Business Development & Licensing Journal

For the Pharmaceutical Licensing Groups

The Future for Generics Business Models
Factors for Success in the OTC Market
Non-Patent Exclusivities in Major Markets
Faster Market Access for Precision & More Personalised Medicines
Generics - Is the Commodity Business Model Sustainable?

Recent diversification behaviour amongst generic companies raises questions as to whether they believe commodity generics have a future. Whilst strong drivers for generics still apply in both developed and emerging countries, diversification strategies such as entering the speciality medicine market, developing biosimilars and breaking into the OTC sector, are increasingly common.

By Guy Clark, Chief Strategy Officer, AMCo

Many of the pharmaceutical companies that have become major players in the generics industry have, in recent years, diversified away from low-price, high-volume “commodity” generics by acquiring companies with branded products, and supplemented the pipeline by developing or licensing-in innovative medicines.

For example, Teva, although it is known as one of the leading generic companies in the world, has had Copaxone (glatiramer acetate injection for relapsing multiple sclerosis), a speciality medicine, in its portfolio for more than a decade. Whereas in 2001 speciality product sales at Teva were less than 20% of the total of US$2bn, in 2013 they were 50% of $20bn. This reflects a company strategy to acquire speciality product companies such as Cephalon in 2011, with its range of branded speciality medicines including Provigil (modafinil), Nuvigil (armodafonil), Fentora and Actiq (fentanyl) and Treanda (bendamustine). Similarly, in 2013, Actavis acquired Warner Chilcott, a company specialising in women’s health branded products, and then in 2014 it also acquired the US company Forest for £25bn.

AMCo is another case in point. It was formed by the merger of two companies owned by the private equity company, Cinven. In August 2012 Cinven purchased Mercury, a company operating in the field of off-patent medicines, for £465m. In October 2012, Cinven also acquired Amdipharm, another off-patent branded pharmaceutical company, for £367m. The two companies were merged in January 2013 and AMCo is now pursuing a strategy both to acquire more marketed branded medicines and establish specialist-led sales forces in countries around the world.

The diversification strategies of generic companies raise the question whether these companies believe the “commodity” generic model is sustainable in the future.

Drivers for Generic Medicines

Several recent presentations provide some clues. Alan Sheppard, Principal, Thought Leadership, Global Generics, at IMS Health, explains that the driver of generic medicines in developed markets is the containment of the drugs bill by either regulated or market-force reductions in product prices following loss of exclusivity. Nevertheless in Europe there are still marked differences between countries. According to IMS data, the volume share of generics in the prescription-bound, unprotected, retail market is more than 80% in Germany but less than 50% in Italy, Belgium and Austria. Apart from these latter countries where generics may increase market share, there is little opportunity for significant sales growth of generics in Europe over the next five years as the number of blockbuster products coming off patent reduces and governments and competition continue to drive down prices.

In the emerging markets, the main driver of generics is to ensure the provision of affordable medicines for the local population.
Western generic companies are buying local companies in emerging countries, with their knowledgeable local management teams, in their quest to become the lowest-cost producer for particular types of generic products.

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The Need for Diversification

Another diversification model adopted by some generic companies is to develop biosimilars. For example, Actavis describes biosimilars as “one of the pillars of Actavis’ strategy to drive long-term growth”. To this end it has established collaborations with Amgen in 2011 and Synthon in 2012 covering Herceptin, Avastin, Rituxan and Erbitux. Mylan was even earlier signing a deal with the Indian company Biocon to develop biosimilars in 2009, and Sandoz and Teva have had success launching new biosimilars in Europe. Due to the cost and complexity of product development, biosimilars is not an area where the little guys can easily compete, and so this is very much a “playground for the rich”.

Yet another diversification trend is to enter the OTC market. This is a popular strategy with many companies that are tired of having their selling prices regulated, mostly downwards, and having to deal with declining margins. In August 2013 Stada acquired the UK OTC company, Thornton and Ross (T&R) for $345m. T&R has the second ranked cough brand and is the market leader in head lice products in the UK. Since then Stada has acquired the Russian Aqualor brand for treatment of sinusitis and sore throat for around $180m and, in June 2014, it acquired the Claire Fisher natural cosmetics brand in Germany.

A further perspective on the future of generic companies is provided by Claudio Albrecht, the former CEO of Actavis and now CEO of Albrecht and Prock. Claudio’s point is that “generics should be essentially similar but nowadays the industry wants to be essentially different”.

The pipeline of the generics industry is patent expired products. In 2013, ten of the top 15 products ranked by sales were biologicals and other “hard-to-make” products such as asthma drugs in inhalers.
Table 1 shows the top 15 products by sales according to PMLIVE (April 2014). This trend is likely to accelerate. As such the number of top-selling, oral, small-molecule products reaching patent expiry will diminish and that is one reason why generic companies either need to develop their businesses in emerging markets, or need to diversify.

