Implications of the Business Strategies of Pharmaceutical Companies for Industry Developments in Australia

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Introduction

The pharmaceutical industry is highly complex. The technologies leading to drug discovery and development are at the limits of human knowledge. The huge size of the companies and the complexities of their processes and technologies presents many organisational and management challenges. The development and management of the distribution system is highly costly.

However while excellence in managing all these aspects of the industry is a necessary condition for the survival of the global pharmaceutical companies, the uncertainty of the discovery process and the potentially huge returns from the discovery of a single drug means that like drilling for oil or randomly choosing the black beans from a jar of overwhelmingly white ones, success in the industry depends on a high measure of luck. Much of the thinking about business strategy in the industry is how best to cope with this uncertainty. This has not always been the case. Colonel Ely Lilly gained his initial competitive advantage, in manufacturing, by producing 'true to label' products in competition with the various 'snake oils' and other dubious concoctions of the era.

The highly skewed nature of the returns from the drug discovery and development process means that a single drug can deliver corporate success at least in the short to medium term. As Scherer et al. has pointed out, in these conditions the normal principles of large numbers in which diversified portfolios produce predictable returns does not apply to this industry (2000). Returns from pharmaceuticals are highly volatile.

For the established pharmaceutical companies the response to the discovery uncertainties has been to build scale through mergers and acquisitions so that the latter stages of their product pipelines have at least a handful of highly prospective blockbuster drugs. Scale offers the capacity to both fund in house research and draw in external research through a variety of licensing arrangements and alliances. It has also provided the necessary marketing resources in an industry in which these costs absorb some 35% of revenues

However since the numbers of NCEs at latter stage are so small and returns so uncertain these 'solutions' may be of very short duration with gaps in the pipeline re-emerging as existing blockbuster patents expire and expected blockbusters fail to materialize – producing another round of M&A. At this stage there seems to be no limit to this pressure to consolidate. The growth rates demanded by the market to sustain current valuations require a significant and questionable expansion in the number of new large selling drugs. One other strategy has been for pharmaceutical companies to diversify their business activities into lower risk activities eg Merck into Medco or Johnson & Johnson into household health products, but it not clear that this has been rewarded by the financial markets. Merck recently announced that Medco would be spun off.

Another diversification strategy is to focus on a comparatively large number of niche market drugs rather than blockbusters. Whether by accident or design a number of European companies appear to have followed this strategy. While their total sales of

pharmaceuticals place them in the first rank of pharma companies they have perhaps only one or two drugs of blockbuster status. Selling a broad range of drugs clearly lessens dependence on the discovery of new blockbusters, but development and marketing costs need to be watched for the smaller markets to be economic.

While large pharmaceutical companies have sought survival in larger enterprises, these agglomeration tendencies has not stopped other firms using a discovery breakthrough to 'chance their arm' at developing a blockbuster of their own, ultimately perhaps through a marketing alliance with a global pharma. These are largely biotech firms that have funded independent drug discovery through direct access to the venture capital market. In other cases their research has been supported by large pharmaceutical companies through alliances and licensing. Such is the return from a single successful blockbuster that a small number of these companies have been catapulted into the first rank. On the other hand many biotech companies fail to realise these ambitions and languish as contract research houses or go out of business.

Given the instability and apparent unsustainability of current pharmaceutical business strategies and structure, other models have been suggested.

There are those who argue that the real added value of the global pharmaceutical company is its capacity to organise, coordinate and finance the various parts of the drug development and distribution pipeline (Kay 2001). This would see a more limited role for the global pharma in which most research and perhaps a large part of the distribution was contracted out. This presupposes that specialization in various aspects of the drug development and distribution process could achieve significant economies.

In addition there is an increasing technical capability (e.g. genomics) to provide personalised medicine. This gives an opportunity for companies specialising in particular therapeutic areas to target smaller patient groups in which the massive distribution machinery of the global pharmaceutical companies becomes less relevant. If the economics of smaller patient markets was improved through the greater selectivity offered by genomics then size would be less critical.

Evolution of the industry along the lines suggested above has implications for developments in Australia. Australian R&D, at least in biology, is seen as world class, but constrained in gaining the attention of large pharma by 'tyranny of distance', and limited in funding opportunities from risk averse Australian capital markets. In a continuing world of big pharmaceutical companies perhaps the best that can be hoped for is to gain research and drug development support at an early stage on a project by project basis from large pharma by more actively pursuing overseas links.

There may also be an opportunity for domestic companies that specialise in a particular aspect of the drug development process to contract out their specialisations on a regular basis to global pharmaceutical companies.

Pharmaceutical Company Business Strategies

One of the constants of pharmaceutical company strategy over the past decade has been increasing scale. Only by growing larger are companies able to afford the considerable costs of drug development and distribution. This is well summarised in the PricewaterhouseCoopers report *Analysis and Opinions on M&A Activity* (1999).

