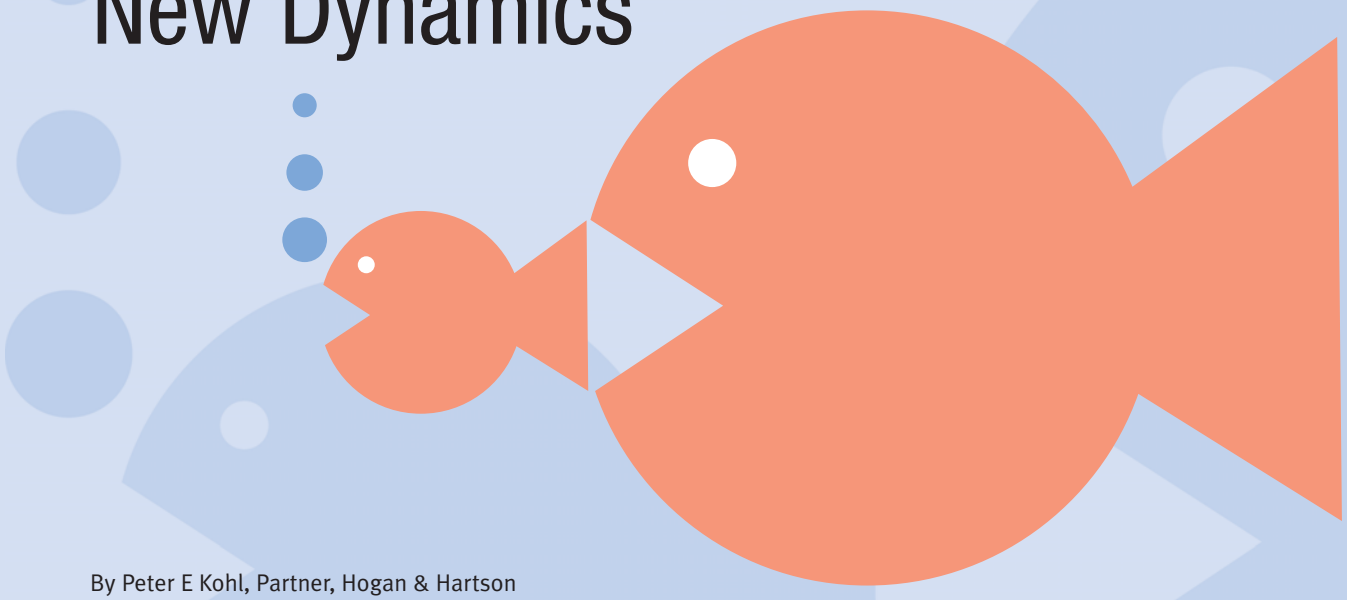
Pharmaceutical M&A: New Dynamics



By Peter E Kohl, Partner, Hogan & Hartson

The pharmaceutical industry has experienced a huge wave of mergers and acquisitions activity in the past several years. The industry has become increasingly concentrated – in 1987, the 10 largest companies represented approximately 12 percent of worldwide sales, whereas in 2002 the 10 largest firms accounted for almost 50 percent of sales. Much of this concentration is a result of mergers.

During this period, companies have combined to create global giants. Astra and Zeneca merged, Glaxo Wellcome joined with SmithKline Beecham, Pfizer acquired both Warner-Lambert and Pharmacia and, most recently Sanofi-Synthelabo (which was a product of a prior merger of Sanofi and Synthelabo) combined with Aventis (which in turn had been created through the combination of Hoechst and Rhone Poulenc). The stakes have been significant, such as the US$87 billion value of the Pfizer/Warner-Lambert merger and the US$65 billion Sanofi/Aventis combination. This trend towards consolidation has been driven by several desires: to achieve enhanced economies of scale, to acquire new drugs to restore a declining pipeline of products, to expand into new geographic and therapeutic markets and to lower costs by reducing excess capacities.