Claudio describes the emerging market hypothesis as “hype” because of the number of challenges in these markets, such as pricing, protection of local industry, compliance and political and economic volatility. As a result, he believes the traditional approach to generics will not work. His view is that generic companies need to diversify into biosimilars or large speciality brands, rather than focus on emerging markets.

**Generics Pricing and Micro-Economics**

The argument that generic companies need to diversify to grow and to remain profitable brings us back to the question, is the commodity business sustainable? Micro-economic theory provides some pointers. In the developed countries, including the US and many countries of the EU, a high proportion of prescription-bound, unprotected sales volume is from generic products (e.g. over 80% in Germany). The generic products with the same active ingredient have to be identical and as such can be considered “commodities”, although they may be sold under a different trademark. The demand for long-established pharmaceutical products where patients have been stabilised on a particular drug is mostly price inelastic. As a result, micro-economic theory explains that in countries where generic prices are set by market forces, for example in the UK, as

<table>
<thead>
<tr>
<th>Rank</th>
<th>Product</th>
<th>2013 Sales $bn</th>
<th>Growth %</th>
<th>Molecule</th>
<th>Patent Expiry*</th>
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<tr>
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<td>4</td>
<td>Segetide / Advair</td>
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<td>5</td>
<td>Small molecule inhaled</td>
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<tr>
<td>5</td>
<td>Abilify</td>
<td>8.0</td>
<td>-3</td>
<td>Small molecule oral</td>
<td>2015</td>
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<tr>
<td>6</td>
<td>Mabthera / Rituxan</td>
<td>7.4</td>
<td>4</td>
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<td>2013</td>
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<td>8</td>
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<tr>
<td>10</td>
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<td>7</td>
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</table>

Table 1: Top 15 products by sales in 2013

* Patent expiry only shown for oral small molecules.

**Figure 1: The effect of inelastic demand on generic pricing**

Inelastic Demand
Rational behaviour

Price
Quantity

COGs

D

S1
S2
S3
S4

P'
P
P'
q'
q'
the volume of supply increases, the price falls by a greater percentage. This soon leads to a situation where some suppliers incur losses as the price falls below the supplier's cost of goods.

This is what has happened in the UK with a number of generic products as illustrated in Figure 1. Two decades ago, this market was attractive for new entrants, and there were several outward supply shifts (i.e. an increased number of suppliers, moving the supply curve to the right), ranging from UK start-ups and other European players and then from further afield, in particular from India.

This increase in supply quantity (S3) led to a market where goods were sometimes being sold at a loss (equilibrium point p3-q3). Since then, many suppliers have left the market and other companies have consolidated, thus enabling the price, linked to a basket of supplier prices, to rise to more rational levels for products in general (move from S3 to S4). Micro-economic theory teachers often make an assumption that buyers are rational, whereas practice often shows differently. There have been periods where buying has clearly not been rational in the UK, and other developed markets.

In other countries where generic prices are determined by government regulation, for example, where each supplier has to launch at a lower price than the last generic, the effect is to deter third or fourth entrants unless they are a lower-cost producer then the earlier entrants. However, given the time it takes for products to get regulatory approval, it can still lead to a position where multiple players co-exist and additional incentives are used to sell competing products, such as bonus stocks.

The conclusion is that whether generic product prices are set by competitive forces or by government, the prospects for the “commodity” generics in developed countries are bleak. Volume growth is generally stable and price is constantly under pressure, and sometimes at a 90% discount or more within days of loss of exclusivity. The result, shown in Table 2, has been companies exiting the market, consolidation of suppliers and price rationalisation.

The generic industry is adapting to the new “commodity” environment in the developed countries. One approach has been M&A to offset declining margins. By M&A the acquiring companies seek to increase market share and reduce costs by economies of scale and by moving manufacture to low-cost countries. The top four generic companies that have been active in M&A – Teva, Sandoz, Actavis and Mylan – now have sales between $5bn and $10bn, significantly higher than the followers such as Aspen, Stada and Dr Reddys, all with sales of less than $3bn. There are still a large number of small generic companies so there is plenty of scope for further M&A.

The second approach to dealing with the “commodity” environment has been for smaller companies to focus on niche generics. Here the barriers to entry are higher, the sales levels are too small for the larger companies, and the niche players with specialised generics can build relationships with the relevant payers.

**Conclusions**

So in answer to the question “Is the Commodity Business Model Sustainable?” ….. “Yes, but not in the same format”. The new format will be further consolidation of larger companies and survival of smaller companies by focusing on niche generics. This will provide opportunities for creative companies that can apply flexible manufacturing and commercial strategies. Such companies can be adaptable across multiple markets, without trying to apply a one-size-fits-all approach, by embracing the strength of local knowledge along with supporting central resources as appropriate.