have been pursued. The original time frame included products which lost patent protection between 2000 and 2012, however due to the uniqueness of two products which expired in 1991 and 1997 these were included in the scope.

The scope is constrained to decisions pertaining specifically to those products and will not consider decisions made at a company level, for example an acquisition of another

pharmaceutical company unless this is directly related to the expiry of the patent for the product under investigation.

The legality or moral philosophy of whether or not patent protection is good for society and other such debates are not included in the scope of the research. It is assumed that patent protection exists for a certain period of time after which it lapses and the market is open for bio equivalent competitors to enter.

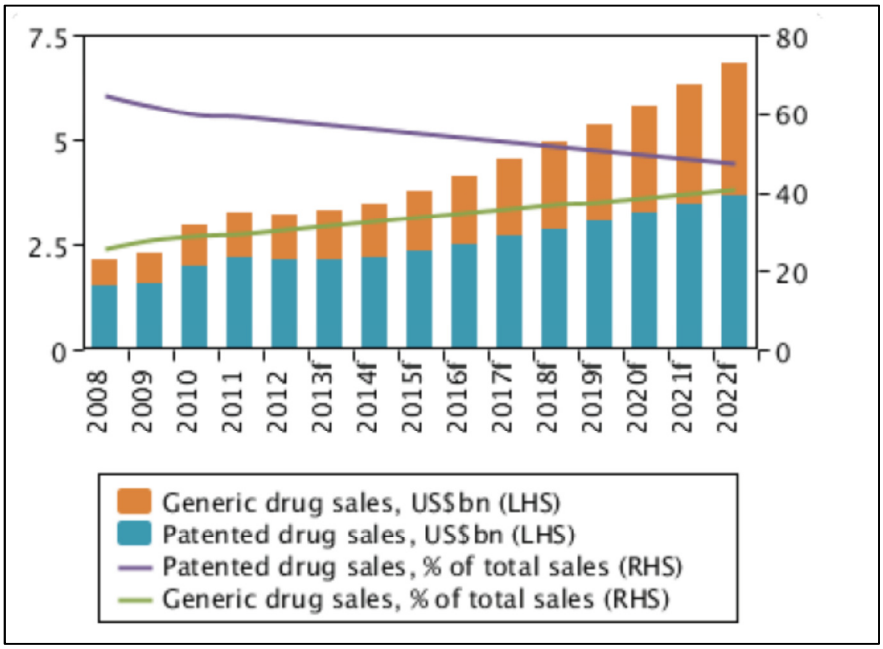
1.5 The South African pharmaceutical market

The South African healthcare market consists of two distinct parts namely the private and public sectors. The private market accounts for approximately half the spend on healthcare but is made up of only 16 percent of the population. This relatively small sector has however been a very profitable for pharmaceutical companies due to the unstable public sector ("Industry Trend Analysis", 2013).

Total pharmaceutical sales for 2012 in South Africa were ZAR 30.5 billion which was approximately one percent of the gross domestic product (GDP) for 2012. Total sales, which includes prescription and over-the-counter drugs, is expected to grow to ZAR 80.8 billion by 2022, this equates to a 10.3% compound annual growth rate ("South Africa Business Forecast Report", 2013).

Generic product sales accounted for ZAR 9.2 billion (30%) of these sales with the balance made up by originator sales. Patented products contributed ZAR 17.6 billion (83%) of the total originator sales, with the remaining ZAR 3.7 billion indicating the dwindling non-patent protected product market. This share is expected to decline as the South African government continues to promote the use of generic products ("Industry Forecast", 2013).

Figure 1: South Africa's prescription drug market ("Industry Forecast", 2013).



As shown in Figure 1, the percentage of sales for patented drugs is expected to decline into the future, this will result in loss of revenue for the innovative pharmaceutical companies. These companies will need to consider more carefully what strategies will be successful in an off-patent market.

The generic utilisation rate, which is the percentage of generic items claimed as a percentage of the total items claimed, was 53.4% in 2012 which is an increase from 50.0% in 2010 (Mediscor, 2012).

Figure 2: Expenditures and volume distribution by product type (Mediscor 2012)

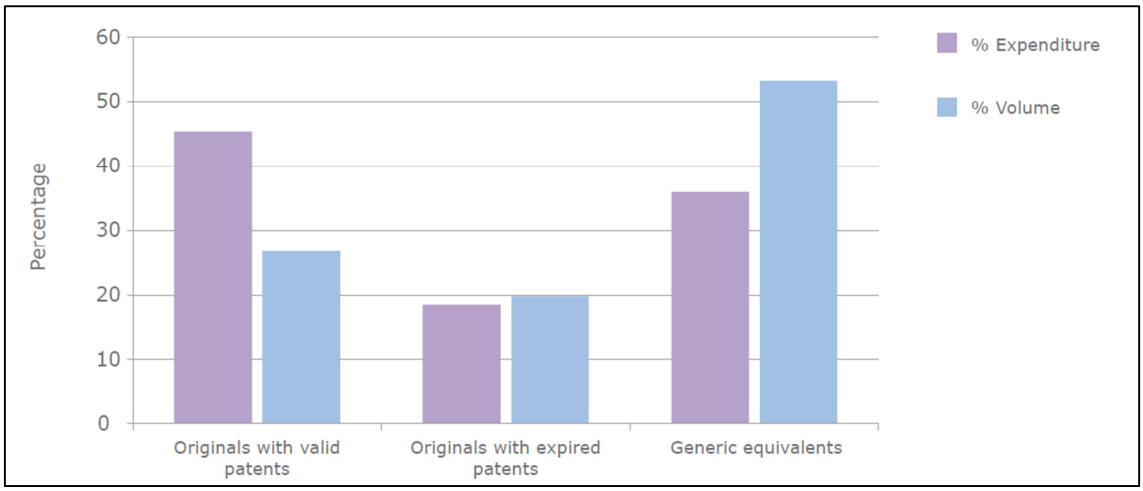


Figure 2 shows further detail regarding the contribution to expenditure and volumes in terms of generic equivalents and patent protected products. Originals with valid patents

are the only version of the product available on the market and although the contribution to the total volume is less than generic equivalents, the high average cost of ZAR 232 per item makes this category the highest contributor in terms of expenditure. Generic equivalents contribute the largest volume and have an average cost per item of ZAR 92. Originals with expired patents show the lowest contribution in both expenditure and volume and have an average cost of ZAR 127 per item (Mediscor, 2012). From Figure 2 the stark contrast between the patent protected market, one of protected volume and high prices, and the low-price high-volume market of generics can be seen.

Further to this the report (Mediscor, 2012) also highlights that generic utilisation is highest in managed care benefits (59%) and chronic medicine (55%). It is lower in acute medicine (53%) and lowest in over-the-counter medicine (38%). These measurements highlight the influence of medical schemes requiring patients to adopt generic medicines or else pay co-payments.

1.6 Conclusion

The loss of patent protection is a significant event in the life cycle of a pharmaceutical product. The traditional approach was to replace expiring patents with new, innovative products. However with the new product pipeline dwindling over recent years as well as patent extension strategies being less successful in emerging markets, pharmaceutical companies need to consider other product strategies.

This research investigates what strategies have been followed in the South African private pharmaceutical market and seeks to further understand the variables considered and decisions taken to arrive at these strategies. The strategies are assessed using an analytical framework which considers price and product quality as the primary variables.

The following chapter discusses current literature around available product strategies and the merits of each strategy. Chapter 3 presents the research propositions which were investigated using the methodology described in Chapter 4. The results of the research are presented in Chapter 5 and then compared and contrasted with the literature reviewed in Chapter 6. Conclusions are drawn and further research recommendations are provided in Chapter 7.

2. Literature review

2.1 Pharmaceutical markets

A brief overview of the pharmaceutical market and the relevance of patent protection are provided in this section. The entry of generic products and the market intricacies thereof are also covered. This is a general overview and certain elements may differ depending on the country or product class. Attention will be drawn to where these are relevant to South Africa and this research project. Scott Morton and Kyle's (2012) chapter from the Handbook of Health Economics volume 2 forms the base for this discussion.

2.1.1 Original pharmaceutical products

The process for developing a new pharmaceutical product or drug is long and expensive with recent estimates ranging between USD 800 million to USD 1.2 billion to be spent per successful molecule brought to market (Scott Morton & Kyle, 2012). As such the enterprise of inventing new pharmaceuticals is risky and contains many sunk costs. In order to recover these costs and therefore incentivise innovation further, intellectual property rights are extremely important in the industry. In most cases the product equals the patent (Thusleem, Shaikh, & Muneera, 2008).

The patent typically provides twenty years of protection, however it is granted when the molecule is first registered. Due to strict regulations to prove the safety and efficacy of the product it must be extensively tested before the product reaches the market. The implication of this is that the effective time on the market under patent protection is between five and eight years (Kvesic, 2008). During this time the company needs to recover its costs as well as make a profit. For this reason the price of these products is often many times the marginal cost to produce the product (Thusleem et al., 2008).

Companies which produce original drugs, also called innovative, brand name or ethical drugs, are referred to as innovator, originator, brand name or ethical firms. Novartis and Pfizer are examples of such firms (Scott Morton & Kyle, 2012).

2.1.2 Generic pharmaceutical products

Once patent protection has lapsed for a molecule, imitation products known as generics may be introduced to the market. These generic products are bioequivalent

products which are accurate imitations of the original product. These products are much cheaper to produce due to the lack of research and development required. There is much less risk since the safety and efficacy of the molecule was tested by the original company. In most countries generics only have to show bioequivalence to be approved (Scott Morton & Kyle, 2012).

Companies which produce generic drugs are referred to as imitator or generic firms. Dr. Reddy's and Teva are examples of such firms (Scott Morton & Kyle, 2012).

A number of firms engage in both originator and imitator activities, for example Novartis has a division Sandoz which specialises in generic drugs (Scott Morton & Kyle, 2012). When a company produces a generic of its own, branded product is referred to as a pseudo-generic, branded generic, authorised generic or a clone. The product is exactly the same as the original product and in most cases comes from the same production line but is branded differently to the original product.

2.1.3 Cost comparison between originator and generic products

Regulations play an import role in the competitive market of pharmaceuticals. One such intervention is the Waxman-Hatch Act of 1984 in the United States of America. This act reduced the regulatory barriers to generic entry which meant that generic companies did not need to invest as much in clinical trials and other quality proving activities. Prior to this act only the most popular drugs tended to lose their monopoly as the investment barrier to entry remained unattractive compared to the market profits. However with the introduction of this act the landscape changed dramatically (Ellison & Ellison, 2007).

This leniency has carried through to South Africa's regulations regarding the registration of pharmaceutical products. Innovator products need to show extensive trials which, under the estimation of the Pharmaceutical Industry Association of South Africa [PIASA], can take eight to twelve years. Generic manufacturers on the other hand need only prove that the product has comparable therapeutic effect to that of the originator. All registrations for original and generic products need to first be approved by the Medicine Controls Council before they are introduced to the market (PIASA, n.d.).

Due to the reduced research and development investment required, generics enter the market at greatly reduced prices, often as low as 80 percent of the originator (Appelt, 2010). This typically results in the originator's market share quickly eroding. As an

example when the blockbuster drug Prozac lost patent protection, generic entry was swift and within 18 months 21 generic competitors had seized 80 percent of its market (Ellison & Ellison, 2007).

2.1.4 Market definitions

The market for a pharmaceutical product is either be defined by the molecule itself with competition occurring between the brand name and generic products or by the disease area or therapeutic class, for example Type 2 diabetes, which would include other drugs used to treat the disease (Scott Morton & Kyle, 2012). For the purpose of this research the market considered for a product is that directly related to the defined molecule. During patent protection the market therefore consists only of the originator product. Once patent protection expires the markets expands due to the entry of generic products.

2.1.5 Condition types

The type of disease treated has been found to have an impact on the entry of generic products (Scott Morton, 2000). There are two major categories of conditions namely acute and chronic. Acute conditions are serious and sudden in onset but generally have a shorter time period during which they are treated. Chronic conditions in contrast develop and worsen over a longer period of time requiring treatment for a number of years and in many cases the rest of the patient's life (Vorvick, 2013).

In terms of drug purchases, acute conditions are treated with short course of treatment whereas chronic conditions are treated with a much longer course of treatment. Scott Morton (2000) found that for chronic conditions the price elasticity was greater as consumers had a greater opportunity to collect information about prices and substitutes due to repeat purchases. Acute conditions on the other hand are treated in most cases with a once-off purchase. However the study did caution that chronic patients are at times reluctant to switch away from a product which has their condition under control to try a cheaper generic product (Scott Morton, 2000).

2.1.6 Demand for pharmaceutical products

The demand for a particular pharmaceutical is driven by a number of stakeholders. These include the doctor or physician prescribing the product, the pharmacist dispensing the product, if required, as well as to a certain extent the patient's choice. The choice is also at times influenced by the medical aid company and in some cases

regulations such as generic substitution (Scott Morton & Kyle, 2012). The implications of these for the producing company is that each stakeholder is essentially a consumer needing to be focused on to generate demand.

2.1.7 Setting the price for pharmaceuticals

The setting of prices has received much attention over the years and in most countries is governed by regulation except in the United States where a free market exists (Scott Morton & Kyle, 2012).

In South Africa, as a means to control the increasing cost of medicines in the private pharmaceutical market, the government implemented Single Exit Pricing (SEP) in 2004. This mechanism is intended to provide transparent pricing throughout the value chain by setting and publishing the price ex-manufacturer. A capped dispensing fee is added to this amount to arrive at the patient price. In 2004 the price for every registered scheduled product was set. From here on, the only increase allowed will be that stipulated by the government annually. Products may decrease in price at any time but may not then be increased again. (Gazette No 26304, 2004).

The introduction of SEP also limited the option to offer bulk discounts or similar incentives to preferred partners in the distribution chain. This further limits the option of price to influence sales (Gazette No 26304, 2004).

The medical aid providers play a significant role in the price setting due to the maximum medical aid price (MMAP). This is the maximum reimbursement rate paid by the medical aid to the patient. MMAP is a pricing reference model maintained by Medikredit with the purpose of serving as a guide to determine the maximum price that medical schemes will reimburse for interchangeable multi-source products. It does not necessarily take the lowest price available but will be less than the original price once generics enter the market (Medikredit, 2013).

The implication of this is that for products higher than the MMAP the patient has to pay in a co-payment. This may have severe ramifications especially for chronic medicine which is taken for the rest of the patient's life.

2.2 Economic model for comparison

The following section discusses the underlying economic principles of market entry in particular when a structural barrier such as the patent protection of a product has been removed. These principles are then discussed in later sections in terms of the chosen strategies. First, the value map is introduced as a framework to assess the decisions made by the company to handle market entry from generic competitors.

2.2.1 Value creation and the value map

Besanko, Dranove, Shanley and Schaefer (2010) introduce the concept of the value map in their discussion of value creation. Economic value is created when the producer combines inputs such as labour, raw materials, capital and purchased components to produce a product whose perceived benefit exceeds the cost incurred to produce.

The value can be expressed as the following:

$$\text{Value Created} = \text{Benefit} - \text{Cost}$$

The value created is divided between the consumer and producer. The price forms the separating point between the producer surplus (value to the producer) and the consumer surplus (value to the consumer).

Therefore:

$$\begin{aligned}\text{Value Created} &= \text{Consumer Surplus} + \text{Producer Surplus} \\ &= (\text{Benefit} - \text{Price}) + (\text{Price} - \text{Cost}) \\ &= \text{Benefit} - \text{Cost}\end{aligned}$$

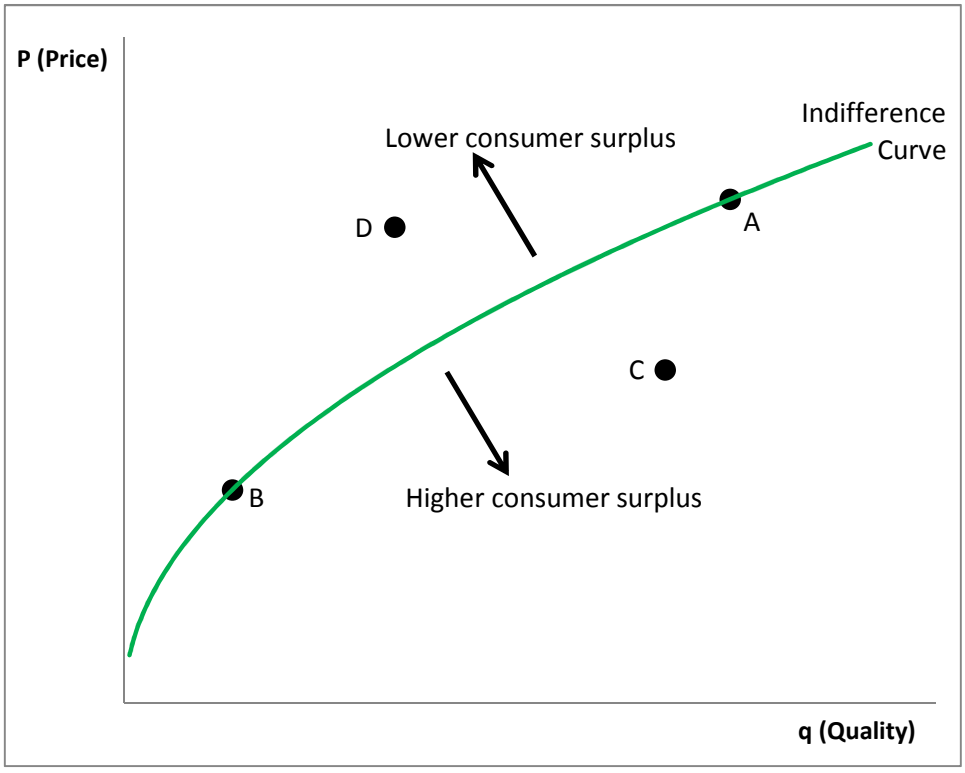
The price is the maximum amount the consumer is willing to pay for the product before switching to a substitute product. In markets with little or no substitute products available, then the price will be higher and the producer will enjoy a greater proportion of the value created. In the case of patent protection the producer may at times enjoy all of the value created due to lack of equivalent substitutes.

For pharmaceutical products, the benefit derived for the consumer is cure or well-being from consuming the product. If a product is patent protected, then the consumer is limited in choice however once the market expands through the entry of generic products the choice widens. The benefit remains the same however the value created to the consumer would now include other factors such as confidence in the quality of

the product and trustworthiness of the brand. Pharmaceuticals may be considered as experience or credence goods, for which the consumer has less information about the quality of the product than the producer (Scott Morton & Kyle, 2012).

The concept of value creation discuss above can be graphically represented by the value map. The value map as described by Besanko et al. (2010) illustrates the price-quality positions of the products in the market. Key to the value map is the indifference curve; this is the solid line which yields price-quality combinations which yield the same consumer surplus. Positions above the line will reduce consumer surplus and positions below the line will increase consumer surplus. Figure 3 shows an example of a typical value map.

Figure 3: Typical value map (Besanko et al., 2010)



A product positioned in position D offers less consumer surplus than its rivals and will lose sales and market share to its rivals. Under patent protection a product may be positioned at position D due to the lack of substitute products available. However once patent protection has been removed and rivals enter consumers may switch to products positioned to offer higher consumer surplus.

The value map is revisited towards the end of this literature review to position the proposed research questions.

2.2.2 Barriers to entry

Market power can only persist when there are barriers to entry which limit the extent of competition. Entry barriers are of interest in terms of corporate strategy and public policy. From a corporate strategy point of view it is of interest to protect market power and profits which result in firms considering profitable entry deterrence objectives. It is similarly important for public policy to limit anti-competitive behaviour and monopoly profits which negatively impact society (Church & Ware, 2000).

Besanko et al. (2010) use economist Joseph Bain's three entry conditions to discuss barriers to entry.

> *Blockaded entry* – This refers to structural barriers that are so high that entry is impossible and the incumbent need not do anything to deter entry. This is most relevant when considering intellectual property protection for pharmaceutical product. While the patent is in place entry is blockaded.
>
> *Accommodated entry* – When structural barriers are too low then entry deterring strategies will be ineffective or unprofitable. In other words entry is so attractive that incumbents should not waste resources trying to deter it.
>
> *Deterred entry* – Entry is prevented, not blockaded if the incumbent can successfully employ entry deterring strategies which simultaneously boost profits.

The conditions of the market determine which strategy to pursue. This is relevant to pharmaceutical products when a patent expires and the market transitions from blockaded entry to either accommodated entry or deterred entry conditions. These considerations form part of the chosen product strategy.

It is important to note that when entry-deterring behaviour is discussed it is from a theoretical economic view point and not anti-competitive or illegal behaviour. Firms are naturally reluctant to report entry deterring behaviour as this may be sensitive, competitive information that might violate anti-trust statutes (Besanko et al., 2010).

