

# Managing patent expiration in the pharmaceutical industry

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## Managing patent expiration in the pharmaceutical industry:

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## **Abstract**

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Managing patent expiration in the pharmaceutical industry:  
The story of the purple pill

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WS 2007-2008

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## 1. Introduction

### 1.1 Color in the pharmaceutical industry: pill color coatings

Color is employed across all commercial industries and across different types of products. However, when one associates color with commercial goods, the examples that are most likely to come to mind range from clothing to cars or pieces of furniture. The chances that one will immediately link color with pharmaceutical products are probably low. Still, most people are aware that, for example, packaging is in itself amenable to design: not only as far as its shape and size are concerned, but also the texture of the outer surface and the colors or pattern of colors that decorate it. One need only think of different medicinal drugs and how distinct their containers can be. However, it is not just the packaging that can be particular but also the drug itself.

This should not really surprise us; pills, in particular, the object of discussion here, can be round, elongated, small, big, thicker or thinner. These variations clearly reflect a practical purpose, such as the quantity of contents that needs to be accommodated, but also the very fact that, at the end of the day, they need to be swallowed. But if the shape makes sense, where is the sense in color? Why can't all pills be the same color?

Even pill color has a practical aspect. Nowadays, there are carefully designed therapeutic combinations and complicated schemes that have to be adhered to by the patient, without the presence of a physician. Different drugs and doses need to be taken at different times and patients need to be aware what it is they are actually consuming. A typical post heart-infarction regime encompasses 7-8 different pills a day, sometimes more than one pill at a time. How will the patient recognize and remember which one they took, or if they simply missed one? Color coatings on pills may reduce the chances of error and introduce a color coded system that helps patients adhere to their therapeutic regime. Also different dosage strengths can be indicated by the color of the coating: darker colors denote higher doses, as opposed to lighter colors which are used to mark lower doses.<sup>1</sup> Therefore color in the service of mere recognition during treatment is definitely helpful. But there is more to pill color coatings than practicability.

In fact, there is more to recognition than practicability. Distinguishing one product from the next confers a competitive advantage, as that product becomes selectable over the competition. Associating the color of the pill with certain values, such as quality and efficacy, immediately makes the consumer more inclined to purchase that particular drug, as opposed to those that leave the consumer neutral. Moreover, certain values become associated with the color a particular company promoted through marketing activities. Furthermore, it has been demonstrated that in the mind of the consumer color is linked with perceived therapeutic efficacy, site of action, and drug strength.<sup>2</sup> Color therefore adds value to drugs by distinguishing them and by steering consumer perception.

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<sup>1</sup> [http://www.opadry.com/best/c01\\_color\\_coat.html](http://www.opadry.com/best/c01_color_coat.html). Accessed 12.2007

<sup>2</sup> [http://www.opadry.com/best/c01\\_color\\_coat.html](http://www.opadry.com/best/c01_color_coat.html). Accessed 12.2007

## 1.2 Branding in the pharmaceutical industry

“Pharmaceutical branding describes the process whereby companies attempt to transform an active chemical compound into a recognisable package of associated brand values.”<sup>3</sup> In other words, branding is the process by which a drug is linked to particular cognitive responses by the consumer, such as perceiving the drug as efficacious, safe, and trustworthy. Branding provides leverage to retain market share, sell at higher prices, and differentiate the product from its competitors. Consumers who believe a drug to be efficacious are more likely to be willing to pay a higher price for it and will stick with it, even when a similar drug comes on the market. But this type of branding did not always exist, especially as far as the pharmaceutical industry is concerned.

Pharmaceuticals have taken a rather conservative approach over the years. The model was to invest heavily in developing a new compound, getting it approved and launched, and then harvest the fruits of one’s labor by pricing it as deemed appropriate. To create viable high pricing schemes, companies invested in creating awareness, on the safe assumption that consumers prefer the brand they know. This will happen a lot more efficiently when a brand is clearly recognizable over others. That was all that branding used to be. What is more, the brand would only last for the life of the patent, and so when the patent expired, a new product would come along and the cycle would start all over again. Things have changed, however, in the face of fierce competition, extensive controls by the regulatory authorities, and price pressures imposed by consumer organizations and national health authorities.

Branding nowadays is about creating product value over and above competitors in the marketplace.<sup>4</sup> It involves finding what matters to the different target audiences, such as physicians, patients, and relevant authorities. Obviously, the messages reaching each target audience will be tailor made to suit their particular profiles. But although the messages will be different, they will all convey for the same brand values. Take Volvo as a general example: whenever one thinks of Volvo, safety comes to mind. Nevertheless, a Volvo S60 in the UK is marketed as a young person’s car, whereas in the US, older drivers are targeted. However, in both cases “Volvo” stands for safety, and safety is Volvo’s brand value over and above the competition.

This raises an interesting question: would it matter if instead of the Volvo S60, one picked the Volvo S80 or any other Volvo model to use in the aforementioned example? Probably not. In other words, it is true that when it comes to Volvo, safety, as brand value, extends not only over and above the competition, but also over and across the full range of Volvo products, i.e. different car models. Therefore, what is of material importance is no longer -only- the individual products but the brand value that they represent. The question now becomes whether this could also happen in the case of medicines.

