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EXECUTIVE SUMMARY



E U L A R I S

After years of relatively easy blockbuster profits, worldwide respect and investment, and loyal customer bases, the Pharmaceutical realm has undergone a seismic shift. Today, the branded Pharmaceutical Companies are in trouble and are increasingly vulnerable to the threats posed by the competition.

And who is the competition? It's not other branded companies anymore. Generics have emerged as the primary challenger to Pharmaceutical Industry success, offering a public hungry for medication and reduced costs exactly what they want and need. Generics have exploded in the last decades, and are poised for even bigger growth. While the Pharmaceutical Industry gets squeezed by internal and external pressure, customers, physicians, governments and insurers push for more Generics.

The reasons for the Pharmaceutical Industry's vulnerability are many, but one culprit is the increasing requirements to create medication. Researching and developing a commercial prescription drug today requires an average total investment of \$500 Million and 10 - 15 years of lab work, clinical trials and extensive regulatory review¹. When the drug is finally out in the marketplace, it enjoys only a brief period of monopoly and profit before patent expiration and plummeting market share in the face of a Generic takeover.

The situation is grim. It can seem like Pharmaceutical Companies have no recourse in the face of the lower prices and operating costs of the Generics Industry and fortunes will only continue to fade. However, options do exist for Pharmaceutical Companies to mount an effective defense strategy against the threats posed by Generics.

In this report, we examine some of these defensive strategies. We analyze the environment for Pharmaceuticals today, as well as the Generic Industry as a whole. We describe the pros and cons of legal defensive strategies as well as opportunities to expand the revenue-generating product life cycle into reformulations and over-the-counter medications. We look at pricing strategies as well as company organizational changes as part of an integrated defense strategy and, to help companies make tough decisions about the best defense, we examine powerful analytics techniques and case studies.

CHAPTER 1: BACKGROUND OF THE GENERIC THREAT



In the past, Generics were seen as the bargain basement end of the greater Pharmaceutical market, with reduced quality and a lack of trustworthiness to match. However, in today's environment, Generics are growing in quality and respect, in market penetration, total sales and company size. The Generics Industry captured 14% of the global Health-care market in 2004, with overall revenues of \$58 Billion. Since then, the numbers have only increased².

And the rest of the Pharmaceutical Industry? The companies that once easily fulfilled the notion of Big Pharma in sales, profits and reputation? Between 2001 and 2005, \$400 Billion of value vanished from the Pharma Industry³. A look at financial statistics was once the easy indicator of the Pharmaceutical Industry's phenomenal value but, today, price per earnings (P/E) ratios (a measurement of a company's stock price relative to earnings) have fallen drastically, from a ratio of 30 in 1998 to as low as 12 in 2006. Across the board, Pharma companies are getting squeezed, with growing expenses and diminishing returns.

Meanwhile, the demand for drugs is growing. The global population is aging and busting at the seams. However, Big Pharma is losing out on this hungry audience. How did we get here? Why is the Pharmaceutical Industry suffering, and the threat posed by the booming Generic market growing? The reasons behind the Pharma Industry's current crisis are many.

THE PHARMA BUSINESS MODEL: The Root Of The Problem?

In Barrie G. James' eviscerating report, "An Industry in Crisis: Desperately Seeking New Strategies", he contends the Industry is at a desperate crossroads and vulnerable to the growing threat of Generics because of our own shortcomings and past failures.

The current "blockbuster" business model evolved in the late 1960's and was built on two key concepts. First, a significant proposition of superior value through product innovation was driven by a set of core capabilities that included a deep skill set, relationships with customers and competitors, and a fully integrated infrastructure.

This system internalized the value chain from drug discovery to marketing to customers. The second concept was a volume-based market opportunity, focusing on a steady stream of Primary Care products designed for highly prevalent, chronic diseases. Taken together, Barrie says, this model was a "magic bullet" guaranteeing superior results.

However, by the 1990's, the times were changing. New biotechnologies, the information age, globalization and rising consumerism all acted as destabilizing forces on this business model. Change was needed. But for decades, the Pharma Industry had relied upon a winning formula and had no need to develop new strategies. So, when the time came when new strategies were essential, Pharma was incapable of creating them.

In addition, this Industry had consistently posted high financial returns and performance, creating excessively high market expectations. When the environment changed, but the business model remained static, companies began missing those benchmarks.