2.2.3 Entry deterring strategies

From a theoretical stand point the following strategies have been suggested to deter entry into a market. Strategies directly related to pharmaceutical post patent behaviour are discussed in later sections, however they are under pinned by the below principles.

Besanko et al (2010) referred to the following barriers used to deter entry:

Sunk costs – Costs which the incumbent has incurred and entrants would need to. These costs must be truly sunk.

Production barriers – Economies of scale or scope; or access to superior production inputs or knowledge.

Reputation – Long standing relationship with customers which manifests into loyalty. This would include intensive advertising to increase brand loyalty.

Switching costs – These are costs involved to change to another product; this includes the scenario when consumers perceive generic entrants to be different from incumbents.

Limit pricing – Prices are lowered before entry to deter entry by making the profits available less attractive to entrants.

Predatory pricing – Incumbent sets a low price to drive smaller rivals from the market.

Holding excess capacity – This allows the incumbent to flood the market to reduce prices.

The above strategies either intend to create high entry costs or create uncertainty regarding post entry profits.

Schmalensee's (1978) study of the ready-to-eat breakfast cereal market in the United States of America provides a good example of entry deterring barriers. The study showed the manufacturers competed through product differentiation using the continual launch of new brands and not through price. This meant that a few large manufacturers had many brands in the markets. The cost to produce many brands was negligible with many being produced through the same production facilities. A new entrant was found to have to produce between six and twelve successful brands in order to enter the market. The focus of incumbent manufacturers was on the continual launch and promotion of new brands.

2.2.4 Impact of institutions on economic progression

Institutions which are human devised constraints give structure to political, economic and social interaction. They have been implemented throughout history to create order and reduce uncertainty in exchange. These institutions determine the transaction costs

of engaging in economic activity, in other words they define the rules of the game (North, 1991). Acemoglu, Johnson and Robinson (2005) support this notion that institutions are a fundamental cause of differences in economic development by determining the incentives of and the constraints on economic actors.

Transaction costs are a critical determinant of economic performance. A major focus of literature has been on institutions as efficient solutions to problems of organisation, and in most cases are taken as given. However, economic history is overwhelmed with economies that failed to produce a set of economic rules of the game which produced sustained economic growth (North, 1991). The performance of these institutions therefore must be considered when assessing the choices made by companies in the economy and cannot be assumed as efficient.

In South Africa, institutions govern the registration of pharmaceuticals as well as regulate the price, the channels to market and advertising of products. In particular the registration of products is critical, as a product cannot be traded on the market until it is registered. Delays or inefficiencies in this registration therefore impacts economic activity.

2.3 Strategies to manage patent expiry

Industrial organisation, which focuses on the behaviour of firms in imperfectly competitive markets, assumes firms are profit-maximising in their behaviour (Church & Ware, 2000). This is a reasonable assumption in the private pharmaceutical industry in South Africa as it was recently described as a highly profitable for companies ("Competitive Landscape", 2013). This profit taking is largely attributed to manufacturers having the market power to charge higher prices. The ability of the firm to raise its prices depends on the extent to which consumers can switch to another supplier (Church & Ware, 2000). This power can be created through a number of mechanisms the most relevant in the pharmaceutical market is that of legal protection via a patent or other exclusivity agreement. (Baye, 2010).

2.3.1 Extending patent protection

The most effective way to maintain this market power is to extend or strengthen the barriers to entry (Church & Ware, 2000). This behaviour is evident in originator behaviour discussed in numerous cases of using patent laws, loop-holes and extensions to prolong the length of time for exclusivity (Dwivedi, Hallihosur & Rangan,

2010; Evans, 2010). Patent extension strategies involve the modification of the product through dosage, use or delivery method. Companies even go as far as attempting to change the shape or colour of the product to extend the protection (Dwivedi et al., 2010).

However this process of renewing patents through extensions or slight adjustments is gaining increased attention from government regulators and the requirements for extensions are becoming more stringent (Evans, 2010). As such other variables need to be considered to maximise profits when market exclusivity is lost.

2.3.2 Variables available to maximise profits

It has been suggested that pharmaceutical innovators have two main instruments to maximise the value of their innovations during the period of exclusivity and post patent protection, namely price and advertising (Caves et al, 1991). This is supported by Scott Morton (2000) in particular when considering how to influence the state of the market upon generic entry. Other authors (Agrawal & Thakkar, 1997; Barak & Wilson, 2003; Kvesic, 2008; Wilkie, Johnson & White, 2012) agreed with these possibilities and added to the alternatives through the introduction of a product extension, transition to a new product or the introduction of a generic product.

Lichtenberg and Duflos (2009) in a study of "virtually all prescription drugs sold in the United States during the period 2000-2004" (p.3) showed that, consistent with expectations, the effect of price on demand was negative and highly significant, and the effect of advertising on demand was positive and highly significant. However, they did caution that the impact of price was not as strong as expected due to complexities of medical schemes resulting in the end user not paying the full price.

Thomas (1999) compared the theoretical research that incumbents can use price, advertising or new products to deter or limit entry with empirical evidence from the ready-to-eat breakfast cereal market. Although there are marked differences to the pharmaceutical market these findings support the consistency of the theoretical research. Simon (2005) completed similar research using subscription magazines and like Thomas found that although the variables used to both accommodate and deter entry were consistent to the theoretical research, the manner in which they were used is not.

The variables of price, advertising and new products can be graphically represented in terms of the value map introduced previously. For an off-patent product positioned [B]

above the indifference curve, either a reduction in price or increase in promotion will potentially move the product closer to the curve to prevent market share loss as shown in Figure 4.

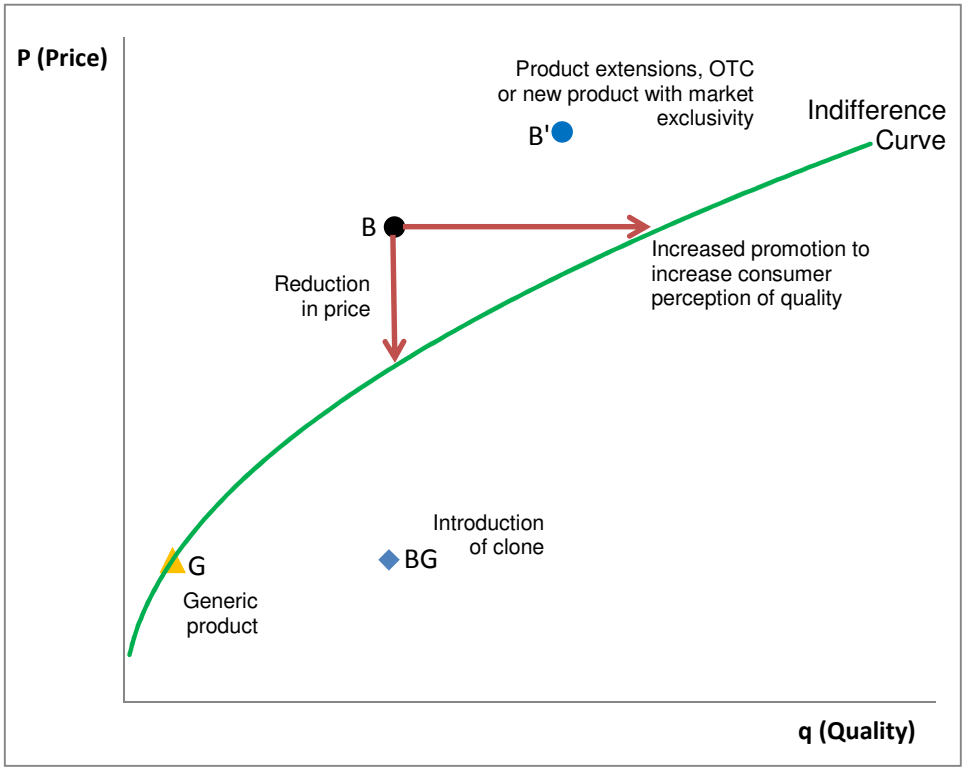
Alternatively a new product is introduced to the market via product extensions, reformulation into an over-the-counter product with market exclusivity [B'] to transfer the consumer base. Finally a pseudo-generic or clone is introduced [BG] to compete directly with generic competition [G]. The positioning of [G], [BG] and [B'] are assumed using the following assumptions.

B' – Improved quality due to meaningful product improvements which are patent protected.

BG – Equivalent to B in quality due to it being an exact clone as the original product. This product may be positioned lower in terms of quality if the nature of clones is not understood by the market and they are interpreted as independent generics.

G – Low priced and lesser quality due to the perception of generics. This product could be higher positioned in terms of quality depending on the company. Position [G] is effectively worse case.

Figure 4: Value map with potential off-patent strategies illustrated



The use of price, advertising and the introduction of a new products or clones however are not consistently applied and various studies have provided conflicting conclusions.

The following sections will consider each variable in isolation and discuss those elements key to each factor. From there a select number of strategies which consider these variables as a combination are discussed.

2.3.3 Price

The entry of generic products can see the average price for the molecule decline by between 65 and 80 percent of the pre-patent expiry price (Berndt, Kyle, & Ling, 2003). This significant difference has therefore focused much of the research on the effects of generic prices on branded prices (Wilkie et al., 2012). Pricing is very important when a product loses market exclusivity and faces the threat of less expensive generic products entering the market. The company must decide whether to maintain the price and potentially lose sales volume, reduce the price and meet the competition head on at the risk of potentially losing profit or even increase the price to increase profitability in the short term (Kvesic, 2008).

The timing of the pricing strategy implementation is also important as changes to the price before market exclusivity loss would indicate an attempt to deter entry whereas changes after generic entry would be more focused on protecting market share from competitors thereby accommodating entry. There is however much debate whether price is the most effective component to use in attempts to both deter entry and protect market share (Wilkie et al., 2012).

Scott Morton (2000) argued that although limit pricing is a well-known theoretical approach it is in fact not sustainable in the pharmaceutical market. In theory the originator lowers the price before patent expiry which will force generic entry at a lower price as generics have to enter at a lower price in order to sell and in some cases as stipulated by law. For example in Canada generics have to be at least 30 percent cheaper than the original (Hollis, 2005). Limit pricing suggests that the lower expected profits do not justify the fixed costs incurred for entry by generic firms (Scott Morton, 2000).

However due to the profit-maximising behaviour of branded pharmaceutical companies this behaviour has yet to be observed (Wilkie et al., 2012). Scott Morton (2000) reasoned that this behaviour is not sustainable as after patent expiration the branded product would not be able to sustain a price low enough to be profitable and deter

entry. Further to this she added that the complexity of the doctor who prescribes the product not sharing in the cost saving will limit the build-up of a consumer base which can be exploited later. In their study of oral solid prescription medicine in the United States over the period January 2003 to December 2008, Tenn and Wendling (2010) found conflicting evidence of how price is used to deter entry. In smaller drug markets incumbents lowered price in response to potential competition and appeared to deter entry. In larger markets however incumbents lowered price only in response to competition, signifying a more accommodating approach. These findings lead to the conclusion that under certain circumstances price can be used to deter entry.

Ellison and Ellison (2007) support this notion through their findings that entry deterrence investments are relevant only in certain market sizes. In large markets these investments are wasted as deterrence is impossible and in smaller markets these investments are unnecessary as entry is unlikely. Magazzini, Pammolli, and Riccaboni (2004) in their study of pharmaceutical markets in four major developed countries (USA, UK, Germany and France) found supporting evidence that markets with high margins attract entry of generic drugs. Although the country's regulatory environment does impact the dynamics between incumbent and generic pricing behaviour, their findings were consistent that the absolute size of the market determined the extent and impact of generic entry.

This conflicting behaviour is not unique to the pharmaceutical industry. In his study of magazine subscriptions, Simon (2005) was largely focused on price and found that in some instances incumbents cut prices to deter entry but in other cases, prices remained unchanged hence accommodating entry. In some cases prices were raised reflecting profit-maximising behaviour. The dominant strategy seemed to be to leave prices largely unchanged and compete through other means such as innovation and promotion.

This is consistent with the findings of Caves et al. (1991) who showed that the average price for branded products only fell by two percent with the launch of the first generic. Numerous studies since this initial study (Frank & Salkever, 1997; Lexchin, 2004; Regan, 2008) have found supporting evidence showing that the branded price did not decline upon generic entry and in some cases actually increased.

Lexchin (2004) in his study of 81 different products in 144 separate presentations in Canada found no statistically significant change in prices when generic competition started. Further to this he found that once there were four or more generic products in the market, there was a rise in the price of the brand name product. Similar results

were found by Frank and Salkever (1997) in their study of 32 drugs which lost patent protection in the United States in the mid-1980s. Their results provided evidence that branded product prices increase after generic entry. Dylst and Simoens (2011) in a study of 35 active substances across ten countries in Europe investigated the impact of generic market share on the price of the overall medicine category. They found that markets with high generic market share had a sharper decline in the overall price of the molecule. However the price competition was found to be between the generic products with the original product maintaining or only slightly lowering in price but losing significant market share in terms of sales volume.

Finally, Berndt et al. (2003) in their study of H_2 blockers, which are used to treat acid reflux, predicted and showed that the branded products did not compete on price with generic entrants following patent expiry. Instead they maintained or even slightly increased brand prices, losing market share and retaining sales to a smaller but relatively price-insensitive segment of brand loyal customers. They concluded that attempts to compete on price would result in a price war which the original manufacturers would not be able to sustain.

Frank & Salkever (1997) were the first to suggest that market segmentation as a result of generic entry was the underlying reason for this observed phenomenon of increasing branded product prices despite increased competition. This phenomenon is referred to as the generic paradox. The conventional economic reasoning that an increase in the number of suppliers results in a decreased equilibrium price seems only to apply to the generic market. The market is segmented into price-sensitive and price-insensitive, brand loyal consumers. This group of brand loyal consumers is a smaller submarket of the initial market served during patent protection. After the initial, almost immediate, decline in market share when generic products enter, the market share for brand loyal consumers seemed to stabilise. This brand loyalty acquired during the years of patent protection was largely created through marketing efforts and physician-prescribing patterns and allows the branded firms to continue charging higher prices despite the presence of lower priced generic competition.

Wiggins and Maness (2004) investigated the anti-infective market in the United States between 1984 and 1990. Their findings showed the opposite effect to that described by Frank & Salkever (1997), finding a statistically significant impact of generic prices on branded prices. As generics entered the market, the brand products did reduce in price. In conclusion they commented that this finding may be due to the relative price sensitivity of the entire class of anti-infectives and the results may not be relevant

across other classes in the market. Although they acknowledge that product differentiation does exist between the original and generic products, they insist that the two do interact and that the market segmentation hypothesis does not necessarily explain this interaction.

In contrast to this, through her study of 18 prescription pharmaceutical products which lost patent protection in the United States between 1998 and 2002, Regan (2008) found further evidence of the generic paradox. The study expanded on the concept of market segmentation. She concluded that market segmentation does exist with branded products being focused at brand loyal, price insensitive consumers to allow companies to still earn market profits despite the presence of lower priced generic competitors. As with most investigations involving pricing in the pharmaceutical industry, there exists a large degree of inconsistency regarding the behaviour of branded prices.

In conclusion, the decisions made regarding price as both a means to deter entry through the lowering of the profitability of the market as well as a means to compete directly with lower priced generics lack consistency and depend on other characteristics of the market. However, although examples do exist to the contrary, the dominant strategy regarding price seems to be to keep the price at the same level and focus on the smaller number of brand-loyal, price-insensitive consumers. This will result in reduced market share when generic products enter the market, however it avoids the inevitable price war as generics will always enter the market at a lower price. This lower price is undesirable for branded products to maintain as both a limit-pricing, entry-deterring strategy and a lowest cost strategy. The main reason for this is due to the profit-maximising behaviour of the firms, although their market share will reduce once market exclusivity lapses, serving a smaller price insensitive market at a higher price is found to be more profitable than serving a larger market share at a lower price.

2.3.4 Advertising

A variety of strategies are employed to promote pharmaceuticals including direct-to-consumer advertising, physician detailing, journal advertising as well as the provision of free samples to physicians. Promotional expenditure represents a significant portion of the post-launch non-research and development costs (Huskamp, Donohue, Koss, Berndt & Frank, 2008). In South Africa, only schedule 2 and below pharmaceuticals are allowed to be advertised directly to consumers, all advertising for higher schedules is

only allowed towards licenced professionals (Gray & Day, 2000). The schedule status of pharmaceuticals is used to categorise products according to their characteristics. Different regulations are applied to the different schedule statuses. As the schedule status increases, the regulations governing its use become more stringent.

Similar nuances exist throughout the global pharmaceutical industry which has a number of important factors to consider when discussing promotional spending and advertising. Firstly, as discussed previously consumers generally need to have a prescription from a physician to buy most pharmaceuticals. The importance of this is shown by the fact that more than 60 percent of the combined promotional spend is aimed at physicians (Huskamp et al., 2008). Detailing, which involves educational and sales calls to physicians, is therefore an important part of promotional activities.

The second feature of this market is that the majority of prescription drug expenditures are paid for by a third party insurer such as a medical aid company. In recent years these companies, in an effort to bring down the total cost of expenditures, have introduced tiered formularies which result in patients having to potentially pay in a co-payment if the full price is not covered (Huskamp et al., 2008).

Theoretically, advertising has been suggested as both a method to deter entry as well as a way to secure, grow or maintain market share in light of competition (Wilkie et al., 2012). However conflicting results in the literature raise questions as to the validity of this approach.

Thomas (1999) argued that by increasing the cost of entry for a competitor through advertising, entry could be deterred. However Scott Morton (2000) counters this by showing that since the cost of entry for generic competitors is so low the use of advertising has been shown not to deter entry. Ellison and Ellison (2007) support this notion for very large markets where they suggest any attempt to deter generic entry is futile. However in medium-sized markets they found that the level of detailing and journal advertising decreased in what is suggested as an attempt to deter entry by letting the “marginal market decay to make it less attractive to generic entrants” (Ellison & Ellison, 2007, p. 29)

This notion is reinforced by Scott Morton (2000) who concluded that advertising in fact could help increase the market size for a particular product category and therefore increases the profit expectations of generic companies wishing to share in the profits. It was therefore suggested that advertising would in fact increase the probability of generic entry.

Wilkie et al. (2012), through their study of three over-the-counter (OTC) allergy products which faced generic competition from 21 generic brands in the Australian market, concluded that advertising had no significant impact on reducing the number of generic entrants. The results did however provide evidence that advertising did help defend the branded product from loss of market share to generic brands.

By incorporating this finding of advertising protecting market share with the market segmentation raised by Regan (2008), advertising spend could be thought to increase in the years preceding patent expiry in order to boost brand loyalty and grow the size of the price insensitive segment. However this was counter argued by Berndt et al. (2003) who found a substantial decline in marketing efforts by firms when patent expiration approached. In their study of Zantac, an H_2 blocker used to treat acid reflux, they found that detailing efforts and journal advertising decreased leading up to the patent expiry as well as after the patent expiry. Marketing efforts continued to decline even as generic products entered the market. It must be noted that the H_2 blocker market as a whole was also in decline due to the entry of superior products; however the findings are consistent with other studies in different markets.

Finally Scott Morton (2000) showed that the amount of time on patent negatively correlates with expenditure on detailing and advertising, this implies that less is spent on promotion the longer the drug is on the market. From this it is concluded that the impacts of advertising and promotion show limited returns due to the life stage of the product. Berndt et al. (2003) arrived at a similar conclusion commenting that the decline in marketing efforts by branded firms as patent expiration approached suggests long-term anticipated sales impacts from marketing rather than short lived influences. Wilkie et al. (2012) agreed that this behaviour is consistent with a profit-maximising strategy of firms which indicates that advertising is reduced to cut costs thereby increasing profits and not to impact the state of the market before or after generic entry.

In summary, although advertising is suggested theoretically as a strategy to both deter entry and protect market share, the literature discussed above shows evidence that the dominant strategy with regards to advertising and promotion is to reduce expenditure to maximise profits both as patent expiration approaches and generic entry occurs.

2.3.5 Product extensions, fighter brands or over-the-counter products

A number of companies have succeeded in securing or maintaining market share following patent expiry through the use of innovation strategies. Such strategies involved the launching of a second generation or reformulated product, indication

extensions or other improvements which provide more value for money or improved therapeutic features (Kvesic, 2008).

These innovations fall short of introducing a new molecule but rather build on or add to the existing molecule. Depending on the extent of the innovation a secondary patent may be awarded which would extend the period of market exclusivity not for the original molecule but for the new form. This patent protection may be awarded due to the new product formulation, a technical characteristic of the product such as a slow release mechanism or the targeting of a new indication such as demonstrating effectiveness in the paediatric population (Kvesic, 2008).