In this report I shall use the example of two medicinal drugs, Prilosec and Nexium, and of one company, AstraZeneca, to elucidate how the modern

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<sup>3</sup> Pharmaceutical branding strategies, January 2006, Business Insights

<sup>4</sup> Pharmaceutical brands: a state of the mind, David Wood, [www.brandchannel.com/papers\\_review.asp?sp\\_id=1228](http://www.brandchannel.com/papers_review.asp?sp_id=1228), Accessed, 12.2007

pharmaceutical industry uses branding to create product value. More importantly, how color, as a protected right, is employed to achieve the transition from one successful product to the next following patent expiration, while retaining market share.

## 2. AstraZeneca's branding strategy: The purple transition from Prilosec to Nexium

### 2.1 The market landscape of heartburn

Gastrointestinal (GI) reflux disease (GERD), commonly known as heartburn, is a condition where gastric acids are regurgitated, causing a burning and painful sensation in the throat and esophagus.<sup>5</sup> Approximately 60 million people experience heartburn once monthly in the US, while 15 million suffer from heartburn once daily.<sup>6</sup> This makes heartburn drugs the second largest medication class by sales, following cholesterol regulators.<sup>7</sup>

There are five different types of heartburn medication currently available: antacids and sodium bicarbonate or baking soda (which neutralize excess stomach acids), H2-blockers (which block acid release into the stomach), alginates (alginic acid found in seaweeds, which blocks acid reflux into the esophagus) and proton pump inhibitors (PPIs, which block acid production from stomach cells). Blockbuster drugs in some of these categories are Maalox<sup>8</sup> by Novartis and TUMS<sup>9</sup> by GlaxoSmithKline (Gsk) for antacids and Zantac<sup>10</sup> by Gsk for H2-blockers. Prilosec and Nexium, the focus of this research report, belong among the PPIs.

PPIs are very valuable to people who do not respond to antacids or alginates. They are not fast-acting like antacids and alginates, but have long-lasting effects.<sup>11</sup> This advantage was reflected in the fact that both branded and generic prescription sales of PPIs in the US reached US\$13.68 billion in 2006 and their inclusion in part D of Medicare resulted in a 5% year-on-year increase in sales.<sup>12</sup> In the same year, the entire GI therapeutics market was valued at \$10.64 billion in Europe, where it is forecast to reach \$11.74 billion in 2013.<sup>13</sup> PPIs have the lion's share of the European GI market, their superior efficacy being the main driving force. In general, PPIs have taken over the lead from the less-effective H2-blockers as a first-line treatment for heartburn in the past 10 years, and since the pipeline is not expected to produce any novel drugs in the near future, PPI dominance will be preserved.

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<sup>5</sup> <http://www.nlm.nih.gov/medlineplus/heartburn.html>. Accessed 12.2007.

<sup>6</sup> <http://www.wrongdiagnosis.com/h/heartburn/prevalence.htm>

<sup>7</sup> Market spotlight: Heartburn drugs, August 22, 2007, Thomson Financial News, [http://news.manta.com/articles/description/200708221747020\\_90343000\\_0-0304](http://news.manta.com/articles/description/200708221747020_90343000_0-0304)

<sup>8</sup> <http://www.maaloxus.com/index.shtml>

<sup>9</sup> <http://www.tums.com/>

<sup>10</sup> <http://www.zantac.com/>

<sup>11</sup> <http://www.nlm.nih.gov/medlineplus/heartburn.html>. Accessed 12.2007.

<sup>12</sup> Medicare Part D lifts sales of heartburn drugs, but generic use crowds out branded use, August 22, 2007, Associated Press, Accessed 12.2007

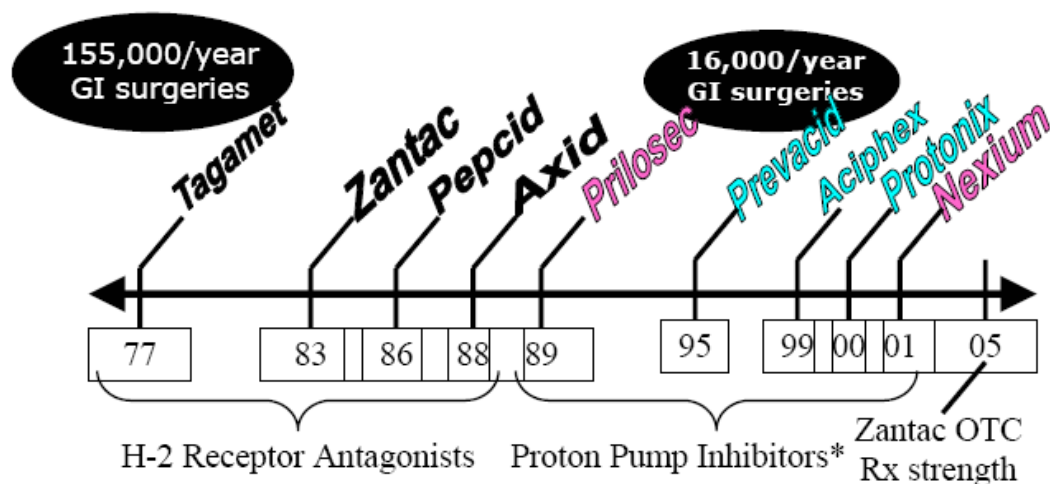
<sup>13</sup> Product life cycle management key to sustaining revenue growth in European GI market, November 26, 2007, Medical News Today, [www.medicalnewstoday.com/articles/89800.php](http://www.medicalnewstoday.com/articles/89800.php), Accessed 12.2007



Over the past decade, there were five branded PPI drugs, namely Prilosec and the follow-up, Nexium, introduced much later by AstraZeneca; Prevacid by TAP Pharmaceuticals; Protonix by Wyeth; and Aciphex by Ortho-McNeil. In 2003 in the US, these five brands collectively made sales of \$12.9 billion, with total U.S. prescriptions for PPIs growing by 10%, from \$86.3 million in 2002 to \$95.2 million in 2003, according to IMS Health.<sup>14</sup> These numbers demonstrate exactly how important the PPI market is in the field of GI therapeutics, but also hint at how much the market landscape was to change as generics started appearing.

