
Battle for the market: Branded drug companies' secret weapons generic drug makers must know

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Abstract Generic drugs now account for more than \$40bn in prescription sales worldwide. More than \$80bn worth of global blockbuster drugs face US patent expiration by 2008. The battle for market share between the booming generics drug industry and the at-risk branded drug industry is raging.

As patent expiry looms, branded drugs can no longer only focus on extending product lives. They need defensive strategies to combat their generics competitors actively and retain market share. To maintain rapid growth, generic drugs makers not only need to understand the nature of these defensive strategies, but they must also be prepared to deal with them as they bring their products to market. The most important and commonly-implemented strategies are discussed in this paper and the authors suggest that branded and generic drugs companies can successfully apply or manoeuvre against these strategies to distinguish themselves within an industry where lines are blurring and competition is increasing.

Keywords: *generic defence strategy, evergreening, line extensions, next-generation drugs, flanking generics, RX to OTC switching, authorised generics*

INTRODUCTION

Branded pharmaceutical companies stand ready to battle the booming generic drugs industry. By 2008, branded drug patent expirations accounting for sales of more than \$80bn will expose a receptive public market to new generic drugs — potentially eradicating large percentages of branded drug companies' profits. The generic drugs industry has doubled since 1998 (Figure 1), and is expected to grow to more than \$60bn by 2007. Currently, with more than \$40bn in annual drugs sales, the generics industry claims more than 50 per cent of all prescriptions filled in the USA, the

world's largest drug market. Yet less than a quarter of all spending on drug discovery, development and commercialisation is for generics.

As generics competition poses a greater threat to the branded drug industry, innovator companies are more vigorously defending their profits and market share. By understanding the defensive motives and strategies of branded drug companies, the generic drugs industry can survive battles over patents, adopt partnering and licensing strategies and successfully launch new products that continue to spur generic drug sales.

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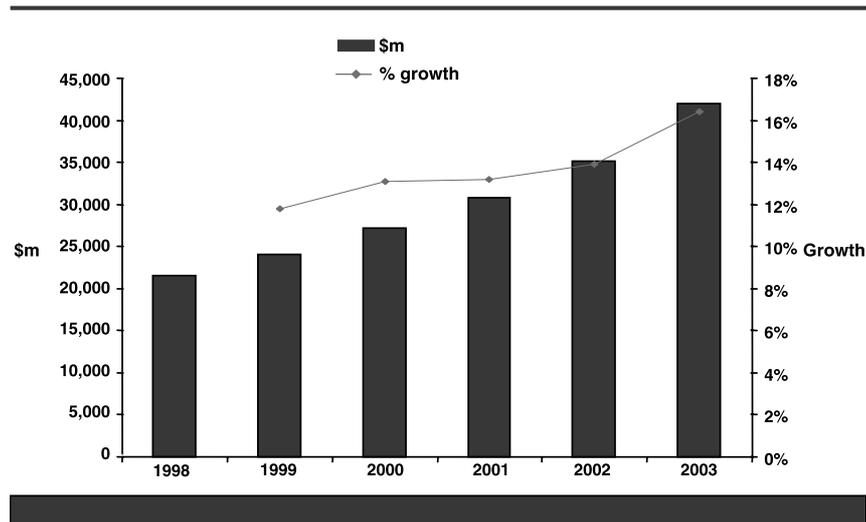


Figure 1: Global generics market growth, 1998–2003

Source: *Combating Generics: Pharmaceutical Brand Defense*¹ © Cutting Edge Information

Since the combination of generics industry growth and patent expirations hinders branded drug companies' success, their brand teams must organise patent defence strategies, even before launch. Facing impending generics competition, teams prepare early and quickly in the product life cycle to avoid losing profits. (The industry concern for profit loss has risen with the ever-increasing pressure to rebuild pipelines, as profits are needed to fund the imperative research and development functions.) Generic drugs companies that discover brand team strategies and tactics can develop counter-attacks against patent defences.

Branded drugs companies develop defensive strategic plans to combat generics competition. While assessing the feasibility of each strategy, brand teams may decide to use multiple strategies in concert to achieve the desired outcome. When developing strategic plans, brand teams often choose from the following commonly used strategies:

- Evergreening — line extensions and next-generation franchise extensions

- Flanking or authorised generics — manufacturing and distribution partnerships between branded and generic drugs makers
- Prescription drug (Rx) to over-the-counter (OTC) switching

Understanding each defensive strategy and how it is exercised can help the generics industry to fight for product launches that branded firms vigorously oppose.