Product extensions or reformulations require significant investment in research and development as well as testing and approval. In some instances as was the case for GSK's Clamoxyl, this strategy was problematic to follow because it was increasingly difficult to improve the product (Chandon, 2004). Product extensions may in some instances therefore not be an option purely because they do not exist.

The introduction of product line extensions is a means of adding further value to the consumer with the distinct aim of shifting consumer preferences towards the new product before the introduction of a competitor to the original product. To this end the product extension is launched prior to patent expiry to deter entry (Reiffen & Ward, 2007). By doing so the number of profitable positions for a rival entrant to target is reduced and the range required to be replicated is larger (Thomas, 1999). The investment required to produce product extensions also signals to potential competitors that the company is investing its resources into growing the product and that existing technology may soon be out-dated (Wilkie et al., 2012).

Huskamp et al. (2008) in their research into the promotional activities around the introduction of new product formulations found that the common strategy was to extend market exclusivity by transferring consumers from the original branded product to the new protected formulation prior to patent expiry. For these original products, which were facing impending generic entry, the product extension was launched long before generic entry, up to 27 months prior in one case. Promotional spend and focus also then shifted to the new product to facilitate the switch in consumer preference.

However, findings by Wilkie et al. (2012) did not conclusively support these findings. The launch of innovative product extensions in the Australian allergy market did not significantly reduce the market share of generic competitors in their sample. Kvesic (2008) identifies this as the major risk of this strategy. He states that if the product

extension is deemed by consumers not to add value or is “perceived as a marketing gimmick” (p 297), not only will generic entry not be affected but the brand may be negatively impacted. Further to this if product extensions are not awarded a secondary patent then they can be replicated by generic companies when the original patent expires (Chandon, 2004).

Finally the trade-off of when to launch product extensions is raised by Huskamp et al. (2008) as vital to the decision. Launching too soon may erode current profits; however delaying the launch may limit the opportunity to switch consumers to the new product before generic products enter the market.

The launch of a fighter brand product follows the same logic of transitioning consumers to a superior product which ideally is still under patent protection. Particularly in cases where the brand loyalty is low and brand sensitivity is high, a fighter brand may be launched to build a stronger brand for the product and switch consumers from the old brand to the new. This approach was used by Smithkline Beecham to maintain the company’s market share in the Dutch antibiotic market through the launch of Augmentin (Barak & Wilson, 2003).

The launch of an OTC version is another way to increase the value of a product. The major benefit of OTC products is that a doctor’s prescription is not required to buy the product. This has obvious benefits to the consumer and as such is a strategy used to further add value to a product reaching expiry. Not only does the consumer need not have a prescription but OTC products can be directly advertised to consumers whereas in Europe and South Africa prescription products may not. Brand loyalty can therefore be built directly with the end consumer and is not reliant a doctor’s preference to prescribe the product (Kvesic, 2008). Due to the nature of some products an OTC version may not be an option due to regulations in place regarding the schedule of the product.

When the successful antacid Tagamet was reaching patent expiry, Smithkline Beecham developed a milder version which could be sold over the counter. This caused a shift in the market resulting in other branded products producing OTC versions of their products long before their patents expired (Kvesic, 2008).

In conclusion, product extensions, fighter brands and OTC versions, when available, ideally need to extend market exclusivity and at the least sufficiently switch consumer preferences to the new product prior to generic entry to achieve their purpose of

securing future revenue. This strategy essentially introduces a new and superior product to the market.

2.3.6 Clones

A practice which emerged in the early 1990's, then declined during the late 1990's and has recently re-emerged, is that of patent holders producing their own generic version of the original product (Reiffen & Ward, 2007). These products are often referred to as authorised generics, pseudo-generics, branded generics or clones. The products in most instances are produced on the same production line as the original product and are then branded and marketed as low price items (Hollis, 2005). The practice has garnered much debate for the harm to potential competitors is clear as the introduction of a branded generic may preclude the opportunity for an independent generic from entering the market. Potential harm to competitors does not imply potential harm to consumers but the risk does exist that the overall equilibrium price may be higher in the long run due to the incumbent firm dominating the market (Reiffen & Ward, 2007).

Several strategic reasons exist as to why a clone would be launched, these include deterring entry from independent generics, gaining first-to-market advantage to capture the majority share of the generic market and helping to control the price of the generic market (Wilkie et al., 2012). Numerous studies (Hollis, 2002, 2003; Reiffen & Ward, 2007; Scott Morton, 2000) have investigated these impacts and their findings are discussed below.

In his study of the Canadian generic market of which 25 percent is made up of pseudo-generics, Hollis (2003) finds evidence that pseudo-generics have slowed or even deterred entry by independent generic products. This is particularly prevalent in smaller markets which have the capacity to support only one generic product. He concludes that the size of the market will impact these strategic effects; however shows that in the Canadian market pseudo-generics both deterred and slowed independent generic entry. By doing so the branded company enjoys continued dominance in the market from both the original product and the generic product.

Reiffen and Ward (2007) added to this argument by showing that due to the advantage of getting to market first by being able to launch the pseudo-generic whilst still under patent, potential independent generics are discouraged from entering. This is highly dependent on being first to the market. Hollis (2002) finds similar evidence using a cross section of data from Canadian markets from the 1990s. He empirically shows that generic companies which are the first to enter can achieve an increased market

share of 30 percent. This provides support to the notion that if pseudo-generics are able to capture the majority of the market it may deter entry from independents.

Hollis (2002) then further postulates that the reason for success for the first mover is related to the switching cost. Through qualitative research to support his empirical findings, Hollis (2002) interviewed a number of pharmacists. The general opinion was that due to the troublesome nature of explaining bio-equivalence to patients, it was easier to continue selling the first generic on the market. The price difference between the branded product and the generic made it easy to switch the patient to the first generic, but the situation got more complicated trying to explain the difference between two generics both at similar price points. Linked to this is the lack of incentive for the pharmacist to sell different generics as the same dispensing fee is earned for both. This creates a switching cost for both the pharmacist and the patient resulting in the first-to-market generic being the market leader.

While there is limited debate as to the success of being first to market, there is still much debate as to the reason why a pseudo-generic is launched. One reason, discussed previously is to deter entry. The other is to compete for market share with generic competition without having to drop the price of the branded product. Kong and Seldon (2004) found evidence which supports both propositions. Using a two stage game model, they hypothesised that under somewhat restricted but plausible conditions pseudo-generics may be used to deter entry. Of more significance however they found that pseudo-generics were more likely to form part of a profit-maximising strategy to supply at least part of the market that would otherwise be served by true generics.

From an empirical standpoint, Appelt (2010) argues against the proposition that the pseudo-generic is launched to deter entry but rather shows evidence to support her argument that the pseudo-generics are a tactic to extract generic profits. Through a study of the German pharmaceutical market which is the second biggest generic market in the world (Appelt, 2010) it was found that independent generic entry decisions were primarily influenced by the drug market's pre-entry revenues. Pseudo-generics were found to have no significant impact on the entry of independent generics.

Wilkie et al. (2012) agree with these findings and show further evidence from their study of the Australian allergy market. However they extend the clarification further by showing that although entry is not deterred, the pseudo-generic presence does reduce the number of generic entrants into the market. The first-to-market advantage is also

shown to have a significant impact with the second-to-market product achieving as much as 19 percent less market share.

Regardless of the reason for launching a pseudo-generic, the originator would still benefit from both the price-insensitive, brand loyal market for the branded product as well as the largest share of the lower priced generic market. This approach, although theoretically appealing, does not consider the overall cannibalising of the original brand's market by the generic. The timing of launching a pseudo-generic is therefore critical. By launching too early the profits from market exclusivity are unnecessarily eroded whereas launching too late, sufficient market traction may not be achieved to secure the dominate position in the generic market (Jain & Conley, 2012).

The pseudo-generic strategy seems to be re-emerging as the preferred strategy to manage the loss of market exclusivity (Wilkie et al., 2012). This strategy is largely dependent on being first-to-market which is mostly guaranteed since the originator company does not have to wait for patent expiry to end before the pseudo-generic can enter. From the advantage of being first-to-market, studies have shown both the benefit of entry deterrence and largest share of generic profits being extracted.

2.4 South Africa specific variables

Pharmaceutical markets are unique to each country due to the varying combinations of regulations in place. The following section highlights major regulatory factors which are relevant to the South African private pharmaceutical market.

2.4.1 Medicines Controls Council

The Medicines Control Council (MCC) was established to oversee the regulation of medicines in South Africa. The primary purpose of this statutory body is to safeguard and protect the public by ensuring that all medicines that are sold and used in South Africa are safe, therapeutically effective and in line with required standards of quality (DOH, 2013). As per the mandate which governs the MCC, all new medicines have to be approved and registered by the MCC before they can be launched.

The MCC has been identified as the main cause for delay when launching new products in South Africa. The registration of product takes much longer when compared to the time take for US or European regulators to approve new products or clinical trials. A new regulatory body, the South African Health Products Regulatory

Agency [SAHPRA] has been proposed to parliamentary cabinet. It is envisaged that this new body will resolve many of the delays (Kahn, 2013).

2.4.2 Generic substitution

As discussed previously, Single Exit Pricing (SEP) was introduced to control the price of pharmaceuticals in the private pharmaceutical market in South Africa. The introduction of SEP prevented discounts and additional levies on drugs and therefore limited price competition through discounting and averted predatory pricing strategies. To further minimise the impact of price premiums, schemes were implemented to encourage generic utilisation (Brems, Seville & Baeyens, 2011).

One scheme, implemented by the South African government to promote the use of generics in order to drive down the cost of pharmaceuticals, was generic substitution. This dictates by law that the pharmacist must offer the cheaper generic alternative and dispense it unless the patient or the doctor has specifically refused to substitute (Medicines and related substances control amendment act of 1997, 1997). This was required as the behaviour of doctors prescribing brand name pharmaceuticals even though cheaper generics were available, was consistent to that described by Caves et al. (1991) wherein the doctors, who were used to prescribing the original product, had no incentive to change their behaviour.

2.5 Market strategies

The previous sections considered the alternatives of price, advertising, new product extensions, new products and the introduction of clones as possible variables to consider when faced with loss of market exclusivity. These are summarised in the following section as a synthesis of approaches put forward by Wilkie et al.(2012), Kvesic (2008), Barak and Wilson (2003), Agrawal and Thakkar (1997).

A brief description of the strategy and key considerations when faced with the loss of market exclusivity are given as follows:

Maintain or even increase the sales price and operate at lower sales volume

This strategy relies on the brand value of the product to maintain support from brand loyal, price-insensitive consumers. It is also applicable in cases where

the threat of generic entry is low. Promotion and advertising may continue as is or could be reduced to truly harvest the remaining profit from the brand. In some cases the advertising spends could be increased to strengthen the brand. It must be remembered that under the regulation of SEP in South Africa the price cannot be easily increased.

Lower prices to meet generic competition head on

The price is substantially lowered either before patent expiry to deter entry or on patent expiry to compete with generic entrants head on. In other markets discounting could be selective, however in South Africa with SEP this discounted price would be standard for all customers. Lowering the price is rarely a good idea as in past cases it has shown to merely cannibalise profits and not defend against generics.

Launch a pseudo-generic to compete with generic competition

A pseudo-generic or authorised generic is a generic product licensed by or directly manufactured by the originator. This comes with the advantage of being first-to-market thereby capturing a large proportion of the generic market. Its primary purpose is to defend against cannibalisation by competitors. The necessary organisational support, partnerships, resources and capabilities need to be available in order for this strategy to be followed.

Launch a fighter brand, product extensions or a new product to convert consumers to a new superior product

The new product is created to cannibalise the market of the original brand with the intention that the consumer base will move to the new product rather than a competitor. In certain circumstances the new product may still be protected by a patent or a more desirable product such as an OTC version. This strategy is dependent on the availability or development of such products.

Divesture

Divesting a product involves cutting all expenses such as research and advertising related to the product. The product is either sold or licensed to another manufacturer once generic competition enters or in some cases completely removed from the market. This can occur at any point and allows resources to be focused on other products in the company. Short-term profits

can be gained by raising the price before the product is discontinued to harvest the remaining brand image. This will not be possible in South Africa under SEP. This strategy depends on the overall company strategy.

2.6 Conclusion

By considering the fundamental economic theory of value creation and its division between producer and consumer surplus, the complexities of successfully managing the transition from a patent protected market to a more open market were considered in the literature review. The variables of price, advertising, new and improved products and the launch of pseudo-generics were reviewed through studies in other pharmaceutical markets in the world.

Price although theoretically a variable which could deter entry through limit pricing was found to be rarely utilised to attempt to deter entry. The primary reason for this was the intention to continue to earn profits from the remaining but smaller market share. As part of this profit-maximising behaviour advertising and promotion were reduced on patent expiry. No short-term benefits were found to justify an increase advertising or promotion activity prior to patent expiry. When available, superior and in some instances patent protected product extensions, fighter brands or OTC products were launched to transition consumers to the more superior product.

As discussed the price of the original product was not used as the primary defence against generic competition. Instead originator companies have with increasing frequency launched pseudo-generic products to compete directly with independent generic products. The timing of the launch is a critical decision with first-to-market products showing a distinct advantage in both the US and Canadian markets. Originator firms are therefore incentivised to launch a pseudo-generic prior to patent expiration. However launching a pseudo-generic product too early may unnecessarily erode profits of the original product.

The choice of product strategy to pursue is not clearly identified and is influenced by the product, market conditions, market size as well as the regulations of the country. The studies reviewed showed conflicting findings for most of the variables considered. The results of this study must therefore be reviewed with this in mind that the findings may not necessarily be transferable to other markets or even products within the South African market.

3. Research propositions

The previous chapter discussed a variety of strategies to be pursed when faced with impending loss of patent protection for a pharmaceutical product. Many studies have been completed by looking at the empirical evidence regarding chosen strategies. The intention of this research is to explore the rationale behind those decisions.

As such the following propositions will be investigated for a select number of products in the South African pharmaceutical market.

1. The price of branded pharmaceuticals is not used as a means to either deter entry or compete with generic products.

2. Clones are launched to capture a share of the generic market and defend market share, not to deter entry.

3. Advertising or promotion of the branded product is reduced on patent expiry to maximise profits.

4. Product extensions, fighter brands, over-the-counter products or new products are introduced to extend market exclusivity.

5. The branded product is always left on the market to capture remaining profit from brand loyal or price insensitive consumers.

4. Research methodology

The following section describes the research design followed to achieve the research objectives. It further discusses the unit of analysis, sampling method and sample size as well as elements relating to the collected data. Limitations of the research are identified at the end of the section.

4.1 Research design

The objective of this research study was to understand the decisions made regarding the management of a pharmaceutical product once patent protection had expired and generic competition had occurred in the South African market. To achieve this objective the research study included considering which factors were assessed in arriving at the decision as well as the decisions made.

Previous studies (Ellison & Ellison, 2007; Hollis, 2005; Regan, 2008; Reiffen & Ward, 2007; Wiggins & Maness, 2004) have focused on the analysis of secondary data available in the public domain and in some cases private datasets to investigate what happened in the market. These studies only provided information relating to certain observable outcomes such a price changes or new product entry. The amount of spend on advertising or changes to internal processes for example were not easily detectable in these datasets. For this reason analysis of secondary data was not an appropriate method as it did not provide all data points required.

Other studies have been performed as a case study (Chandon, 2004) focusing in detail on a single product. The objective of this research was to focus on more than one product in order to be able to compare and contrast decisions made within the South African market. The case study approach was therefore not appropriate due to its narrow focus.

A structured interview or survey is a method of data collection using a questionnaire in which each respondent is asked the same set of questions in the same order by the interviewer who records the responses. This is a good method for collecting data which can then be used for descriptive analysis studies (Saunders & Lewis, 2012). This tool was appropriate for collecting data regarding the factors considered in the decision-

making process. This allowed for uniform data to be compared between products to draw conclusions.

A structured interview or survey provides a quantitative description of trends, attitudes or opinions of a sample of the population. Quantitative data is best used for descriptive or explanatory studies whereby the sample is sufficiently large from which to draw conclusions (Creswell, 2003).

Saunders and Lewis (2012) caution however that the method of sampling, level of bias as well as the size of the sample needs to be carefully considered when attempting to draw conclusions regarding the total population. This was a risk due to the time limitations of the research study which limited the study to a small sample set.

The opposing approach was to use qualitative data, which is non-numerical data or data that has not been quantified. Qualitative approaches are best suited for exploratory studies into areas requiring in depth research due to the complexity or newness of the topic (Saunders and Lewis, 2012).

In order to achieve the objectives of the research project both quantitative and qualitative methods were used to provide both descriptive analysis and exploratory findings. A mixed method approach using a structured interview with a section of open-ended questions was used to gather the required data. Davies (2007) suggests that both quantitative and qualitative methods can be used to describe, monitor or investigate but substantiates further that the approaches will produce different kinds of descriptions.

The structured interview ensured that all respondents were asked the same questions in the same order which allowed for similarities and differences to be identified. The open-ended questions provided flexibility for the respondents to elaborate on the quantified answer. This provided more depth into the decision-making process.

The process of deduction was used to formulate the structured interview. Saunders and Lewis (2012) define a deductive research approach as the testing of a theoretical proposition by using a research strategy specifically designed for the purpose. This approach builds a theory from the literature and then tests that theory. The relevant and possible product strategies were identified in the literature. These strategies were then positioned on the value map framework to guide the collection of data and analysis.

4.2 Unit of analysis

The research study focused on the product strategies followed once patent protection had lapsed. The unit of analysis was therefore the product or brand manager responsible for deciding on and deploying that product specific strategy.

In some cases the person responsible was not available and a member of the product team then provided the information.

4.3 Population

Saunders and Lewis (2012) define the population as the complete set of group members that meet the requirements of the study. The requirements of the study included products which had lost patent protection in the South African pharmaceutical market and experienced generic competition. The time frame was initially restricted to the years between 2000 and 2013.

Due to the strategic nature of patents and the impact of their expiration, a complete listing of all patents which expired during the selected time period was not available in the public domain and not accessible for this research. As such the complete population size is unknown.

4.4 Sampling method and size

In order to employ any form of probability sampling the complete list of the population must be used. This ensures that each member of the population has the same probability of being selected at random (Saunders & Lewis, 2012). Due to the complete population being unknown non-probability sampling was used.

The strategic nature of patent expiry which, as mentioned previously led to an unknown population, created further difficulty in selecting a sample of products. In order to overcome this, a combination of purposive sampling and self-selection sampling was used. In purposive sampling researchers, using their judgement, select members of the population which will be in a position to provide information to answer the research objectives (Saunders & Lewis, 2012).

Purposive sampling was used to select which pharmaceutical companies in South Africa would be approached to form part of the study. These companies were selected due to their known involvement in patent expiry strategies during the sample time frame. The relevant managers of these companies were approached to form part of the research study.

Once a company agreed to form part of the study, self-selection sampling was used to isolate which products would be researched. Self-selection sampling relies on sample members to identify themselves as willing participants for the research study (Saunders & Lewis, 2012). In this research study the company managers indicated which products would be relevant to discuss. In order to be relevant, a sufficiently knowledgeable product manager needed to be available to be interviewed and the product strategy had to have been actively pursued post-patent. The products used in the study were therefore self-selected by the company. Each company was asked to select a minimum of two products.

The following table provides a summary of the sample size.

Table 1: Summary of sample size

Companies approached	Declined	No response	Agreed	Number of products surveyed
6	1	1	4	14

The response rate from the companies was 66 percent resulting in a product list of 14 products. Six products were from one company, four products from another and two products each for the final two companies.

The company which declined to participate in the study cited reasons of confidentiality and corporate policy for their decision. This is understandable as the product strategy pursued is a form of competitive advantage. Those companies which agreed to be part of the study excluded certain products from the possibility of discussion due to the sensitivity of disclosing strategic information.

The 14 products surveyed met the requirements set out to achieve the research objectives. The data range was expanded to include two products which lost patent protection in 1991 and 1997 respectively. These products were included in the research due to the uniqueness of the strategies followed.

4.5 Data collection process

4.5.1 Research instrument

A questionnaire for the structured interview was designed using the literature and results of previous studies. The questionnaire consisted of both closed and open-ended questions. Closed-ended questions are best used to test existing theories described by the researcher whereas open-ended questions allow the respondent flexibility to express other thoughts which have not necessarily been identified by the researcher (Saunders & Lewis, 2012). For the purpose of this research study, closed-ended questions were used to gather information related to the factors considered in the decision process. The open-ended questions were used to understand what decisions were made and the reasoning justifying the choice.

For the closed-ended questions a combination of category and rating questions were used. Category questions are used when the answer needs to fit into a select number of categories, this allows for easier comparison between respondents. Rating questions are used to collect the respondent's opinion (Saunders & Lewis, 2012). The open-ended questions were preceded with a closed category questions [Yes or No] and then allowed for elaboration or reasoning to be given. This provided the opportunity for the respondent to further explain the decisions taken.

