Journal of Management in Practice
Vol. 4, No. 1, 15 MAY 2019, ISSN: 2456-1509

The Generic Threat in Global Pharmaceuticals

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Executive Summary

In recent times, the pharmaceutical industry has seen a lot of changes. Big players like Pfizer and Merck are focusing on industry consolidations. The reason is obvious; the threat from competition. Many blockbuster drugs, like Lipitor, are slated to lose their patent protection over the period from 2010-2013 and would be open for generic substitution.

Price is the primary differentiator between a branded drug and its generic substitutes. Currently, this is the only basis for competition between the two. Generic drugs have gained popularity amongst consumers, governments and third-party payers (like insurance companies) because these are cheap.

The increased competition from generics should have driven down drug prices and benefitted consumers. Unfortunately, it has not. The average price rise of branded drugs has been three times faster than the average price rise of generic drugs. The complex pricing model and the relatively inelastic demand for drugs make it easy for companies to increase prices and maintain margins. From a consumer point of view, increasing prices should be the last strategy adopted by pharmaceutical companies to counter the losses due to increased competition. OTC drug production, reformulation, and mergers and acquisitions are some viable alternatives.

In this report, we examine the genesis and the magnitude of the generic threat and look at some of the consumer-friendly corporate strategies to counter the generic threat.

1. Competition in the Pharmaceutical Industry

The pharmaceutical industry usually experiences three forms of competition: among branded drugs which can substitute one another, between branded drugs and generic/local substitutes and among generic/local versions of the drug. Of late, there has been an astronomical growth in the competition between branded and generic drugs. According to an article published in 'Advertising Industry Newswire'; by the end of 2008 drug patents accounting for sales of more than $80 Billion have expired, resulting in major losses in company profits. One of the primary reasons for loss is the availability of substitutes. Our focus hence would be on the competition between branded drugs and one form of substitutes – generic drugs.

Companies manufacturing branded drugs try to capture market share primarily through advertising and product quality (side effects and efficacy), and through pricing. Companies manufacturing generic drugs usually increase their market share primarily by lowering prices. Companies generally produce either generic or branded drugs but not both. However, some

generic drug manufacturers are subsidiaries of branded drug producing companies churning out generic versions of the parent's off-patent drugs. One example is Greenstone LLC, a wholly owned subsidiary of Pfizer.

1.1 Dramatic Rise of the Generic Threat

In 1984, nearly 20 percent of prescription drugs sold in the USA (measured in total countable units of products such as tablets and capsules) were generic. By 1996, this figure was 43 percent. There are three factors behind the dramatic rise in sales of generic drugs: the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Act), drug-product substitution laws, and government health programs, such as Medicaid, promoting generic substitution.

Hatch-Waxman Act of 1984 was designed to promote generics while maintaining the incentive to invest in developing innovative drugs. The act thus tried to balance two competing objectives and fell short in achieving that balance, in part, because it shortened the average time between the expiration of a drug's patent and the arrival of generic copies from more than three years to less than three months. This act also substantially increased the number of drugs experiencing generic competition and thereby contributed to an increase in the supply of generic drugs. In the end, the cost to producers of branded drugs from faster generic entry roughly offset the benefit of extended patent terms. Meanwhile, the greater competition from generic drugs has somewhat eroded their expected returns from research and development.

Drug-product substitution laws allowed pharmacists to dispense a generic drug even when the prescription called for a branded one. By 1980, most states in the U.S. had passed such laws as a necessary component in reducing escalating health costs. The Drug, Price and Competition act of 1984 forced the Food and Drug Administration (FDA) to publish, on a regular basis, an 'Orange Book' listing all drugs approved for safety and effectiveness. This book helps physicians and pharmacists learn about the latest generic substitutes.

Government health programs, such as Medicaid, intended towards low income groups and many private health insurance plans actively promote generic substitutes because generics cost much less compared to their branded counterparts.

It may be interesting to note that the factors discussed above are very U.S. centric. The basis for this bias is because the U.S. enjoys the largest market share in the worldwide pharmaceutical market. According to statistics supplied by the German Association of Research-Based Pharmaceutical Companies in 2007, the U.S. held 43% of the world market. Europe stood second with a share of 31%. Japan came third with a market share of 9%. All others put together could snare only 17% of the pharmaceutical market. This global playground is discussed in slightly more detail in the next section.

1.2 Branded Drug Market vs. Generic Drug Market: A Global Comparison

The global pharmaceutical market (branded and generic markets taken together) stood at a whopping 712 billion U.S. dollars in 2007. Most pharmaceutical sales originate in the U.S., EU (comprising of France, Germany, UK, Italy and Spain) and Japanese markets. These three geographic markets account for over 80% of the global pharmaceutical sales. The remaining 20% of sales mostly came from emerging markets like Russia, India, China and Brazil. As noted in the previous section, the U.S. enjoyed 43% of this market; an approximate sales value of 306

billion USD.

