

Developing Cymbalta

## Executive Summary

Eli Lilly is a Pharmaceutical multinational company that was established in 1876 after Eli Lilly bought a laboratory on Pearl Street in Indianapolis, Indiana. Since its inception, Eli Lilly has been a market leader in the pharmaceutical sector and has been involved in various pharmaceutical advancements throughout the years. Among other breakthroughs, the company is recognized for being the creator of the first process for applying gelatin coating to pills for easier swallowing. Eli Lilly is also credited for introduction of insulin products, and introduction of new class antibiotic products in the 1950s.

In the case study, Prozac's patent expiry date is fast approaching meaning that productions of generic versions of Prozac are also about to begin which is expected to result in generic manufactured antidepressants flooding the market. To safeguard its interest and retain the 15% market share that Prozac holds, Eli Lilly has not only established a Research and Development Committee to expedite the development of new drugs but has also formed an Antidepressant Team specifically charged with the development of the drug to replace Prozac. The New Antidepressant Team (NAT) is comprised of five members who worked diligently to identify Cymbalta as the best probable replacement of Prozac.

While carrying out their investigations, NAT found out that all antidepressants were actually almost the same and didn't have major differences between them. This justified the need for a patent that would protect the company's Cymbalta drug which had been developed few years ago. Once the patent was registered, a marketing strategy that would position Cymbalta as the ultimate successor of Prozac would then be executed. Analysis concluded by NAT showed that Cymbalta was the best drug to succeed Prozac. However, the analysis recommended two options that were to be discussed between parties and finally agree on one option. One of the alternatives was that Cymbalta could be used as a efficacious for treating major depressive disorders by use of a one day (QD) dosing while the other option was that Cymbalta could be used as a separate pain indication in addition to submitting for MDD using twice daily dosing.

This report analyzes Eli Lilly's situation and recommends the best alternative to a product that would successfully succeed Prozac. The report starts with an introduction of the pharmaceutical industry with common characters of the pharmaceutical industry been discussed. Thereafter management problems in the case study company are discussed followed by a situation analysis of the case company. In order to conduct a better situational analysis, a SWOT analysis is carried out where strengths, weakness, opportunities and threats of the case study company are highlighted. Alternatives of the successor to Prozac are then discussed in depth with advantages, disadvantages and opportunities of all the alternatives being highlighted. The report concludes with the recommendation that the company should adopt the twice daily with pain indicator alternative and at the same time apply for indicator for pain. Marketing strategies that the company should implement to help position Cymbalta as the ultimate successor of Prozac are also discussed.

## **Introduction**

The pharmaceutical industry is currently the world's largest industry contributing generously to the Gross Domestic Products (GDP) in different countries. The industry is also associated with major changes and innovations due to extensive research conducted in this area. The emergence of new diseases, failure or reduced potency of existing drugs and expiration of patents has forced many pharmaceutical companies to allocate significant resources to research in order to remain competitive and viable. Eli Lilly and Company has been the leading producer and seller of Prozac, an antidepressant belonging to the SSRI class. However, the drug is approaching patent expiration and the company has to look at likely replacements, customer needs, as well as the best marketing strategy to reach the public and medical community. Competition in the industry is formidable, with strict legislation that all pharmaceutical companies have to adhere to. The entire process of producing a drug, taking it through clinical trials and obtaining approval by the Food and Drug Administration (FDA) is a very expensive and tedious process which is regulated by numerous legal and ethical issues. For a successful introduction of a drug to the market, a company has to endure and overcome these challenges.

## **Management Problems**

From the case study presented, it is evidently clear that Eli Lilly's problem was to research and develop the most suitable antidepressant that would replace the hugely successful antidepressant named Prozac which had dominated the market for decades and had annual sales of \$ 2 billion that would be hard to fill the gap once the patent expired since generic antidepressants would be produced by the company's competitors. Even though the company had other successful products like Zyprexa, Gemzar, and Evista, Prozac was the most successful of all products that Eli Lilly produced and failure to replace the drug with another more potent drug would leave Eli Lilly in a very unstable position since the company would lose revenues and 15% market share. The tension was elevated to another level by the fact that despite knowing that Prozac's patent would expire in December 2003, a court ruling expected in April 2000 had the power to alter the expiration date. However, patent expirations were not anything out of the ordinary to the management of Eli Lilly and Company since this was a regular occurrence in the pharmaceutical industry. The pressing issue was that Prozac was the market leader and failure to immediately replace the drug with another market buster would plunge the company into financial difficulties as a result of competition (Ofek & Laufer 2008).