## 2.2 Prilosec: how a blockbuster drug poses a challenge

Prilosec appeared at a time when H2-blockers dominated the GI market as a first-in-class drug, i.e. the first drug in an entirely novel class of medication, the PPIs. Prilosec soon proved to be much more efficacious than its two main competitors at the time, Zantac and Tagamet.<sup>15</sup> This gave it a tremendous market advantage over its main contemporaneous competitors, and also over any future competing PPIs by virtue of being the first PPI ever, thereby creating a clear lead in that market.



**Figure 1:** Serial market introduction of leading H2-blockers and PPIs. NB the efficacy of PPIs is marked by the concomitant reduction of GI surgical operations. **Source:** Pricing Nexium: “Faux innovation” and market leader, Jeffrey L. Moe, October, 2006, Fuqua School of Business, Duke University

Indeed Prilosec came to be a blockbuster drug. In 2000 alone, Prilosec alone accounted for 39% of AstraZeneca’s sales. By 2002 Prilosec had made \$36 billion in sales, brought in an annual \$6 billion, and became the world’s best selling prescription drug and the top medication prescribed for seniors.<sup>16</sup> AstraZeneca was clearly not going to give up this lead without a fight.

<sup>14</sup> 2 New fronts in heartburn market battle, Gardiner Harris, August 20,2003, The New York Times

<sup>15</sup> The other side of drug discovery, Jason Socrates Bardi, <http://query.nytimes.com/gst/fullpage.html?res=9F04E6DD1E30F933A1575BC0A9659C8B63&sec=&spon=&pagewanted=2>, Accessed, 12.2007

<sup>16</sup> The story of the purple pill, November 11, 2007, Accessed 12.2007

The challenge is how to follow a blockbuster once the patent expires, as blockbusters are very hard to surpass. A company that has a successful drug in its portfolio will do anything in its power to avoid losing market share after patent expiration, and one approach is investing heavily in drug discovery and innovation. However one should not overestimate the available room for innovation. Interestingly enough, 433 distinct molecules make up, on their own or in combinations, the majority of the 10,300 FDA-approved US medicinal drugs at present. What is more, approximately half of those molecules were approved already before 1938 and 50 are the so-called “me-too” drugs, constituting a slight modification of the ones already on the market. Taking this into consideration it becomes clear how imperative it is that other strategies are employed to remain ahead of the competition.

### 2.3 Switching from Prilosec to Nexium

The reason behind Prilosec’s economic success was not just its higher efficacy or its innovative nature, but was also a result of its high price of \$4 per pill. AstraZeneca was able to charge such a high price because it owned the patent for the drug. The patent for omeprazole, Prilosec’s active substance, was to expire in 2001, and AstraZeneca worked for 6 years in advance, starting already in 1995, preparing for the moment when the company would have to face the threat of generic erosion.

The “Shark Fin” team was formed, with the responsibility of leading the company safely through Prilosec’s expiration on to the next step. The approach was two-pronged. On the one hand efforts were made to identify a new drug that would either be significantly better, or simply a “me-too” follow-on drug that would only be slightly improved, but still patentable. On the other hand, the legal department fought hard to keep generics at bay. In combination, the two approaches worked.

With Prilosec healing stomach sores in 84% of patients suffering from chronic heartburn, the likelihood of getting a better drug on the market was rather low. The company opted for a follow-on drug. Although Prilosec was a great drug, still extensive surveys revealed that a mere 50% of patients treated with Prilosec were entirely satisfied. This was encouraging, since the more unsatisfied patients are with the existing drug, the higher the chances that they will switch to an improved follow-on. Several molecules were tested, and esoprenazole, an enantiomer of omeprazole, was chosen. AstraZeneca invested \$120 million in studies, hoping to prove that esoprenazole, later marketed as Nexium, was better than Prilosec. While two of four comparative studies did not show any improvement, the other two showed improvement in patients taking a double dose of Nexium. Only one study showed that Nexium was 3% better than Prilosec at healing ulcers at equal dosage. In spite of the FDA case officer’s conclusion that AstraZeneca’s contention of significant improvements of Nexium over Prilosec was unfounded based on the data at hand, still the FDA top management approved Nexium in 2001.<sup>17</sup>

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<sup>17</sup> The costly side effects of Nexium’s ad blitz, Robert Bazell, August 14, 2007, NBC News, : <http://www.msnbc.msn.com/id/20249591/>, Accessed 12.2007