The generics market stood at slightly over 90 million USD. The U.S. attained generic sales worth $25.4m in 2007, accounting for 26.3% of the global market. The generic markets of EU countries accounted for 14.2% of the global sales in 2007. The emerging markets of Russia, India, China and Brazil recorded a combined sales figure of around $13m in 2007.

Can a $90m market be a threat to a market with over $700b in sales? The comparison of these two markets seems absurd and it is so if some facts like the following are ignored.

- Not all off-patent drugs have generic substitutes. The threat from a generic should be viewed in terms of the market share loss its branded counterpart experiences once the patent protection expires. As per an article published in 'Advertising Industry Newswire', this loss could be as high as 70%. According to a blog published in the Wall Street Journal, the worldwide market for off-patent drugs is set to balloon to $520 billion in 2012, up from about $270 billion in 2006. If we compare the two statistic, the potential loss could be anywhere between $200 billion to $400 billion.
- The sales figures do not indicate anything about the profitability of a specific branded drug. A top selling drug might have negative profitability because the sales volume was less than expected before the generic version eroded its market share and so the production costs (R&D, Manufacturing and other costs) could not be recovered.
- The generics market is growing at a faster pace than the branded drug market, with a CAGR (Compounded Annual Growth Rate) of 16.4% during 2004-2007. The branded-drug market has grown at a CAGR of 8.3% in the same period. Generic sales in the US market grew at a CAGR of 13% during 2003–2007 and approximately 63% of all prescriptions given out in the country are for generics.

As we include more such factors into consideration, the playground gets more and more flat. The flat playground has forced major corporate players to actively monitor the production of generics and participate in the generic markets.

1.3 Changes in Market Dynamics: A Corporate Overview

Consolidation has been a trend for the major pharmaceutical companies and merger activity has been intense within the industry in the last few decades. In 1985 the 10 largest pharmaceutical companies contributed 20% of worldwide sales. In 2002 this contribution was 48%. A common argument for this consolidation is the existence of economies of scale in R&D and in sales and marketing. However, the productivity of the pharmaceutical industry measured by the number of compounds approved by the Food and Drug Administration (FDA) and the number of new drugs entering clinical trials has declined since 1998 despite rising R&D spending. Clearly, the rationale (say Rx^1) cited is no longer the only rationale. Patient expiry and the increasing threat from generic competition must be important factors driving consolidations. Now the rationale (say Rx^2) behind mergers and acquisitions seem to more about 'buying growth' and diversification.

The change in market dynamics can be better understood if we look at a specific company example. Let us look at the merger and acquisition activity of Pfizer, currently the largest pharmaceutical company in the world. Pfizer is a natural choice among the top 10 for the following reasons.

- Pfizer was relatively conservative about mega-mergers through most of its history until 2000.
- The company has been involved in some of the biggest M&A deals since 2000.
- Of late, it has been deemed a major player in the generics market.

In 2000, Pfizer merged with Warner-Lambert and acquired full rights to Lipitor. With global revenues of $12.4 billion, the Lipitor franchise accounted for over 28% of Pfizer's total prescription pharmaceutical sales in 2008. In 2002, Pfizer merged with Pharmacia to not only become the largest pharmaceutical company in the world, but also to earn exclusive rights to Celebrex. Celebrex was another blockbuster drug which accounted for $1 billion in revenues within the first year of launch. In 2003, Pfizer acquired SUGEN and added two more compounds (SU11248 and SU14813) to its pipeline. These mergers and acquisitions perfectly justify the rationale Rx[1]. Then came the acquisition of Wyeth, on 26 January 2009; a very surprising deal for analysts. Both Pfizer and Wyeth face a series of patent expiries and subsequent threats from generics over the period from 2010-13. Given Pfizer's already huge $40 billion-plus scale, its internal R&D pipeline cannot support sales expansion organically. The only way forward is to 'buy growth' through M&A; a clear justification of a move towards rationale Rx[2]. The Wyeth acquisition should benefit Pfizer in two ways.

- The merger will bring strategic product portfolio diversification for Pfizer. Wyeth will expand Pfizer's presence in non-prescription pharmaceutical markets, like consumer healthcare and animal health. Pfizer will also find a foothold in the therapeutic protein and vaccine markets. These markets are considerably less susceptible to the threat of generic erosion.
- Pfizer enjoys roughly 4% of the fragmented generics market. Its Greenstone unit has been producing generic versions of its off-patent drugs since 2003. Now, with a reduced focus on R&D, Pfizer can enter the generics market in a big way by selling generic versions of competitors' off-patent drugs.