In addition, the company faced stiff competition from other pharmaceutical companies and failure to replace the drug with another more effective drug would have given generic manufacturers of Prozac an added advantage since they would sell a drug similar to Prozac for very low prices. This meant that Cymbalta had to be made to stand out from other antidepressants already in the market since most physicians viewed the existing ones to be equally potent with no special one. The submission of the drugs to the FDA had to be slowed down so that all the objectives could be met, but this was still another critical issue since quality time would be wasted. These are some of the ideas that Kaiser, the marketing director of Eli Lilly and Company, is said to have had. However, as he headed to present his ideas, another problem became imminent since different opinion-holders such as Jim Lancaster were anticipated.

The main neurotransmitters that were associated with causations of depression were also linked with chronic pain. For instance, serotonin and nor epinephrine deficiency are the key contributors in the etiology of depression. The understanding of the link between these two neurotransmitters and depression led to the development of drugs such as Mono Amine Oxidize Inhibitors (MAOIs) and selective serotonin reuptake inhibitors (SSRIs). Researchers also linked the deficiency of the circulating levels of these neurotransmitters in the brain with decreased pain threshold and therefore increased pain sensitivity. With the understanding that depression was associated with lower levels of these hormones and at the same time painful symptoms, a drug therefore needed to be developed that could take care of both depression and other related side effects, especially pain. Cymbalta had to be put on clinical trials to see whether it can manage painful symptoms alongside depression, and at the same time see how the drug dosages can be adjusted in both cases to take care of the depression and pain, as well as check on the risk of failure (Ofek & Laufer 2008).

### **Situation Analysis**

The pharmaceutical industry is universally dynamic and characterized by continuous research to develop better products and remain profitable. Since pharmaceutical products are meant for consumption, stringent regulation measures are usually employed to ensure that whatever is prescribed to a patient does not have any side effects. Apart from the strict regulations, there are also ethical issues to consider. Conducting clinical trials with human beings mandate appropriate ethical standards. The products have to always go through several stages of testing and approval which increases the chances of failure or rejection. However, even after being approved by the FDA, this is not the end of the process as advertisements have to be created to develop product familiarity for the consumer and arouse the need for the product. The marketing department of any pharmaceutical company has to make sure that the medical community is educated about their products and convinced that there is a cogent reason why they need to prescribe one drug and not another. The buyers/consumers also need to be convinced that they should buy a new product to replace an existing one that they currently use. In the pharmaceutical sector, some of the challenges that are faced by the pharmaceutical companies are increased competition, and in some cases unethical accusations being targeted to fellow competitors, low levels of customer know how and high training costs of the sales personnel.

The process for new drug development is cumbersome and usually involves heavy expenditures. Only the large multinational pharmaceutical companies can apportion significant resources for research and development. Since the products are an output of resources, pharmaceutical companies tend to patent their research findings giving them pricing power through which they make profits.

Overdependence on one product is a risky business strategy and places a company in a difficult situation if a competitor develops a more effective product. Diversification of your product line along with the appropriate guidelines to avoid undesirable side effects is necessary. For example, by the year 2000, Eli Lilly and Company had reduced its dependence on Prozac and other drugs such as Zyprexa (used for treatment of schizophrenia) which were generating almost the same revenue as Prozac. (Case p.7)

Analyzing Eli Lilly and Company as well as the basis for the development of a strategic and marketing plan, a SWOT analysis approach was taken and revealed that the company has the following aspects that it can take advantage of:

- Reputation: The Company has a well known track record of producing quality drugs. This is seen with the case of Prozac which helped to give Eli Lilly the nickname, of the “Prozac Company.” In addition the fact that Eli Lilly has been involved in a number of scientific advancements also helps in building reputation of the company.
- Resources: the company is well-endowed with resources that the company makes use of to achieve success in most of its endeavors. Among other, the company has a well established Research and Development team that is credited for the numerous successes that the company has experienced.
- Strong brand names: Eli Lilly and Company is associated with strong brand names such as Prozac, Evisa and Gemzar. This names gives the company a unique competitive advantage
- Management: The Company has an excellent management body to oversee all the operations of the company. This can be justified by the fact that the company has expanded tremendously since its inception in 1876.
- Existing channels of distribution: The Company has well-established channels of distribution including handling, shipping, distribution, and promotion and information feedback for its products in various markets in the world.
- Company image: this is how the company is viewed by the clients. Eli Lilly and Company has an impressive image owing to its reputation as opposed to other competitors.

The company has the following weaknesses to address and try to convert into strengths.