In parallel the legal team managed to contain the emergence of generics on the market. Fifteen months after the expiration date for Prilosec, the latter still enjoyed market exclusivity. The way they achieved this was by constantly filing patents around the main Prilosec patent, for example on the pill coating, on combinations with antibiotics for battling duodenal ulcers, even on transient chemical forms that omeprazole assumed after being swallowed. Obviously this effort was more strategic than juridical. First, Federal US legislation prescribes that when a generic pharmaceuticals manufacturer enters into a legal battle with a pharmaceutical company, this generic manufacturer enjoys generic exclusivity for one year following completion of the proceedings. This means that the pharmaceutical company has only one generic company to face in the year immediately following patent expiration and can better develop strategies to tackle generic competition. Secondly, as long as proceedings are pending, the branded drug enjoys exclusivity. The reason for that is that FDA is prohibited from approving a generic drug application for 30 months following onset of litigation, regardless of the merits.<sup>18</sup> Each day proceedings continued, Prilosec brought in \$10 million in sales.

At this point, it was already February 2001, and Nexium got FDA approval. AstraZeneca began selling Nexium in March, but with Prilosec's patent expiring in April of the same year, there was simply not enough time to deploy the full marketing strategy to support Nexium's launch. This is where careful strategic planning paid off once again: AstraZeneca commenced clinical trials for Nexium in children, thereby taking advantage of a Federal Law that prescribes six months' exclusivity additional to the prescribed patent term for a marketed drug whose active compound enters clinical trials in paediatrics.<sup>19</sup>

All in all, the additional period of market exclusivity meant that AstraZeneca was able to hold off generics for just the time required to accomplish the successful switch of patients from Prilosec to Nexium.

## 2.4 Branding-in-launching

### 2.4.1 The birth of the purple pill

Omeprazole, marketed under the name Prilosec, was launched in 1989.<sup>20</sup> That was the year that marked the birth of "the purple pill," as purple was the color chosen to mark Prilosec pills. Purple, as applied to the pills, is a registered trademark of AstraZeneca.



**Figure 2:** The first ever purple pill, Prilosec

<sup>18</sup> Evergreening patents, Pamela Winston Bertani, December 10, 2004, Daily Recorder News

<sup>19</sup> Rule 505A ('Paediatric Rule) of FDA

<sup>20</sup> Launchdates\_index, Top 500 Prescription Drugs, Pharmalive.com, Accessed 12.2007

The distinctive purple coloration made Prilosec one of the world's most recognizable drugs. The entire marketing campaign was based on the color purple, the main logo being "Ask your doctor about Prilosec, the purple pill,"<sup>21</sup> and doctors were prescribing "the purple pill," not "Prilosec."

The messages clearly centered on Prilosec's high efficiency in tackling the adverse symptoms of heartburn. "A little dose of life," "Don't let heartburn slow you down," and "One pill a day helps you take a vacation from heartburn"<sup>22</sup> are only a small selection. Marketing activities were launched throughout the US around the theme of purple.<sup>23</sup> Since messages that focused on efficiency accompanied every marketing activity, and every marketing activity was colored purple, the color purple became associated with the brand value of efficiency.

#### 2.4.2 Transferring brand value: The purple campaign for Nexium

Prilosec accounted for nearly 40% of the company's total turnover, making Nexium a make-or-break drug. All too aware of this fact, AstraZeneca invested \$1 billion in Nexium's launch by late April 2001, according to analysts' reports.<sup>24</sup> With so much at stake, nothing was left to chance.

First came name selection. The brand "*Nexium*" was intended to remind people of *next*<sup>25</sup> and perhaps it is no coincidence that *nexus* means "connection," thus reflecting precisely what AstraZeneca was trying to achieve, linking Prilosec to its follow-on, and taking its heartburn portfolio to the next step. Color followed, from packaging and advertisements down to the capsules. With Prilosec being one of the most recognizable drugs owing to its distinctive purple coloration, carrying over the purple color to Nexium would leverage brand recognition and create the link between Nexium and Prilosec. Messages read "Today's purple pill is Nexium"<sup>26</sup> and "better is better."<sup>27</sup> Figure 3 presents two of the most representative advertisements, clearly demonstrating AstraZeneca's intention to move prescriptions from Prilosec to Nexium, using purple as the vehicle; purple is also clearly visible in the sign "AstraZeneca."

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<sup>21</sup> Prilosec's maker switches users to Nexium, thwarting generics, Gardiner Harris, June 6, 2002, [http://faculty.msb.edu/homak/HomaHelpSite/WebHelp/Pharma\\_Prilosec\\_Switch\\_to\\_Nexium\\_WSJ\\_6-6-02.htm](http://faculty.msb.edu/homak/HomaHelpSite/WebHelp/Pharma_Prilosec_Switch_to_Nexium_WSJ_6-6-02.htm), Accessed 12.2007

<sup>22</sup> Intellectual property strategy and value articulation, James G. Conley, 2005, Kellogg School of Management, Accessed 12.2007

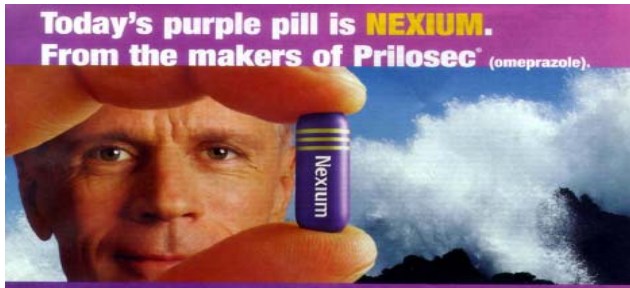
<sup>23</sup> Prilosec's little OTC little pill Paints CVS Stores Purple, Christine Bittar, March 7, 2005, Brandweek