The questionnaire consisted of four sections:

- Section A – Product specific factors relating to the type of product, its significance to the company, market conditions prior to expiry and threat of generic competition. These questions were used to set the context and position the product prior to expiry of patent protection.

- Section B – Rating of factors considered when deciding on the product strategy pursued. These questions considered all factors stated in the literature to be relevant to the decision. Cost of production, brand value, company expertise, investment in advertising, generic competition and costs, role of governments, impact on other products were all considered. These questions form the basis for positioning the decision in terms of the value map.

- Section C – Product strategies considered and pursued. This section consisted of open-ended questions. The relevant strategy was introduced and responses were given in two stages. Firstly, was the presented strategy considered, and

secondly if it was, did the company pursue the strategy? This section formed the majority of the interview due to the open-ended nature of the questions. Propositions 1, 2 and 4 were addressed by this section.

- Section D – Post patent decisions made in light of the factors identified as profit-maximising. The factors of cost, advertising, divesture were investigated in open-ended questions. Propositions 3 and 5 were addressed by this section.

The questionnaire can be viewed in Appendix 1.

4.5.2 Pretesting questionnaire

The questionnaire was pre-tested with three pharmacists working at UTi Pharma. The pharmacists tested the questionnaire for content and construct validity. Content validity ensures that sufficient data is collected through the questionnaire to answer the research objectives whereas construct validity ensures that the correct data is collected (Saunders & Lewis, 2012). The pre-testing also allowed the questions to be tested for ambiguity, clarity and relevance. Feedback was given on specific questions which were then refined to remove the error or improve the question.

The questionnaire was also tested with two colleagues at UTi Pharma to review the question sequence, clarity of instructions and design. Feedback was incorporated into the final questionnaire.

The pre-testing phases allowed for the length of the interview to be measured. Initially the interview took 90 minutes which was deemed too long as this would negatively impact respondents due to time constraints. Repetitive questions were identified and the questionnaire was reduced. The planned interview time was reduced to 60 minutes.

4.5.3 Data collection

All interviews were completed face-to-face. This allowed the researcher to probe further on the open-ended questions and allowed for any ambiguity to be clarified with the respondent. All interviews were personally conducted by the researcher.

The questionnaire was provided to the respondent two days before the interview to allow for preparation if required. Respondents were asked to pre-complete sections A and B in order to allow more time to focus on section C and D for the open-ended questions. Sections A and B were briefly covered in the interview to ensure that all items had been completed correctly.

The letter of informed consent was supplied with the questionnaire and was confirmed as signed before the interview would commence.

The interviews took place at the respondents' offices in a meeting room without distraction. The order of questions was followed as per the questionnaire for all interviews. All answers were captured by the researcher on the questionnaire. Only details directly related to the product in question were captured even though in some cases the respondents discussed strategies followed for other products. These points were recorded if they had relevance to the product in question. For the open-ended questions, responses were paraphrased back to the respondent by the researcher to ensure the response was correctly understood.

The interview was completed by confirming that all questions had been completed and that the respondent was satisfied with responses given.

4.5.4 Data confidentiality

The nature of the discussion was deemed as confidential by the companies who agreed to be part of the study. As such it was agreed that no product or company names would be published in the report and all descriptions would be generalised in nature to prevent the identification of products.

All products were disguised using numbers and all companies were disguised using letters of the alphabet. The following table provides the breakdown of the products and companies as coded.

Table 2: Coded products and companies

Company	Product
Company A	Product 1 to Product 4
Company B	Product 5 to Product 10
Company C	Product 11 and Product 12
Company D	Product 13 and Product 14

4.5.5 Data capturing and cleaning

The data consisted of predominantly categorical data. Categorical data represents both descriptive and ranked data (Saunders & Lewis, 2012). The descriptive data was used to set the context of the market, product and decisions made whereas ranked data was

used to prescribe importance to the factors considered in arriving at the decision. All qualitative responses to open-ended questions were recorded as text.

All questionnaires were captured into Microsoft Excel for analysis. All responses were numerically coded which allowed for easier summation and analysis (Saunders & Lewis, 2012). For questions involving a rated response, ratings were given a numerical value. Responses to open-ended questions were summarised and captured into a text block linked to the relevant question.

4.6 Data analysis

The data collected through the structured interview process was analysed using a combination of descriptive analysis techniques. The research objectives were to understand what strategies were considered and explore the reasoning behind these decisions. The analysis therefore consisted of describing the number of occurrences of certain strategies and then the collation of the most important and relevant themes supporting these decisions.

Rank ordered analysis and central tendency analysis using the mean and median was used to analyse the factors considered in arriving at the chosen strategy. This information was collected using Section B of the questionnaire. The purpose of this section was to identify the most important factors considered. Respondents were asked to rate the factor using a scale from not important to very important. Responses were assigned a rank and the mean and median were calculated per factor across all respondents. Saunders and Lewis (2012) described ranking data as an efficient way to categorise data into a meaningful sequence. By ranking those factors using the mean, the most important factors were identified for the sample. The data range did not contain any outlying or extreme variables; therefore the mean was the correct central tendency measure to use to represent the sample (Davies, 2007). The median was used to confirm the rank order.

Frequency distributions are a simple yet very effective way to review the breakdown of responses (Davies, 2007). These were used to analyse the responses in Section C. For each question presented the number of responses per category was counted. Each question tested if a defined strategy was considered and then if considered tested if that strategy was pursued. The two questions were analysed together. Pie charts,

which are appropriate to shows proportions (Saunders and Lewis, 2012) were used to graphically present the findings.

Section C also contained open-ended questions for respondents to further elaborate on the response given. The responses to these questions were recorded, compared and formulated into a narrative section to identify the most common responses related to a strategy choice. Unique responses were also highlighted where relevant. Davies (2007) suggests that this approach is best used to support the responses given and allow "the reader to get a sense of the nature and meaning of the responses offered" (p. 189).

4.7 Validity and reliability

Validity considers whether the findings are really about what they appear to be. It refers to the extent to which data collection methods accurately measure what they intended to and that the research findings are really about what they profess to be (Saunders & Lewis, 2012). Validity is therefore important in the design and execution of research. Walonick (2011) indicates that validity is generally determined by the judgement of the researcher and is therefore difficult to determine. Each question used in the structured interview had its foundation in literature from previous studies. The validity of these studies therefore may carry an impact on this study.

Reliability refers in essence to the ability to repeat the measurement to produce consistent findings over time (Walonick, 2011). It is the degree to which measures used will produce the same results on different occasions or when used by other researchers. The structured questionnaire can be used to repeat the study on different occasions. The results may be influenced by observer error whereby different researchers may ask the same question in different ways thereby biasing the answer (Saunders & Lewis, 2012). Due to the structured nature of the questionnaire this risk is minimal. Observer bias however is more relevant as different researchers may interpret the same responses in different ways. Reliability was ensured during the data collection process by the researcher repeating or paraphrasing the open-ended answers back to the respondents to confirm understanding.

4.8 Research limitations

The nature of this research study has potential research limitations. These include the following:

- Due to the time available only a small sample of products was investigated. General conclusions for the population therefore cannot be drawn without further research.
- Non-probability sampling further restricts the relevance to the sample group.
- For some products the primary product manager was not available to be interviewed. In these cases a sufficiently knowledgeable team member was interviewed.
- The focus of the interview was on factors directly related to the product under review. Only limited company specific and external non-product related factors were considered, those omitted may have impacted the product strategy
- Due to the open-ended nature of Section C and D the researcher may misinterpret the response or substitute his own understanding of the response. During the interview this was limited by the researcher repeating or paraphrasing the responses back to the respondent.
- The interviewer may lead or influence the respondent through the manner in which the question is asked.
- Due to the sensitive nature of profit taking perceptions of pharmaceutical companies, there is the risk of social bias where by the respondents will answer untruthfully to appear less profit seeking in particular when responding to questions of price increases
- The small sample of self-selected products carried the risk that the respondents answered in line with what the researcher was expecting.

5. Results

The following chapter presents the most prominent results from the interviews held with the product managers. As described in Chapter 4, data gathering took the form of face-to-face interviews using a structured questionnaire with open-ended questions to allow the respondent to elaborate. Descriptive statistics for the sample are provided first, the most important factors considered when developing the strategy are then presented and finally results relating to the actual product strategy pursued are given. The most relevant qualitative feedback from the open-ended questions is provided in support of the presented data. The presentation of data follows in the same order as the questionnaire.

5.1 Sample characteristics

The sample consisted of 14 products which lost patent protection between 1991 and 2013. The initial time period for the sample was 2000 to 2013 however the two products with patent expiry outside of this range, 1991 and 1997 respectively, were included due to uniqueness of their strategies. The product with patent expiry in 1991 has only experienced generic entry in 2013, so the interview was largely focused on what caused this delay of entry and how the original company responded. The product with patent expiry in 1997 has followed a brand defence strategy as opposed to a clone strategy. This provided variability to the sample. Table 3 illustrates the range of years in which products lost patent protection in South Africa.

Table 3: Year of patent expiry in South Africa

Year	1991	1997	2000	2003	2007	2009	2010	2011	2012
Number of Products	1	1	2	1	2	1	2	2	2

All products were registered as either schedule 3 or schedule 4 which means all products require a doctor's prescription to be purchased. Five of the products treat acute conditions, seven treat chronic conditions and two products are used to treat both chronic and acute conditions. All products are manufactured internationally.

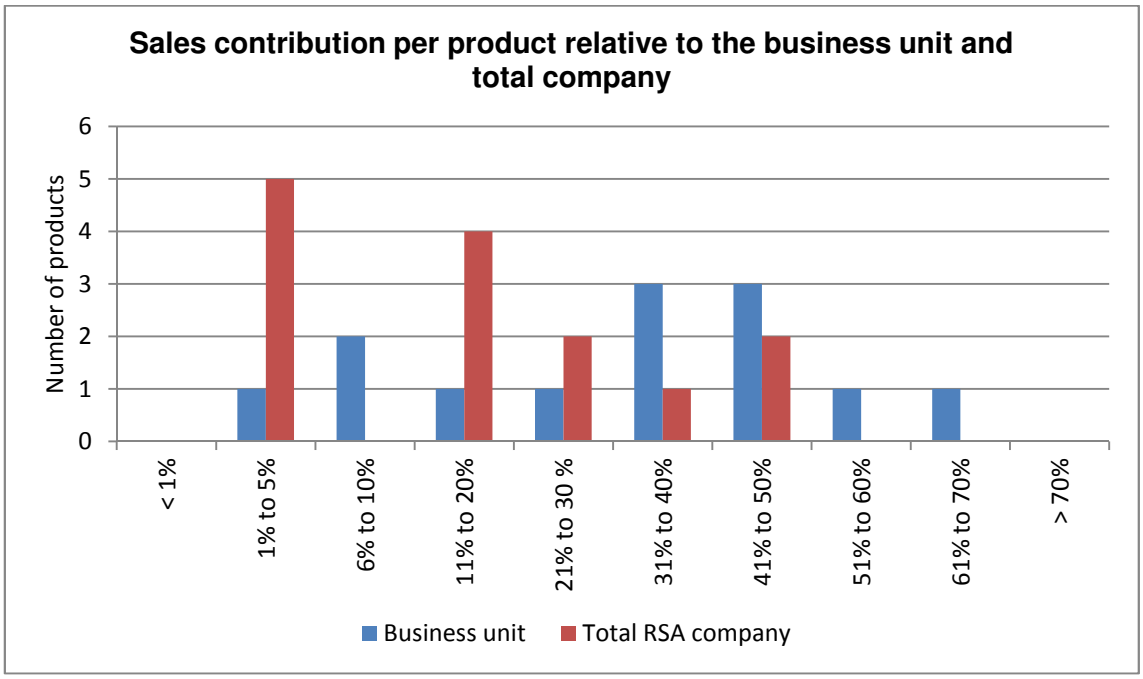
A range of pharmaceutical classifications were represented by the sample of products as shown in Table 4.

Table 4: Number of products per pharmaceutical classification

Pharmaceutical Classification	Number of products
Cardio-Vascular Agents	4
Anti-microbial	3
Blood and Haemopoetic	1
Central Nervous System	1
Dermalogicals	1
Ear, Nose and Throat	1
Genital System	1
Musculo-Skeletal Agents	1
Respiratory System	1

All products researched had significant impact in terms of contribution to the business unit sales with five products contributing between 41 percent and 70 percent of sales in the year of patent expiry. The impact on the total South African company sales is less severe however remains significant with two products contributing up to 50 percent of total sales for the company in the year of patent expiry. Figure 5 shows all contributions for both the business unit and the South African company.

Figure 5: Sales contribution per product



The significance of these patent expiries was reinforced with 12 of the 14 respondents stating that this patent expiry importance was either high or somewhat high when compared to other patent expires in the company.

Table 5 shows the number of products per category for each question presented in the first row relating to the intensity of competition, brand strength and the threat of generic entry.

Table 5: Intensity of competition, brand strength and threat of generic entry

How intense was the competition experienced for this product?		The brand strength for this product was:		The threat of generic entry for this product was:	
None	1	Very Weak	0	Low	0
Weak	1	Weak	0	Average	2
Strong	6	Strong	4	High	5
Very Strong	6	Very Strong	10	Certain	7
Don't Know	0	Don't Know	0	Unknown	0

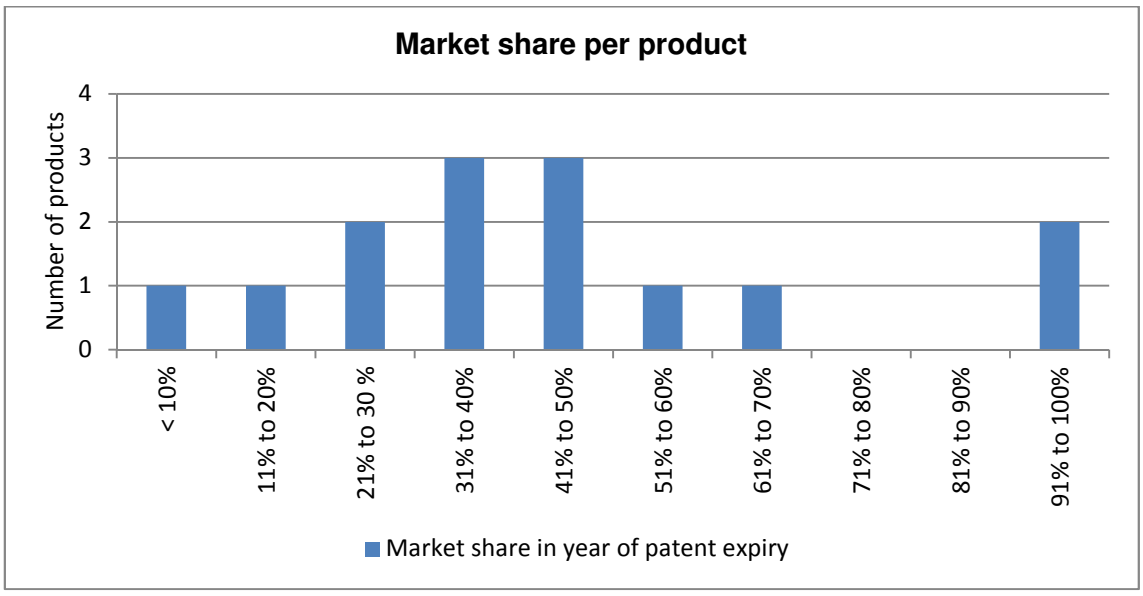
Competition for market share was strong or very strong for the majority of products. This is in alignment with the number of substitute products in each market. Besides one product which had no substitute products in the market, eight products had between one and four substitutes on the market and the remaining five products had between

five and ten substitute products. Substitute products were classified as those products which could be prescribed as an alternate source of treatment for the condition presented by the patient.

These substitute products compete for market share in the pharmaceutical class. For the market share assessment, the market was defined using the primary market for the product and not the market for the molecule. Due to the molecule being patent protected in the year of patent expiry, the market share for the molecule would have been 100%. For this reason the market was defined as the treatment area in which the product was used. Figure 6 shows the number of products per market share category. The majority of products had market shares of between 31 percent and 50 percent.

In terms of the product life cycle, six products were still in stages of high growth, in some cases showing double digit growth year-on-year. Seven products were in stages of slow growth with one product experiencing no growth in the year of patent expiry.

Figure 6: Market share per product



Nine markets were described as large or enormous. This was defined in the interview as being big enough to support between five and ten products for large and more than ten products for enormous. Two products were part of medium markets which could accommodate between three and five products. The remaining three products formed part of niche or small markets which can be fully satisfied with one or two products.

Table 6: Statements relating to the threat of generic entry

Question Number	Statement	Disagree	Somewhat disagree	Neutral	Somewhat agree	Agree
A9	Existing products in the market competed so intensely that profit margins were so low that entry was extremely unlikely	11	1	2	0	0
A10	The market size and profitability were so great for this product that entry from generic competitors was inevitable	0	0	1	2	11
A11	Entry from generic competitors was inevitable so the best strategy was one of earning what you can before entry occurred	0	0	3	6	5
A12	The probability of entry was so remote that no action was necessary to reduce it	13	0	0	1	0
A13	The probability of entry was so high that no action was attempted to reduce it	7	3	1	3	0
Key	Maximum					

Question A9 and A10 in Table 6 were exact opposites with the majority of product managers of the opinion that the market profitability was inviting for generic entry once patent protection had lapsed.

The reaction as to the best strategy to pursue however was somewhat more varied. The majority of respondents somewhat agreed that the best strategy was earning what you could before generic entry occurred. The main reason for not completely agreeing was that behaviour prior to patent expiry could disrupt the strategy planned to manage patent expiry. For instance, the brand would be weakened if the company was perceived to be maximising profits at the expense of patients due to the impeding patent expiry.

Statement A12 became redundant due to the fact that most product managers were of the opinion that generic entry would occur. The negative response is therefore related to the first part of the statement regarding the remote probability of entry. In contrast for statement A13, having agreed in A10 that generic entry is inevitable, the majority of respondents disagreed that no action would be attempted to reduce it. Of the three respondents that “somewhat agreed”, all three felt that focus should be on other products or strategies as the outcome was inevitable and any effort would at best only slow the entry of generics.

5.2 Factors considered in preparation for patent expiry

Section B of the interview asked respondents to rate the importance of certain relevant factors which were isolated from the literature. These factors included elements of brand value, cost of production, market share, generic competition, production complexity and price. Table 7 shows the outcomes in a ranked order table. Where the mean value was identical, the factors have been ordered by the question number sequence.

The primary focus areas are the strength of the brand-value of the product and the company, as well as the price of the product and the threat to market share. Cost of production is less important; this can be expected as all products in the sample are manufactured internationally so the cost of production is essentially fixed. Recovery of research and development (R&D) costs also feature low on the priority list. The general comment to this was that R&D costs should have been fully recovered during the patent protection.

