Is the biotech model the future for pharmaceuticals?

Mixed response to UK’s patent box proposals

How to occupy the valuation high ground

The secrets of a successful coalition
An alternative future for the pharmaceutical industry

The past 25 years has witnessed an unparalleled consolidation of the pharmaceutical industry, leading some to predict a fate similar to the agchem industry, where six companies currently control 75% of the global market. Certainly there are some parallels: increasing regulatory burdens resulting in escalating costs of new product introductions; price sensitivity in the customer base; and both slower and lower returns on investment in biotechnologies, to name but three. But we would like to project an alternative future, characterised by extensive deconstruction to produce a diversity of strategically independent participants along an extended value chain. There will be a split between innovators, service providers and marketers, representing a wholesale adoption of the biotech model.

In the recent past there have been several distinct trends of pharmaceutical industry strategy, as shown below.

**Organic growth**

The modern pharmaceutical industry evolved from the growth of national family-owned businesses that built international franchises in their given therapeutic fields. This was arguably the first Golden Age of the industry, and was massively boosted during the antibiotic era, which started in the 1950s, the cardiovascular era of the 1960s and the anti-ulcer/asthma era of the 1970s and 80s.

**Diversification**

Throughout the 1980s, research-based ethical companies such as Beecham, Glaxo and Roche diversified, adding diagnostics, consumer health, veterinary health, generic pharmaceuticals and even fine chemicals interests. This produced mirror images of those diversified companies that had evolved from a purely chemical industry base, such as Hoechst, BASF and Ciba-Geigy. Simultaneously, companies such as ICI and Stuart built multiple, parallel sales forces to maximise franchise power in an era when detailing – and other approaches to influence prescribing practice – provided a healthy return on investment.

**Back to basics**

Starting at the beginning of the 1990s, there was a move back to pure-play pharma, led by Glaxo, involving the divestment of veterinary medicines, diagnostics and other ‘non-core’ interests. The alternative strategy of the day was to create pure ‘life science’ entities such as Zeneca (demerged from ICI) and Aventis – the life sciences vehicle formed following the merger of Hoechst and Rhône-Poulenc, both of which had been the product of multiple mergers.

**Niche plays**

In parallel with the focus on life sciences, many companies explored approaches to defend and extend their therapeutic franchises. A key strategy involved bolt-on acquisitions, often of activities that had been divested in the past, such as drug delivery, injectables and generics. For a brief period, Rx-to-OTC switching was viewed as a franchise saviour, although it became clear that the dynamics of a consumer product business were radically different from the traditional pharma space. In addition,
national and regional players were acquired to fill gaps in the globalisation jigsaw.

**Managed Care**
The mid-1990s saw mergers with pharmacy benefit managers to create ‘integrated healthcare organisations’. This trend, ultimately to be revealed as an expensive sideshow, was initiated by Merck’s acquisition of Medco, hailed at the time as a game changer. This was followed by the acquisition by SmithKline Beecham of Diversified Pharmaceutical Services, and by Eli Lilly of PCS Health Systems. These were reversed after the collapse of the Clinton healthcare plan.

**Mega-merger**
Although mergers and acquisitions (M&A) had been a feature of the pharmaceutical industry since its inception, 1995 ushered in the first wave of merger mania, triggered by Glaxo’s dramatic acquisition of Wellcome. During the ensuing five years, the pace and scale of deal-making accelerated, culminating with Glaxo-Wellcome’s merger with SmithKline Beecham (see figure 1).

**Increasing pressures**
For most of its history the pharma industry’s key driver has been new products dependent on innovation and up to the 1990s this reliably underpinned double-digit growth and profitability. The strategies described above were responses to increasing pressures as research and development (R&D) productivity declined, patent cliffs loomed and healthcare cost-containment escalated.