Within this broad approach at least two business models are discernable:

(i) Blockbuster model involving the search for, and distribution of a small number of drugs that achieve substantial global sales (say in excess of $1 billion p.a.). The success of this model depends on achieving large returns from a small number of drugs in order to pay for the high cost of the drug discovery and development process for a large number of candidates. Total revenues are highly dependant on sales from a small number of drugs.

(ii) Diversification model in which a larger number of drugs are marketed to smaller niche markets. The advantage of this model is that its success is not dependant on sales of a small number of drugs. However without a blockbuster to help pay for the high development costs, the model only works for small markets where distribution costs are low.

(iii) Intermediate model which borrows some of each.

To date the blockbuster model has been recognised by industry analysts as the dominant model (see for instance Mercer Management Consulting 2001). However interest in alternative models is growing as consideration is being given to the marketing of biotech drugs with smaller markets and higher treatment costs and the expectation of more personalised medicine. This paper is mostly concerned with the blockbuster model.

The blockbuster model

There are some in the industry who would argue that the dependence of global pharmaceutical companies on a small number of high selling drugs is an outcome of the industry's economics not a result of a deliberate strategy.

There is little doubt however that a large number of the largest pharmaceutical companies are highly dependent on the sales of a handful of drugs for most of their sales and an even higher proportion of their profits.

Table 1 Blockbuster sales by major pharmaceutical companies, 2001

Company	Pharma sales $m	Blockbuster Sales (> $US $1b) $m	Blockbuster ratio	Number of blockbuster drugs
Pfizer	$26,761	$18,241	68.2%	7
GlaxoSmithKline	$24,777	$9,372	37.8%	6
Merck	$21,351	$16,575	77.6%	7
BristolMyer Squibb	$17,051	$4,552	26.7%	3
AstraZeneca	$16,500	$9,221	55.9%	2
Johnson & Jonhnson	$14,851	$5,541	37.3%	2
Aventis	$13,543	$2,871	21.2%	2
Novartis	$12,013	$2,208	18.4%	2
Pharmacia	$11,970	$3,114	26.0%	1
Eli Lilly	$11,542	$6,054	52.5%	3
Total Top 10	$170,358	$77,748	45.6%	35

Source: Annual reports and CSFB (2002).

The table above lists the 10 largest global pharmaceutical companies by sales of pharmaceuticals for 2001 together with total sales of those drugs with global sales exceeding $US1 billion ('blockbuster'). This is a comparatively narrow definition of a 'blockbuster' – some refer to sales over $US500 million (HBS 1999; Malknight 1999), other analyses take the sales of the companies top five drugs as the relevant measure. Both alternatives tend to increase the importance of the blockbusters.

According to the measure used in Table 1, there are only 35 blockbusters representing on average 46% of pharmaceutical sales of these companies. The blockbuster ratio however varies widely between companies from a high of 78% for Merck to a low of 18% for Novartis. Ownership of the blockbusters is highly concentrated with the three largest companies by sales owning 20 of the 35.

Table 1 demonstrates that success with an extraordinarily small number of drugs substantially determine the fate of the largest companies. This is not a recent observation. Grabowski and Vernon (1994, 2001) calculated the sales profiles for all NCEs for two periods 1980-84 and most recently 1988-92. This showed that half of the value of sales was in the top 10% of drugs. Comparing the sales profiles for the two periods, Grabowski and Vernon demonstrate that the peak sales achieved by the top decile drugs ($US3.2 billion in the later period) had more than doubled.

They also calculated the NPV of drug sales for the earlier period. The NPV of a drug in the top decile of sales in the period 1980-84 was of the order of $US1000m. They compared the NPV of each decile with the estimated average cost of R&D for a drug, which they put at just over $200m, showing that only the top 20% of drugs exceeded this amount.

The management literature outlines the efforts that Ely Lilly has made through the 1990s to improve the focus and efficiency of its drug development pipeline for its blockbuster drugs. The strategies are discussed in a series of Harvard Business School cases. The efforts most recently captured in the acronym QSV (Quality, Speed, Value), began in the early 1990s with efforts to improve speed to market, leveraging existing products and establishing a global and focused therapeutic presence. It narrowed its R&D focus from eight to five therapeutic areas. It implemented product or 'heavy weight' teams. These were to break down the functional silos – development, marketing, sales etc into multi functional teams that were designed to take a single drug through the testing process, launch and subsequent marketing.

The first such teams were established in 1995 – one for the osteoporosis drug, Evista and the other for Zyprexa, the antipsychotic drug. These teams had an almost free call on resources from the functional groups (Burgleman et al. 2001). Their role evolved over time so that as well as focusing on the sales, marketing and distribution of their blockbuster drugs, they also came to exert more discipline on the drug discovery and development process.

The sum total of these initiatives was a remarkable period of share price out performance. Lilly's stock price increased by almost six times over the five years to 1998 compared with increases of about 3.5 times for Merck, Johnson & Johnson and American Home Products and almost three times for the S&P 500 (Burgleman et al. 2001).

