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by Stuart Carroll

As economic forecasts become increasingly gloomy, Stuart Carroll, health economist and policy analyst, reflects on how drug companies are faring and what strategies they are adopting to protect their futures in an age when the profitability of the blockbuster drug is in sharp decline.

One of the major issues confronting the pharmaceutical industry is the challenge to, and shifting focus of, the traditional business model. It is widely considered that the conventional strategy of pursuing blockbuster medicines (products achieving peak sales of £1bn or more) is in sharp decline, as patents expire on major products and the output of product pipelines diminishes.

Recently, Pfizer announced the buy-out of Wyeth for £68bn — a merger designed in part to buttress a sparse pipeline and the impending loss of revenue from its major selling statin Lipitor, which loses patent protection from 2011. The situation is compounded by the stark fact that industry is investing twice as much in research and development compared with 10 years ago, but is only producing two-fifths of the resultant medicines.

Even when promising products reach the market, few become blockbusters and generate a sufficient level of profitability relative to investment.

The decline of the blockbuster drug presents a serious financial challenge to the current business model. It also calls into question the strategic focus of an industry undergoing fundamental change. In February 2007, Jean-Pierre Garnier, then of GlaxoSmithKline, stated of the blockbuster model:

“This is a business model where you are guaranteed to lose your entire book of business every 10 to 12 years. The first reflex of companies is to merge and that buys them a little time to deal with patent expiries,
but fundamental changes will ultimately be necessary.”

This has been reaffirmed by his successor at GSK, Andrew Witty, who recently remarked that the blockbuster model was analogous to “finding a needle in a haystack right when you need it”, and left companies open to “sudden torpedoes” in the form of lawsuits from generics firms or regulatory crackdowns such as that levelled against Avandia, GSK’s diabetes drug.

Adding further credence to the view that the scene is shifting, Daniel Vasella of Novartis commented in 2005: “In the medium term, 50 per cent of the market will be generics.” In financial terms, it has been estimated that in 2005 total global pharmaceuticals sales were $533bn, but $104bn of this will be lost to generics medicines between 2005 and 2010.

IMS Health forecasts that $130bn of prescription drugs will come off patent by 2012, leaving a financial vacuum for those companies where markets will be flooded with “me too” alternatives.

The current growth of generics is outperforming the rate of growth in branded drugs, with 2007 sales reaching $72bn. Teva, the largest generics firm, has a revenue target of $20bn for 2012 alone.

With the blockbuster business model facing severe difficulties, the expansion of generics has the potential to grow further as the focus for product development essentially shifts to clinical margins rather than scientific absolutes. This, in turn, increases the challenges and difficulties confronting the industry.

### Spreading risk

One method of spreading risk and protecting market share is for companies to acquire generics operations. Examples include Novartis owning an in-house generics arm in Sandoz, and Sanofi-Aventis making takeover bids for the generics company Zentiva.

In July 2008, Andrew Witty announced that GSK would enter the generics business by striking a deal with the South African company Aspen. This is seen as an attempt to protect the business from financial turbulence.

Wall Street experts have suggested that pharmaceutical companies are not necessarily buying into generics to stem the drip of lost profits to off-patent medicines, but as a way of accessing high-growth markets.

Vijay Karwal, managing director of consumer, retail and healthcare at RBS Global Banking and Markets, states: “The most effective way of accessing those markets or building brand awareness, building market share is through branded generic products because … the economic wherewithal of consumers in those markets is not yet there in terms of their ability to buy high priced, patent-protected products.

“Many of these markets will not have health insurance; they will be cash-pay. And, certainly, large parts of the population at this stage will be buyers of generic products.” In other words, these new populous markets are likely to look to purchase generic products due to the more attractive price.

Thus, the benefit of these acquisitions is contingent upon local market factors. In Japan, for example, which is less liberalised and competitive relative to other established markets, it is estimated that the healthcare system pays $30bn for off-patent medicines, which would cost just $3bn in the US.

As a consequence of these figures, pharmaceutical firms are not primarily interested in making generic
acquisitions to access the US market, but to gain a foothold in markets such as Japan and the emerging markets of the E7 (China, India, Brazil, Russia, Indonesia, Mexico and Turkey).

