Factors in the Generic ‘Ripple Effect’

Approximately 30 branded pharmaceutical products have or will come off patent between 2010 and 2012. These patent losses have implications for the branded drugs, but also for many of their competitors. These implications involve the effect of generic launch on overall market dynamics and what pharmaceutical companies can do to anticipate these effects.

Pharmaceutical companies are anxious to know the degree to which a branded competitor’s patent expiration will affect their own product. Once understood, companies must plan and make decisions based on this anticipated effect. We advocate several tools to aid in this process. Benchmarking, analogue analysis and understanding customer and influencer insight can help anticipate the effect of generic competition; weighing return with risk and investment can help companies cope with the effects. Before adopting these tools, it is important that companies understand key factors — differentiation, treatment condition and payer focus — that cause and amplify ripples across a market, and the effect that these factors are likely to have.

Differentiation

The level of product differentiation (or lack thereof) between brands and a competitor coming off patent has a profound effect on the market. Differentiation, in this context, can mean several things, including demonstrable safety or efficacy advantages, unique benefits for certain patients or a special delivery mechanism.

The level of market disruption is usually in inverse proportion to the amount of differentiation among competitors. This is illustrated vividly in the statin market, when Merck’s Zocor (simvastatin) lost patent protection in the previous decade: doctors wrote 22 million prescriptions for Zocor in 2005; by 2007, after Zocor lost patent protection, the number fell to less than 1 million.1,2

For the statin market, annual growth jumped to 9%, compared with 6% annually prior to the introduction of generic Zocor.1,2 But for Pfizer’s Lipitor, a branded competitor, sales dropped 6% in 2007, compared with growth of 4% in 2006 (Figure 1).2,3 The lack of differentiation (in the eyes of payers) between Zocor and Lipitor played a major role in the decline — about 80% of patients on Lipitor had been using formulations of comparable efficacy to Zocor; thus, there was almost immediate substitution of Lipitor with generic simvastatin.4

Greater differentiation has led to lower market shocks, even to the point where the generic affects one branded product.
**Insomnia Market**

![Graph showing new prescriptions for Ambien, Zolpidem, Ambien CR, Rozerem, and Lunesta from 1/5/07 to 7/5/09.](Image)

**Figure 2**

only. Risperdal, a Johnson & Johnson atypical antipsychotic, lost 80% of its sales almost immediately after generic introduction (the first generic of an atypical antipsychotic). Yet other antipsychotics, such as market leader Seroquel, were barely affected. Why? One reason is that atypical antipsychotics have vastly different safety and side-effect profiles that differentiate them, and lead to prescribing decisions based on individual patient conditions.

And in the case of GlaxoSmithKline’s antibacterial Augmentin (amoxicillin-clavulanate), at least one competitor’s sales continued to rise after Augmentin lost patent in 2002. Whereas Augmentin sales fell 52% in the 12 months after it lost patent protection, sales of Pfizer’s Zithromax antibiotic rose 17%. There was a good reason for this — Augmentin required two tablets per day, Zithromax only required one.

**Treatment Condition**

When generic Ambien (zolpidem) went off patent, within a fortnight its market share of nonbarbiturate sleep aids fell from 42.4% to 12.5%. Unlike Lipitor, however, even as branded Ambien’s market share fell dramatically, the market share fell moderately for Rozerem (to 0.9% of the market) and Lunesta (6.7%), and only within several years (Figure 2). Compared with atypical antipsychotics, the difference is large — insomnia is usually a far less urgent condition than psychosis, and physicians are much more likely to allow for generic substitution for a sleep aid than an antipsychotic. Markets such as oncology, which treat serious conditions and demand specific treatment protocols, are also much more likely to resist generic effects. Payers are unlikely to demand physicians change their product preferences for treating a serious illness.

**Payer Focus**

In 2008 — even after generics were introduced — statins represented nearly 13% of all Medicare drug spending, making it the largest single drug class for Medicare. Prior to Zocor going off patent, statins were considered the largest driver of increases in total prescription spending nationwide. Because they were one of the largest payer burdens prior to patent expiration, statins were a clear candidate for generic product substitution.

Compared with statins, generic entry for nonbarbiturate sleep aids had a moderate effect only on the market. Sleep aids were moderately expensive products and so, payers were less focused on keeping costs down in this market as they were for statins. Because Ambien had a huge market share, payers immediately substituted its generic on formularies. It took them several years, however, before they became savvy as a group to the potential savings regarding generics.

**Tools to Anticipate and Cope With Disruption**

**Benchmarking and Analogue Analysis**

Benchmarking and analogue analysis supplement brand manager analysis of differentiation, treatment condition and payer focus. By comparing their market to similar ones in which generics have recently been introduced, companies can get an idea of their future in which a branded competitor loses patent protection.

Take the expiring patent of Cozaar-Hyzaar, and its effect on the angiotensin receptor blocker (ARB) class of products. When evaluating this market, brand managers could have looked to the statin market for clues to help predict what would happen next. Both statins and ARBs have relatively limited differentiation and heavy payer control.

**References**

1. [www.drugs.com/top200_units_2005.htm](http://www.drugs.com/top200_units_2005.htm)
2. [www.drugs.com/top200_units_2007.htm](http://www.drugs.com/top200_units_2007.htm)
3. [www.drugs.com/top200_2006.html](http://www.drugs.com/top200_2006.html)
Most of the branded ARBs lost market share to generic Cozaar-Hyzaar. Novartis’s Diovan, for example, went from 41.5% of the market in April 2010 to 34.2% a year later. But that only told part of the story — Diovan actually saw total sales increase 1% from the second quarter of 2009 to the second quarter of 2010. A possible reason is that Diovan is the only ARB approved for three cardiovascular indications. It’s important to stress that brand managers and prognosticators should not simply assume parallel results: dynamics change rapidly, and companies must be careful to avoid stale analogues and validate analysis with additional research.

Examining Customer and Influencer Insight
In the US, payers generally favour generics to branded products; the former often replaces the latter in the first tier whereas brands are demoted to second- or third-tier status. This demonstrates that marketers need to consider the power of treatment influencers, such as payers and customers (physicians and patients).

The brand’s value proposition weighs heavily when considering how customers and influencers determine the effect of generic entry, as the value proposition often has a direct correlation to differentiation. When a brand has a unique benefit that makes it irreplaceable, customers and even payers will hesitate before substituting a generic.

Weighing Return With Risk and Investment
In markets with little differentiation, high payer focus and a non-life-threatening treatment condition, a market leader may not want to take any action when a competitor goes off patent. That might seem counterintuitive to some marketers, but taking such a viewpoint is consistent with taking into account a life cycle evaluation of alternatives.

There may be some situations in which a company is unable to stop a generic of a competing brand from wreaking havoc on the market, and it may make sense to shift sales and marketing resources elsewhere. Being able to anticipate this possibility enables executives to make optimal managerial decisions.

Patent expirations are leading to what could be a tumultuous time for branded competitors, but the market reaction to any given generic introduction is as varied as the pharmaceutical market itself. Likewise, when evaluating the effect of patent expiration on the market as a whole, disruption cannot be predicted by a single factor, nor can companies rely upon a single tool (Figure 3). Using all three tools in combination, however, can help give them insight into how the market will react — and provide guidance on what to do next.