CHAPTER 1:

Background Of The Generics Threat



By Dr. Andrée K. Bates
June 2008
www.eularis.com

Governments, ranging from state and national governments of the United States, national governments in Europe and other continents, and regional organizations for the EU, are increasingly encouraging the use of Generics through varied policies⁶. Governments are funding awareness programs aimed at the general population, and even Physicians, touting the benefits and trustworthiness of Generic drugs. Generic substitution rules are being put in place, enticing Pharmacists to dispense Generic drugs whether or not a Doctor explicitly details the Generic substitute.

The extents to which Generics are pushed by governments are directly related to pricing controls⁷. Markets with free pricing and active competition, including the US and UK, experience significantly reduced Healthcare costs for payers after patents expire and Generics become available. Generics are, therefore, actively encouraged by government programs. Countries with price controls (including Italy and France), however, are much more stable over time, even with patent expiration. Generics are less utilized and promoted by governments.

PATENT EXPIRIES: Brands At Risk

For an Industry weakened by inappropriate business models, reduced R&D and increasing Generics promotion by governments and patients, patent expiration is a knockout punch.

Patent expiration can prove disastrous. Sales revenues and market share drop dramatically and quickly for brands in the face of the resulting cheaper Generic alternatives. It's not unusual to see sales reductions of branded medicines over 70 percent after just a single year of Generic availability⁸, and all this after millions sunk into drug development, marketing and sales efforts.

Patent expiration has been an especially troubling and powerful problem in the last decade. Just in the last few years, some of the big players have gone off patent to directly face the crises ahead:

- 2005: Advair/Seretide, Cefzil, Duragesic, Lovenox, Plavix, Pravachol, Rocephin, Zithromax
- 2006: Ambien, Coreg, Lamisil, Proscar, Zocor, Zofran, Zolof
- 2007: Camptosar, Imigran/Imitrex, Kytril, Nexium, Norvasc, Paxil/Seroxat, Pulmicort, Risperdal, Zyrtec

Plus, in the next two years, more brands face this issue:

- 2008: Casodex, Delix/Tratace, Depakote/Valcote, Effexor, Fosamax/Bonalon, Lamictal, Mobic, Prograf and Protopic, Serevent
- 2009: Adenoscan/Adenocard, Cellcept, Flomax, Omnic, Harnal, Keppra, Lexapro/Cipralext, Protonix, TriCor/Lipanthyl, Xenical

Analysts suggest total sales of drugs coming off patent will exceed US \$160 Billion by 2015⁹.

CHAPTER 3:

LEGAL AND PATENT DEFENSE STRATEGIES



E U L A R I S

The first line of defense against the Generics threat, for most branded Pharmaceutical companies, is legal and patent strategies. To understand how effective patent defense can theoretically work, companies must first have a thorough knowledge of patents themselves.

DEFINITION AND CRITERIA

A patent is defined as a monopoly which provides the owner with the exclusive right to prevent any unlicensed manufacture, use, sale, and offer for sale, storage or importation for the above purposes of the patented object³¹.

To qualify for patent protection, a product must meet basic criteria. Of course, these principles are vague and to be decided on a case-by-case basis by experts in the field. However, the basic principles for what are and not patentable in all countries and for all technologies are³²:

- **Novel:** The product has never been available to the public before
- **Inventive:** The product is not an obvious creation
- **Useful:** The product is capable of industrial exploitation and use. In other words, the product can be made and sold.

PATENT PROCESS

In general, the filing of a first patent application sets the priority date, from which all key expiration dates are based. If a patent application meets the criterion for patentability, the application is granted. This usually happens 1 to 5 years after the application is filed. Depending on the country, the process of granting a patent can involve publishing the patent documents, formal examination and more. The U.S., for example, does not publish patent applications.

Patents can be challenged at any part of the process. The grounds for challenging are based on the criteria of patentability, meaning patents can be challenged for lack of novelty, obviousness or lack of utility.

Generally, patents last for 20 years from the date of the patent application filing. After this time, the patented product or procedure enters the public domain and can be freely used by anyone.

For many years, this was adequate protection. But in the last few decades, the costs of putting a new medication on the market have increased dramatically. In addition, the official requirements set by reviewing institutions became more severe. As result, the time required for a company to enter a new medicine on the market has lengthened significantly. Although the patent monopoly is theoretically for 20 years, in practice, it was usually only 10 years³³. Recent legislative maneuvers, as described in later sections, have addressed this problem.

