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SALES & MARKETING INSIGHTS

Generics: The Ripple Effect

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Introduction

When a pharmaceutical patent expires and generic competition moves in, the branded product's market share erodes rapidly. Less clear is what happens to a branded product when a *competing* product's patent expires—changes in market share can vary extraordinarily and seem unpredictable.

Generic entry has turned entire markets in the United States upside down, while others barely feel a ripple. But which generics fundamentally change market dynamics, and how great are the effects? Answering these questions has become critical to pharmaceutical companies, as more than 30 patents will expire during the next three years (see Figure 1).

Despite the wide range of potential scenarios, there are ways to help predict how generic entry can affect a competing product still under patent protection. Analyzing differentiation, treatment condition and payer focus will help indicate how generic entry in the United States will alter an entire market.

Likewise, companies that benchmark, analyze customer and influencer insight, and weigh product risk as part of an overall strategy are more likely to be able to predict how generic entry will reduce sales for their branded product, and act far in advance of any patent expiration to mitigate the effects.

Figure 1. Expected Patent Expirations Through 2012 (Source: Going, Going, Gone. Drug Topics, 10 August 2009)

EXPECTED PATENT EXPIRATIONS 2010-2012

2010	2011	2012
Lipitor – Pfizer	Advair – GSK	Crestor – AstraZeneca
Arimidex – AstraZeneca	Plavix – Bristol-Myers / Sanofi-Aventis	Symbicort – AstraZeneca
Cozaar – Merck	Zyprexa – Eli Lilly	Maxalt – Merck
Levaquin – J&J	Effexor VR – Wyeth	Avandia – GSK
Flomax – Boehringer Ingelheim / Astellas	Aprovel – Bristol-Myers / Sanofi-Aventis	Lexapro – Forest Laboratories
Protonix – Wyeth	Xalatan – Pfizer	Viagra – Pfizer
Hycamtin – GSK	Astelin – Wallace	Zometa – Novartis
Climara – Bayer	Synarel – Roche	Diovan – Novartis
Invirase – Roche	Actos – Takeda	
	Follistim – Schering-Plough	
	Viramune – Boehringer Ingelheim	

Examining Diagnostic Risk Factors

Each product's individual characteristics and market status will affect its market share when a competitor goes off patent. Three factors clearly change how a branded product will fare when a competitor faces generic competition:

1. **Differentiation:** The degree of differentiation will determine how resistant a single product is to generic disruption. Differentiation could be a clear efficacy or safety advantage, benefits unique to certain patients or an alternative delivery mechanism.

2. **Treatment Condition:** Products that treat serious or urgent conditions resist generic entry better than those that treat less-harmful conditions. Payers are not likely to discourage physicians' product preferences for a serious disease.
3. **Payer Focus:** Drug categories that treat small patient populations generally face fewer pressures from generic substitution. These markets attract less attention, account for a small percentage of total spending and are less likely to be subject to generic substitution.

Several examples show just how differentiation, treatment condition and payer focus alter the market dynamics of generic entry for all players, not just those companies whose patents have expired.

When Generics Have a Dramatic Impact

In 2005, before Merck statin Zocor (simvastatin) lost patent protection, doctors wrote nearly 23 million prescriptions for the treatment; in 2007, a year after losing patent protection, that number dropped to less than 1 million.

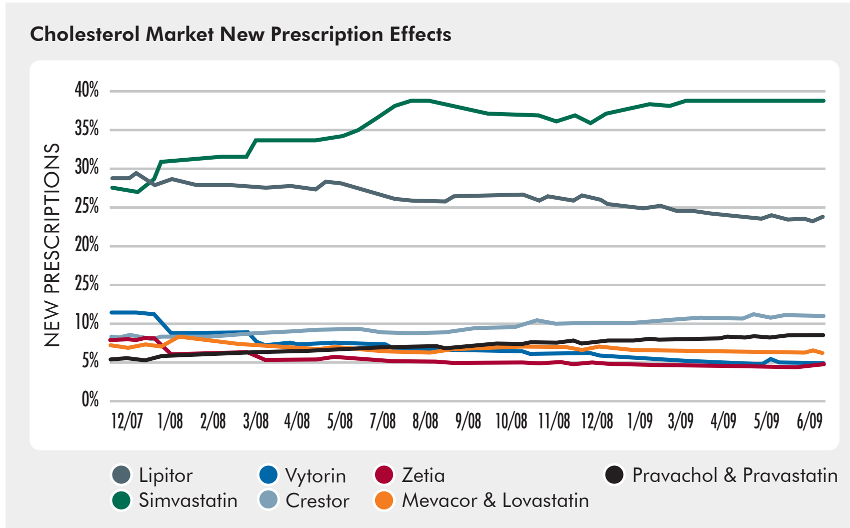
With the advent of generic simvastatin, overall annual market growth was 9%, compared with 6% prior to generic entry. But Zocor's branded competitors did not necessarily benefit; sales for Lipitor, a competing branded statin from Pfizer, shrank 8% in 2007, after rising 7% in 2006 (see Figure 2).

