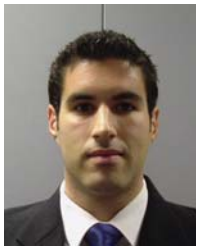
# Key Factors Affecting Brand Erosion at Patent Expiry

**While the erosion of branded sales to generics is inevitable on patent expiry, the speed and severity of erosion depends on a number of factors which – if borne in mind when developing lifecycle management strategies – can be used by manufacturers to protect their branded sales.**




## By Alistair Sinclair at Datamonitor

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**With declining returns from drug development pipelines, the preservation of branded revenues is key for pharmaceutical manufacturers. Inevitably though, once the core product patent of a pharmaceutical compound expires, generics companies will launch their own, cheaper versions. With products worth nearly $140 billion in sales coming off patent by 2016 (1) – including the US patent expiries of Pfizer's blockbusting drug Zyrtec (cetirizine) (2) and GSK's blockbusting Imigran (sumatriptan) (3) later this year – brand manufacturers can expect to face a decade of unrelenting generic competition. However, according to a new report from Datamonitor (4), the severity and speed of brand erosion can vary significantly depending on a number of factors; manufacturers can potentially use these factors to their advantage to lessen the impact of generic competition.**

It is inevitable that once the product patent of a pharmaceutical compound expires, generics companies will launch their own versions. These are usually at a discount price to the brand, which encourages switching from the branded product to the cheaper generic. This switching can be driven by mandatory regulations, by physician and pharmacist incentives, or by reducing or eliminating out-of-pocket spend for the patient. Switching from a branded product to a generic erodes the volume of branded drugs prescribed and so usually also erodes the brand's revenues. However, the severity and speed of brand erosion can vary significantly, depending on factors such as country-specific prescription, pricing and reimbursement (P&R) regulations, product formulation, success of the targeted brand and implementation of lifecycle management (LCM) strategies.

### VARIATIONS BY COUNTRY

Following the patent expiry of a drug, generic manufacturers enter the market as soon as they possibly can in order to gain first-to-market status – taking the first and usually largest bite of the cherry that is unprotected brand revenues.

In Germany, an analysis of 11 branded products showed that they faced competition from varying numbers of generic entrants after two years of generic incursion – ranging from one to more than 20 generic versions for global blockbusters, such as Merck & Co's high cholesterol therapy Zocor (simvastatin), Pfizer's antihypertensive drug Norvasc (amlodipine), and Roche/GSK's Dilatrend/Kredex (carvedilol) also for the treatment of hypertension (see Figure 1).

By comparison, in the US, although the majority (75%) of expired brands faced competition from between one and six generics companies, the two biggest-selling brands – Bayer Schering's antibiotic Cipro (ciprofloxacin) and Forest's antidepressant Cipramil (citalopram) – faced competition from 14 and 15 generics companies respectively.

One factor influencing the fewer number of generics entering the US market is the 180-day exclusivity period given to first-to-file generics manufacturers that launch a Paragraph IV challenge on a patent. This 180-day generic market exclusivity for Barr Labs' generic version of Bayer Schering's Cipro is clearly observed, with subsequent generics manufacturers prevented from entering the market until the second quarter after patent expiry.

Conversely, as Forest's Celexa (citalopram) was no longer patent-protected, with only data exclusivity

preventing generics from entering until Q4 2004, generics manufacturers were unable to gain 180-days of exclusivity. As a result, multiple generics entered the market as soon as they were approved.

Nevertheless, on average, between two and four generics generally enter the market during the first three months following a patent expiry, with additional generics manufacturers subsequently launching. Of the six major pharmaceutical markets (US, France, Germany, Italy, Spain and the UK), brands in Germany experience the greatest number of generics competitors, while those in the US and UK experience the least after two years of generic competition.

## HIGHER REVENUE BRANDS: MORE GENERIC COMPETITORS

Across the US and five EU markets, brands with high revenues generally faced a greater number of generic competitors than brands with low revenues. This is because generics companies can earn potentially greater revenues through targeting more successful brands. The situation is exemplified in Germany where, after two years of generic competition, brands generating sales of between $50 million and $100 million per quarter prior to patent expiry faced competition from 26 generics companies, while brands yielding less than $10 million experienced competition from only four generics companies.