We are in a second wave of mega-merger, which has seen the combination of Merck/Schering Plough, Roche/Genentech, Pfizer/Wyeth and Sanofi-Aventis/Genzyme over the past three years. Industry giants have found that R&D has been unable to support sales forces, and these have been significantly downsized. However, as noted in Burrill & Company’s recent report, Biotech 2011 – Life Sciences: Looking Back to See Ahead, these aggressive M&A strategies do not seem to have paid off, given the spectacular US$1 trillion loss in value by some of the industry’s most active acquirers over the past decade.

Franchise areas have evolved unpredictably. Anti-infectives have gone from boom to bust while vaccines and (companion) diagnostics have gone the other way. Oncology was found to be blockbuster-capable after all, while cardiovascular faces partial saturation in more than moderately satisfied markets. New areas have emerged including antivirals, obesity, neurodegeneration and lifestyle drugs. Some areas have been effectively forgotten, though given the cyclical industry patterns, some are coming back into focus, such as antimalarials and selected anti-infectives.

Technology continues to promise new products, despite unreliable delivery. Following the breakthrough success of Herceptin, monoclonal antibodies gained respectability and now biologics such as antibodies, Ab fragments and siRNA are central to the R&D strategy of almost every innovative pharma company. Tomorrow’s great white hope may be personalised, or at least stratified, medicine, offering the prospect of better matching of therapy to patient and more efficient, targeted clinical trials – at the expense of deliberately smaller market opportunities.

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When times got tough in the past for the multinationals, it was possible to strip costs by sweeping away entire levels of management. In the face of today's pressures, headcount reductions have certainly accelerated but no one imagines that cost cutting alone can solve tomorrow's problems. Likewise, the internal R&D engine has proven severely underpowered, unable to accelerate the majors out of the morass. Instead, business development (now fully established as a profession) and corporate venturing have taken centre stage. Accordingly, portfolios are being vigorously reshaped through a combination of product/company acquisition, licensing and partnering on the one hand, and project terminations and divestments on the other.

We're all biotech now

The new perceived wisdom is ‘let’s all be like biotech’. Applying the model to big pharma has already shifted pipelines toward 50% in-house molecules and 50% externally sourced molecules. This trend is not confined to big pharma – medium-sized companies have announced strategic adjustments. Lundbeck is eliminating approximately 50 positions in research to be offset by a greater emphasis on external partnerships in its areas of specialisation.

Pharmaceutical companies have also been busy shedding non-core assets and functions to service providers, exemplified recently by Sanofi Aventis’s disposal of two CMC sites to Covance in September 2010, in a deal reported to be worth up to US$2.2 billion in revenues over the next ten years. Outsourcing to an ever-growing cadre of contract service providers in low-cost centres has been accelerating and shows no sign of abatement. Headquarters allocates resources within a global capital market, shifting funds to activities/functions that add the greatest value. If this requires a function to be carried out by an external party, so be it. The philosophy is based on a belief that anything that introduces competitive pressures will help drive performance. The model has arguably been successful in the automotive sector, where car manufacturers are really now just assemblers; parts manufacturing is outsourced through sophisticated just-in-time procurement networks and car sales are outsourced through dealer networks.

Move away from bigger is better

We are witnessing renewed questioning of the ‘bigger is better’ strategy. During the analyst call following its acquisition of King Pharmaceuticals, Pfizer’s Chief Financial Officer was asked whether the corporation would be worth more split into several parts. Tellingly, the response was that Pfizer has “no preconceived notion” about its future, only that the company will be managed “from a total shareholder return perspective”.

If the major pharma players are no longer the one stop FIPCO shop, they are transforming themselves into a series of smaller enterprises. Where is this heading? In the first instance, big pharma could shed all in-house research, restructuring into three types of company: research and early development companies (earlycos), late stage development, marketing and sales companies (latecos) and functional service providers (FSPs), which undertake preclinical development, pharmaceutics, process development/manufacturing and so on.

For each earlyco or lateco, deciding what to outsource becomes a key strategic parameter. Market dynamics and multiple rounds of deal-making could reshape and further fragment the industry landscape into pure-play ventures. At that point we will have a full buy-in to the biotech model. Gone is the security blanket of knowing if the product goes down the company does not go with it. Instead, we have that key evolutionary tool – survival of the fittest.