Why did this happen? Payer focus on statins and little differentiation between products.

Statins represent one of payers' largest financial burdens. Until Zocor went off patent, lipid-lowering drugs were largely behind increases in prescription-drug spending nationwide. Even after the introduction of multiple generics, lipid-lowering agents still comprised the largest share (12.5%) of Medicare drug spending in 2008.

In addition to heavy payer focus on statins, Lipitor might not have been differentiated enough in the eyes of payers to fend off a steep sales decline. According to published reports, about 80% of Lipitor patients used low-dose formulations of comparable efficacy to Zocor, and payers almost immediately substituted Lipitor with less expensive generic simvastatin.

Figure 2. In the U.S. statin market, generic entry had a huge impact on branded competition to Zocor (Source: IMS Health).

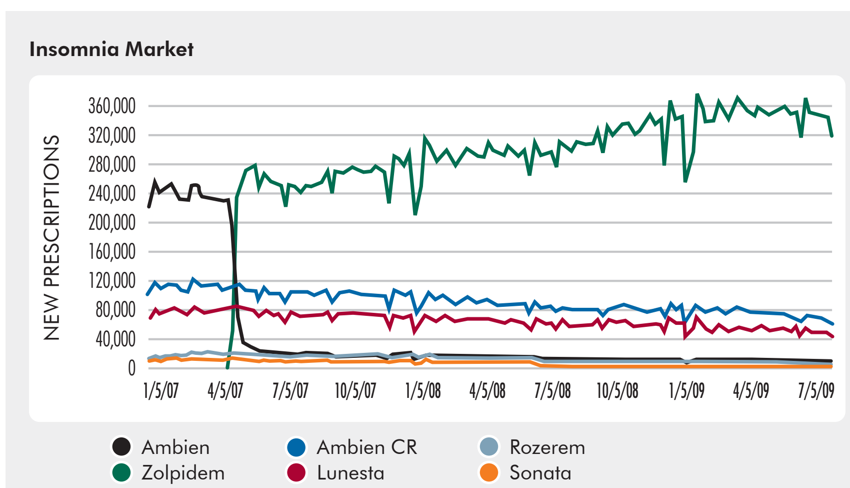


When Generics Have a Moderate Effect

During the last full week of U.S. patent protection for Ambien (zolpidem), the Sanofi-Aventis sleep aid accounted for 42.4% of non-barbiturate sleeping pills prescribed nationally, totalling $55.4 million of sales that week.

Two weeks after generic zolpidem was introduced, Ambien's market share fell to 12.5%. But it was only over a period of several years that all sleep aids experienced moderate share erosion. As generic zolpidem's market share rose to 46% in 2009, competing brands, such as Rozerem and Lunesta, saw their share figures decline slightly, to 0.9% and 6.7%, respectively (see Figure 3).

Figure 3. The introduction of a generic substitute for Ambien had a huge effect on the branded product, but other branded competitors lost market share only over time (Source: IMS Health).



The experience of sleep aids was unlike statins because of differentiation and payer focus. Measures of efficacy, such as sleep onset, maintenance and quality, differed from product to product, and each treatment had different safety profiles in terms of potential for dependency and control.

Sleep aids were moderately expensive products that did not command the same level of payer attention as statins. Ambien's huge market share meant immediate payer savings through substitution. Eventually, payers became savvy to the potential savings in substituting generics for other branded treatments, but not immediately.

When Generics Affect One Product Only

When it launched in June 2008, risperidone, the first generic atypical antipsychotic, caused its branded parent, Johnson & Johnson's Risperdal, to lose 80% of sales in relatively short order. Meanwhile, AstraZeneca's market leader, Seroquel, maintained about a 30% market share. Concerns over weight gain and metabolic profiles of agents such as Zyprexa have allowed branded competitors Abilify and Geodon to gain patients (see Figure 4).

So why is this market different than statins and sleep aids? The most apparent reason is clear differentiation between compounds. Notably, the safety issues associated with first-generation atypicals are less of a concern for newer atypicals. Even newer brands have trade-offs pertaining to safety and side effect profiles that set them apart and encourage patient-specific prescribing decisions.

Figure 4. The different efficacy and safety profiles of atypical antipsychotics made the introduction of generic Risperdal a nonevent for many branded competitors (Source: IMS Health).

U.S. TOTAL PRESCRIPTION DATA: 13-WEEK YEAR-ON-YEAR GROWTH (2009)

Drug	Company	9/4	9/11	9/18	9/25	10/2	10/9	10/16	10/23
Antipsychotics		5%	4%	4%	4%	3%	3%	3%	3%
Abilify	Ostuka America	24%	23%	23%	23%	22%	22%	21%	20%
Geodon	Pfizer	3%	2%	2%	2%	1%	1%	1%	1%
Risperdal	Johnson & Johnson	-81%	-79%	-77%	-73%	-69%	-66%	-65%	-64%
Seroquel	AstraZeneca	-2%	-3%	-4%	-4%	-4%	-4%	-5%	-5%
Seroquel XR	AstraZeneca	205%	203%	205%	207%	208%	209%	210%	212%
Seroquel Fran.	AstraZeneca	3%	3%	2%	3%	2%	2%	2%	2%
Zyprexa	Eli Lilly	-5%	-5%	-5%	-5%	-6%	-6%	-6%	-6%
Invega		0%	-1%	-1%	-2%	-3%	-3%	-3%	-3%

Approaches to Help Anticipate Disruption

Analyzing these three factors helps companies make accurate forecasts about market behavior after a key competitor loses exclusivity. We recommend several approaches and market perspectives that can help determine the effect of these key factors. While these do not represent a full solution to a complex issue, the steps below can be used in a framework for pharmaceutical companies to attack the problem.