Table 7: Factors considered in preparing off-patent strategy

Rank	Factor	Very Important	Fairly Important	Slightly Important	Not Important	Not Applicable	Mean	Median
1	Brand Value of the product	79%	21%	0%	0%	0%	3.79	4
2	Brand loyalty of customers	79%	21%	0%	0%	0%	3.79	4
3	Brand value of the company	86%	7%	7%	0%	0%	3.79	4
4	Price of the product	79%	21%	0%	0%	0%	3.79	4
5	Current market share for the product	79%	21%	0%	0%	0%	3.79	4
6	Size of the total market for the product	71%	29%	0%	0%	0%	3.71	4
7	Impact on market share of the product	71%	29%	0%	0%	0%	3.71	4
8	Impact on customers of the product	79%	14%	7%	0%	0%	3.71	4
9	The threat of generic competition	86%	0%	14%	0%	0%	3.71	4
10	Contribution of product to total sales	57%	36%	7%	0%	0%	3.50	4
11	Therapeutic class	64%	29%	0%	7%	0%	3.50	4
12	Government legislation and regulatory environment	57%	36%	0%	7%	0%	3.43	4
13	Type of treatment	64%	21%	7%	7%	0%	3.43	4
14	Public perception of generics in South Africa	57%	21%	21%	0%	0%	3.36	4
15	Type of disease state	57%	29%	7%	7%	0%	3.36	4
16	The life cycle stage of the product	57%	21%	14%	7%	0%	3.29	4
17	Coverage by medical aid policies	57%	29%	7%	0%	7%	3.29	4
18	Number of substitute products on the market	50%	29%	14%	7%	0%	3.21	4
19	Marketing efforts of companies producing generic products	43%	21%	36%	0%	0%	3.07	3
20	Impact on related products in your company	29%	36%	29%	7%	0%	2.86	3
21	Availability of product line extensions	43%	7%	29%	21%	0%	2.71	3
22	Cost of production	21%	43%	14%	14%	7%	2.57	3
23	Decisions made in other regions regarding end of patent strategies	14%	36%	43%	7%	0%	2.57	3
24	Availability of excess production capacity	43%	7%	14%	29%	7%	2.50	3
25	Advertising and promotional spend for the product	14%	36%	36%	14%	0%	2.50	3
26	Cost advantage over generic competitors	14%	29%	43%	7%	7%	2.36	2
27	Recovery of R&D costs	21%	21%	21%	29%	7%	2.21	2
28	Use of other patent protected methods such as slow/extended release or combinations	14%	36%	0%	43%	7%	2.07	2
29	Impact on other regions still under patent protection	21%	7%	29%	29%	14%	1.93	2
30	Impact on State tenders	14%	21%	14%	43%	7%	1.93	2
31	Proprietary knowledge required to produce the product	14%	14%	21%	43%	7%	1.86	2
32	Impact on unrelated products in your company	7%	14%	36%	43%	0%	1.86	2
33	Cost of production for generic companies	7%	14%	29%	43%	7%	1.71	2
34	Sunk costs such as facility costs required to produce the product	7%	7%	14%	57%	14%	1.36	1

Ranked by mean value

Key Maximum

Weighting Used: (0 - Not Applicable, 1 - Not Important, 2 - Slightly Important, 3 - Fairly Important, 4 - Very Important)

5.3 Strategies considered and executed

The following section provides results regarding the investigation into which strategies were considered and which ones were eventually pursued. Each strategy has a time element to it, either implemented before or after patent expiration. The strategies as introduced in Chapter 2 include:

- Using price as a variable to compete directly with the generic by lowering it or maximising profits by raising it
- Introducing product extensions, a fighter brand or superior product to switch users from the original product to this newer product
- Introducing a clone of the original product to the market to compete directly with generic products
- Withdrawing the original product from the market

Finally, by considering the value map presented in Chapter 2, the marketing, promotion, advertising and detailing efforts and investments were also investigated to evaluate if companies focus on increasing product value as an alternative to using price or the introduction of newer and more superior products.

The discussion of each strategic alternative consists of testing whether it was considered as a potential strategy and then if it was implemented. The results for each decision will be displayed in a pie chart, with a secondary section showing the implementation decision. The number shown per segment is the number of products which make up that segment. Supporting qualitative feedback will be provided for each strategy with the most prominent comments being addressed.

Table 8 provides an overview of the strategy most pursued per product investigated. Some strategies did have overlapping characteristics but the primary strategy has been summarised here.

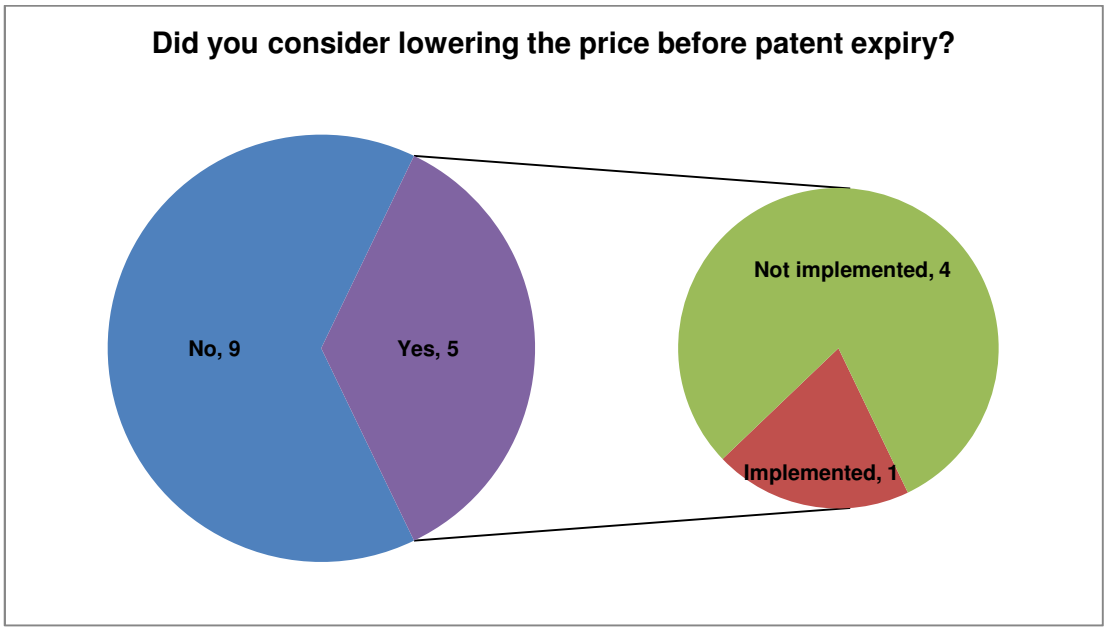
Table 8: Summary of strategies pursued

Product	Patent Expiry Year	Strategy followed
Product 1	2000	Did nothing but extract the remaining profits, eventually lowered the price to slow decline of market share loss
Product 2	2009	Clone launched after generic entry
Product 3	2003	Promoted the unique attributes of the product which were not replicated in the generics
Product 4	2000	Clone launched after generic entry
Product 5	2010	Clone launched prior to patent expiry
Product 6	2011	Clone launched after patent expiry
Product 7	2007	Clone launched on patent expiry
Product 8	1997	Increased promotion of original brand
Product 9	1991	Clone launched on threat of generic entry (22 years after patent expired)
Product 10	2007	Clone launched on patent expiry
Product 11	2011	Clone launched after patent expiry, price of originator lowered
Product 12	2012	Clone launched after generic entry
Product 13	2010	Clone launched prior to patent expiry
Product 14	2012	Multiple clones launched, 1 prior to patent expiry, 3 on patent expiry

5.3.1 Price as a strategy

There were two elements to the price variable. Firstly, the option of lowering the price of the original product to deter entry from generic competition and then competing directly with the generic product on price or second, raising the price and maximising profits off the premium priced product.

Figure 7: Lowering of price before patent expiry



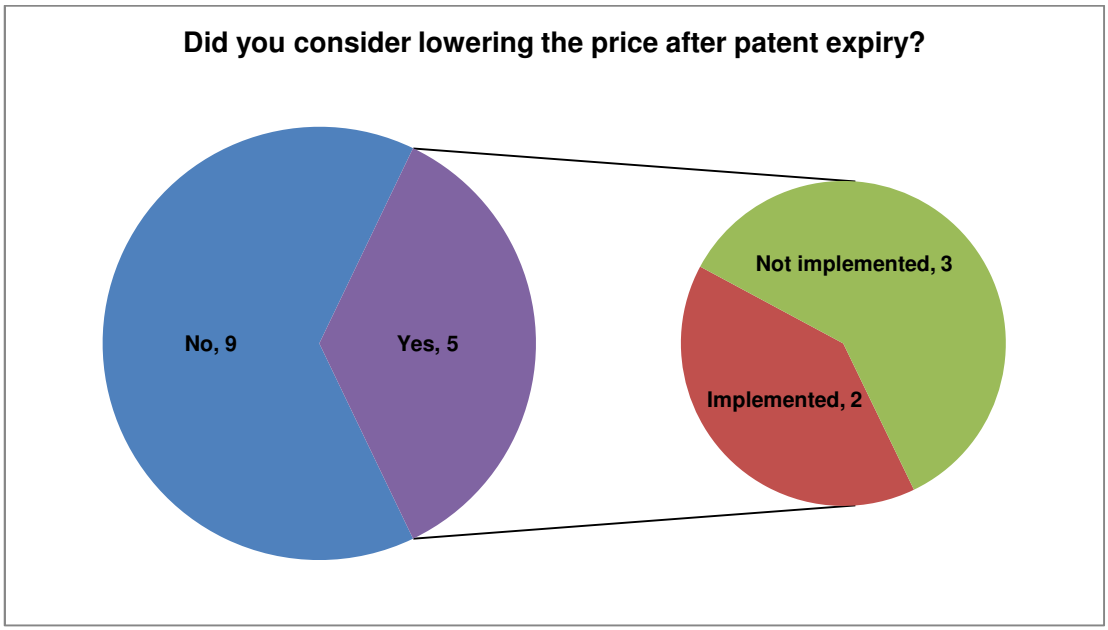
The nine respondents who did not contemplate lowering of price prior to expiration of the patent, as per Figure 7, all stated the main reason for not considering it was to avoid eroding of profits whilst still under patent protection. It was not seen as an effective way to deter entry as generics would always enter the market at a lower price. The thinking was to keep the price unchanged whilst still in a protected market.

Further to this, one respondent elaborated further with regards to leaving the originator price unchanged in the market. “Generics will always enter lower by as much as 30 percent so by leaving the original product at the premium price, this effectively ‘pegs’ the market at its true value.”

The five respondents who considered the strategy of lowering price did so as the last option to use, in order to defend market share from generic competition. Those who did not pursue it further followed other strategies instead. The one product which did lower its price did so with the primary purpose of defending market share against another branded product in the class. However the product manager did comment that there were secondary benefits with regards to delaying generic entry, even though this was not the intended purpose.

Figure 8 shows the decisions made regarding the lowering of price after patent expiry and in most cases once generics have entered the market.

Figure 8: Lowering of price after patent expiry



Of the five respondents who indicated that they considered lowering the price after expiry, one did so because there were delays in registration with the clone through the Medical Controls Council (MCC). There was concern that generics would enter the market first and take the advantage away from the originator. However the clone was registered in time and thus the price was not altered. Lowering the price would have been a poor decision as the generics ultimately entered the market much lower than expected.

This was the first mention of having to make alternate plans or use secondary strategies due to delays with registration at the MCC. This theme will continue throughout the other strategies.

Although not the initial planned strategy the two products that did lower their price did so after one year of generic competition. The intention was to slow down the more rapid than expected market share decline. Both reported moderate initial success in slowing down the market share loss.

The final two respondents, who considered lowering the price of the original product, were considering competing with generics directly through price since their clone strategies were only moderately successful. In the end they did not pursue this due to the scheduling status applied to the generics at registration. In both cases, the generics and clones were awarded schedule 2 status as opposed to the schedule 3 status of the original product. This meant that the original product required a prescription whereas

the generics could be bought over the counter. The dynamics of the competition had therefore changed and lowering of the original price would have no impact.

For the nine respondents that did not consider lowering price post patent expiry as a feasible strategy, the main reason was so they could continue earning profit at premium price point. The clone was used to compete with generics on price. Product 8, which did not have a clone, continued to hold its premium price in the market and competed with generics on value.

Three respondents elaborated on similar value focused initiatives to justify maintaining a premium price. Initiatives such as patient and nurse education, patient monitoring and patient support programs were promoted as extra value items only available to original product users.

In contrast to lowering the price, these nine respondents, including the three who eventually did not lower the price, stated that the annual price increased offered through the Single Exit Pricing (SEP) regulations is taken. This fixed percentage increase available to all products controlled through the SEP regulations effectively moves the whole market up by that percentage, so prices remain the same relative to each other. Three products have not taken the SEP increase at one time but did not realise any gains from this in terms of market share growth.

Other than the SEP increases, no respondents considered raising the price of the product either before or after patent expiry. Even though the SEP regulations would not have allowed a further price increase, the overwhelming sentiment in response to this strategy was to avoid negative market image. Prices were already at the premium price point and further increases would be negatively received by the market.

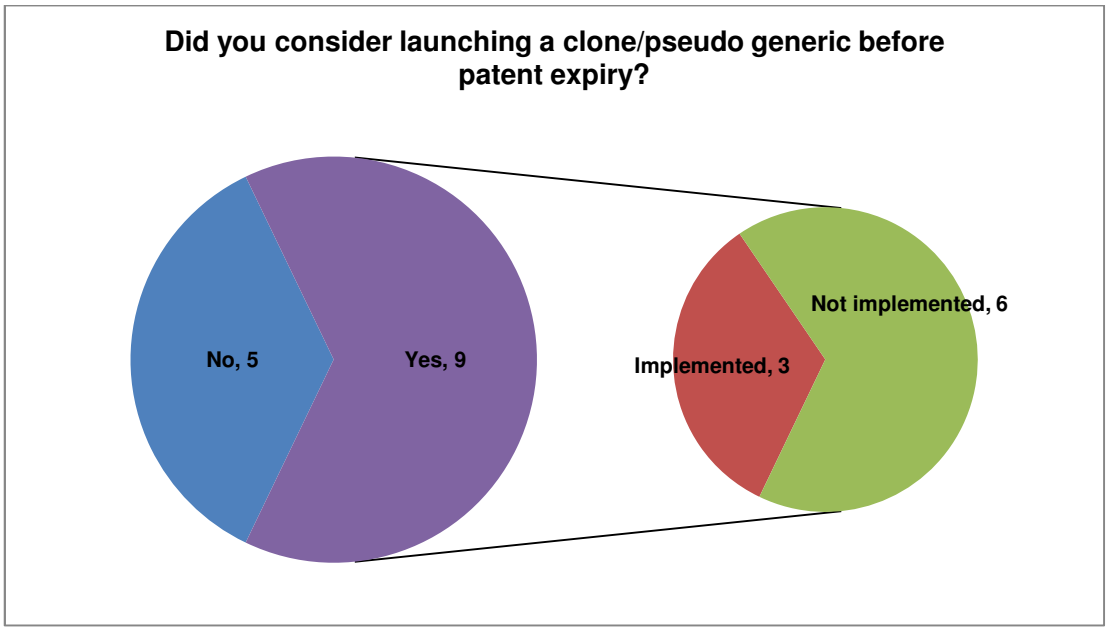
5.3.2 Clones as a strategy

The clone strategy was the dominant strategy pursued, with 11 of the 14 products in the sample following this strategy. Once a clone strategy was decided on, the next critical decision was the timing of the launch.

Nine respondents wanted to launch before patent expiry to achieve first to market advantage. The length of time before ranged from the month of expiry to six months prior to expiry. One product already had a clone on the market for ten years, however had maintained the clone at the premium price point. As generics entered, this price was lowered. This strategy was also pursued by another product's clone which entered

a few months before expiry. Initially the price was just below the premium price and then was lowered as generics began to compete.

Figure 9: Launching a clone before patent expiry



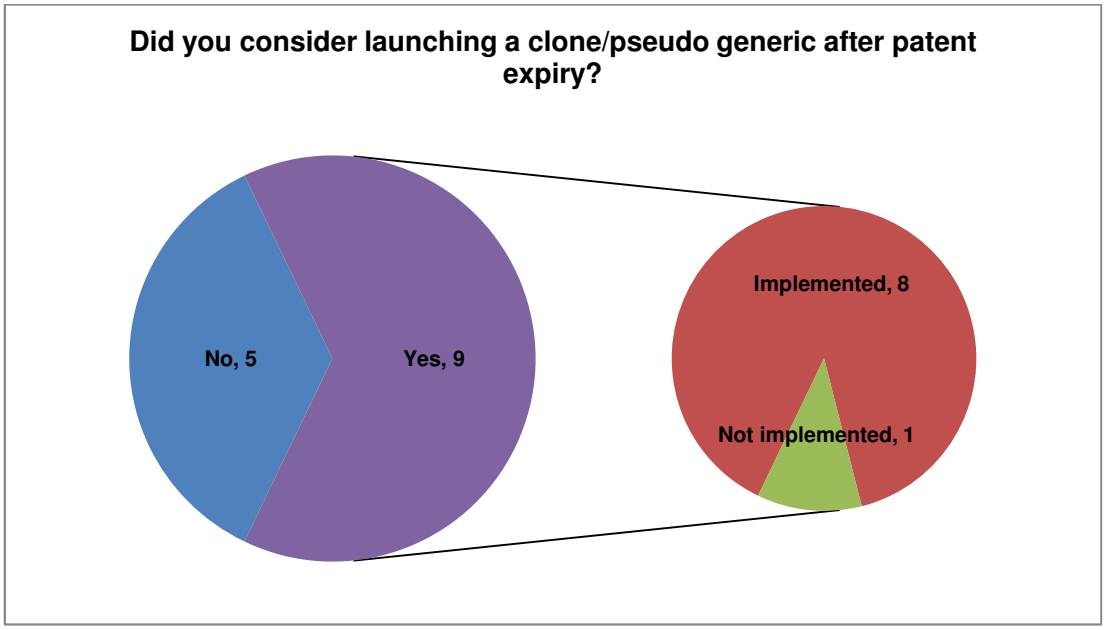
As seen in Figure 9 above, nine respondents wanted to launch clones before patent expiry but only three managed to implement this strategy. For Product 2, although launching before expiry was considered, the eventual strategy was to be ready to launch in the month of the first generic entrant. This strategy had been followed by another product in the company (Product 4) with success. Both respondents for Products 2 and 4 claimed that there is no first-to-market advantage if the clone is launched at a similar time to the first generic. In both cases, the clone is the market leader according to unit sales.

Of the remaining eight products, Product 14 had already had a high priced clone in the market for ten years, further to this only Product 5 and Product 13 managed to launch before the patent expired. The other five products were hindered due to delayed registration processing by the MCC. Although one respondent admitted that there was a delay in application from the company, the other respondents stated that delayed registrations meant the first-to-market advantage was lost and clones were only launched after patent expiry and in two cases, after generic entry.

Respondents also expressed concern about launching the clone too soon and eroding profits unnecessarily. This is in light of the fact that generic products also experience delays in registration so launching a clone too soon may result in cannibalising the original products profits. Product 7 experienced a different legislative impact regarding

the expected date of patent expiry. The South African patent expired three years before the patent expired in the USA. Product 7's clone was launched in the month of the South African patent expiry but generic competitors were working according to the USA patent date and as such Product 7 experienced three years with no generic competition but lost profit due to its clone eroding the market. The decision was made not to remove the clone from the market due to the negative impact on the long-term brand image.

Figure 10: Launching a clone post patent expiry



Eleven products eventually did have clones launched in the market. The one clone not implemented in Figure 10 above, is the fourth clone for Product 14. Even though Product 14 already had three clones in the market already, these clones were priced between the originator and generic products. The generic product however entered at 80 percent less than the originator. With the previous clones only 30 percent less than the originator, it was considered to launch a fourth clone to compete with the generic. However the launch was held back because the generic price seemed to be unsustainable for the generic company and its future in the market is uncertain.

Product 9 which lost expiry in 1991, has followed a brand focused strategy for 22 years until recently when a generic product planned to enter the market. The reason for the delay in the generic entrant was related to the complexity of the product in terms of manufacturing and storage, as well as the type of condition it treats. However since the threat of generic entry was certain, a clone was launched two months before the generic entered the market.

Table 9: Reasons for launching a clone

	Question Number	Statement	Disagree	Somewhat disagree	Neutral	Somewhat agree	Agree	Not Applicable
Questions asked if clone was launched **prior to patent expiry**	C19	A clone/pseudo generic was launched prior to expiry to deter entry from other generic competitors	0	0	0	0	3	11
	C20	A clone/pseudo generic was launched prior to expiry to capture generic market share through first-to-market advantage	0	0	0	0	3	11
Questions asked if clone was launched **after patent expiry**	C21	A clone/pseudo generic was launched after expiry to deter entry from other generic competitors	2	0	0	4	2	6
	C22	A clone/pseudo generic was launched after expiry to capture generic market share	0	0	0	2	6	6
	Key	Maximum						

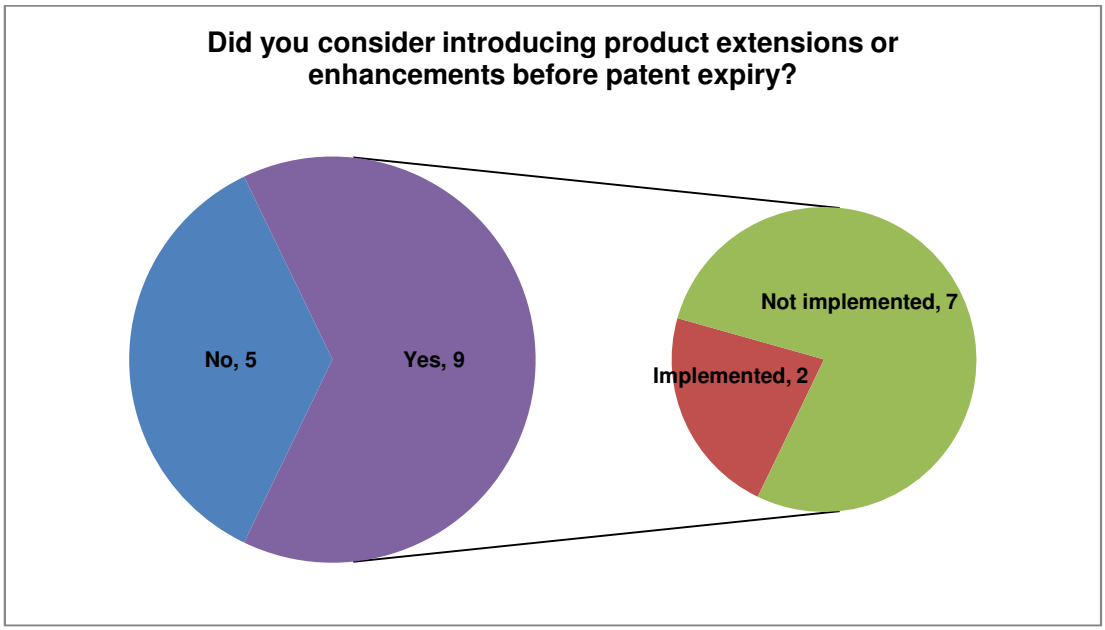
The above questions in Table 9 were asked in regard to the actual launch period for the clone and not the intended launch period. For example even though nine products were intended to launch before patent expiry, only three products did launch prior to expiry.