<sup>24</sup> Pursuit of the pill prescribers, Francesco Guerrera, April, 26, 2001, Financial Times, <http://specials.ft.com/pharmaceuticals2001/FT3715MN0MC.html>, Accessed, 12.2007

<sup>25</sup> Pursuit of the pill prescribers, Francesco Guerrera, April, 26, 2001, Financial Times, <http://specials.ft.com/pharmaceuticals2001/FT3715MN0MC.html>, Accessed, 12.2007

<sup>26</sup> Prilosec's maker switches users to Nexium, thwarting generics, Gardiner Harris, June 6, 2002, [http://faculty.msb.edu/homak/HomaHelpSite/WebHelp/Pharma\\_Prilosec\\_Switch\\_to\\_Nexium\\_WSJ\\_6-6-02.htm](http://faculty.msb.edu/homak/HomaHelpSite/WebHelp/Pharma_Prilosec_Switch_to_Nexium_WSJ_6-6-02.htm), Accessed 12.2007

<sup>27</sup> Intellectual property strategy and value articulation, James G. Conley, 2005, Kellogg School of Management, Accessed 12.2007



**Figure 3:** Two of the most representative advertisements for Nexium: The intention to move prescriptions from Prilosec to Nexium and the central role of purple are evident. **Source:** Intellectual property strategy and value articulation, James G. Conley, 2005, Kellogg School of Management, Accessed 12.2007

As already discussed, different approaches are taken to different target groups. Trial patients described their experience with Nexium as a feeling of coolness and freshness taking over from the burning sensation and pain as the symptoms of heartburn subsided. Hence the cool sea waves in the lower of the two advertisements in figure 3. Doctors, on the other hand, want to relieve their patients as quickly as possible, and they were shown a healthy, muscular man running in shorts, with wheels replacing his feet, representing the fast pace at which the painful symptoms of heartburn disappear upon treatment with Nexium. Albeit by means of distinct messages, the brand value of efficiency is consistently kept in focus and purple is used to transfer this brand value from one product to the next.

## 2.5 Nexium: The most successful launch in the modern pharmaceutical industry

### 2.5.1 Launch figures

At launch, Nexium was priced just below Prilosec, reaching optimum price at \$5 when generic omeprazole (generic “Prilosec”) was introduced. At the same time AstraZeneca marketed Prilosec OTC (AstraZeneca’s own generic Prilosec) at \$0.71, when the price range of generic omeprazole was between US \$1.10 and \$3.80<sup>28</sup> (see figure 4 below). This was the so-called sandwich approach, whereby AstraZeneca could dominate both the low-price end and the branded, innovative, top-price niche, thereby satisfying two different market segments and profiting from both the generic and the follow-on product. Thus AstraZeneca was now in a position to control both price levels, the low and the high, and both types of market, the generic and the branded. Although it is not in any case difficult to imagine how Prilosec OTC would have an edge over the competing higher priced

<sup>28</sup> Price per pill

generics, it was the entire marketing concept, transferring brand value from Prilosec to Nexium, that supported the latter's elevated pricing scheme.



**Figure 4:** AstraZeneca's sandwich pricing scheme. **Source:** Intellectual property strategy and value articulation, James G. Conley, 2005, Kellogg School of Management, Accessed 12.2007

Still an elementary question remains, namely why would someone pay for the more expensive Nexium when they already had the much cheaper and equally effective Prilosec OTC? The answer lies in the low market availability of Prilosec OTC at the time following Nexium's launch. The reason why prescription trends moved to Nexium, and not to the next-cheaper competing generics in the absence of Prilosec OTC, lies in brand value transfer that was instrumental in moving Prilosec's loyal customers to Nexium, making them willing to pay 4 times more for esoprenazole to get a mere 3% improved efficiency over omeprazole.

In addition, an astounding 6,000 sales representatives were employed in the US alone solely to promote Nexium, targeting medical practitioners<sup>29</sup> and capitalizing heavily on the fact that Nexium was the proud follower of a very successful drug. Sales representatives also took care to replenish the free-sample stocks of Nexium in doctors' drawers. As the majority of physicians considered that Nexium and Prilosec were equally efficient over the same indications, they were inclined to prescribe whichever they had in stock as free samples.<sup>30</sup> Ensuring that doctors would hand out free samples of Nexium was extremely important, as people trust what they know, and so patients starting on Nexium would, in the majority, stay on Nexium after the flow of free samples had ceased. Along these lines, brand value transfer would patients more likely to ask for a Nexium prescription, since Nexium was produced by AstraZeneca, the producer of the miracle drug Prilosec.

