BRIEFING No.4
Research findings from Innogen

Changing Strategies of Big Pharma

The Impact of the Life Sciences on Merger, Acquisition and Strategic Alliance Behaviour

Dr James Mittra

The life sciences are transforming pharmaceutical companies in terms of both internal R&D processes and strategies for external knowledge capture - mergers, acquisitions, strategic alliances and licensing. Dr. Mittra's research on life science innovation and the pharmaceutical industry reveals that these are a cluster of related activities that provide various strategic options for managing innovation and productivity deficit. However, because the preferred balance between in-house R&D and externally sourced knowledge appears dependent on a number of firm-specific factors, as well as challenges posed by an uncertain operating environment, there appears to be increasing variation between large companies in how these activities are exploited and managed. His findings beg the question of whether it is still useful to talk about 'Big Pharma' as if it were homogeneous, and have important implications for how we understand the evolution of the multinationals and their relationships and interactions with the smaller biotechnology sector.

Genomics and biotechnology have had a significant impact on many innovation-driven industries. In pharmaceuticals, large firms have adopted various strategies to extract value from new technologies and maintain a competitive advantage as a biological-based innovation trajectory for therapeutic products has emerged. Multinational discovery companies have been forced to reconsider the organisation and strategic management of internal R&D - as well as their strategies for capturing knowledge, technologies and products from external innovators - as conventional strategies in small-molecule development no longer seem sustainable.

Conventional strategies in small-molecule development no longer seem sustainable

It is now common to describe pharmaceutical R&D as a complex and distributed innovation system; that is it requires much greater interaction and knowledge exchange between different types of firm and public sector research organisations. Because the life sciences are so complex, and the knowledge and expertise required so widely dispersed, traditional pharmaceutical companies cannot fully exploit their potential without diversifying in-house R&D functions and strategies for external knowledge capture. This has been accomplished through the increasing use of merger, acquisition, strategic alliance and licensing activities.

Greater interaction and knowledge exchange between different types of firm and public sector research organisations

INDUSTRY CONSOLIDATION THROUGH LARGE-SCALE MERGERS

Over the past 15 years, there has been a series of large-scale mergers in the pharmaceutical industry. Between 1990 and 2004, there were twenty-two major M&A deals. There have been a number of key drivers of industry consolidation, through merger activity.

Between 1990 and 2004, there were twenty-two major M&A deals

- Patent expiry on high-value drugs, coupled with a deficit of compounds in late-stage development, can drive a company to pursue a merger to quickly acquire a stronger product portfolio.

- Firms will pursue M&A to acquire greater critical mass, and reduce the inefficiency of duplicated research activities, as the costs of R&D continue to rise.
- A need for greater marketing presence, particularly in the North American markets, can be a significant factor in M&A decisions.
- Faced with gaps or general weakness in its product pipeline, M&A can enable a company to quickly restore balance or build capacity.

The continuing trend of large-scale M&A raises important questions about the value and sustainability of further consolidation

The continuing trend of large-scale M&A raises important questions about the value and sustainability of further consolidation. The factors that have generally driven consolidation have tended to be negative; that is they are a defensive response to internal weakness, such as innovation deficit and managerial concerns about R&D efficiency and productivity. Our interview respondents claimed that mergers could provide some short-term benefits to a company in difficulty, but continued industry consolidation was unsustainable. Many now rejected a previously held belief that 'scaling-up' would facilitate the technological and commercial exploitation of life science capabilities. One respondent claimed that all the sensible mergers have now happened, and that any more would simply result from desperation of individual companies. The consensus was that companies have reached a critical size, beyond which they will no longer be able to function efficiently.

SMALL-SCALE ACQUISITIONS OF BIOTECH TARGETS

Large firms pursue small-scale acquisitions to acquire new dynamic capabilities and potentially high-value products

In contrast to large mergers, pharmaceutical companies are continuing to acquire small biotechnology companies to capture and exploit disruptive knowledge, technologies and products that they do not have the ability or inclination to develop in-house. Interview respondents regarded such acquisitions as an expedient means of getting access to new science, technologies and expertise that may usefully complement or successfully be integrated with existing R&D processes. In an uncertain commercial environment, where traditional capabilities in small-molecule development are no longer sufficient to sustain profitable growth, large firms pursue small-scale acquisitions to acquire new dynamic capabilities and potentially high-value products. Recently a number of the largest firms have acquired monoclonal antibody companies, as this highly innovative and technologically sophisticated niche is generally considered to be a potentially major growth area for therapeutic innovation.

BALANCING IN-HOUSE R&D WITH STRATEGIC ALLIANCES AND LICENSING

M&A activities have not significantly mitigated the R&D innovation and productivity crisis

Nevertheless, M&A activities have not significantly mitigated the R&D innovation and productivity crisis. Therefore, companies have also pursued more vigorously strategic alliance and licensing deals, which has contributed to a reshaping of the innovation network for therapeutic products. There was a general consensus amongst interview respondents that most companies were increasingly dependent on strategic alliances with the smaller biotech sector, although some companies appear more reliant than others. Strategic alliances allow a large company to 'dabble in new technologies' without having to go through the expense and effort of acquiring an entire company.

Strategic alliances allow a large company to 'dabble in new technologies'

In a time of technological uncertainty, alliances can broaden firms' strategic options

Furthermore, if a pharmaceutical firm has no expertise in an emerging technological or scientific area, they can 'learn through collaboration' before building internal capabilities. These kinds of strategic alliances have been particularly successful in the context of monoclonal antibodies, with many of the top companies partnering with small firms long before they acquired them. Strategic alliances, according to interview respondents, provide large firms with a flexible strategy. In a time of technological uncertainty, alliances can broaden firms' strategic options. However, respondents also claimed that there had to be a clear business case for a strategic alliance. That is, the

small company must be able to provide expertise or technology that can solve a tangible R&D problem.