The results are still valid, as the intention to launch prior to patent expiry is clearly an attempt to both deter market entry and capture market share, whereas for products launched after the patent expiry date (or even in the month of patent expiry) the focus is on securing market share and less so on deterring entry. Responses to this question centred around timing, if a clone is launched prior to patent expiry it signals to the market that a clone is competing, however if the clone is kept until after expiry, the generic companies will have planned to enter on patent expiry so will enter regardless of the launch of a clone.

5.3.3 Product extensions

Product extensions can be used to improve the value of the product or in some cases can be used to extend patent protection through a secondary patent related to the product extension. Figure 11 shows that nine respondents actively considered the use of product extensions before patent expiry, however only two were eventually implemented in the market.

Figure 11: Product extensions before patent expiry



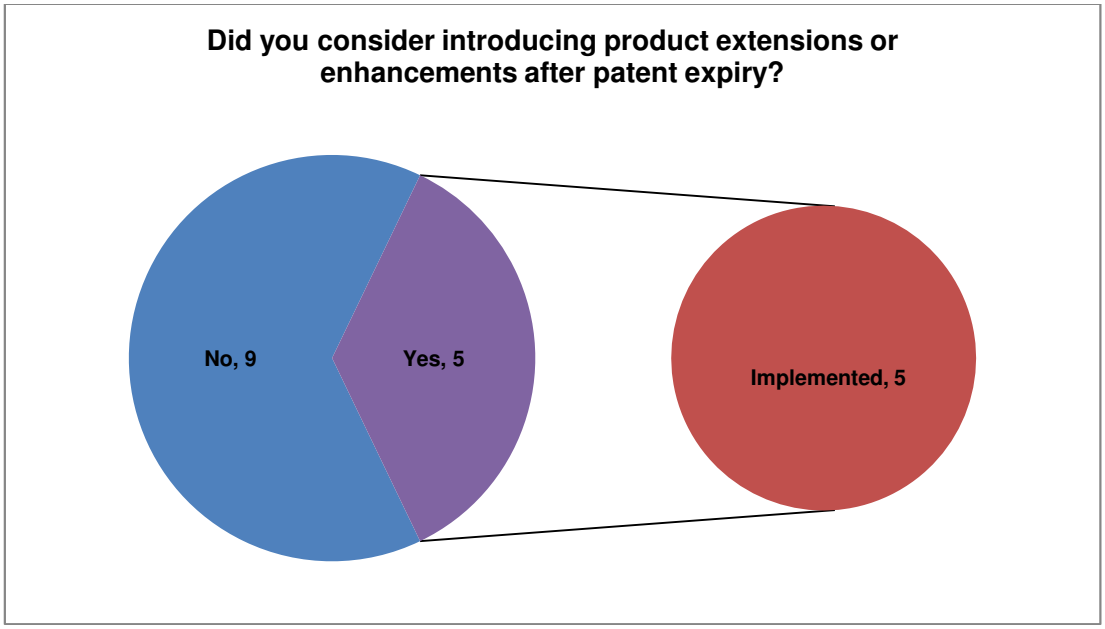
Product 1 intended to use the new extended release formulation to further increase the value of the product. However due to a delay in registration with the MCC the product extension was not launched. The opportunity to launch product extensions prior to patent expiry due to delayed registration by the MCC was also lost for Products 5, 6 and 7. Product 13 did not implement this strategy either as market research showed the product extensions, which would not have extended the patent, added little further value. This was similar for Product 10 for which significant value adding extensions were not available. Product 12 chose to instead launch the considered product extensions as part of the clone range.

Of the nine respondents who considered product extensions, the primary reason for launching product extensions was to expand the range of products that generic competitors would need to replicate in the market. Patent extensions were also considered but secondary patents were viewed as less robust than the original patents.

Product 14 launched product extensions and then actively marketed to transition the current customer base to the new, superior product. The product extensions did provide extended patent protection. The strategy was deemed a success as it increased value to the customer as well as extended market exclusivity to the manufacturer. Product 11 had contrasting results, although the new delivery system did extend patent protection, the market did not perceive any value to the enhancement and therefore the strategy had limited success.

Product extension unavailability was the reason that the five respondents did not consider this strategy. Three respondents felt that the products were already superior for the class and no further improvements could be made.

Figure 12: Product extensions after patent expiry



After patent expiry, five respondents said that product extensions were launched with four out of five stating the reason to launch was to expand the product range in order to target new markets and not to try gain back lost market share from the original product. This supports reasoning by the nine respondents shown in Figure 12 who did not consider product extensions post patent expiry because they believed the opportunity had passed to compete with generic competition through product extensions. The fifth respondent launched the product extension to further strengthen the brand loyalty for the small number of consumers who had remained with the original brand.

5.3.4 Fighter brands

The fighter brand strategy was only considered by three respondents. All three considered the strategy prior to patent expiry but only one managed to implement. The other two were delayed by MCC registration and therefore could only implement post patent expiry.

Product 1 implemented a fighter brand before patent expiry and used this new brand to target the specific and specialised area of respiratory infections, a change from the general anti-biotic market in which the original product competed. The goal of the

strategy was to build intense brand loyalty in this specialised area. To achieve this, a large investment in promotion was also made on this fighter brand.

The remaining two products who followed this fighter brand strategy partnered with retail pharmacy chains to develop in-house brand names of the original product. The purpose of which was to earn royalties through an expansion of the range. In-house brands are promoted higher on the formulary by the retail pharmacy chain and therefore have a greater chance of capturing more market share.

The 11 respondents who did not consider a fighter brand indicated that the original product's brand strength was already very strong. Promotion and brand development was focused on the clone and not another higher priced brand.

5.3.5 Over-the-counter (OTC) and new products

The scheduling status of 12 products prevented the OTC strategy to be pursued. For the remaining two products, the original products were registered as schedule 3 which excluded them from the opportunity to be converted to OTC products. However the clone and competing generics were registered by the MCC as schedule 2. This allowed the clone and generics to be sold without prescription. Applications have been made to the MCC to re-classify the original products as schedule 2 products instead so they can compete in the OTC market.

Launching a new product was a strategy only considered by three respondents. The remaining eleven respondents all stated that there was no other product available to switch consumers to. Product 2 did consider switching consumers to a new product however the new product was found to be less effective than the original product and therefore was not pursued further.

Although not truly a new product, Product 7 did consider launching a higher dose of the original product at the same time that the clone was launched at the original dosage. The intention was to switch consumers to the higher dose for which there was no generic competition. This strategy has had limited success with doctors preferring to prescribe the lower dose formulation. Product 1 focused on switching a select set of consumers to another product better suited to treat urinary tract infections than the original general anti-biotic. The intention was to at least maintain the market share of this set of consumers by transferring them to a patent protected product.

5.3.6 Withdrawal from the market

None of the 14 respondents considered withdrawing the product from the market once patent protection had lapsed. The reasons for not withdrawing the product from the market were consistent across all respondents with the primary reason being that the product was still valuable to the company and continued to generate sales. Even though significant market share was lost, the original products continued to make profitable sales.

Secondly the brand value of the products continued to be strong and withdrawing the product from the market would create a negative perception. The brand value of the original product was leveraged to develop the brand strength of the clone. One respondent commented that the original brand under pins the entire range so even though market share has drastically reduced it is important to maintain the product in the market.

Two respondents commented that the original product initially lost market share and now has stabilised at this smaller new market share. They both attributed this to brand loyal customers and entrenched prescribing habits by doctors. Therefore the product continues to generate sales.

Due to the nature of the chronic disease treated by Product 9, patients who are stable on the medication have remained with the original product despite cheaper generics entering the market. The original product is therefore sustained to support these patients.

Two respondents commented that in the long term the products may be sold off to a third party to produce or else eventually removed from the market. This would depend on market conditions and the timing of the withdrawal cannot be accurately forecasted at this stage.

5.3.7 Intensity of promotion and advertising

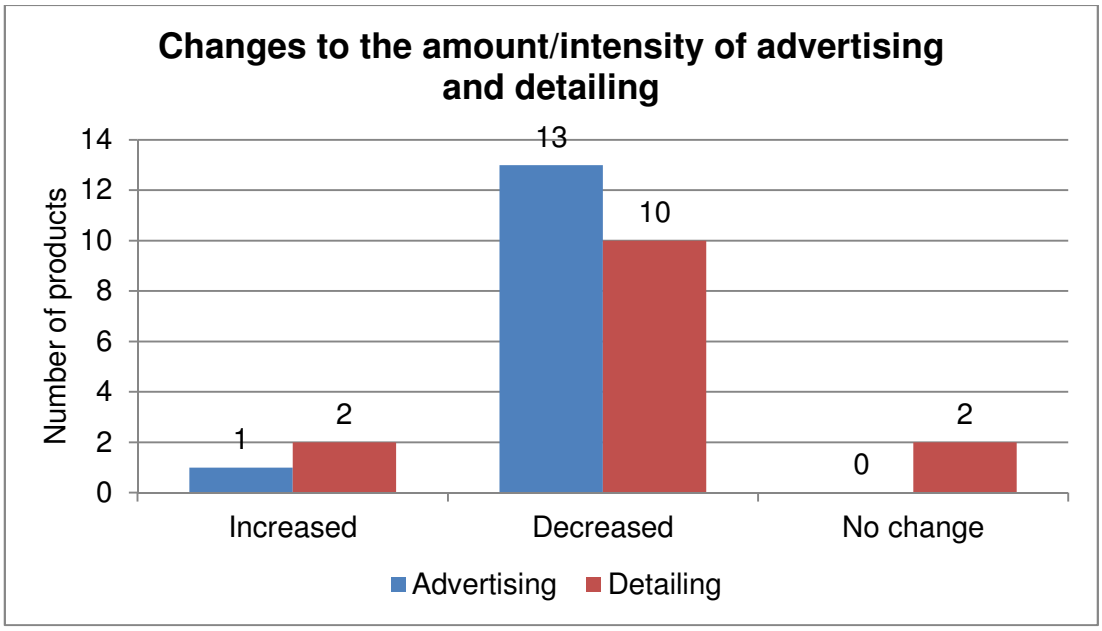
Despite not withdrawing the product from the market, investment in advertising for 13 products was reduced to almost none and detailing to doctors was decreased for ten products post patent expiry. The main reason provided for this was a focus on the clone if available or other products within the company. It was commented that investment in the original product was a waste of resources. A small number of consumers would stay with the original product regardless and no new consumers would be attracted through increasing either advertising or detailing.

The two products shown in Figure 13 to have increased detailing were Product 8 and Product 14. Product 8 had followed a non-clone original brand strategy and therefore continued to actively promote the product. The increase in intensity was specifically around high season for the product whereby it was moved back to the number one position on the detailing list. Product 14 continues to have increased spend on promoting the original product into specialist areas. The original product has a greater dosage range than both the clone and generics and it is these dosage ranges that are promoted.

Product 3 and Product 6 maintained the same level of detailing. Product 3 had chosen a non-clone strategy due to its unique delivery system so continued as normal post patent expiry. Product 6 to date has continued with the same level of promotion but may reduce this in future depending on loss of sales as generics enter the market.

Besides these four exceptions the dominant approach has been to disinvest in the promotion of the product in order to maximise profits.

Figure 13: Changes to advertising and detailing



A similar trend was seen in the advertising of products once patent protection had lapsed. The only product to continue increasing advertising was Product 8 due to its original brand strategy followed.

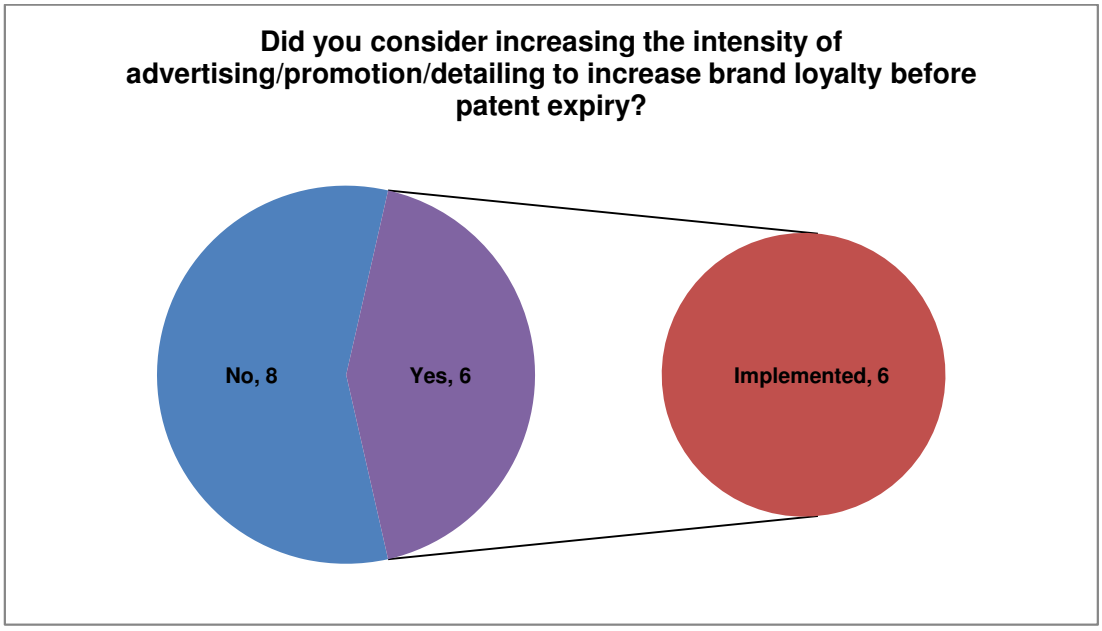
Although the majority of respondents stated a decrease in the promotion and advertising of the original product, the overall investment in the molecule (clone and original) had stayed the same. Resources were allocated from the original to the clone in order to grow the brand value of the clone.

Five respondents said the best strategy is to have an overall molecule market share target to limit the amount of cannibalisation of the original product by the clone. The ultimate goal was to keep volume market share for the molecule at the same level or greater than achieved by the original product whilst under patent protection.

In all cases the clone was promoted by a separate marketing team to that of the original product. Seven clones were promoted by third parties through a marketing agreement and the remaining clones were marketed in-house.

The activity before patent expiry was slightly different when compared to the actions taken post patent expiry. Figure 14 shows that six respondents did consider and then also increase the amount of promotion prior to patent expiration.

Figure 14: Promotion and advertising before expiry



For two of the products, the increase in promotion was focused on creating a greater consumer base from which to launch the clone and not necessarily to increase brand loyalty for the original product. However the original product did show some benefit from the activities. Product 13 was actively promoted to increase brand loyalty and the product manager believes it did slow the decline of market share once patent protection expired.

Product 14 was actively promoted to show the greater dosage range available in the original product that was not available in the clone or generic products. The focus of the promotion was on specialised areas which would benefit from the dosage ranges for which there was no generic competition. The promotion was also focused on

creating a stronger overall brand image for the company which would benefit both the original product and the clone.

Product 7 increased promotion to counter the market activities of a competing branded product and not to build brand loyalty for the original product to counter the efforts of generic competitors.

The products for which promotion was not increased prior to patent expiry all maintained the level of promotion that was already in place. Once patent protection lapsed, these activities were then reduced as discussed previously.

5.3.8 Conclusion

This chapter presented the results from the 14 structured interviews conducted for the purpose of this research. The dominant product strategy for the sample of products investigated is that of launching a clone to compete with the generic products whilst leaving the original product on the market to capture a smaller share of the market.

The other variables of price, promotion or advertising, product extensions and the use of alternate products were used more discretely in conjunction with the clone strategy. The strength of the brand of both the product and the manufacturing company were identified as among the most important factors considered when evaluating which strategy to pursue.

The results presented in this chapter will be compared to the literature presented in Chapter 2 in order to draw conclusions regarding the propositions suggested in Chapter 3. These findings are discussed in the following chapter.

6. Discussion of results

The loss of market exclusivity through the expiration of patent protection is a fundamental part of the pharmaceutical product lifecycle. The objective of this research was to investigate what strategies were followed and what the underlying reasons were for following a particular strategy, for a selection of pharmaceutical products in the South African market. The literature reviewed in Chapter 2 provided insight into theoretical strategies available as well as empirical studies done in other countries. This assessment led to the development of propositions presented in Chapter 3. The discussion in the following chapter will use these propositions as the basis for which to compare the results gathered from the 14 structured interviews with the findings of other studies presented in Chapter 2.

6.1 Proposition 1: The price of branded pharmaceuticals is not used as a means to either deter entry or compete with generic products

Price is a variable which can theoretically be manipulated to influence market entry and limit competition, through approaches such as limit pricing to deter entry or predatory pricing to drive smaller rivals from the market. Price can also be used to extract further profits from the market, particularly if the market or parts thereof is relatively price inelastic (Besanko et al., 2010). The proposition presented in this research is focused on the use of price to either deter entry or to compete with generic products directly on price to maintain market share or both. The results show that price was not the primary measure to achieve either initiative.

6.1.1 Limit pricing to deter entry

Limit pricing is a strategy whereby prices are lowered before loss of market exclusivity to deter entry by making the profits available less attractive to potential entrants (Besanko et al., 2010). As shown in Table 6 the majority of respondents, 11 out of 14, agreed to the statement that generic entry was inevitable due to the market profitability and size. Further to this 11 respondents either somewhat agreed or agreed that considering that generic entry was inevitable the best strategy was to earn what profits you can before entry occurred.

The combination of these two statements leads to the conclusion that the strategy of limit pricing was not used due to the belief that the market profitability was already perceived as high and that earning maximum profits cannot be achieved through lowering the price of the product.

The notion that limit pricing was not used by the majority of respondents is further supported by considering that nine of the fourteen respondents did not consider lowering the price of the original product prior to patent expiry as shown in Figure 7. The primary reason provided was to maintain profits whilst still in a protected market. The secondary motivation for maintaining a higher price was that attempts to deter entry by lowering the price were futile since generics would always enter at a lower price.

Of the five respondents who considered lowering the price, four admitted this was considered as a last option in case more preferred strategies did not work. Only one product manager did lower the price before patent expiry and this was to compete with another branded product and not to deter generic entry. In this case the strategy of lowering the price to deter entry would have been a poor one as the generics entered even lower than expected. This again supports the notion that attempting to deter entry through limit pricing is not effective.

These findings are consistent with those of Scott Morton (2000) and Wilkie et al. (2012) who suggest that although theoretically plausible, evidence of limit pricing is yet to be observed in the pharmaceutical markets studied. Wilkie et al. (2012) attributes this to the profit-maximising behaviour of pharmaceutical firms. Scott Morton (2000) argued that a limit pricing strategy is unsustainable for the incumbent firm. This supports the comments made regarding generic products being able to enter the market consistently much cheaper than the original product.

Tenn and Wendling (2010) found evidence of limit pricing only in small markets. Of the 14 products investigated, 11 were described as being part of either large or enormous markets. Only three markets were considered as small or niche markets, however only one of these three considered lowering the price before patent expiry and in the end did not follow through with this strategy.

The findings from this sample of 14 products is therefore consistent with those in other markets that limit pricing prior to patent protection expiry is not used to deter entry from generic competition.

6.1.2 Price used in direct competition with generics

All respondents commented that generic products always enter the market at significantly lower prices than the original products. One strategy suggested by Kvesic (2008) is to compete directly on price with generic products in order to maintain market share. The other options are to maintain the same price and potentially lose sales volume or raise the price to increase profitability in the short term (Kvesic, 2008).

As with price manipulation prior to patent expiry, nine respondents did not consider lowering the price of the original product once patent protection had lapsed. All nine in fact continued to take the annual price increases offered to the market through SEP regulations. Although the absolute price therefore increases, the whole market tends to take the price increase so the price relative to the market remains unchanged. The main motivation for this price maintenance strategy is to continue earning a premium profit on the remaining market share. All nine respondents had clones in the market which were used to compete on price.