Branded drugs companies try to implement their anti-generics strategies as early and quickly as possible to defend against generics competition. The generics industry's comprehension of strategies and tactics is key to overcoming branded companies' tactics and sustaining generics industry growth.

Many branded and generic drugs makers have reached alternative agreements that enables them to avoid the high legal costs that come with patent battles. Many firms have begun to form alliances and establish partnerships that are blurring the lines between these two industries. Such co-licensing agreements, alliances and

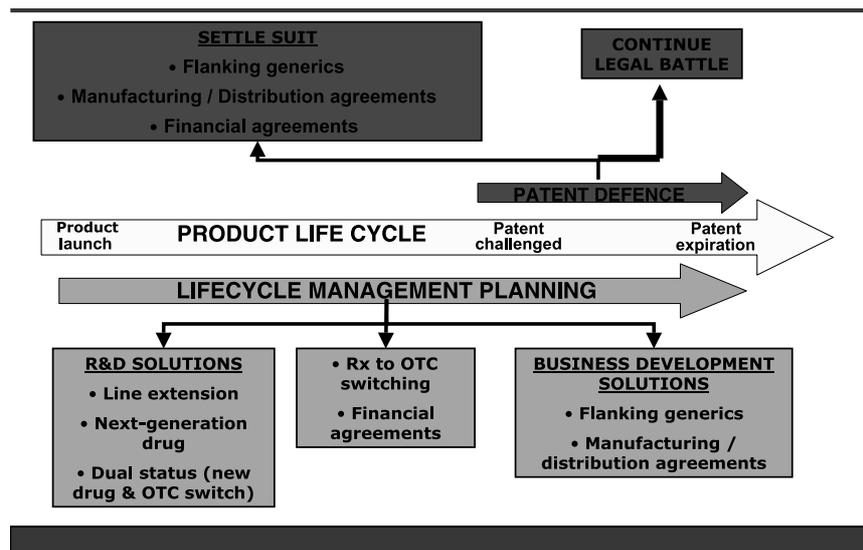


Figure 2: Menu of generics defence strategic options

Source: *Combating Generics: Pharmaceutical Brand Defense*¹ © Cutting Edge Information

manufacturing and distribution agreements provide opportunities for generics companies to improve their own R&D competencies, avoid costly legal battles and save on manufacturing costs. Branded drugs companies get to keep their manufacturing facilities running at full capacity, retain market share and even capture a small share of the generics market for their own drugs via royalty payments on the generics companies' sales.

STRATEGIC PLANNING

Brand teams, product life cycle managers and portfolio planners pursue both legal and product-based defence strategies against generics competitors. It is the responsibility of these teams to produce returns on the extensive research, development and commercialisation investments that their firms poured into their drugs over the years.

Branded drugs companies have focused on new, innovative and non-patent strategies as regulatory changes and market forces have increasingly changed in favour of generics companies over the past ten to

15 years. By considering a variety of strategies, brand teams form a sound course of action in a strategic plan to minimise the extent to which generics competitors can erode their sales. The strategic plan dictates a course of action and outlines how to work proactively to benefit the brand. Effective plans also include contingency options to enable brand teams to respond quickly to unexpected changes in their markets. Proactive strategies to retain market share and maximise returns include developing a franchise or line extension (evergreening), flanking or authorised generics and switching an Rx to OTC availability (Figure 2).

EVERGREENING: TRANSITIONING PATIENTS TO NEXT-GENERATION DRUGS

The practice of evergreening — developing line extensions or next-generation franchise extensions — has proved to be one of the most successful strategies used by branded drugs companies