CHAPTER 4:

Reformulation Strategies



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June 2008
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The trick for next-generation products is to glean patients off the existing drug and switch them to the newly patented drug, all before the original patent expires. Doing this staves off and minimizes market share loss and makes it less attractive for Generic competition to enter the market, where they would face a depleted patient population⁴².

Developing next-generation products is a risky endeavor. Research and development for new drugs costs millions, and companies risk losing that investment if the new product is not effective, safe, or otherwise, does not gain approval. Companies can be in a worse situation then. Rather than simply losing market share to a Generic drug honing in on the original brand, companies can also be out massive money on a failed next-generation product.

To minimize risk when planning for next-generation products, smart companies turn to the recipients for advice. What do consumers and doctors wish was better with the original product? What issues would they like to see addressed and solved? What kind of improved product would they stay loyal to? By turning to consumers and doctors for help, companies can create a better drug. This works wonders to entice patients to switch.

KEY FEATURES OF SUCCESSFUL REFORMULATIONS

In developing line extensions and next-generation products, the challenges are many. As the legal environment surrounding reformulation becomes harsher, the trials grow. Companies must balance the allocation of resources between creating new drugs and creating line extensions or 'switches off' of drugs losing patents⁴³. To successfully reformulate a brand drug, creating something valuable enough to ward off Generic competition, comprehensive research and development is needed. However, true success often only comes with careful business planning.

Timing

One of the biggest challenges, most fraught with risk, is the timing of line extensions and next-generation products. Timing going wrong can be disastrous. Consider the case of Clarinex. In 2002, Schering Plough introduced Clarinex as the next-generation replacement for Claritin, their blockbuster going off patent. The plan was to switch the consumer base for Claritin to Clarinex in a seamless maneuver. But, in reality, their marketing efforts fell short: not enough patients were switched to Clarinex before FDA approval of the Generic competition. As a result, Clarinex not only failed to reach blockbuster status, but sales of Claritin dropped from 3 Billion to 300 Million.

Timing gone right? That can result in astounding success. The case of AstraZeneca's Nexium is an Industry paradigm for this reason. As their blockbuster gastrointestinal drug, Prilosec, neared patent expiration, AstraZeneca submitted their next-generation Nexium product to the FDA, early enough to ensure approval before Prilosec's expiration. After FDA approval, the company embarked on one of the biggest marketing campaigns in United States history. They spent \$500 Million on DTC advertising, hospital discounts for the drug, free samples for Doctors' offices and other media advertising. The company transferred 40 percent of Prilosec patients to the next-generation Nexium, managing 9 percent growth in 2001 alone. As a result, Generic competition wasn't able to capture large portions of AstraZeneca's share of the GI market.

And AstraZeneca didn't stop there. When Prilosec prescriptions began to slow down, the company switched the drug to an over-the-counter option. Sales stayed strong, as did brand equity. We'll discuss switching to OTC formulations in the next chapter.

CHAPTER 5: DTC & OTC STRATEGIES



E U L A R I S

Since patent expirations are, in many ways, an inevitable business reality for Pharmaceutical companies and for Generic competition an increasing fact, companies that move to expand their revenue-generating cycle will be the companies that persevere and grow.

One method of looking beyond the period of patent protection is reformulation, discussed in the last chapter. However, as discussed, reformulation to new prescription products is increasingly losing out in the legal environment. Another more attractive strategy companies can turn to is incorporating revenue streams from over-the-counter medications.

OTC STRATEGIES

The decision to expand into over-the-counter products must be based on a number of different factors that influence long-term profitability⁴⁶:

- *Existing market position*
- *Anticipated existing and new competition in the OTC sector*
- *The expertise the organization has in a particular therapeutic area*
- *The fit with the rest of the product portfolio and branding*
- *Opportunities for innovation, which might lead to new product development*
- *External pressures to make certain drugs available at reduced cost*
- *The need to obtain good return on investment*

The OTC field is an inherently more crowded arena of products, and competitive wins come less through exclusivity and ownership and more through innovation. Plus, when branded Pharmaceuticals switch to OTC, they automatically give up some sales revenue.

So, why take the leap? Expanding into OTC medication will make the market unattractive to Generics, meaning more opportunity for market share and the ability for companies to keep more of revenue streams. Experts agree: most defense strategies against Generics have risk, including the switch to OTC products, and are not guaranteed to work. However, the alternative of doing nothing is much more dangerous⁴⁷.