This is consistent with the findings of Caves et al. (1991) and Regan (2008) who postulated that the entry of generic competition divides the market into price sensitive and price insensitive segments. The original products maintain their price and profit from the brand loyal price insensitive consumers.

Dylst and Simoens (2011) found that price competition existed only between generic products and the original product maintained or only slightly lowered in price. Respondents all believed that lowering the price would create a price war that the original manufacturers could not win. Global policies within the companies often dictate the minimum allowable price, so once reached the generic companies would price just below this price point.

Of the five respondents who considered lowering the price of the original, three only considered it as a strategy of last resort in case the other strategies pursued did not succeed. Despite acknowledging the risk of a price war, the remaining two respondents did lower price as a final attempt to combat the faster than expected decline of market share. Both reported moderate initial success in slowing down the rate of market share decline. However both did not see it as a long-term success strategy.

6.1.3 Proposition 1 – Conclusion

The findings of the 14 structured interviews are consistent with those of other studies and from this it is concluded that proposition 1 is true for the majority of the sample.

Although theoretically plausible, the price of the original product was not used to deter entry or compete directly with generic competition once patent protection had expired.

Further to this there was no evidence of price being increased to further maximise profits, instead the relative price was maintained to continue earning profits from the remaining but smaller market share.

6.2 Proposition 2: Clones are launched to capture a share of the generic market and defend market share, not to deter entry

The clone strategy was the dominant strategy followed in the sample with 11 of the 14 products following this approach. A clone was launched for three of the products prior to patent expiry. Clones were launched for four products after patent expiry and the remaining four products introduced clones only after generic entry. One product in particular only launched a clone when generic competition entered 22 years after patent expiry. The timing of the launch of the clone is therefore relevant in understanding the reasons for the launch of a clone.

6.2.1 Launching a clone prior to patent expiry

Three clones were launched prior to patent expiry with one clone having already been on the market for ten years. The main motivation for launching a clone prior to patent expiry was to gain first-to-market advantage. This advantage seems to be derived from brand building in the market rather than initially low price, because two of the clones entered the market at premium price points. When generic products entered the market, the prices of the clones were immediately lowered to compete.

Product managers for these products stated, as per Table 9, that the reasons for launching a clone were both to deter entry of potential generic competitors as well as to capture the generic segment of the market. Strategies were focused on maintaining total molecule sales volume which includes sales from both the original product and the clone. The advantage of being first was deemed greater in the long run than the potential loss of profits in the short term due to the clone eroding the market. However this risk was further mitigated by launching the clone at a premium price.

Reiffen and Ward (2007) and Hollis (2002) through their empirical studies of the United States and Canadian pharmaceutical markets respectively support these decisions.

They both showed that significant advantage was achieved by being first-to-market in both deterring entry as well as capturing the largest market share.

The three clones to launch prior to patent expiry were contributed only one third of the nine products for which the strategy was considered. For the six products which did not launch a clone before patent expiry, four did not launch due to delays in registration from the MCC. The remaining two products decided to launch only once the first generic competitor had entered.

Although generic entry was not ultimately deterred by this strategy, these findings corroborate those presented in Table 6 which showed that ten respondents disagreed that no action would be attempted to reduce generic entry even though it was inevitable. The failure to deter entry aligns with the findings of Applet (2010) and Wilkie et al. (2012), who through their studies showed that the launch of a clone had no impact on the entry of independent generic products.

Regardless of the success, the intention to launch a clone prior to patent expiry was both to deter entry as well as to capture the generic portion of the market through first to market advantage. The timing of the launch was aimed at allowing sufficient time to build brand knowledge of the clone before independent generics entered the market.

6.2.2 Launching a clone after patent expiry

Four of the clones who were delayed through registration were then launched as soon as possible once the registration came through. The remaining clones were launched by choice following the entry of the first generic competitor. Those products which launched only with the entry of the first generic product all reported that the combined market share of the clone and original product was the largest share of the market for the molecule. This brings into question the concept of the advantage for being first-to-market.

One product manager stated it unnecessarily eroded profit whilst there was no competition and if the clone is launched within a couple of months then it was as good as having first-to-market advantage due to the brand strength of the company and original product. This contradicts the empirical findings of Reiffen and Ward (2007) and Hollis (2002) discussed previously. Although four products launched a clone once generic products had entered, only two specifically intended to do so. The other two were delayed through registration by the MCC and could not launch sooner.

As shown in Table 9 for those products entering after patent expiry the primary motivation was to capture the generic share of the market. This is supported by the findings of Appelt (2010) who argued that clones are used to extract generic profits as the decision to enter the market by independent generics is driven by pre-entry revenues and not deterred by the presence of a clone.

However six of a possible eight respondents also indicated that the purpose of the clone was to deter entry of independents. Even if generic products had already entered the market, the intention was for the clone to limit further entry. Only the two products who strategically waited for generics to enter the market place stated that the intention of the clone was not to deter entry. Once again even though the strategy was unsuccessful the objective of the research was to understand the reasons behind the chosen strategy.

Product 14 has three clones in the market with a fourth ready to launch if required. Combined with the original product, the company therefore currently has four products in the market. The strategy has been to focus each brand on a separate segment of the market. This strategy is not dissimilar to that of the ready-to-eat breakfast cereal market described by Schmalensee (1978) whereby he concluded that the cost of producing new brands was negligible and therefore the barriers to entry were raised because a new company would need to enter with multiple brands to compete with the incumbent.

Considering that a clone is the same product from the same production line, but is branded differently, the same strategy could be easily replicated for pharmaceutical products. The original company could produce many brands and hold multiple positions in the market thereby reducing the potential entry points for a generic competitor. The launch of clones in this manner therefore is used to deter entry.

6.2.3 Proposition 2 – Conclusion

For this sample of 14 products, the intention to launch a clone was both to capture the generic share of the market as well as to deter entry. Although not successful in deterring entry from independent generics, strategies pursued had the intention of deterring entry with only two product managers following an accommodating strategy.

The debate as to the purpose of clones is on-going in the current literature with empirical evidence supporting entry deterrence (Hollis, 2002; Reiffen & Ward, 2007) and the capture of generic market share (Appelt, 2010; Wilkie et al., 2012). The more

recent literature however supports the findings of this sample, that even though the intention may have been to deter entry, the clone strategy does not succeed in deterring entry but only manages to extract generic market profits.

Of significance however is the role the MCC played in determining the timing of the clone launch. Due to the delay in registration a number of clones missed the opportunity to launch prior to patent expiry or before other generic competitors. In contrast, in one product's case the generics were delayed and the clone unnecessarily eroded profits for the originator. The efficiency of the MCC therefore has had an impact on the implementation of the chosen strategy. This will be discussed further towards the end of the chapter when reviewing the impact of institutions in general on strategy choice.

6.3 Proposition 3: Advertising or promotion of the branded product is reduced on patent expiry to maximise profits

Advertising or promotion of the branded product both pre- and post-patent expiry theoretically could increase the perceived value to the customer of the product due to the building of brand loyalty. This would move the product to a position of higher quality and therefore potentially justify the higher price when considering the value map framework presented in Chapter 2. However evidence from the sample of products in this study shows that advertising and promotion spend is reduced as patent protection expiries.

6.3.1 Advertising and promotion prior to expiry of patent protection

In the year leading up to patent expiry, six of the 14 respondents considered and then implemented an increase in the intensity advertising, promotion or detailing. Only two respondents said that this increase was directly related to attempts to increase brand loyalty. Product 8 followed this strategy as the chosen strategy was to compete using the original product and Product 13 used this strategy to build brand loyalty prior to patent expiry to help maintain market share. This was claimed to have been moderately successful.

Although the other four products increased advertising and promotion intensity the intention was not to focus on the branded product but rather to develop a strong base from which to launch the clone or product extensions. The general sentiment was that

due to the lifecycle of the product and the impact of lower priced generics, those consumers who were loyal to the brand would remain and additional consumers would not be attracted to the original branded product. If a consumer was not using the product during the time of market exclusivity, additional advertising spend would not have an impact.

This was the same rationale provided by the eight respondents who did not consider raising the intensity of advertising or promotion prior to expiry. All eight respondents maintained the current spend in the year leading up to patent expiry.

Although Thomas (1999) argued that entry could be deterred through increasing the cost of the entry through advertising, the results of other studies (Ellison & Ellison, 2007; Scott Morton, 2000) have shown that due to the low costs incurred by generic companies, primarily from the lack of research and development expenditure, the cost of advertising is not seen as an entry barrier. This is particularly relevant in large markets where available profits are high. None of the respondents indicated that the increase in advertising or promotion was to deter entry from generic competition. This is in line with the findings of Wilkie et al. (2012), which showed that an increase in advertising had no impact on generic entry. That study did however show that the increase did help to protect market share from competing products. This was supported by two of the respondents who stated that the increase in advertising was to protect market share from generic competition.

6.3.2 Advertising and promotion after expiry of patent protection

Once patent protection had expired only five respondents considered increasing the intensity of advertising and promotion. Again, besides Product 8 which followed an original brand strategy, the main motivation for increasing the promotion of the branded product was to facilitate and support the growth of the clone in the market. The original product provided some transferable brand value to the clone, so by increasing awareness of the branded product, the clone benefited.

This total molecule strategy of promoting the clone and the original product was followed for all products which implemented a clone strategy. However in all cases, resources were proportioned more in the support of the clone as sales of the branded product declined. Products which did not experience generic competition on patent expiry continued with normal operations in terms of advertising and promotional spend.

As generic competition entered the market and the branded product lost market share advertising was reduced as reflected in Figure 13. The reduction was done in proportion to declining sales and in some cases completely stopped. Detailing was reduced for ten products with two products maintaining the same level of detailing. Only Product 8 continued to advertise and detail with increasing intensity. Product 14 increased detailing with the intention of increasing awareness of product extensions in specific niche markets. This response to declining sales is indicative of profit-maximising behaviour by these companies.

This profit-maximising behaviour is supported by Regan (2008) who, through a theory of market segmentation caused by lower priced generic entry, suggests that a price-insensitive brand loyal market segment is created. Although significantly smaller than the original market share, this group of consumers continues to pay a premium price for the original product. The study concludes that this loyal segment will continue to use the product regardless of current marketing efforts and therefore the promotional spend should be decreased to maximise profits. The behaviour of the sample group is therefore aligned with these findings.

The brand strength of all 14 products was rated as either strong or very strong by the respondents. Further to this, the brand value of the product and company as well as the brand loyalty of customers, were ranked by respondents as the top three factors considered when developing the strategy to pursue post-patent protection. Further down in Table 7, advertising and promotional spend on the product was ranked as number 25 and the marketing efforts of generic companies was ranked 19. From these comparisons it is concluded that the long-term benefit of brand building has a greater impact than shorter term marketing efforts.

The above conclusion is reinforced by the findings of Berndt et al. (2003) in their study of the H_2 blocker market from which it was concluded that the decline in marketing efforts by branded firms was based on long-term benefits of previous marketing efforts and not short-term influences. The spend on promotion and advertising was also found to decrease the longer the product remained on the market which leads to the conclusion that marketing and promotion is most impactful on the launch of a product and during initial growth stages and not in the latter part of the life cycle (Scott Morton, 2000).

6.3.3 Promotion 3 - Conclusion

This proposition was testing the profit-maximising behaviour of the firm by suggesting that marketing efforts were reduced on patent expiry. Despite marketing efforts being increased for six products prior to patent expiry, the intention of these activities was not to increase the brand loyalty for the original product but instead facilitate the launch of the clones or product extensions.

Once patent protection had expired marketing efforts were reduced in all but two cases, indicating that advertising and promotional activities were not used to build brand loyalty but instead reduced to maximise profit.

For the sampled 14 products, advertising, promotional activities and detailing were not used to deter entry or protect market share from generic competition but were instead reduced to maximise profits from the remaining price insensitive, brand loyal market segment. The long-term brand building which occurred during market exclusivity was deemed to be more valuable than short-term marketing efforts.

Proposition 3 therefore holds true for the sample that advertising and promotion of branded products was reduced on patent expiry to maximise profits.

6.4 Proposition 4: Product extensions, fighter brands, over-the-counter products or new products are introduced to extend market exclusivity

Innovation strategies have been used by companies to manage the expiry of patents with much success in the past. These strategies involved the launch of new, improved variations of the original product to maintain market share (Kvesic, 2008). When these new formulations manage to secure secondary patents which extend market exclusivity the strategy is particularly effective.

6.4.1 Launching product extensions

Due to the historical success of product extensions in extending patent protection for the industry, this strategy was considered by nine of the respondents who investigated the option of launching product extensions prior to patent expiry. The five that did not consider this strategy stated that there were no product extensions available so it was not considered. However three mentioned if there were product extensions available in

the company portfolio for the product then they would have considered this more seriously as a strategy.

Of the nine who considered the strategy only two implemented product extensions. Both of these product extensions were launched to extend market exclusivity through a secondary patent. Product 1 intended to launch but was delayed in registering the product through the MCC. This product extension was not patent protected but the company felt it added to the value of the product and launched as soon as the registration was approved.

Kvesic (2008) identified the major risk of the product extension strategy to be the market not perceiving the value of the extension. This was experienced by Product 11, for even though market exclusivity was extended through a secondary patent for the product extension, the new delivery system was not seen as an improvement to the product and consumers remained on the original formulation and then switched to the generic of the original formulation. Product 14 achieved success through the product extensions and successfully converted a large percentage of the consumer base to this new patent protected formulation. Both product managers stated the reason for launching product extensions was to extend market exclusivity.

The seven respondents who considered launching product extensions and then did not cited a number of reasons for not pursuing the strategy. Firstly delays in registration from the MCC meant that the product extensions could not be launched prior to patent expiry and therefore the advantage would be lost. This is supported by Huskamp et al. (2008) who found that product extensions needed to be launched before the loss of market exclusivity in order to have sufficient time to switch consumers to the new product formulation. Four of the seven were delayed by registration and only one pursued the strategy further.

Besides the delay in registration this strategy was not pursued further for two products because secondary patents were not rewarded. This adds further evidence to the proposition that product extensions are used to extend market exclusivity.

Even though secondary patents were not applicable to three of the products, product extensions were still planned in order to expand the range of the portfolio. The product extensions were seen as valuable improvements and would have been launched if not delayed by the MCC. The intention was to launch these before patent expiry to expand the range required to be replicated by generic competitors. This strategy is supported by Thomas (1999) who noted that product extensions increase the size of the range

required to be replicated and reduce the number of profitable positions into which a rival may enter.

The notion of launching product extensions prior to patent expiry was also investigated by Reiffen and Ward (2007) who concluded that product extensions can both extend market exclusivity and expand the range required to be replicated. The extensions needed to be launched prior to patent expiry in order to be effective.

The primary reason for launching product extensions prior to patent expiry for the sample group was to extend market exclusivity however in the absence of a secondary patent, product extensions were still deemed a plausible strategy to deter entry by expanding the range to be replicated.

After patent expiry product extensions have been launched for five products, none of which have market exclusivity. The intention of launching these product extensions has been to target new market segments through product differentiation.

6.4.2 Launching fighter brands

The brand strength was considered to be strong for four products and very strong for the remaining ten products. These statements were reinforced by the fact that only three respondents considered introducing a fighter brand as part of the patent expiration strategy. Barak and Wilson (2003) suggested that a fighter brand is most relevant in markets where brand sensitivity is high and brand loyalty or strength is low. Therefore considering the strong brand strength of the sample products, the fighter brand strategy by default was not attractive.

The rationale for introducing a fighter brand for Product 1 was to have a brand of the product which was focused on a specific and specialised area. The other two products which introduced fighter brands did so through in-house brand names in retail pharmacy chains with the intention of capturing more market share. The fighter brands were therefore launched to increase market share through brand development.

6.4.3 Launching over-the-counter products or new products

Over-the-counter (OTC) products have the benefit of not requiring a doctor's prescription to be sold. In South Africa OTC products can also be advertised directly to the consumer and therefore brand loyalty can be better developed without having the complexities of a prescribing doctor in the middle. However the regulations related to

the schedule of pharmaceutical products does limit the availability of this option. Due to this 12 products were unable to pursue this strategy.

The remaining two products although registered as schedule 3 products and therefore excluded from the OTC strategy were faced with an interesting challenge in that their clone and independent generic products were registered as schedule 2 products by the MCC. Despite the products being bioequivalent and in the clones' case the same product the scheduling status was different.

This added complexity to the original product strategy as the originator product now had the distinct disadvantage of requiring a doctor's prescription. Applications were made to re-register these original products as schedule 2 however these are still delayed in the MCC.

Kvesic (2008) cites the example of the successful Tagamet antacid product which altered the market landscape by following an OTC strategy to manage patent expiry. The market has been similarly affected for the two products which now face OTC competition from the generic products due the registration change instituted by the MCC.

The lack of new products in the company portfolios limited the option of switching consumers to a new, superior product. The intention of this strategy is to transition the market to a new product which has patent protection. The new product needs to be superior to the previous product (Kvesic, 2008). Two of the respondents who attempted to switch consumers to a new product were unsuccessful because the market did not see superior value in the new product. The third respondent who did switch consumers to a new patent protected product did so by focussing only on a selected condition for which the new product was successful. The strategy was based on the notion of securing market share through patent protection for this segment of the market.

6.4.4 Proposition 4 – Conclusion

Product extensions were actively considered when the possibility of market exclusivity was available. For the sampled products this prospect was the primary reason for considering the introduction of product extensions. However a strong secondary reason for introducing product extensions, in particular prior to patent expiration, was to expand the range of products needing to be replicated by generic companies entering

the market. Product extensions, launched post patent expiry, were introduced with the intention of targeting new segments of the market and not to extend market exclusivity.

Fighter brands were not considered by the majority of respondents due to the strong brand strength of the original products. Those that did consider introducing a fighter brand did so to capture a greater market share and not to transition current consumer of the original product to the new brand.

The lack of suitable new products and OTC products limited these possibilities as strategies to be pursued. The registration of the generic products and clones as Schedule 2 OTC products illustrated the effectiveness of the OTC strategy if available.

The introduction of product extensions, fighter brands, OTC products or new products was followed not only to extend market exclusivity but to broaden the range of products available and target new market segments as well. Although market exclusivity was a reason for considering these options, in particular product extensions, the proposition is found to be false. This is due to the underlying reason for following these strategies being broader than just the extension of market exclusivity.

6.5 Proposition 5: The branded product is always left on the market to capture remaining profit from brand loyal or price insensitive consumers

In all cases the original product was left on the market as all product managers deemed it still to be of value to the company. For Product 8 which followed an original brand strategy this by default was not an option. For the remaining 13 products, even though sales volume had reduced since the introduction of the clone or other generic competition the sales were still profitable and significant. Two respondents mentioned that the market share quickly reduced but then stabilised albeit at a much lower share of the market. This is supported by the market segmentation shown by Regan (2008) with the brand loyal or price insensitive consumer base remaining with the original product.

As previously discussed in proposition 3 and shown in Figure 13 all advertising and promotional spend was reduced to maximise profits from the original products. Five respondents said the strategy involved milking the original brand and that the product would remain on the market until the sales decline to almost nothing. This supports that proposition that the original product is left on the market to extract remaining profits.

All respondents for products which followed a clone strategy commented that the brand value of the original product remained high in the market and this assisted in the marketing of the clone. Further to this withdrawing a product from the market also has negative connotations in a pharmaceutical market and three respondents said that withdrawing a product would confuse the market and damage the brand value of the company and or clone.

Only one respondent stated that in the long term the product may be sold to a third party to market but that it would still be available.

Kvesic (2008) cautioned that a divesture strategy is only appropriate if a company is confident that no further benefit will be derived by continuing to offer the product to the market. In the current environment of reduced product pipelines and strengthening generic industry, Kvesic (2008) concludes further that completely withdrawing the product may no longer be appropriate. Instead investment should be reduced from the product and marketing resources allocated elsewhere, in other words a profit-maximising or milking strategy.

6.5.1 Proposition 5 – Conclusion

In all cases the original product remained in the market as all respondents indicated that the product was still valuable to the company and profits continued to be received from sales of the original product. The proposition is therefore shown to be true that the original product remains on the market to capture the remaining profit from the smaller brand loyal market segment.

Further to this however, the original product is left in the market to support the marketing efforts of the clone strategy where applicable.

6.6 The impact of the Medicines Control Council

Although not initially part of the research objectives, the role of the Medicines Control Council (MCC) requires discussion considering the impact it has had on the product strategies pursed to manage the expiration of patent protection. As mentioned in the discussion of the previous propositions the MCC created uncertainty in the choice of strategy due to delays in registration of clones, product extensions and generic products. This uncertainty resulted in secondary, less preferred strategies such as price reductions being considered as a last resort. Although respondents did admit that

knowing of the delays experienced in registration, they were late in submitting their applications, the delays were much longer than experienced by the company in other regions. As well as the delays, the uncertainty as to the length of the time to register a product added extra complexity to the situation.