When analysing the number of generics manufacturers per branded drug across the US and five EU markets, it becomes clear that generics companies in the US, UK and Germany are only willing to launch a drug if there is a relatively large brand revenue potential that can be eroded. In Italy, Spain and France, on the other hand, generics manufacturers launched a product even if there was only a relatively small brand revenue potential – reflecting the lower levels of generic competition that branded manufacturers experience in these countries. This is exemplified by the fact that, after two years of generic competition, there was one generic entrant for every $67 million of annual branded sales revenue in the US, $10 million in the UK and $7 million in Germany, compared with just $1.5 million for Italy, Spain and France.

Overall though, as more generics enter the market, the revenue potential for each individual generics company decreases accordingly, and the number of generics manufacturers entering the market decreases.

## REFORMULATION STRATEGIES

In general, it was found that the value of a brand – whether a blockbuster or one with revenues of less than $50 million per year – is not linked to the level of attrition it experiences after patent expiry, with both drugs expected to suffer the same degree of

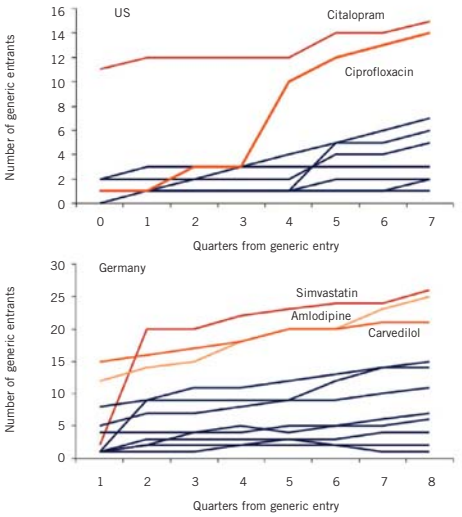


**Figure 1:** Number of generics companies entering the US and German markets following a drug patent expiry.

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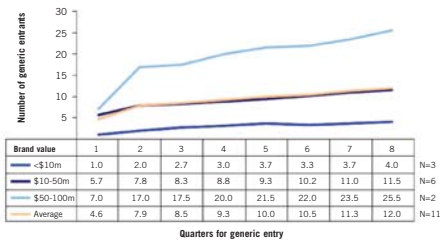
generic erosion. One characteristic which does affect sales erosion, however, is the formulation of the brand. Manufacturers of standard oral tablets experience a greater level of brand erosion than those producing alternative formulations. This is indicative of the relative ease of producing oral tablets, capsules and liquids, as well as the higher prescription rates for such formulations. This in turn leads to greater revenue potential. The majority of leading generics companies have the capacity to produce standard oral formulations, while fewer have the capability to produce – for example – injectable formulations.

Branded oral long-lasting drugs and other technologically advanced formulations generally do not experience significant erosion from standard immediate-release versions of the molecule. This demonstrates the significant value of these extended-release formulations, as well as the brand-protecting ability of such lifecycle management (LCM) strategies. It also represents a significant financial benefit to the manufacturer if it can switch patients to patent-protected formulations, as this will protect or potentially even increase total franchise revenues despite competition from generics.

The brand-protecting effect of long-lasting oral formulations is exemplified in the US by Bayer Schering's Cipro XR (extended release ciprofloxacin), and in the UK by Abbott's Klaricid XL (modified release clarithromycin). Despite the launch of generic immediate-release versions of both drugs, branded revenues of the long-lasting formulations were not affected. However, once the formulation patent covering branded, long-lasting formulations expires, or when generics companies develop and launch their own non-infringing, long-lasting formulations – which is happening more frequently – the branded drug

**Figure 2:** Average number of generic drugs entering the market following drug patent expiry in Germany, by brand value.