In addition to alliances, many companies increasingly rely on licensing to balance their product portfolios. The commercial benefit of a good licensing strategy is that large firms can cherry pick desirable compounds from external innovators without having to commit to the expense and time of acquiring or partnering with the smaller companies. Over the past 15 years, licensing has become a key growth strategy for the top 20 global pharmaceutical companies, with some companies embracing licensing as their core business development strategy. This is reflected in the large percentage of externally sourced candidates in many companies' product pipelines. However, there is significant variation in individual firms' dependency and commitment to licensing. Roche and Novartis have been particularly dependent on licensed-in drug candidates to supplement internal R&D. Other companies, in contrast, have managed to sustain a healthy level of internal R&D. Indeed, some respondents claimed that licensing to fill a portfolio gap was risky if the company lacks the in-house expertise to adequately evaluate the product's potential. The scale and scope of licensing strategies, and their success, depends largely on individual firms' existing R&D capacity and financial status. Indeed, as competition for the best late-stage compounds increases, many companies are faced with having to settle for riskier, early-stage compounds. Large pharmaceutical firms often have very different risk-exposure, which will influence the type of strategies that they are able and willing to implement and determine success.

Licensing has become a key growth strategy for the top 20 global pharmaceutical companies

There is significant variation in individual firms' dependency and commitment to licensing

THE CHANGING COMMERCIAL ENVIRONMENT FOR PHARMACEUTICAL INNOVATION

The rapid development of life science-based technologies and approaches to drug discovery has created and shaped new organisational relationships between traditional pharmaceutical companies and biotechnology firms. In the distributed innovation system, multinationals are increasingly reliant on externally sourced knowledge, expertise and products. In what is a turbulent social, scientific, commercial and regulatory environment, companies must strategically configure M&A and strategic alliance activities, and successfully coordinate a dynamic range of capabilities, to narrow their risk profile and sustain profitable growth. This is becoming increasingly difficult as competition from similar-sized competitors, as well as the small-firm sector, continues to grow. There are important and unresolved questions about the very future of the multinationals.

New organisational relationships between traditional pharmaceutical companies and biotechnology firms

The ultimate question is whether the pharmaceutical industry will continue to be dominated by large multinationals pursuing blockbuster small-molecule therapies, with the smaller innovative companies in a perpetually subservient relationship. Although the successful exploitation of life science capabilities requires large companies to source knowledge and technology from the SME sector, in addition to maintaining a sufficient level of in-house capacity, ultimate control still rests with the multinationals. Large and medium-sized pharmaceutical companies continue to be the only organisations with the ability to integrate discovery, development and marketing functions for small-molecule treatments and distribute them to large patient populations. Therefore, large pharmaceutical companies already have a competitive advantage in the sense that they can strike the best licensing and strategic alliance deals with the SMEs. Furthermore, through M&A and alliance strategies, the traditional pharmaceutical companies do appear to be slowly building internal expertise in biologics.

Ultimate control still rests with the multi-nationals

Contrary to arguments that big pharma is incapable of fully exploiting biotech and genomic innovation, many companies are trying to add-in biologics to their traditional pipeline of small-molecule drugs. Indeed, some of the medium and small

The balance between biologics and small-molecules in large companies' pipelines does appear to be shifting

Large companies will, through a combination of internal and external pressure, begin to appear increasingly diverse in terms of their preferred R&D model and core commercial strategy

pharmaceutical companies have made concerted attempts to reorganise their conventional R&D processes and therapeutic priorities in light of the knowledge and opportunities emerging from the life sciences (Novo Nordisk and Ferring, for example). Furthermore, although the therapeutic market continues to be dominated by small-molecule treatments for common diseases, interview respondents did claim that the balance between biologics and small-molecules in large companies' pipelines does appear to be shifting. However, the rate at which the biomedical paradigm is fully embraced may be determined more by current strategic priorities, such as therapeutic foci, market valuations and internal finance, rather than inherent lack of technological capability. Indeed, because the largest firms are adopting a diverse range of strategies to extract value from the new technologies – each trying to achieve a preferred balance between in-house R&D and externally sourced knowledge and products – it may no longer be useful to talk about big pharma as a homogenous sector. It seems likely that in the coming years large companies will, through a combination of internal and external pressure, begin to appear increasingly diverse in terms of their preferred R&D model and core commercial strategy.

NOTES

This policy brief emerged from research on innovation in the pharmaceutical industry, conducted within the ESRC Innogen Centre. It is based on an article which has been published in a special issue of the journal *Technology Analysis and Strategic Management* (Mittra, J. (2007), "Life Science Innovation and the Restructuring of the Pharmaceutical Industry: Merger, Acquisition and Strategic Alliance Behaviour of Large Firms", *Technology Analysis and Strategic Management*,19/3: 279-301). The data on which the article is based were derived from interviews with senior scientists and managers within five large pharmaceutical firms, and secondary data on general industry trends.

EGN research ranges across the whole field of genomics, covering areas as diverse as plant and animal genetics, embryonic stem cell research, and associated health applications.

The Network ranges across five of the UK's leading universities, and involves over a hundred researchers, from professors to PhD students, as well as administrative and support staff and an international cast of visiting research fellows. It is one of the largest social science investments in the ESRC's current portfolio, and is growing into the largest concentration of social scientific research on genomics in the world.

Dr James Mittra is a Research Fellow at the ESRC Innogen Centre, University of Edinburgh, High School Yards, EH1 1LZ, UK
Tel: +44 (0)131 650 9113; Email: james.mittra@ed.ac.uk