AstraZeneca relied heavily on marketing over the web to more than 50 different countries worldwide, thus setting the standard for e-marketing of

<sup>29</sup> Pursuit of the pill prescribers, Francesco Guerrera, April, 26, 2001, Financial Times, <http://specials.ft.com/pharmaceuticals2001/FT3715MN0MC.html>, Accessed, 12.2007

<sup>30</sup> Prilosec's maker switches users to Nexium, thwarting generics, Gardiner Harris, June 6, 2002, [http://faculty.msb.edu/homak/HomaHelpSite/WebHelp/Pharma\\_Prilosec\\_Switch\\_to\\_Nexium\\_WSJ\\_6-6-02.htm](http://faculty.msb.edu/homak/HomaHelpSite/WebHelp/Pharma_Prilosec_Switch_to_Nexium_WSJ_6-6-02.htm), Accessed 12.2007

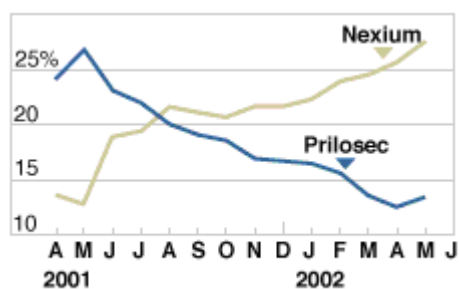
pharmaceuticals.<sup>31</sup> Starting in 1999, two years ahead of the actual launch, an entire website was created dedicated to Nexium, and by now, it should come as no surprise that the website was dripping in purple, nor that it reiterated the campaign messages.

What is important to note at this point is that regardless of the marketing tool that was used to promote Nexium to support its launch, the brand value was preserved irrespective of the form and content of the individual messages.

## 2.5.2 The result: post-launch sales figures

Bearing in mind that the entire launching effort cost AstraZeneca close to \$1 billion and that failing to achieve the switch from Prilosec to Nexium would mean surrendering 40% of its turnover to generic erosion, effectively signaling a shattering corporate defeat, we must now turn to the question of how effective this entire exercise was.

In 2003, Prilosec sales in the US dropped below \$1 billion, a stark reduction from the staggering annual \$6 billion, but Nexium brought in an impressive \$3.3 billion. According to ImpactRx, a market analysis company, 60% of the patients who stopped taking Prilosec switched to Nexium (see figure 5 below), and this already in the first year following Nexium's launch.<sup>32</sup> In terms of market share, Prilosec gave way to Nexium and as was expected, Nexium cannibalized Prilosec's share, triumphing over the competition from Aciphex, Protonix and Prevacid, but also over generic omeprazole (see figure 7 below). Nexium's growth at the expense of Prilosec is clearly illustrated in figure 8.



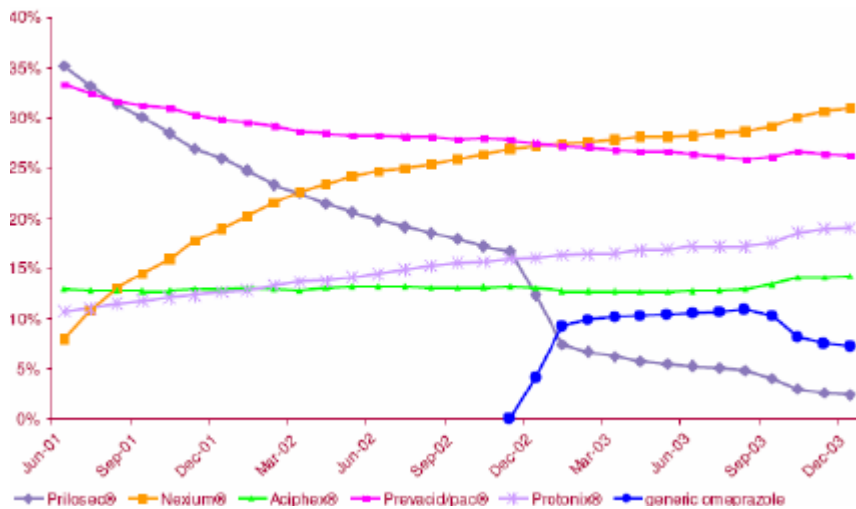
Source: ImpactRx

**Figure 5:** Prescription trends for Prilosec and Nexium in the first year following Nexium's launch. **Source:** ImpactRx.

<sup>31</sup> AstraZeneca: Launching a mega-brand with support from the internet, <http://www.eyeforpharma.com/print.asp?news=33247>, Accessed, 12.2007

<sup>32</sup> Prilosec's maker switches users to Nexium, thwarting generics, Gardiner Harris, June 6, 2002, [http://faculty.msb.edu/homak/HomaHelpSite/WebHelp/Pharma\\_Prilosec\\_Switch\\_to\\_Nexium\\_WSJ\\_6-6-02.htm](http://faculty.msb.edu/homak/HomaHelpSite/WebHelp/Pharma_Prilosec_Switch_to_Nexium_WSJ_6-6-02.htm), Accessed 12.2007





**Figure 6:** Prilosec, Nexium, Aciphex, Prevacid, Protonix, and generic omeprazole: market shares between June 2001 and December 2003. **Source:** AstraZeneca

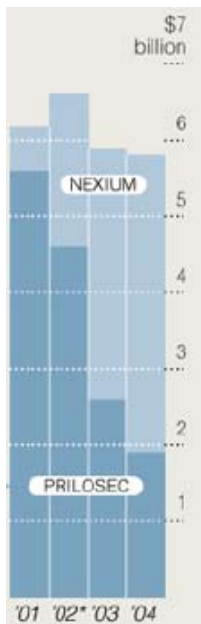
By 2004, Nexium had become one of the most prescribed drugs in the US, ranking seventh.<sup>33</sup> As David Brennan, CEO of AstraZeneca, reported last year in his second quarter results speech,<sup>34</sup> Nexium was one of the company's five growth drivers, with sales of \$1.3 billion in the second quarter of 2007. However, at the same time as Nexium grew by 5%, generic omeprazole grew by 48%. Still Nexium managed to outperform the other three competing brands.