| Brand value | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | |
|---|---|---|---|---|---|---|---|---|---|
| <$10m | 1.0 | 2.0 | 2.7 | 3.0 | 3.7 | 3.3 | 3.7 | 4.0 | N=3 |
| $10-50m | 5.7 | 7.8 | 8.3 | 8.8 | 9.3 | 10.2 | 11.0 | 11.5 | N=6 |
| $50-100m | 7.0 | 17.0 | 17.5 | 20.0 | 21.5 | 22.0 | 23.5 | 25.5 | N=2 |
| Average | 4.6 | 7.9 | 8.5 | 9.3 | 10.0 | 10.5 | 11.3 | 12.0 | N=11 |

Quarters for generic entry

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will inevitably experience generic erosion. Examples of this include an 80% decline in volume and value for Abbott's Biaxin XL (clarithromycin) in the US after only two quarters following patent expiry, and an 18% fall in sales of Cipro XR in the first year of generic competition. In the UK, sales of Astellas's urological drug Flomaxtra XL (tamsulosin) also declined by 16% in volume and value during the first three quarters of generic competition.

As observed, reformulation strategies can be implemented to either protect or increase the sales of a branded franchise. However, for this strategy to be successful, manufacturers must ensure that the reformulated product is competitively differentiated from the original branded product in terms of side effect profile, dosing, compliance issues and – ideally – efficacy, although this is tough to achieve. Also, the reformulation must satisfy a viable unmet market need. If patients, physicians and payers do not see the added value of a once-daily, once-weekly or combination therapy, the cost-saving advantages of the generic (once available) will likely prevail, impacting overall sales of the branded franchise. Thus, while reformulation strategies may be effective at staving off generic competition in the short term, ultimately manufacturers need to develop truly novel drugs in order to maintain franchise and portfolio revenues in the face of generic competition.

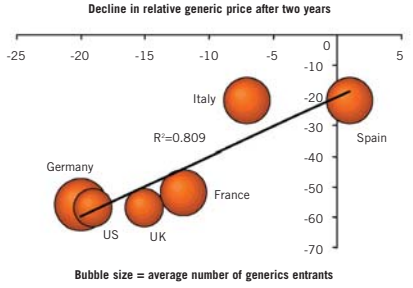
## PRICING OF GENERIC PRODUCTS

Generics manufacturers usually price their products at a discount to the brand, which encourages switching from the branded product to the cheaper generic. However, as more generics enter the market, in order to remain competitive, generics manufacturers in the free pricing markets of the US and UK, as well in the German reference pricing market, lower their prices further – resulting in the declining cost of generics over time.

However, in France, Italy and Spain, according to mandatory regulations, generics must enter the market at a significant discount to existing brands. Subsequent generic entrants are therefore unlikely to willingly drop the price of their products, given the already tight profit margin and this results in the generic price remaining flat.

Therefore, in the cost-conscious US, UK and German markets, patients, physicians and payers generally favour the price incentive offered by low-cost generics, while generic incursion is lower in the brand-loyal southern European markets. There is a strong correlation ($R^2$ = 0.809) between the decline in generic drug prices and the level of erosion of branded drugs after two years of generic incursion.

**Figure 3:** There is a strong correlation between declining generic drug prices and the level of brand erosion after two years of generic incursion.

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## CONCLUSION

While the erosion of branded sales to generics is inevitable on patent expiry, the speed and severity of erosion depends on a number of factors. In the US, UK and Germany, products with larger branded sales attract more generic entrants, resulting in greater brand erosion. Being free pricing markets also results in more generic entrants and hence lower generic prices. In markets such as France, Italy and Spain, the converse is true: the number of generic entrants is not proportionate to revenues of the branded drug, and neither brand erosion nor the price of generic drugs is proportionate to the number of generic entrants.

One factor that does affect sales erosion, however, is the formulation of the brand, with technologically advanced formulations generally not experiencing significant erosion from standard immediate-release versions of the molecules – at least until the patent covering the advanced formulation expires.

By bearing these factors in mind when developing LCM strategies, manufacturers can use them to their advantage to defend their branded sales.

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