Having enjoyed enormous success and profitability over the past 20 years, however, pharmaceutical companies now face several significant threats: the lack of productivity in their research and development activities, the expiration of patent protection for many of their existing blockbuster drugs, intense competition from generic drug producers and other branded drugs and a more demanding market that threatens to drive down revenues. In addition, technological developments in the biotech and genomics sectors may revolutionize the way drugs are developed and targeted. What role will M&A activities play as companies try to address these factors?

Uncertain times

Research productivity

One study has reported that the leading pharmaceutical companies spent approximately US$35 billion in R&D in 2001, almost twice the amount that they spent in 1997 and triple the amount spent in 1992. Despite this significant increase in R&D spending, fewer new molecular entities (NMEs) have been developed. For example, in 2001 the FDA approved 24 NMEs, which was less than in any of the prior six years. The development of new drugs using traditional chemical-based technologies appears to be becoming more difficult and expensive. In part, this is a consequence of the past success of pharmaceutical firms to commercialize a large number of drugs that had been under development during the past few decades, which has emptied the pipeline and compelled the industry to embark on a broader search for novel drugs.

Costs for developing and commercializing new drugs continue to increase. On average, it takes over 10 years, at a cost of US$800 million or more, to develop and commercialize a new drug. Additionally, the last few years have seen the emergence of new technologies that may become instrumental in the discovery of new drug targets – including bioinformatics, new screening techniques for genomics and automation processes. The industry excitedly hopes that these

new technologies will significantly advance our ability to identify new targets and, consequently, expand the range of new drugs that may be developed. However, in the near-term it is likely that pharmaceutical and biotech companies will need to increase their R&D expenditures to investigate and utilize these new technologies, with uncertain future results.

Patent expiration and generic products

At the same time, pharmaceutical firms' revenues are at risk due to the expiration of patents on major 'blockbuster' drugs. One study has estimated that, for the period between 2002 and 2007, US patents will have expired on 35 drugs representing approximately US$73 billion in revenues. When a patent expires, revenues generally decrease precipitously due to sales from competing generic products, which can be sold at lower prices. Sales for Prozac, for example, fell by approximately 22 percent in the first year alone after it came off patent. The lack of revenues stemming from drugs coming off patents can lead to overcapacity in pharmaceutical companies' production, marketing and sales operations unless new drugs can be developed or acquired to fill the pipeline.

Demanding market

Of significant importance are the effects that managed care (health insurance providers) and governmental bodies are having on the pharmaceutical industry: increasing pressure to cap or reduce the price of existing branded drugs and imposing cost reimbursement policies that may adversely affect the successful commercialization of new drugs. The US, the single largest market for branded blockbuster drugs, historically has provided the least restricted pricing regime. Now, however, pharmaceutical companies are facing increasing efforts by US state and local governments to encourage the re-importation of drugs from Canada at cheaper prices, prompting increased price competition for branded drugs. At the same time, powerful managed care organizations in the US are increasingly tightening their policies for reimbursement of prescription drugs. Managed care organizations are negotiating price discounts for established drugs and creating financial incentives (through the use of tiered reimbursement categories) that favor generic and existing branded drugs over new branded drugs unless the new branded drugs are measurably better than the alternatives.

In 1990, the top 10 pharmaceutical companies made up only 28 percent of the global market. Since that time the proportion is over 45 percent and is still moving. Since 1998 alone, market share of the leading 10 companies has increased from 36 percent.

***NGP* takes a look at the major moves that have led to the current market situation.**

1994 – Roche acquired Syntex
American Home Products (now Wyeth) acquired Cyanamid
The top 10 companies accounted for over 30 percent for the first time

1995 – Hoechst acquired Marion Merrell Dow – which itself was a merger between Marion and Merrell Dow.
Formation of Glaxo Wellcome

1996 – Novartis formed through the merger of Ciba-Geigy and Sandoz

1998 – Roche acquired Boehringer Mannheim

1999 – Astra and Zeneca merged to form AstraZenica
Hoechst Marion Roussel merged with Rhone-Poulenc Rorer forming Aventis
Pfizer acquired Warner-Lambert

2000 – Glaxo Wellcome and SmithKline Beecham merge
The top 10's market share at this stage formed 45 percent of the market

2003 – Pfizer completes the takeover of Pharmacia

2004 – Sanofi-Synthelabo (which was a product of a prior merger of Sanofi and Synthelabo) merged with Aventis

M&A strategies

Pharmaceutical companies, therefore, are facing the challenges of a declining pipeline of products, a continuing increase in the costs to develop and commercialize new products and a more demanding market that is reducing the prospects to achieve premium pricing for new drugs. These market dynamics are likely to effect pharmaceutical M&A activities in the following ways.