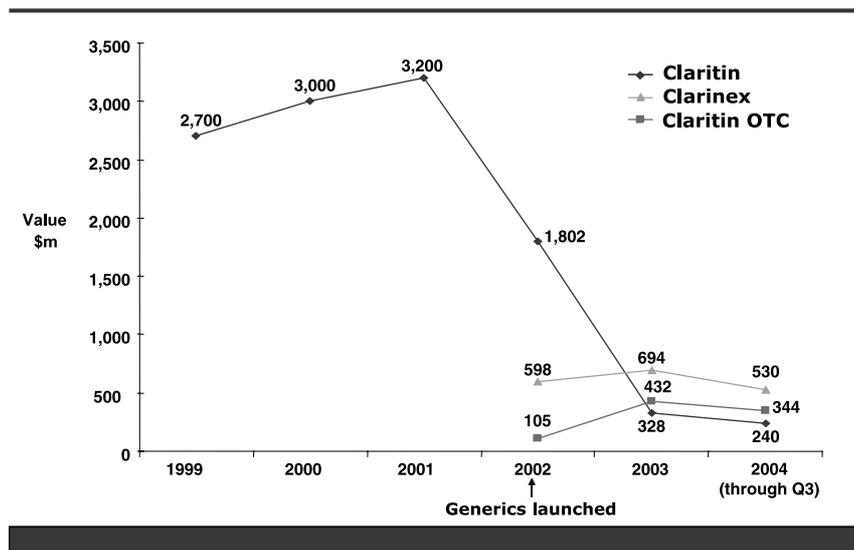


Figure 3: Claritin/Clarinex sales, 1999–2004 (Q3)

Source: *Combating Generics: Pharmaceutical Brand Defense*¹ © Cutting Edge Information

to maintain market share. Line and franchise extensions present patients with an improved drug, usually based on the original compound. Brand teams attempt to switch patients to the newly patented drug before the patent on the original drug expires. Switching patients to the line extension staves off and minimises market share loss and makes it less attractive for generics competitors to enter the market because they must target a depleted patient population.

Yet evergreening carries with it a high risk to companies utilising the strategy. Research and development for next-generation drugs costs companies tens or even hundreds of millions of dollars, which they risk losing if the next-generation drugs lack efficacy, are proven unsafe or otherwise fail to gain regulatory approval.

Schering-Plough found itself in an unenviable situation in 2002 with the introduction of Clarinex as a next-generation replacement for Claritin. Delays in US Food and Drug Administration (FDA) approval for Clarinex opened the door for generics to enter the market

before a sufficient number of Claritin patients could be switched to Clarinex to maintain adequate market share. Schering-Plough faced double disappointment: Clarinex failed to reach blockbuster status and sales of Claritin dropped dramatically from \$3bn to only \$300m within a short time (Figure 3).

Evergreening failures, such as Clarinex, cause branded drugs companies to be cautious in planning and launching next-generation extensions. To reduce the risk of problems for new drugs entering the market, brand teams turn to consumers and doctors for advice. Considering different opinions when developing a new drug allows the brand team to create a better drug by addressing issues with the original product. By correcting the original drug's problems with an improved next-generation drug, brand teams hope to entice patients to switch to the new drug. Making this switch before the patent expiration of the original drug creates a disincentive for a market influx of generic drugs. When a branded drugs company puts together an effective strategy to combat generics, such as in AstraZeneca's

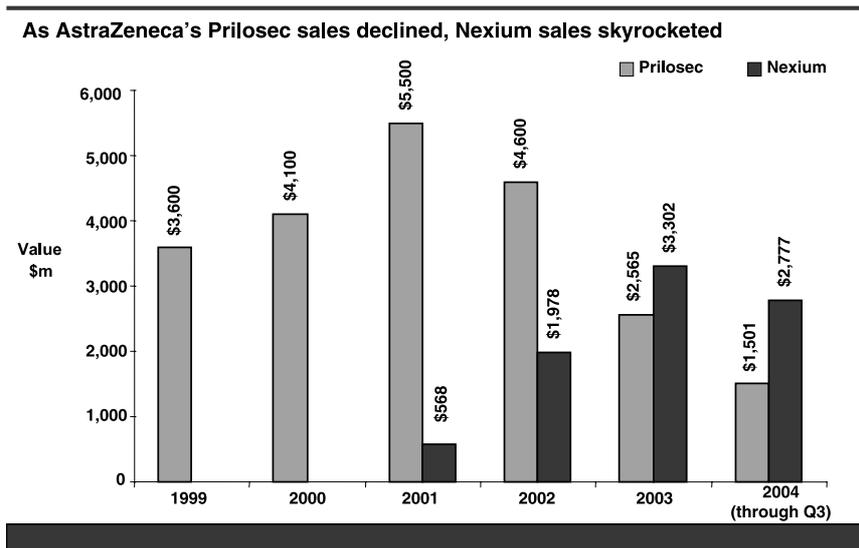


Figure 4: Transitioning Prilosec to Nexium

Source: *Combating Generics: Pharmaceutical Brand Defense*¹ © Cutting Edge Information

Prilosec to Nexium switch, good results amaze the branded drug industry.