However, in spite of this, some liberalised markets, such as the UK and US, are becoming increasingly competitive for generics firms as governments look to increase cost-effectiveness, thereby fostering the need for economies of scale.

It may, therefore, be that such acquisitions are not just beneficial to the pharmaceutical industry but also to individual generics companies. In many cases, this, in turn, can see some generics firms welcome opportunities to merge with pharmaceutical companies.

Malvinder Singh, of Ranbaxy, recently suggested that the alliance with Japan’s Daiichi Sankyo will be beneficial not only in terms of cheap manufacturing capacity, but also in facilitating a more expansive customer base. Nonetheless, many generics firms may view mergers as difficult and cumbersome due to differences in business models.

Unless pharmaceutical companies are able to resolve the issues undermining the sustainability of the blockbuster model, or decide to invest aggressively in an increasingly fluid and competitive generics market, the likely outcome is significant financial loss at a time of ongoing economic uncertainty.

Sustainable and substantive resolutions for the former are unlikely, not least given the relative emptiness of product pipelines and the decreasing returns to scale associated with scientific advance. This means consolidated investment in the generics market could confer potential strategic advantages moving forward.

While each company has its own structure, strategy and emphasis, another method of meeting the challenges associated with the decline of the blockbuster model and rise of generics is to diversify business plans. A number of firms have developed their businesses as “healthcare companies” as opposed to pure pharmaceutical companies.

Perhaps the biggest of these is Johnson & Johnson (J&J). Alongside pharmaceutical products, J&J produces a range of products, including bandages, baby products, shampoos, dental products, face washes, contact lenses, and the Neutrogena skin product range.

Abbott is one of the fastest growing companies in the UK and Europe. In September 2008 the Abbott board of directors declared a quarterly common dividend of 36 cents per share, marking the 339th consecutive quarterly dividend to be paid by Abbott since 1924.

The company has had the second highest average annual return of all originally listed companies in the Standard and Poor’s 500, and in June 2008 featured in the “Fortune 40: best stocks to retire on” list, with earnings in the previous quarter surging 35 per cent and a growth projection of 11 per cent.

Abbott represents more of a healthcare company than a pure pharmaceutical firm. In the UK, its four main areas of business encompass pharmaceuticals, medical devices, diagnostics and nutritional products.

This diversity has enabled Abbott to produce major selling pharmaceutical products, such as Humira (a fully human anti-TNF medicine) and Kaletra (a protease inhibitor for HIV), while also being able to capitalise on the shift towards personalised medicines through its diagnostics work.

Jeff Stewart, UK general manager, recently stated: “Having the ability to offer both molecular diagnostics and a novel therapeutic to our customers can be a real strength of our business model.”
Abbott is also known for nutritional products such as Ensure, Enlive! and Jevity. Abbott’s vascular department recently attained US Food and Drug Administration approval for a drug-eluting stent called Xience V, and its diabetes department last year received European CE mark approval for FreeStyle Navigator, its continuous glucose monitoring system.

Diversity

It is through this diversity of business operations that consistent and sustainable market advances have been achieved. As Jeff Stewart recently commented: “Diversity is our ethos. It’s what we look for when we recruit and develop our staff. Our portfolio and pipeline is diverse. It’s integral to our business model and to maintaining and expanding our competitive edge.”

Moving into the future, the progressive application of biotechnology, which seeks to maximise information about patient genetics and proteomics to tailor patient-specific medicines, is a growing trend.

Although the Association of the British Pharmaceutical Industry (ABPI) has acknowledged through the Ministerial Industry Strategy Group (MISG) that the “scientific revolution” involving gene therapies and the human genome has been slower than expected, it has noted that a “revolution” of this kind should be anticipated.

New medicines, genomically targeted to smaller patient cohorts, are likely to produce greater efficacy and fewer side effects. More pertinently, such medicines almost by definition are likely to produce better clinical outcomes against which the blockbuster model will struggle to deliver.