Benefits

One of the greatest advantages of switching to OTC medication is the public relations boost⁴⁸. Purposely offering lower-priced drugs to a public growing increasingly upset by rising drug and healthcare costs shows a company responsive to customers, willing to innovate and create new opportunities and deserving of trust and loyalty.

Done well, a company's switch to OTC medication harnesses this positive publicity. Successful examples include Imodium and Nizoral, which took franchises far beyond initial patent expiration dates and became global brands. However, to perform a switch well, companies must consider a blinding array of factors.

Company Organization

A switch to an OTC drug is much more than a label change and shift in marketing. Many tried and true business methods must change in order for success. Company organization is one of those.

CHAPTER 6:

DEFENSIVE PRICING STRATEGIES



Ideally, companies will employ a number of different tactics in their arsenal to defend against Generics. Defending patents through legal challenges to Generic competition, tweaking products to line extensions, next-generation products or over-the-counter options, or a combination of both, should be methods companies regularly employ to maintain market share and sales.

However, to truly reduce damage from patent expiration and the rise of Generics, companies must employ pricing changes as well.

Several defensive pricing options are open to manufacturers. The best method to choose will depend on a number of factors, including the way in which the brand relates to the company's portfolio, the over-arching commercial objectives of the company, the degree of price sensitivity in the market, the potential to maintain different prices for different customers, and the level of competition expected⁵¹.

PRICE INCREASE

Can companies actually increase prices in the face of Generic competition and survive? Theoretically, yes. The idea in increasing prices is that Generic drug prices will then be established at higher levels after patent expiration. Higher prices will be a quick and dirty way to protect revenues for companies despite reduction in market share.

In practice, however, raising prices doesn't usually work. In private markets with few drug and price controls, brands that have good loyalty may find success with this tactic. However, in markets where government price controls dictate limits, this is not a feasible option. In both types of markets, competition from other brands is usually stiff enough to disallow a price increase.

PRICE MAINTENANCE

Market penetration varies for Generic drugs, as we've demonstrated. In those markets where widespread use of Generics is rare due to manufacturing difficulty, low product volume, special storage needs, low margins or already existing low prices, maintaining price can actually be a viable option. In these markets, existing prescription brands will still be prescribed in the face of cheaper Generic options. Keeping the price at the same level can encourage customers to stick with the drug, and even enhance the reputation of the drug for better brand equity.

PRICE DECREASE

When staring down the stiff competition of Generics with lower prices, companies often choose the price decrease as a sound pricing strategy. It's a rational and effective method: by making a move to be closer to the competition's selling price, the product can remain relevant and desired by cost-conscious prescribers, Pharmacists, payers and customers.

CHAPTER 7: Organizational and Integrated Defense Strategies



By Dr. Andrée K. Bates
June 2008
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Authorized Generics are defined as a Pharmaceutical branded product relabeled and marketed under a Generic name. Usually, this works by distributing through third party licensing arrangements, agreements with Generics manufacturers or through a company's own Generics subsidiary, such as Pfizer's Greenstone and Schering-Plough's Warrick.

In 2004, three out of the top ten best-selling Generics in US were authorized. It's an attractive option for many companies for clear reasons. The brand name manufacturer can create exclusive partnerships with chosen Generic manufacturers before patent expiration, creating brand name loyalty for a Generic version while earning royalties on the product.

The use of authorized Generics gives branded companies additional revenues and erodes the potential economic value of Generics. The FTF exclusivity holder has to share the market with the authorized competitor, and price erosion during the 180-day period increases from 20-30 percent to 40-50 percent in this authorized scenario⁵⁴.

The turning point for authorized Generics, when the Industry sat up and took notice of a powerful new trend and technique, was the maneuvers around Paroxetine. GlaxoSmithKline authorized Par Pharmaceuticals to sell Paroxetine, the Generic form of GSK's branded Paxil. The authorization took place during the 180-day exclusivity period for Apotex, the FTF challenger of Paxil. GSK was able to leverage equity, maintain some market share and bring in profit. Estimates put their earnings at \$200-300 Million⁵⁵.

The FDA's view on authorized Generics is, so far, positive for branded companies. Procter and Gamble authorized a Generic version of Macrobid (nitrofurantoin) with Watson Pharmaceuticals on the same day that a 180-day exclusivity period in the U.S. began for Mylan's Generic product. When Mylan appealed, the FDA stated they saw "no reason to interfere with marketing of authorized Generics"⁵⁶.