Case study: AstraZeneca's next-generation Prilosec to Nexium switch

AstraZeneca's switch from Prilosec to next-generation Nexium is an industry paradigm (Figure 4). The company transferred 40 per cent of Prilosec patients to next-generation Nexium as well as managing a 9 per cent growth in its gastrointestinal franchise in 2001 alone. Next-generation Nexium, developed from Prilosec, proved more effective in treating patients. AstraZeneca submitted the drug to the FDA early enough to assure its approval before the patent expiration of Prilosec. When the FDA approval came through, one of the most massive marketing campaigns in US history began. The company spent \$500m on direct-to-consumer marketing, hospital discounts on the drug, free samples for doctors' offices and media advertising. Its marketing efforts resulted in an abundance of patients transferring to the next-generation product with the new patent, thus thwarting the

ability of the generic to capture a large portion of AstraZeneca's share of the gastrointestinal market. To further trump its would-be generics competitors, AstraZeneca switched Prilosec to an OTC drug as its prescriptions dwindled. Branded drug companies follow AstraZeneca's example when developing defensive strategies, and generics companies should study this case to determine how to remain viable in the face of such successful strategies.

LINE EXTENSIONS: BUYING TIME

The evergreening strategy also includes line extensions. Planning for and developing line extensions for a patented drug requires a sound life cycle management plan to outline the future for the drug. Brand teams can anticipate potential product line extensions when long-term planning begins about one year after product launch. Market research provides the necessary information, such as disease direction and important legal or clinical issues, to plan the future for a branded drug.

The greatest benefit of line extensions is their ability to buy additional time. Choices available to branded drugs companies when issuing a line extension include changing the dose of a drug, altering its form of delivery or modifying its formulations by adding safety profiles or producing extended-release drugs.

Line extensions produce hit or miss situations. The Claritin/Clarinet case failed to maintain market share for Schering-Plough; however, cases such as GlaxoSmithKline's (GSK's) Zyban worked well as a line extension of Wellbutrin. GSK found the antidepressant Wellbutrin to be effective as a smoking-cessation product, renamed the product Zyban and marketed the drug to consumers who smoke.

Branded drugs companies often run into problems, such as lacking ways to make a drug more convenient than its current delivery method. Moreover, R&D may be unable to find a clinically viable new product when a line extension proves ineffective with altered indications. If branded drugs companies can avoid such problems and create a line extension, brand teams will be able to utilise the added clinical or economic benefits of the extension to convince patients to avoid generic alternatives.

Marketing line extensions

When marketing line extensions to patients and doctors, brand teams take two approaches. First, they can release a 'critical mass', or moderate amount, of information in conjunction with product launch. After launch, the team periodically releases additional small amounts of information to keep the market informed and up to date about the drug.

Continually reminding the market about the drug in this way helps to maintain market share when generics competition arrives. The second option for brand teams

requires the release of a bulk of information about the drug at one time to build interest and news around the product. The immense amount of press increases attention and buys time for the brand by increasing market interest. These factors cause the public to ignore the generics competition for a brief period of time.

Timing the line extension correctly becomes crucial. Brand teams take advantage of the time and attention gained through either approach by switching as many patients as possible to the line extension during the overlap of the patents for the new and original drugs.

Giving a line extension the same name — or one that is similar to the original drug's brand name — helps marketing efforts by leveraging the old brand's equity. Next-generation drugs, which are truly different compounds, often require entirely different names to gain individual identity in the market.

Brand teams spend a great deal of money on advertising campaigns for next-generation and line extension products — total direct-to-consumer spending tallies more than US\$4bn. Television and print advertising absorb the bulk of advertising dollars. Television advertisements account for more than 57 per cent of total advertising spending, while print advertisements follow closely, with more than 31 per cent of spending. Spending on advertising is tremendous because brand teams must maintain consumer awareness and intent to purchase to beat out generics competition.