As advances in biotechnology could soon enable companies to produce a greater number of products for a larger number of genetic subgroups, and such medicines would be genetically tailored, clinical efficacy and effectiveness is likely to be higher. That, in turn, could enable greater patient compliance and higher reimbursement potential from healthcare payers.

In other words, many more products across a range of conditions could be developed that treat a smaller population of patients than the blockbuster medicine, but which are more clinically tailored and efficacious for a particular patient cohort.

The cumulative profit generated could be as large as that of a blockbuster medicine, but as biologic treatments can be more difficult to manufacture these products might be less exposed to patent expiries.

Many pharmaceutical companies have responded to this possibility by investing in biotech opportunities. These include Novartis, Wyeth, Abbott, BMS and Roche, but also other big pharmaceutical companies more generally. This trend has been triggered not simply by future potential and the logic of patient-specific medicines, but by the prevailing force of the economic bottom line.

The biotech industry is expanding far more rapidly than the pharmaceutical industry, with US biotech sales growing by 20 per cent to $40.3bn in 2006, while pharmaceuticals sales grew by a relatively modest 8 per cent to $275bn, according to IMS Health.

The pharmaceutical industry is, therefore, looking to invest in a current growth trend, which is likely to increase further as the clinical imperative shifts to a more patient-specific focus.

It is not just the pharmaceutical industry that is investing in genetically tailored medicine research and
The European Commission recently gave the French bank OSEO the go-ahead to make available €89.5m in grants and repayable loans to a French personalised medicine R&D initiative called ADNA. It is envisioned that this could have “major implications” for a range of diseases and illnesses.

A further change that is set to transform future pharmaceutical activities and operations irrevocably is the increased emphasis on preventive rather than curative healthcare. As the population ages and demand on healthcare budgets increases, pre-empting rather than reacting to illness and disease constitutes the prevailing aspirational mission statement driving the direction of modern healthcare policy. This is an area of focus industry has thus far largely avoided.

The reason for the shift to prevention is clear. The population of the UK is ageing and there is a greater risk of numerous conditions and disease states increasing in prevalence. If these can be prevented, or mitigated by more rapid and effective diagnosis, the savings to the NHS budget could be substantial. For example, it has been reported that the cost to the NHS from diabetes stands at £1m per day, and this figure is expected to grow.

Heart disease has been estimated by the Health Economics Research Centre at Oxford University to cost the UK economy £29bn per year. However, it is not just the Department of Health that would benefit from preventive medicines.

The Department for Work and Pensions would also welcome preventive medicines or novel pharmaceutical products that would reduce the number of people claiming incapacity benefit — a figure that currently stands at 2.6 million people — and that would help people remain in work.

It is therefore increasingly likely that payers will confer a greater reward for diagnostic devices, vaccinations and other medicinal products that offer preventive capabilities. Future governments are likely to change pricing and reimbursement policy to reward the production of those products that pre-emptively offset reactive treatment costs falling on the NHS.

This has been echoed in a recent report by PricewaterhouseCoopers: “Without such a change of strategy, no country will be able to meet the healthcare needs of its inhabitants by 2020.”

Conclusions

The blockbuster medicine will always exist because science — either by chance or design — will always throw up medicines that appear to be a panacea for a given condition at a given time. What is less certain is whether the frequency of blockbuster medicines seen in the past will continue in the future.

Given that each company has its own organisational structures and business models, there are no one-size-fits-all solutions to combat the prevailing challenges. Moreover, the fundamental nature of these changes necessarily requires tailor-made responses to individual circumstances. A case-by-case approach for each company is therefore important.

Some general considerations and rules of thumb are likely to define a wider industry strategy. Some companies may look to invest in acquisitions of generic companies to offset lost profits from patent expiries and to gain access to lucrative emerging markets. Some large companies may opt for mergers with other firms.

Other companies may seek to diversify their product portfolios to foster a more flexible and broad-ranging
business model. A blend of these options is being sought by a number of companies.

One thing that seems certain is the direction of future healthcare. Personalised medicine based on patient genomes, combined with the application of biotechnology, is set to become prevalent and important. It is clear that companies will need to judiciously plan for this eventuality to provide opportunities for strategic advantage moving forward.
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