Benchmarking and Analog Analysis

Brand managers should evaluate their own brand's risk based on the factors outlined above, then compare their market to similar ones in which generics have been introduced recently.

For example, the statin market could help predict the effect of Cozaar/Hyzaar's expiring patents on the ARB class. Heavy payer control and relatively low differentiation characterize both ARBs and statins.

These dynamics change rapidly and without warning, as payers' influence and pressure to contain costs increases. Prognosticators must remain wary of stale analogs and validate retrospective analyses with forward-looking research.

Examining Customer and Influencer Insight

Today's marketers must understand not only customer (physician and patient) reactions, but also the reactions of other treatment influencers, most notably payers.

Generally, U.S. payers prefer generics to brands, and when an efficacious generic substitute emerges, payers often promote the generic to first tier and demote branded treatments to second- or third-tier status. As copays increase and prioritizations and step edits become common, the effects of generic entry resonate strongly across the brand's market as a whole.

A brand's value proposition weighs heavily on how a generic's entry affects the brand. A pharmaceutical company should define and protect its value proposition long before a competitor's patent expires. The ultimate goal is developing true differentiation—a unique benefit so great that prescribers and payers view any generic as an imperfect substitute.

Weighing Return With Risk and Investment

As part of an overall approach, it is important to include well-formed life cycle management decisions that combine an evaluation of the commercial potential of alternatives with an accounting of investment requirement, risk tolerance and portfolio strategy. In markets susceptible to generic disruption, the market leader's best course of action may be to maintain the status quo or not to invest further in the product at risk.

Viewing the market as such will help executives understand the risks their products face, allowing them to make optimal managerial decisions in the face of competitive disruption (see Figure 5).

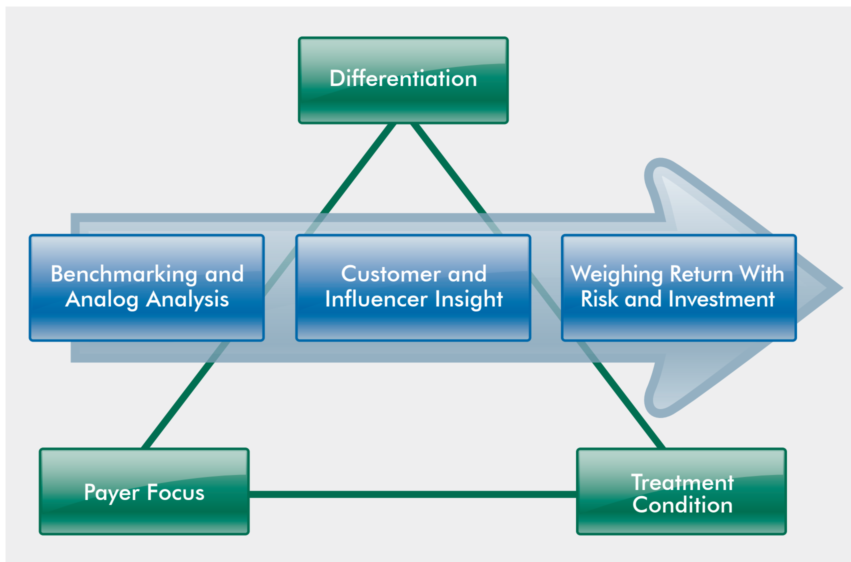


Figure 5. By using a matrix that takes numerous factors into account, pharmaceutical companies can help predict the fallout from a key competitor losing patent.

Conclusion

Life cycle management, once considered a strategy to extend a brand's potential in anticipation of its own patent expiration, today requires planning for and responding to the impact of any competitive patent expiration.

Though daunting, this challenge is not insurmountable. Examining product differentiation, the treatment condition and payer focus will help anticipate the impact of competitive generic entrants on brands; engaging in a thorough review of prescriber and influencer perceptions provides a better understanding of a brand's unique value proposition. And a deliberate and holistic evaluation of brands provides the insights necessary to make well-informed decisions in the face of generic competition.

About the Author

Judith Kulich is an Associate Principal with ZS Associates in San Francisco, responsible for ongoing development of ZS' forecasting capabilities along with dedicated client work. She focuses on international forecast generation, platform development and capability building in the biotech and pharmaceutical industry. Judith holds a B.S. in industrial engineering and operations research and an M.B.A. from the University of California, Berkeley.

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