The aforementioned figures for Nexium are by no means comparable to the blockbuster dimensions of its predecessor, Prilosec. It was however a strategic decision not to spend valuable time in anticipation of Prilosec's expiration by trying to devise another drug that would outperform it. Nexium was therefore not expected to exceed or even match the performance of Prilosec. The hope was rather that it would be able to shield AstraZeneca's share in the PPI market against generic erosion and minimize the losses. Comparing the generic erosion suffered by Zantac, an H2 blocker by Gsk, following patent expiration, to that of Prilosec, it becomes obvious that Prilosec's loss of sales was a lot less steep, thanks to Nexium (figure 9 below).

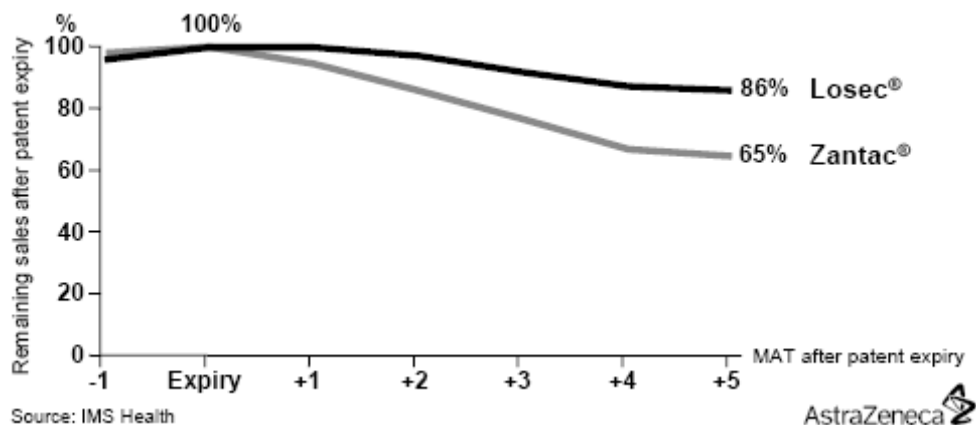
<sup>33</sup> Questions on the \$3.8 million Billion Drug Ad Business, Stuart Elliot and Nait Ives, October 12, 2004, The New York Times,

<sup>34</sup> Second and half year results, David Brennan, CEO AstraZeneca, Speech, 2007





**Figure 8:** Worldwide sales of Nexium and Prilosec. Note how Nexium replenishes sales as Prilosec sales subside, and how Nexium grows beyond it. **Source:** AstraZeneca



**Figure 9:** Sales erosion of Prilosec vs Zantac. **Source:** AstraZeneca

### 3. The future

#### 3.1 The outlook for the pharmaceutical industry

IMS Health, an analyst company, forecasts that the pipeline will remain dry in 2008, which will mean drug development stays at low levels. With approximately 70% of branded drugs launched in recent years not contributing significant improvements over existing drugs, the FDA is now reluctant to grant approvals and applies intense scrutiny. At the same time there have been quite a few cases of late-stage clinical trial failures. This, combined with the fact that \$12 billion worth of branded drugs are expected to go generic in 2008 and that generics have infiltrated practically every major therapeutic area, is going to keep the

pharmaceutical industry growing at very low levels of 4-5%, its slowest growth recorded so far.<sup>35</sup>

As with the entire industry, so with PPIs: the pipeline is not expected to deliver anything new, the anticipation being that the next wave of novel drugs will not arrive before 2010.<sup>36</sup>

This suggests that the PPI market landscape will stage a continuing battle between the already existing branded drugs and their generic competitors, and the survival of brands will depend on how long they are able to fend off generic erosion and then, following exclusivity exhaustion, how the brands will respond and reinvent their competitive strategies.

For Nexium in particular, and as David Brennan, AstraZeneca's CEO, reported,<sup>37</sup> the strategy needs to be refined. With the launch hype long gone, it is imperative that clinical differentiation comes to the forefront and quite possibly a more competitive pricing strategy.

In this context it will be interesting to see how branding strategies work, and in particular examine the strategic role of trademark in branding, as well as how much weight branding will bear from now on in the fiercely competitive pharmaceuticals market. In other words, whether trade marks, as integrated tools of branding strategies, will help maintain market share for the respective PPI brands. The story of the purple pill, where the color purple as trademark was the vehicle for brand value transfer from Prilosec to Nexium, shows how this concept can work successfully as a central part of a broader strategy, as is nicely summarized in figure 10 below. This success story is undoubtedly a powerful demonstration that trademarks can drive entire marketing strategies and have a decisive impact on whether a brand survives in a particular market or not.

### 3.2 Future trends in pharmaceutical branding

What is true nowadays, except for a few exceptions like the one discussed in this report, is that in many cases branding is still a question of how recognizable a particular product is and is not necessarily a matter of brand equity,<sup>38</sup> i.e. of added value created by branding in relation to a particular product. The launch of mega brands, as they are now being called, i.e. leveraging brand value on a global scale, has demonstrated that they may indeed lead to considerable returns, both in term of sales as of market share, also sowing the seeds of future successful product launches.