Some companies are going an additional step and experimenting with Generics, producing their own Generics' unit and products. The thinking behind this is that operating a Generics business will leverage assets and gain back sales, as well as gain favor with cost-conscious buyers. Some analysts contend the reality of the marketplace is far more complex⁵⁷. In addition, the infrastructure of Pharma companies is designed to support brands with gross margins between 1,500 and 7,000 percent more than those in the Generic marketplace. Operating a Generics business then offers little added value from either customer or company perspective.

INTEGRATED PRODUCT DEFENSE PLANNING

Perhaps the best means of mounting an effective defense against Generics is through a combination of reactive and proactive measures. These include the methods we've discussed thus far, and a few more, focused on facilitating overall company growth.

Company Change

Some companies need radical change as the only truly effective means to stave off the Generic threat. James offers several prescriptions for change, the details of which are beyond the purview of this paper. Overall, he contends companies must change their mind-sets on spending strategies and focus on how other successful companies think, not what they do.

CHAPTER 8: NEW TACTICS EMPLOYED BY GENERICS



NEWER UNANTICIPATED APPROACHES TO GENERIC MARKETING BEING SEEN

Generics companies are facing enormous competition from other Generics companies which is leading them into new forms of marketing rather than simply competing on price as they used to. Branded Pharma need to understand the new approaches Generics are now using as price is not the only battlefield anymore.

Generic Differentiation other than Price

Prasco's authorized Generic version of Organon's oral contraceptive, Desogen, called Solia, is a good example of a Generic manufacturer adding value to a product. Prasco conducted research and found that women did not like the cardboard card that most birth control pills came in.

So, when Solia was launched, it made the box smaller (to take up less space on the Pharmacist's shelf) and used a plastic card to hold the pills. Prasco are looking at what the marketplace wants and are starting to cater for it, which Generics companies tended not to do until recently.

The Branded competition is not the only competition; the increased competition between Generics makes it a necessity to look at other ways to compete that are not solely on price alone⁴⁸.

Branded Generics

There is now the emergence of Generics companies who brand their product and conduct advertising as well as many of the traditional marketing activities that the big Pharma do.

Branded Generics are the key Generics that really need to conduct analytics against Big Pharma Branded competitors, and also against other competitor Branded Generics. A recent report by Medco⁴⁹ found that:

“One quarter of the physicians surveyed stated that they do not believe Generic medication to be chemically identical to their Branded counterparts; more than eight percent said they were unsure. This despite FDA rules that require Generic versions of the drug to be bioequivalent to the brand medication.”

Nearly one in five physicians believe Generic drugs are less safe than Brand-name medications, and more than one in four doctors (27 percent) believe Generic medications will cause more side effects than brands.

Figure 8.1 highlights these results of the survey which surprisingly show that physicians are even less informed about Generics than their patients!



Analytics can be used to determine what can be done to defend a brand being eroded by Generics. This chapter will show one case study of a brand that was a large brand being eroded gradually by Generics and how analytics helped them.

CASE STUDY: GENERICS DEFENSE ANALYTICS

Background

A well respected, large brand which accounted for significant revenue for the company found that, despite its high market share and popular status, it was being gradually, little by little, month by month, eroded by Generic competition.

New Approach

The marketing head employed the Eularis' 94.8 Analytics Approach, designed especially for this industry, which involved a five-step process:

- *Evaluate marketing elements & market environment*
- *Validate actual influencers for a therapy category*
- *Use Predictive Algorithm Analytics and Dynamic Modeling*
- *Analysis of findings implications*
- *Implement the recommendations throughout the sales and marketing processes*

These processes highlighted where the problem lay. The brand was well liked by physicians (hence, the high market share), the messages were strong, the sales force were skilled, the promotional activities were also strong and yet, Generics were stealing market share nibble by nibble. It would be easy to say "That's just how it is - we will have to live with it" but the analytics uncovered three interesting areas.

Firstly, they showed that the reps were de-motivated because they had nothing new to say. The doctors loved the brand already and the reps had nothing new to say.

The second finding was that cost was an issue, which was really the brand's only weakness. To deal with this, the company was asked if they had Pharmaco-economic data, which they did. It was recommended that they take the Pharmaco-economic data and add it to their rep calls to give the reps something new to discuss hand-in-hand with the original product benefits. They could incentivize reps to compete region by region, as the analytics also showed performance by region, and use the Pharmaco-economic data to show the cost was actually a saving in the long term.

The third aspect the analytics showed was that the market had three market share points in play, and it was clear that one of the stronger brands could take some of these vulnerable market share points if they were positioned correctly.