Regardless of the advertising approach that a brand team takes to create a 'buzz' around a new line extension, the investment in commercialisation is enormous. Not only do marketers have to spread the word about the new drug, but they also face the challenge of differentiating it from its predecessor. In a

recent study,¹ industry business intelligence firm Cutting Edge Information (<http://www.CuttingEdgeInfo.com>) found that more than 40 per cent of companies were willing to invest between \$100m and \$150m in R&D to produce a line extension for a blockbuster drug — one whose peak annual sales exceed \$1bn. Many others have backed line extension R&D with as much as \$250m. Despite these staggering numbers, companies still invested in new product commercialisation at an astounding two to one ratio by comparison with the R&D budgets of such drugs.

At the end of the day, however, one question lingers: when a line extension is not feasible, at what point does marketing a drug that is competing with generics cease to yield positive returns on investment and actually begin to have the *opposite* effect of boosting sales for a drug's generics competitors? The jury is still out on this; however, industry experts point to the drastic fall-off in a branded drug's sales when generics come to market. Often, a brand name drug can lose 80 per cent or more of its market share in the first year in which it faces generics competition. Such a decrease in sales forces brand name drug makers to slash advertising spending. Within the first year of a generic formulation's launch, branded manufacturers often re-focus their attention and marketing dollars on more promising drugs that yield higher returns on investment.

FLANKING GENERICS

A second defensive strategy available to branded drugs companies involves entry into the generics market via their own subsidiary generics units or by distributing generic versions of their own brands. The involvement of branded drug companies in the generics market often is a result of strategic partnerships between branded and

generics drugs companies. Frequently, these partnerships function as out of court resolutions to patent infringement suits.

The strategy, referred to as 'flanking' or 'authorised' generics, allows branded drugs companies to manufacture at capacity by producing a portion of their own drugs under a generic label to be distributed by a generics company in exchange for royalties on sales. This method encourages the existence of only one generic form of the drug, preventing lost market share from multiple generic drug introductions (when one generic establishes itself in the market prior to patent expiry, it is much less appealing to other generics manufacturers to try to compete, given the industry's comparably small profit margins). Retaining revenue from a branded drug after patent expiration motivates companies to prevent multiple generic drugs from entering the market.

Partnerships with generics companies create win-win situations for both parties. Generics companies do not have to invest in expensive manufacturing facilities because that need is fulfilled by the branded firm, which can easily produce the generic version within its existing manufacturing operation. This allows the branded company to recover more R&D investment in the drug, as well as capital investment in manufacturing.

Case study: GSK's Paxil deal

Generic drugs maker Apotex launched a substitute for GSK's immediate-release antidepressant blockbuster, Paxil. To stave off this generics competition, GSK developed a new controlled-release formulation, Paxil CR. The company transitioned patients to Paxil CR and arranged a licensing agreement with generic drugs maker Par Pharmaceutical. GSK supplies Par Pharmaceutical with generic Paxil immediate-release tablets and

Par Pharmaceutical distributes the immediate-release drug in the USA. Par Pharmaceutical pays a royalty to GSK for the generic pills, which helps GSK to capture a small segment of the generic Paxil market, reducing its losses after Paxil's patent expiration. Their partnership reduces the competition introduced by Apotex because the controlled-release tablets distributed by Par Pharmaceutical cannot be replaced with the immediate-release medication that Apotex offers. GSK retains a larger percentage of the overall Paxil revenue stream by both transitioning patients to its new, proprietary controlled-release formulation and by partnering with Par Pharmaceutical to produce and distribute a generic version of the immediate-release form to compete with Apotex's drug.

Branded drugs companies create generics

The introduction of a branded drugs company's own generic replacements provides it with competitive advantage only if it arrives in the market early. Being first to market helps companies to retain a devalued market share of their off-patent drug.

Branded drugs companies can arrive earliest by taking advantage of the multitude of resources readily available to help them reach the generics market. Most branded drugs companies possess thorough legal departments to handle patent cases, developed and skilled marketing/sales forces and extensive existing manufacturing capabilities. A company needs a healthy revenue stream in order to compete with the branded companies.

New positions for generics

Generics companies find new ways to succeed in the industry as the role of branded drugs companies changes. One opportunity for generics includes filling

market niches left by branded drugs.

Generics companies that develop larger, more innovative R&D functions see greater growth in business through these niches. Open sectors, including urology, contraception and treatments for systemic lupus erythematosus, offer generics higher returns and exclusivity than generic copies of branded drugs.