- High cost of manufacturing: The process of developing a drug is very expensive to the extent that the company may experience losses if the products fail to meet the target consumer needs.
- Slow adaptability: The Company has to be quick to conform to the changing technological environment and consumer needs. Slow adaptability might cause the company to fail to appreciate changes in the environment and make it too weak to compete. Customer segmentation and proper analysis needs to be done to avoid such a situation.
- Lack of patent protection: This is very dangerous to the company since patents in this sector are only valid for a number of years. This on the other hand could make Eli Lilly lose its competitive edge since other companies may take advantage of the company’s innovation for their success.

- Dependence on one product: The Company has to a large extent depended on the sale of Prozac until recently. This would lead the company into losses if the company becomes too weak to compete or the products lose value among consumers.

Some of the opportunities that the company has are listed below.

- Established presence in various markets: The Company could use its presence in various markets to target all the different customer segments and reach out to them. This could be achieved by carrying out advisements and promotions in specified markets.
- Technological change: For any company that believes in success, innovation is very important. This is achievable through the work of a research and development committee. Innovations make the process of manufacturing more efficient as well as increase the efficacy of the products.
- Media: The Company could use media to advertise its range of products to potential customers. The most effective types of media in this case could be through national newspapers in the selected markets and televised advertised in popular TV stations to be broadcasted during peak time.
- Social cultural changes: In some markets like in India, China and some African countries, people used to go to traditional medicine men who were also known as herbalists to seek cure for their ailments. However with globalization and civilization taking its course most people have now turned to the modern way of life meaning that Eli Lilly have a larger market to serve.
- Unfulfilled customer needs: In the treatment of depression, pain has been a serious co-morbidity that has never been dealt with. Eli Lilly and Company can take this advantage and make use of this opportunity to develop it.

The market is filled with threats and they need to be fully understood and strategically dealt with. Threats include the following:

- New legislation: Pharmaceuticals, just like any other consumables, are subject to a very unique legislative process that changes from time to time. Such legislation may not favor the company's processes and, therefore, pose a serious threat.
- Shift in consumer tastes: Consumer tastes change from time to time and the company needs to be aware of this threat, launch comprehensive market research and convert it to an opportunity.
- Obstacles faced: The development of any pharmaceutical product is faced with many obstacles both from the company and outside markets. The entire process is very expensive with the need to develop clinical trials that take into account ethical considerations.
- Political effects: Politics can negatively influence the development of a new product and its acceptance by the users. The company needs to be diligent about how the

political system works in the U.S. and other countries where its products are marketed or branches are established.

The table in Appendix 1 summarizes the above information using the SWOT approach.

### **Alternatives with Explanations**

In order to decide which alternative Eli Lilly could pursue, we initially need to establish the most likely market share that Cymbalta may have under both options. We then assume that same prices will be charged in both situations. Final decision could then be made according to the possible market share, related advantages and disadvantages and lastly any future opportunities. According to the segmentation profiles available in exhibit 10, it can be estimated that 42% of the total market is with pain where as 30% of the market has pain with no compliance problems (Ofek & Laufer 2008).

#### **Twice daily with pain indicator**

The number of patients that states pain as a sign is more or less half of the total market. Assuming all patients with major compliance issues are uninvolved because of the enormous increase in compliance problems associated with BID in contrast to QD and the remaining number which is an approximate of 42% is halved, the market share would be large than the earlier Prozac's 15% market share.

#### **Advantages of twice daily with pain indicator**

Differentiation would be the main merit of pain indication. Since the market is about to be in full supply of cheap generic versions of Prozac, differentiation might play a major part in positioning Cymbalta as a new product. Cymbalta could have advantages compared to other products in the market if it could be proved that it had effective pain relief. In addition, a pain indicator on an antidepressant can be an easy option for primary care physicians who have depressed patients with any pain signs.

#### **Disadvantages of twice daily with pain indicator**

The main disadvantage of choosing this alternative is that a physician might not establish the gain of pain reduction worth risking a patient's compliance by subscribing a BID drug. Tests conducted could in some cases show that Cymbalta doesn't have any measurable effect on a patient's pain implying the drug could fail to be awarded an application as a pain indicator. In addition, negative reviews and feedback could be collected in cases where patients forget to take their pills twice a day or in situations where they take lots of pills all at one.

## **Opportunities**

It is important to highlight that emphasis on Cymbalta's capabilities in aiding pain relief could be open new markets for Eli Lilly.