Further market consolidation

Despite the spate of mergers over the past several years, large pharmaceutical companies are likely to continue to explore horizontal mergers to fill unused production and marketing capacity (resulting from drugs going off patent among other factors) and to achieve further economies of scale to reduce costs. The recent Sanofi-Aventis merger is an example. In today's climate, however, there is significant uncertainty whether mega-mergers can produce significant research efficiencies or increase profitability from economies of scale.

These mega-mergers often create further M&A activity through spin-off disposals required by regulatory concerns or in regard to drugs that are not complementary to the acquiring company's portfolio. As a consequence of the Sanofi-Aventis merger, for example, Sanofi sold its Campto drug to Pfizer and its Arixtra and Fraxiparine drugs to GlaxoSmithKline.

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Acquisition of biotechs by pharmaceutical firms

Biotech companies offer one obvious source of new products. Large pharmaceutical companies have partnered with biotechs to develop and commercialize particular products for many years. A more recent, less cautious, trend is for pharmaceutical companies to make outright acquisitions of biotechs. Recent examples are the Roche acquisition of Antisoma, the acquisition of Esperion Therapeutics by Pfizer and the Johnson & Johnson acquisition of Scios. Through the acquisition of a biotech, a pharmaceutical firm can add new products, product platforms and technologies in a way that is more cost effective than developing these items from scratch. Additionally, biotech products are more difficult to reproduce by competing generics companies and therefore may be less vulnerable to patent expiration. A biotech company, in turn, can benefit from a pharmaceutical company's enhanced financial and marketing strength and greater experience in developing drugs through trials. Also, in the absence of a robust IPO market for biotechs, a sale may be the best way for the biotech founders and venture capital backers to realize a return from their investment.

There may, however, be greater difficulties in achieving a successful integration of a pharma-biotech merger. The R&D expertise of a biotech (which is likely to be engaged principally in developing large-molecule biologics) may not be compatible with that of a pharmaceutical company (which historically is likely to have developed chemically-based, small-molecule drugs), although this issue may become less of a factor as the therapeutic platforms of biotechs and pharmaceutical companies move toward convergence. Perhaps more important are the differences in culture that may be faced between pharmaceutical firms and biotechs. Biotech scientists and managers, who have generally grown up in an entrepreneurial culture, may have difficulty in adjusting to a big-business culture of a large pharmaceutical company.

Biotech-biotech mergers

Another relatively recent trend is for large biotech companies to acquire or merge with other biotechs. Examples are the Biogen-Idec merger and the acquisitions by Amgen of Immunex and, most recently, Tularik. As biotechs have grown into significant players (with a few large biotech companies now having market capitalizations exceeding those of many pharmaceutical companies) large biotechs, like the big pharmaceutical companies, have increasingly looked to mergers with other biotechs to achieve needed critical mass and economies of scale. Merged biotech companies hope to achieve enough sales revenue to support their own manufacturing, marketing and sales operations. These types of deals demonstrate an increasing maturation of the biotech industry. Also, a biotech-biotech merger may face less problematic integration issues (such as R&D compatibility and culture) than pharma-biotech acquisitions.

In sum, the pharmaceutical industry faces numerous uncertainties driven by market, technological and regulatory factors. In light of these factors, pharmaceutical and biotech companies certainly will continue to employ M&A activities as a short-cut in product development and a means to maintain and enhance their competitive edge. ■

Peter E Kohl can be contacted at Hogan & Hartson, One Angel Court, London EC2R 7HJ, England.
Tel: 44 20 7367 0253 (Direct). Tel: 44 20 7367 0200 (Main). Fax: 44 20 7367 0220.
E-mail: **pekohl@hhlaw.com.** Mobile: 44 7710 581 963