Establishing the generic threat in terms of exact numbers is beyond the scope of this paper. To get an exact picture one would have to first identify a therapeutic area (say for example, cardiovascular) which did not lose its importance for a 'substantial period'. This 'substantial period' has to cover the R&D time, patent duration, and the period post patent expiry after which the therapeutic area lost focus in the market. Then he must obtain all the R&D, production and sales data of a blockbuster drug in that prescription area. Hence, the facts and arguments presented in this section are simply an attempt to lay down the genesis and the magnitude of the threat that branded-drug makers face from generics. We would now move our focus towards the basis of this competition; price. Branded drugs are often sold at much higher rates compared to their generic equivalence. For example, Coreg 12.5mg, a branded drug commonly used for the treatment of high blood pressure can cost a consumer about $128 a month. However, its generic substitute, Propanolol 20mg, will cost just $13 a month. In the next section we look at the economics of pricing in the pharmaceutical industry for both branded and generic drugs. In doing so, we will try and answer the question: Has the more intense competition driven down branded drug prices and benefitted consumers?

2 Consumer Friendly Counter Generic Defense Strategies

In this section, we examine some of the non-price defensive strategies that branded pharmaceutical companies can employ to counter the threat from generics. Our focus would be on (1) legal and patent defense, (2) reformulation, (3) Direct-to-Consumer (DTC) and Over the Counter (OTC), (4) organizational and integrated defense, and (5) M&A strategies.

Legal and Patent Defense Strategies

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 object. However, patent filings can be challenged during any part of the patent approval 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 (novelty, exclusivity and utility are basic criteria across the globe).

Aggressive legal defense remains the most favored brand defense strategy against patent challenges and often such defenses are successful. Patent litigation remains popular because a patent usually ensures a steady stream of revenues till its expiry. The key to success in such a strategy is the ability to file a patent early and defend the proposal until granted.

Reformulation Strategies

Reformulation is the trick to glean patients off the existing drug and switch them to the newly patented drugs, all before the original patent expires. Doing this minimizes market share loss and makes it less attractive for generic competition to enter the market. The reason is that the generic was designed to replicate an older drug whose patient population has depleted.

The key elements for a successful implementation of this strategy are timing, product differentiation and smart promotion. Timing is important because the company must come up with a new drug and have it patented before the patent for the old drug expires. Product differentiation is necessary for the patent approval. Smart promotion is required to minimize market share loss and encourage patients to switch.

DTC and OTC Strategies

Direct-to-Consumer strategies involve selling drugs directly to consumers. This allows consumers to purchase drugs without the wholesale and retail markups and thereby might contribute towards brand loyalty and trust, ensuring a steady stream of revenues. The flip side of such a strategy is the investment that would be required to setup a retail-like consumer database. Such strategies would be more effective if implemented over a longer horizon of time. Besides, legislative differences among countries might prevent such strategies from being effective.

OTC drugs differ from DTC drugs in the sense that the former does not require prescriptions. Such drugs may be sold directly to consumers or through drug stores. The decision to expand into OTC products is usually based on several different factors that influence long-term profitability:

- Existing market position
- Anticipated existing and new competition in the OTC sector
- The expertise the organization has in a 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

Success in OTC strategy implementations includes Imodium and Nizoral, which took franchises far beyond initial patent expiration dates and became global brands.

Organizational and Integrated Defense Strategies

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 generic manufacturers or through a company's own generics subsidiary, such as Pfizer's Greenstone and Schering-Plough's Warrick.

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.

Mergers and Acquisitions (M&A)

Merger-mania is the current trend in the global pharmaceutical industry. We have already seen how the acquisition of Wyeth by Pfizer defied the commonly cited rationale of increasing economies of scale in R&D, and sales and marketing. Of late, there has been a spate of deals in the pharmaceutical space. Merck has merged with Schering Plough. Experts believe that Bristol-Myers Squibb may be the next target of an acquisition.

The primary drivers of global mergers and acquisitions are the increasing threat from generics and a shrinking blockbuster drug pipeline. Pharmaceutical companies are trying to augment revenues through acquisitions and alliances with generics and other companies where they see additional businesses like vaccines, biotech drugs and specialist therapies. For instance, Pfizer gets the biotech business and OTC business of Wyeth to increase its revenues through the acquisition.

Mergers and acquisitions can be viewed as buying growth and insurance against all threats. It is a superset of all the strategies we discussed thus far.

Conclusion

In this paper, we examined the genesis and magnitude of generic competition in the pharmaceutical industry. Thanks to the Hatch-Waxman Act, drug-product substitution laws, and government health programs, 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 few decades and are poised for even bigger growth. However, the increased competition has not benefited the end consumer. Prices of all drugs in general and branded drugs have increased in a manner which cannot be justified by economic fluctuations alone. The complexity of pricing an innovator drug and the inelasticity of demand for such a drug has allowed pharmaceutical companies to increase prices and maintain profits. We argued that increasing prices should be the last strategy to counter the generic threat specifically when several alternative strategies, like reformulation, extension of the product portfolio (production of OTC/DTC drugs) and mergers and acquisitions, are available.

Several blockbuster drugs will see their patents expiring in the period between 2010 and 2013. It will be interesting to study the competition then. Currently, industry consolidations through mergers and acquisitions seem to be the one strategy which most companies are adopting. Will it

remain so? Only time will tell.

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