The success of a product strategy is highly dependent on the timing of the execution. In particular the timing of the launch of a clone has been shown to be critical in its success (Hollis, 2002; Reiffen & Ward, 2007). This first-to-market advantage was missed by four products due to delayed registration. The opposite impact was experienced by one product whereby the generics were delayed in registration and the clone unnecessarily eroded the profits of the original product.

Product 4 anticipated the delays in registration of generic products and deferred the launch of the clone until the first generic had actually entered the market. The delay in launching the clone was a number of years, and resulted in batches of the clone expiring in the warehouse and having to be destroyed.

Product 11 and Product 13 were further impacted by the MCC when the generic products and clones of the original products were registered as schedule 2 instead of the schedule 3 status of the original product. A schedule 2 product may be sold over the counter, which has the distinct advantage that it does not require a doctor's prescription to be sold (Kvesic, 2008). Through the registration process the MCC created a market advantage for the generic products which impacted the ability of the original product to compete.

North (1991) proposed that institutions set the rules of the game which determine the transactions costs of engaging in economic activity. These transaction costs are a critical determinant of economic performance. Previous studies referred to in this research study have been from developed markets such as the United States (Regan, 2008; Reiffen & Ward, 2007), Canada (Hollis, 2002), France (Chandon, 2004), Germany (Applet, 2010) and Australia (Wilkie et al., 2012) amongst others. Although not specifically stated it is assumed that the strategies pursued were investigated without regard to the efficiency of institutions in these countries.

This is a valid assumption for, although a major focus of literature has been on institutions as efficient solutions to problems of organisation, in most cases this is taken as a given. However, economic history is overwhelmed with economies that failed to produce a set of economic rules of the game which produced sustained economic growth (North, 1991). The performance of these institutions therefore must be

considered when assessing the choices made by companies in the economy and cannot be assumed as efficient.

For the sampled 14 products the inefficiency of MCC had to be considered in the choice of strategy and in some case as impacted in the execution of the chosen strategy.

7. Conclusion

This chapter highlights the major findings of the research study and provides insights to stakeholders based on these findings. To conclude, recommendations for future research are given.

7.1 Summary of research objectives

This research study investigated the product strategies considered and then implemented for a sample of 14 pharmaceutical products which lost patent protection in the South African pharmaceutical market. The primary focus of this research study was to determine the reasons behind the product strategy. The strategies were compared to those discussed in other international studies as well as to economic theory; in particular to the theory focused on the dynamics of market entry. The strategies were positioned on the value map framework to illustrate the variables considered.

The research was structured around the following propositions:

1. The price of branded pharmaceuticals is not used as a means to either deter entry or compete with generic products.

2. Clones are launched to capture a share of the generic market and defend market share, not to deter entry.

3. Advertising or promotion of the branded product is reduced on patent expiry to maximise profits.

4. Product extensions, fighter brands, over-the-counter products or new products are introduced to extend market exclusivity.

5. The branded product is always left on the market to capture remaining profit from brand loyal or price insensitive consumers.

7.2 Research findings

The results of the 14 structured interviews were compared to those of other international studies and were found to be consistent, in particular when considering the manipulation of price. The price of the original product was not used as a variable to deter entry though the theoretical mechanism of limit pricing. The respondents commented that such an approach is unsustainable as generic competitors are always able to enter at a lower price. It was suggested that lowering the price of the original product would result in a price war that the originator companies could not win. Proposition 1 was therefore found to be true for the sample with price not being used as a variable to either deter entry or compete with generics.

Price instead was maintained at a premium price point to extract the remaining profits from the reduced but loyal consumer base. This is in line with market segmentation theory put forward by Caves et al. (1991) and Regan (2008). This is further supported by the results of proposition 5 which found that no products were withdrawn from the market once the patent had expired. The primary reason for not withdrawing a product was that the product was still valuable to the company and continues to generate profitable returns.

To support this profit-maximising behaviour, the intensity of advertising, promotion and detailing was reduced for the majority of products. Except for one product, which followed an original brand strategy, any further investment in promotion of the original product was done with the intention of building a stronger consumer base into which to launch the clone. Proposition 3 was found to be true with investment in advertising and promotion being reduced once patent protection had lapsed. This is in line with other international studies which cite the reason for such behaviour being reliance on long-term brand building during the period of market exclusivity rather than short-term influence. This again supports the market segmentation theory and shows profit-maximising behaviour with regards to the original product.

Product extensions, fighter brands or new products were launched if market exclusivity could be extended through secondary patents. These strategies were limited due to the lack of significant value adding extensions being available. One product found success in deploying a product extension strategy; however one product was also negatively impacted as consumers did not perceive the extension to add superior value. Kvesic (2008) identified this as the major risk of this strategy. The findings were consistent with the motivation for this research that the use of secondary patents to extend market

exclusivity is becoming less successful and therefore other strategies are being pursued.

The dominant strategy pursued was to launch a clone. This strategy was implemented by 11 of the 14 respondents. The clone was launched with the intention of both deterring entry and capturing the generic portion of the market thus showing proposition 2 to be only partly true.

Responses around the timing of launching a clone were varied. It was suggested that clones should be launched prior to patent expiry to secure the first-to-market advantage. This is consistent with studies by Reiffen and Ward (2007) and Hollis (2002) who both concluded that being first-to-market had a significant advantage. In contrast to this, two products purposefully waited until generic products had entered the market. The clones were launched in the same month as the generic products. It was reasoned that this was close enough to limit the exposure of being second-to-market. The rationale behind this strategy is to maintain original profit margins without unnecessarily eroding the market by the early introduction of a clone.

The delays in registering products through the Medicines Control Council further added to the complexity of the timing. A number of strategies, which originally intended to launch a clone before patent expiry, had to be altered due to the delay in registration. For two products, the scheduling status of the clone and competing generic products was changed to allow the clone to be sold over the counter. This fundamentally impacted the ability of the original product to compete as it still required a doctor's prescription to be sold. North (1991) proposed that institutions set the rules of the game which determine the transaction costs of engaging in economic activity. The delays in registration as well as the inconsistency of assigning schedule categories by the MCC has shown how institutions cannot be assumed to be efficient when considering a specific strategy.

7.3 Recommendations to stakeholders

Although the findings of this research study show the dominant strategy to be the clone strategy, the recommendation to product managers facing future patent expiry challenges is not to merely adopt a clone strategy but rather consider all options to make sure the chosen strategy is suitable for the product. As shown in the results Product 8 achieved a successful original brand strategy despite the dominance of the

clone strategy. However, in the South African market, current legislation and the impact of third party payment parties, namely medical aids, does lead to the conclusion that a clone strategy holds the most potential.

The impact of institutions on the efficient functioning of an economic system cannot be ignored. As such a further recommendation to stakeholders is to consider this impact. In order to mitigate this risk it is recommended that product managers prepare sufficiently in advance if the implementation of the strategy depends on a requirement being fulfilled by an institution which is known to be inefficient. In addition to this those institutions which impact the efficient functioning of the system need to be reviewed.

7.4 Limitations of the research

The results and conclusions drawn in this research study are limited to the 14 products investigated. As discussed in Chapter 4 the sample was chosen using non-probability sampling due to the total population being unknown. Conclusions can therefore not be drawn for the population. Further to this by relying on product managers to self-select which products will be investigated, the research study may have been biased to products for which the chosen strategy was a success.

The research study, through its design, identified a finite number of strategies to be investigated. Although open-ended questions did allow respondents to elaborate on answers given, other strategies may have been excluded from the discussion unintentionally.

The study only focused on the South African market which has unique characteristics which are not necessarily present in other markets. As such, conclusions reached in this study cannot be transferred to other countries. The consistency of results when compared with those of other international studies does however show that certain characteristics of the study may hold true in other markets.

7.5 Recommendations for future research

This study was limited in its findings due to the relatively small sample of products investigated and therefore the first recommendation is to expand the sample to include more products to be able to draw conclusions from a larger sample of the population.

The open-ended responses yielded two distinct areas for future research. First, the impact of maintaining the original product in the market should be investigated. By keeping the original product at a high price in the market it was suggested that this reflects the true value of the market. Clones and independents were then priced relative to this value. The impact the original product's price could be investigated through an empirical study to see if this does indeed hold the overall value of the market higher.

Secondly, there was much debate around the benefit of being first-to-market with regards to launching a clone. In other markets it was shown through empirical studies to have a distinct advantage, however as discussed in this research study, clones which launched second have managed to achieve dominant positions in the South African market according to the product managers. It would be of interest to empirically test the first-to-market advantage in the South African market

7.6 Conclusion

The management of pharmaceutical products as patent protection is lost continues to be a much researched topic, particularly at current due to a significant number of high profile products recently going off-patent. The objective of this research was to add to the current literature relating to the management of patent protection loss by investigating a sample of products which have lost patent protection in the South African market.

Through 14 structured interviews, five propositions relating to the strategies considered and then those pursued were investigated. The dominant strategy for the sample was that of launching a clone to compete with independent generics. The price of the original product was not used as a primary mechanism neither to deter entry of independent generics nor to compete with lower priced generics. When available, product extensions which provided extended market exclusivity were pursued. Advertising and promotion of the original product were reduced on patent expiry which is indicative of profit-maximising behaviour.

The research study successfully achieved the research objectives set out in Chapter 3 and provides insight to stakeholders seeking to understand the decisions made regarding the management of pharmaceutical products facing the loss of patent protection in South Africa.

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APPENDIX 1 – QUESTIONNAIRE

The questionnaire has been formatted to reduce the length of the appendix. The original questionnaire allowed more space for the reason/comment to be captured in Sections C and D.

Questionnaire

A copy of the questionnaire will be provided to the participant, however it will be completed during the interview and captured by the researcher

A.	**Assessment of the Threat of Entry** Date of patent expiry in South Africa (Month_Year):_____ **In the year of patent expiry:**
A1	What would you say the approximate market share of the product was? ☐ < 10% ☐ 11% to 20% ☐ 21% to 30 % ☐ 31% to 40% ☐ 41% to 50% ☐ 51% to 60% ☐ 61% to 70% ☐ 71% to 80% ☐ 81% to 90% ☐ 91% to 100%
A2	The contribution of this product to the business unit sales was: ☐ < 1% ☐ 1% to 5% ☐ 6% to 10% ☐ 11% to 20% ☐ 21% to 30 % ☐ 31% to 40% ☐ 41% to 50% ☐ 51% to 60% ☐ 61% to 70% ☐ > 70%
A3	The contribution of this product to the total South African company sales was: ☐ < 1% ☐ 1% to 5% ☐ 6% to 10% ☐ 11% to 20% ☐ 21% to 30 % ☐ 31% to 40% ☐ 41% to 50% ☐ 51% to 60% ☐ 61% to 70% ☐ > 70%

A4	How many substitute products were available in the market:				
	☐ None	☐ 1 to 4	☐ 5 to 10	☐ > 10	
A5	How intense was the competition experienced for this product?				
	☐ None	☐ weak	☐ strong	☐ very strong	☐ Don't know
A6	The brand strength for this product was:				
	☐ Very weak	☐ Weak	☐ Strong	☐ Very Strong	☐ Don't know
A7	The threat of generic entry for this product was:				
	☐ Low	☐ Average	☐ High	☐ Certain	☐ Unknown
A8	Compared to other patent expiries, the strategic importance of this product was:				
	☐ Low	☐ Somewhat low	☐ Average	☐ Somewhat high	☐ High

Please rate the following statements according to the options given:

A9 Existing products in the market competed so intensely that profit margins were so low that entry was extremely unlikely

☐ Disagree ☐ Somewhat disagree ☐ Neutral ☐ Somewhat agree ☐ Agree

A10 The market size and profitability were so great for this product that entry from generic competitors was inevitable

☐ Disagree ☐ Somewhat disagree ☐ Neutral ☐ Somewhat agree ☐ Agree

A11 Entry from generic competitors was inevitable so the best strategy was one of earning what you can before entry occurred

☐ Disagree ☐ Somewhat disagree ☐ Neutral ☐ Somewhat agree ☐ Agree

A12 The probability of entry was so remote that no action was necessary to reduce it

☐ Disagree ☐ Somewhat disagree ☐ Neutral ☐ Somewhat agree ☐ Agree

A13 The probability of entry was so high that no action was attempted to reduce it

☐ Disagree ☐ Somewhat disagree ☐ Neutral ☐ Somewhat agree ☐ Agree

A14 The product life cycle stage was best described as:

☐ High growth ☐ Slow growth ☐ No growth ☐ Declining ☐ Redundant

A15 The product can easily be replicated

☐ Disagree ☐ Somewhat disagree ☐ Neutral ☐ Somewhat agree ☐ Agree

A16 The product is relatively expensive to manufacture

☐ Disagree ☐ Somewhat disagree ☐ Neutral ☐ Somewhat agree ☐ Agree

A17 The product requires special storage (e.g. cold temperature, special handling, hazardous)

☐ Yes ☐ No

A18 The market size is best described as

☐ Niche/Specialist ☐ Small ☐ Medium ☐ Large ☐ Enormous

A19 Where is the product manufactured:

☐ Locally ☐ Internationally

A20 The treatment type is:

☐ Acute ☐ Chronic

B Preparing for Patent Expiry

How important were the following factors when assessing the product strategy to pursue after patent protection:

	Factor	Very Important (4)	Fairly Important (3)	Slightly Important (2)	Not Important (1)	Not Applicable (0)
B1	Cost of production					
B2	Availability of excess production capacity					
B3	Proprietary knowledge required to produce the product					
B4	Sunk costs such as facility costs required to produce the product					
B5	Recovery of R&D costs					
B6	Cost advantage over generic competitors					
B7	Cost of production for generic companies					
B8	Brand Value of the product					
B9	Brand loyalty of customers					

	Factor	Very Important(4)	Fairly Important(3)	Slightly Important(2)	Not Important(1)	Not Applicable(0)
B10	Brand value of the company					
B11	Advertising and promotional spend for the product					
B12	Impact on related products in your company					
B13	Impact on unrelated products in your company					
B14	Price of the product					
B15	Size of the total market for the product					
B16	Current market share for the product					
B17	Impact on market share of the product					
B18	Contribution of product to total sales					
B19	Impact on customers of the product					
B20	Impact on other regions still under patent protection					

	Factor	Very Important(4)	Fairly Important(3)	Slightly Important(2)	Not Important(1)	Not Applicable(0)
B21	Decisions made in other regions regarding end of patent strategies					
B22	Number of substitute products on the market					
B23	The threat of generic competition					
B24	The life cycle stage of the product					
B25	Public perception of generics in South Africa					
B26	Government legislation and regulatory environment					
B27	Impact on State tenders					
B28	Type of treatment					
B29	Type of disease state					
B30	Therapeutic class					
B31	Marketing efforts of companies producing generic products					

	Factor	Very Important(4)	Fairly Important(3)	Slightly Important(2)	Not Important(1)	Not Applicable(0)
B32	Coverage by medical aid policies					
B33	Availability of product line extensions					
B34	Use of other patent protected methods such as slow/extended release or combinations					

C Product strategy considerations

For each scenario described please respond Yes or No and then provide supporting comments regarding the decision making process for that scenario:

C1 Did you consider lowering the price before patent expiry?

☐ Yes ☐ No

Reason/Comment:

C2 If yes, did you lower the price before patent expiry?

☐ Yes ☐ No

Reason/Comment:

C3 Did you consider lowering the price after patent expiry?

☐ Yes ☐ No

Reason/Comment:

C4 If yes, did you lower the price after patent expiry?

☐ Yes ☐ No

Reason/Comment:

C5 Did you consider raising the price before patent expiry?

☐ Yes ☐ No

Reason/Comment:

C6 If yes, did you raise the price before patent expiry?

☐ Yes ☐ No

Reason/Comment:

C7 Did you consider raising the price after patent expiry? ☐ Yes ☐ No Reason/Comment:
C8 If yes, did you raise the price after patent expiry? ☐ Yes ☐ No Reason/Comment:
C9 Did you consider increasing the intensity of advertising/promotion/detailing to increase brand loyalty before patent expiry? ☐ Yes ☐ No Reason/Comment:
C10 If yes, did you increase the intensity of advertising/promotion/detailing to increase brand loyalty before patent expiry? ☐ Yes ☐ No Reason/Comment:
C11 Did you consider increasing the intensity of advertising/promotion/detailing to increase brand loyalty after patent expiry? ☐ Yes ☐ No Reason/Comment:
C12 If yes, did you increase the intensity of advertising/promotion/detailing to increase brand loyalty after patent expiry? ☐ Yes ☐ No Reason/Comment:
C13 Did you consider launching a clone/pseudo generic before patent expiry? ☐ Yes ☐ No Reason/Comment:

C14 If yes, did you launch a clone/pseudo generic before patent expiry? ☐ Yes ☐ No Reason/Comment:
C15 Did you consider launching a clone/pseudo generic after patent expiry? ☐ Yes ☐ No Reason/Comment:
C16 If yes, did you launch a clone/pseudo generic after patent expiry? ☐ Yes ☐ No Reason/Comment:
C17 If a clone/pseudo generic was introduced was it produced in-house? ☐ Yes ☐ No Reason/Comment:
C18 If a clone/pseudo generic was introduced was it produced under license? ☐ Yes ☐ No Reason/Comment:

If a clone/pseudo generic was launched continue with the below. If not skip to C23

C19	A clone/pseudo generic was launched prior to expiry to deter entry from other generic competitors ☐ Disagree ☐ Somewhat disagree ☐ Neutral ☐ Somewhat agree ☐ Agree
C20	A clone/pseudo generic was launched prior to expiry to capture generic market share through first to market advantage ☐ Disagree ☐ Somewhat disagree ☐ Neutral ☐ Somewhat agree ☐ Agree
C21	A clone/pseudo generic was launched after expiry to deter entry from other generic competitors ☐ Disagree ☐ Somewhat disagree ☐ Neutral ☐ Somewhat agree ☐ Agree
C22	A clone/pseudo generic was launched after expiry to capture generic market share ☐ Disagree ☐ Somewhat disagree ☐ Neutral ☐ Somewhat agree ☐ Agree

C23 Did you consider introducing a fighter brand or similar before patent expiry?

☐ Yes ☐ No

Reason/Comment:

C24 If yes, did you introduce a fighter brand or similar before patent expiry?

☐ Yes ☐ No

Reason/Comment:

C25 Did you consider introducing a fighter brand or similar after patent expiry?

☐ Yes ☐ No

Reason/Comment:

C26 If yes, did you introduce a fighter brand or similar after patent expiry?

☐ Yes ☐ No

Reason/Comment:

C27 Did you consider introducing product extensions or enhancements before patent expiry?

☐ Yes ☐ No

Reason/Comment:

C28 If yes, did you introduce product extensions or enhancements before patent expiry?

☐ Yes ☐ No

Reason/Comment:

C29 Did you consider introducing product extensions or enhancements after patent expiry?

☐ Yes ☐ No

Reason/Comment:

C30 If yes, did you introduce product extensions or enhancements after patent expiry?

☐ Yes ☐ No

Reason/Comment:

C31 Did you consider switching customers to an Over-the-counter alternative?

☐ Yes ☐ No

Reason/Comment:

C32 If yes, did you switch consumers to an Over-the-Counter alternative?

☐ Yes ☐ No

Reason/Comment:

C33 Did you consider switching consumers to another product?

☐ Yes ☐ No

Reason/Comment:

C34 If yes, did you switch consumers to another product?

☐ Yes ☐ No

Reason/Comment:

C35 Did you consider withdrawing the product from the market?

☐ Yes ☐ No

Reason/Comment:

C36 If yes, did you withdraw the product from the market?

☐ Yes ☐ No

Reason/Comment:

C37 Did you consider a co-marketing/licensing agreement for the product? ☐ Yes ☐ No Reason/Comment:
C38 If Yes, enter a co-marketing/licensing agreement for the product? ☐ Yes ☐ No Reason/Comment:
C39 Please describe the product strategy chosen to manage the expiry of patent protection

D Post Expiry of patent

For each scenario please indicate the most appropriate answer and provide supporting comments:

D1 What changes were made to production costs?

☐ Increased ☐ Decreased ☐ No change

Reason/Comment:

D2 What changes were made to the amount or intensity of advertising?

☐ Increased ☐ Decreased ☐ No change

Reason/Comment:

D3 What changes were made to the amount or intensity of direct selling or detailing?

☐ Increased ☐ Decreased ☐ No change

Reason/Comment:

D4 In your opinion, was the chosen strategy appropriate?

☐ Yes ☐ No ☐ Undecided

Reason/Comment:

D5 For future products what would you differently?

Reason/Comment:

End - Thank you