Another opportunity for generics companies is the option to form partnerships with branded drug companies. In 2003, GSK teamed with generic drugs maker Ranbaxy to develop collaborative research in a variety of therapeutic areas. The agreement delegated responsibility for early clinical work to Ranbaxy, while GSK would improve the compound after its approval for development. An executive steering committee was appointed to oversee all R&D.

Marketing and sales

When the hurdle of marketing a generic seems too high, generics companies can partner with branded pharmaceutical companies to accomplish marketing and sales functions. Building a new marketing department or sales force from the ground up may take more time and money than a generics company can afford. One innovative workaround that has become more common in the USA is the 'flanking generics', or 'authorised generics', strategy, discussed above. In exchange for sales royalties, generics companies team up with branded drugs companies to market their products. Generic drugs makers also acquire companies with existing sales and marketing functions or outsource marketing and sales. Outsourcing proves effective in reaching physicians more quickly than other methods because contracted sales forces already have an established rapport with physicians. Choosing any of these options, however,

means that companies forgo a portion of sales revenues.

RX TO OTC SWITCHING

Switching branded prescription drugs to OTC status is the third defensive strategy option for branded drugs companies. Rx to OTC switching occurs when a branded drug, whose patent is about to expire, gains approval by the FDA for OTC sale. When branded pharmaceutical companies switch drugs, they give up some sales revenue. The switch will make the market unattractive for generics, however, allowing branded drugs companies to keep more of their revenue streams than if they had done nothing in the face of generics competition.

Although this defensive strategy is the least common, employing Rx to OTC switching in conjunction with line/franchise extensions sometimes proves effective for branded drugs companies. The combination of strategies can help to maintain some sales revenue for the branded drug. Giving patients the option to switch to either the extension or the OTC drug makes the market less attractive to generics.

AstraZeneca's Prilosec to Nexium switch provides an excellent example of the combination strategy. The company succeeded in keeping 40 per cent of Prilosec patients by introducing them to the next-generation drug Nexium. Shortly afterwards, Prilosec gained OTC status, keeping generics competition from flooding the market to take AstraZeneca's revenue and market share.

Other factors

As the battle between generics and branded drug companies continues, managed care groups have stepped in as a new player in the conflict. In 1998, Wellpoint Health Networks petitioned the FDA for an entire class of second-

generation antihistamines to be switched to OTC status. Wellpoint Health Networks argued that these branded drugs, including Claritin, Zyrtec and Allegra, are less dangerous than similar OTC products. The petition highlighted the rising prices of drugs and the need to lower overall costs for patients.

The list of candidates for Rx to OTC switches has grown dramatically since 1997, and includes blockbuster drugs like Celebrex, Flonase and Prevacid.

In response to Wellpoint's FDA petition, Schering-Plough preemptively switched Claritin to OTC in an attempt to maximise revenue and maintain market exclusivity. Switching offers branded drugs companies a public relations advantage by offering lower-priced drugs to a public upset by rising drug costs. Recently, the FDA increased its budget for OTC switching evaluations and now periodically approves classes of drugs for OTC status. OTC approvals for entire drug classes forces switching by branded drugs companies, and these switches, while rare, are more common than voluntary switching by the branded drugs companies. Keeping generics from the market rarely justifies branded drug-makers cutting revenue drastically by voluntarily switching products from Rx to OTC status.

CONCLUSION

The lines that traditionally divided branded pharmaceutical companies from generic drugs makers are blurring. Generics companies are building their R&D competencies to reap higher-margin benefits from proprietary drug sales and, at the same time, branded drugs companies are attempting to establish names for themselves in the generics market through deal-making strategies. Branded drug company Novartis is pursuing both branded and generic drugs markets.

Re-branded in 2003, Sandoz encompasses the loose conglomerate of businesses formerly under Novartis Generics in a single business unit. Sandoz markets more than 200 generic drugs in a wide array of therapeutic areas. Novartis' goal for the subsidiary is to expand the company globally and capitalise on the reputable Sandoz name.

Industry experts predict that the two industries will continue to mesh together as competition for patients increases, the drive for higher profits continues and more branded drugs patents expire. Defensive strategies that include

partnerships, alliances and manufacturing and distribution agreements between branded and generic drugs makers will provide the greatest benefit to the branded drugs companies as their role in the industry changes and as generic drugs manufacturers become larger players in overall industry competition.

Reference

1. Cutting Edge Information (2004) *Combating Generics: Pharmaceutical Brand Defense*, available at <http://www.PharmaGenerics.com>.