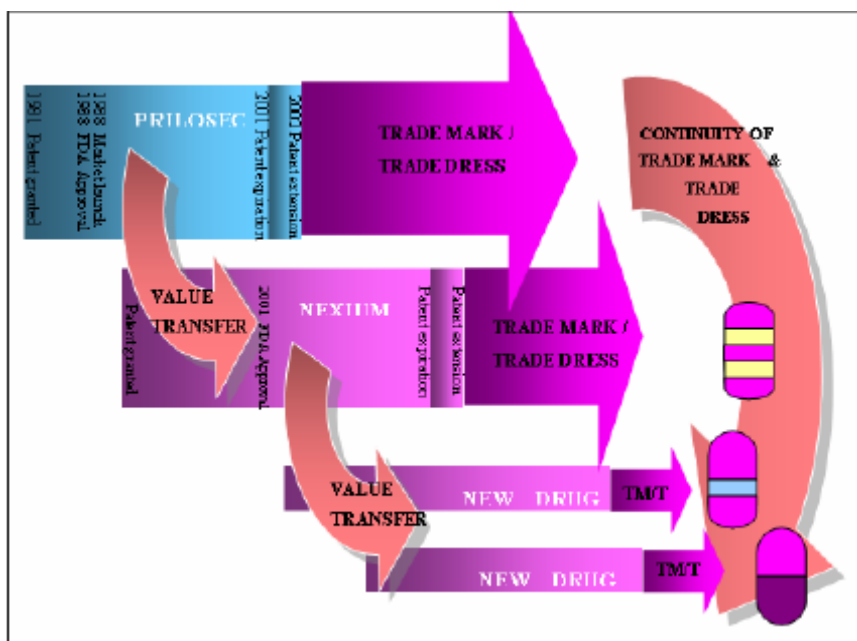
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<sup>35</sup> 2008 Pharmaceutical pipeline is not expected to produce blockbuster drugs, November 20, 2007, AIS's Health Business Daily, <http://www.aishealth.com/Bnow/hbd113007.html>, Accessed, 12.2007

<sup>36</sup> 2008 Pharmaceutical pipeline is not expected to produce blockbuster drugs, November 20, 2007, AIS's Health Business Daily, <http://www.aishealth.com/Bnow/hbd113007.html>, Accessed, 12.2007

<sup>37</sup> Second and half year results, David Brennan, CEO AstraZeneca, Speech, 2007

<sup>38</sup> Pharmaceutical brands: a state of the mind, David Wood, [www.brandchannel.com/papers\\_review.asp?sp\\_id=1228](http://www.brandchannel.com/papers_review.asp?sp_id=1228), Accessed, 12.2007



**Figure 10:** Schematic representation of AstraZeneca's value transfer strategy, based on trade mark and trade dress and how it could function for future follow-on drugs. **Source:** Intellectual property strategy and value articulation, James G.Conley, 2005, Kellogg School of Management, Accessed 12.2007

What also holds true is that currently pharmaceutical companies need five new blockbuster drugs a year in order to achieve the double digit growth figures that the market now expects of them.<sup>39</sup> It is disputed how useful the global branding strategy approach is in terms of increasing sales or cutting costs. Some skeptics say that all one needs in order to make money in this industry is a good drug, one that really does what it says it does. The analyst company Datamonitor<sup>40</sup> doubts the contribution of branding, as its findings suggest that careful analysis of local trends, such as the requirements of reimbursement authorities and local health plans, could prove more profitable than a mega brand. On the other hand, Jon Parton,<sup>41</sup> marketing director at AstraZeneca, is of the opinion that global branding need not cost more than traditional branding has cost so far, and that it certainly cuts costs by averting the need to redesign the campaign for each different country.

In my view, however, these considerations look only at one aspect of global branding, namely how much it costs to build and run it, and how much its value is reflected in sales figures. Still, if there is one lesson to be drawn from the purple pill story, it relates to the use of branding tools to maintain and propagate brand value across products and from one drug to the next, clearly demonstrating that such an exercise, when successful, can be a deciding factor for whether a product withstands competition or not. It is certainly also a prime example of how

<sup>39</sup> Prescribing a global identity, Edwin Colyer, brandchannel.com, [http://www.brandchannel.com/features\\_effect.asp?pf\\_id=102](http://www.brandchannel.com/features_effect.asp?pf_id=102), Accessed 12.2007

<sup>40</sup> Prescribing a global identity, Edwin Colyer, brandchannel.com, [http://www.brandchannel.com/features\\_effect.asp?pf\\_id=102](http://www.brandchannel.com/features_effect.asp?pf_id=102), Accessed 12.2007

<sup>41</sup> Prescribing a global identity, Edwin Colyer, brandchannel.com, [http://www.brandchannel.com/features\\_effect.asp?pf\\_id=102](http://www.brandchannel.com/features_effect.asp?pf_id=102), Accessed 12.2007

consumers may treat the pharmaceutical industry like any other and be brand loyal at the level of the company, not just in terms of individual products. Hence what was once the main differentiation point between pharmaceuticals and other products seems to be less strong now, at a time when consumers can choose AstraZeneca over another company that has drugs for the same indications, much as they can choose Volvo over another car manufacturer for the same car types. However that may be, branding is powerful and it remains at the discretion of individual companies how they will manage and incorporate their trademarks and other intellectual property rights in their branding strategy.