### **Single pill regimen**

Though comparisons between Cymbalta and Prozac showed that Cymbalta was more effective, the distinction was not quite significant. The question that Eli Lilly needs to ask their selves is; since patients would be able to buy cheaper generic versions of Prozac, what is it that would make them try Cymbalta which is obviously going to be more expensive and to which they do not know of the side effects. The unfortunate scenario in such situations would be that Cymbalta would not maintain the 15% market share maintained by Prozac but considering company reputation of "The Prozac Company" and Prozac brand recognition might help position Cymbalta as an advanced version of Prozac.

### **Advantage single pill regimen**

The advantage of this alternative is that as far as patients' compliance is concerned, this is the better alternative since majority of the patients would prefer having one pill each day compared to many times a day. This alternative would place Cymbalta on the same position with other competing products.

### **Disadvantage single pill regimen**

The main disadvantage of this alternative is that 60mg dosage might have difficult reactions with side effects that were shown in initial trials being different to the one shown with BID dosing. In addition, higher dosage that is given only one time in a day doesn't guarantee that the medicine will be effective for 24 hrs as assumed.

## **Opportunities**

Although it would be quite hard to make massive alterations to Cymbalta's positioning without an initial differentiation, if Cymbalta experienced positive feedback on its effectiveness as a pain relief, it could be possible for Eli Lilly to launch a later version with pain indicator approved. This on the other hand would allow venturing into new global markets with an established name in place.

### **Recommendations**

Considering the competitive nature of the pharmaceutical industry and the demand for their products, there are various ways in which pharmaceutical companies can succeed in these competitive markets. Success can be argued to depend on the quality of a product and how aggressive a marketing strategy has been implemented. In reviewing the above alternatives, I would recommend that Eli Lilly chooses twice daily with pain indicator alternative and at the same time apply for indicator for pain. This alternative presents a very big market opportunity that would not only serve a larger market share of Eli Lilly current antidepressant by addressing a previous ignored sign, but also expanding into additional larger markets where competitors face accusations of their products having adverse side effects. Cymbalta would also differentiate itself from a market that is flooded with QD SSRI medications and soon going to be flooded again with generic versions of Prozac once the patent expires.

Since Cymbalta will be a new brand that seeks to position itself through differentiation, Eli Lilly needs to market the products to physicians, general physicians, psychiatrists and to customer themselves which could be through road shows. Networks already built and established through Prozac should be used to push Cymbalta further. Another approach that Eli Lilly could apply is to place strategic advertisement of Cymbalta in health magazines as well as sponsoring health events in local communities. Cymbalta should be advertised to the end user as the only drug that can offer more than the successful Prozac. While it is good to advertise on the low side effects of Cymbalta compared to Prozac, it is as well important to focus on the new and improved focus on management of pain. Such advertising strategies could make Cymbalta to be seen as the only ultimate pain reliever drug. Free samples could also be given to doctors who would then be expected to give the samples to their patients. This would help have a positive impact on a patients mind and the company would be almost guaranteed of a sales to the patient who had a free dose once need arises. Advertising campaigns should be well coordinated to make sure that all advertisements regardless of the mediums used send out the same message. It should be specific that Cymbalta is the ultimate anti depressant of choice which is loaded with a pain management ability in its composition. Advertisements messages should be very simple and clear to anyone. A good catch phrase would be, "Cymbalta, the ultimate depression specialist".

Reference List

Ofek, E. & Laufer, R. (2008). Eli Lilly: Developing Cymbalta. *Harvard Business School*, 1-28,

## Appendix 1 SWOT analysis

	Helpful	harmful
Internal Factors	<b>Strengths</b> <ul style="list-style-type: none"> <li>➤ Reputation</li> <li>➤ Finance</li> <li>➤ Management</li> <li>➤ Strong brand names</li> <li>➤ Existing channels of distribution</li> <li>➤ Company image</li> </ul>	<b>Weaknesses</b> <ul style="list-style-type: none"> <li>➤ High cost of manufacturing</li> <li>➤ Slow adaptability</li> <li>➤ Lack of patent protection</li> <li>➤ Overdependence on one product</li> </ul>
External Factors	<b>Opportunities</b> <ul style="list-style-type: none"> <li>➤ Large consumer base</li> <li>➤ Technological change</li> <li>➤ Media</li> <li>➤ Social cultural changes</li> <li>➤ Unfulfilled customer needs</li> </ul>	<b>Threats</b> <ul style="list-style-type: none"> <li>➤ Legislation</li> <li>➤ Shift in consumer tastes</li> <li>➤ Obstacles faced</li> <li>➤ Political effects</li> </ul>