Despite these kinds of improvements, the cost of R&D per drug has climbed exponentially over the last 30 years (Grabowski and Vernon 2001). While NCEs discovered by the industry show a rising trend, expenditure on R&D has been increasing even more rapidly. Current estimates put the cost of R&D per drug at $802m whereas the equivalent study conducted 10 years previously and adjusted to 2000 dollars put the cost at $318m (DiMasi 2001).

There are other ways in which the blockbuster model influences industry structure. To be successful the model requires a constant replenishment of the sales pipeline. It needs a consistent and dedicated approach to drug R&D. This appears to require considerable in house research expertise either to develop the drug from discovery, exploit successfully public domain research or utilise various alliance strategies and licensing arrangements to bring prospective drugs into the later stage development processes in which the large pharmaceutical companies excel. The later stages of the development pipeline must always contain drugs of blockbuster potential. Since the number of blockbuster drugs at any point in time is relatively small, the risk with the strategy is that there will not be new blockbusters to take the place of those losing patent protection.

A number of companies have found themselves caught short, without new blockbusters to keep sales growing. In some cases this arises from a failure to invest adequately in the pipeline. Gambardella (1995) outlines the case of SmithKline which failed to reinvest the proceeds of its Tagamet success in upstream research and it was forced to merge with

Beecham in 1989. More often than not mergers occur to cover weaknesses in the R&D pipeline.

In some cases companies have combined mutually supportive capabilities. For example between one with a drug pipeline and the other with a sales and distribution capability. By merging they create a company with a credible business model – possessing both a valuable drug development pipeline and an effective sales and distribution capability. A recent example of such a merger is AstraZeneca – Astra with the blockbuster drug Losec, and the ex ICI Pharmaceuticals, Zeneca with the financial strength and scale to underwrite further R&D.

The element of desperation in the continual rounds of consolidation in the industry reflects the difficulty presented by the underlying uncertainty of the economics of new drug development. The skewness of the returns to drug development makes it difficult for a company of any size to achieve stable and predictable returns. It is not sufficient for a pharmaceutical company to know that its 'pot' contains an adequate number of blockbusters with revenues protected for their patent life. It also needs to be cognisant of the constantly emerging competition from follower drugs which according to the industry has cut market exclusivity from say 4 years in the 1980s to less than 1 year in the 1990s (PhARMA 2001).

The squeeze between higher R&D costs and lower returns from blockbuster drugs appears to be one of the factors driving companies towards consolidation. In yet most of the larger companies, appear to gain little from R&D expenditure economies of scale or scope, once R&D expenditure reaches $1000m (Walton 2001, p. 92).

Distributing Blockbusters

An area where scale delivers clear advantage is in sales and marketing. Sales per representative typically rise with company size (Walton 2001, p. 90). Marketing absorbs 35% of revenues, larger than R&D (less than 20%) and its efficiency can have a major impact on company value. Lilly for instance has a very high ratio of sales per rep and a high P/E for its size. A survey of US pharmaceutical companies suggests that marketing and sales capability accounts for 42% of the variation in financial performance (Accenture White Paper) (George and Perrone 2001; Blumberg and Perrone 2001). Each major new drug is launched with a comprehensive and expensive global marketing campaign that involves the full range of marketing tools including media advertising, comprehensive information packs, special events for doctors, conference presentations, dedicated sales forces and increasingly the Internet.

Sales and distribution is emerging as a major issue for pharmaceutical companies. Traditionally there have been a number of distribution channels. In the US, clinical settings (hospital, in-patient facilities) have accounted for about 25% of pharmaceutical sales while the remainder have been distributed through various wholesale and retail channels. Typically the manufacturer sold the drugs to a wholesaler which distributed the drug to retail pharmacies. In this relationship the doctor had a pretty much unfettered

ability to prescribe drugs as he saw fit. Traditionally he has been the focus of marketing campaigns.

However over the last decade in the US, there have been two major changes. One is the growth of mail order firms and the second is the partly associated growth of Pharmacy Benefit Managers (PBMs). The mail order firms have catered in particular for the supply of drugs to chronic sufferers providing longer-term treatments for a single dispensing fee. The PBMs (which can also supply by mail order) have had a major impact on doctor drug choice. The PBMs require participating doctors to prescribe according to a formulary (approved list) and may further guide the choice of the drug to what they deem to be the most cost effective. Drug companies are therefore required to market to the PBMs on their terms according to a highly structured process.

Merck shook the industry when it purchased Medco, a PBM in 1993, and both SmithKline and Ely Lilly followed in 1994. The FTC circumscribed the ability of the drug company owners to influence the formularies to such an extent that Ely Lilly sold its PBM. Until the recent announcement to spin off Medco, Merck had persisted. Merck-Medco sales have increased at over 30% per annum and its share of Merck-Medco sales had increased from 10% pre merger to 15% by 1997 (HBS Inside Biotech and Pharmas 2000, p. 86). Not only do PBMs affect sales of new drugs but their insistence on generic substitution once patent protection expires can also be just as dramatic. For instance the recent generic substitution for Ely Lilly's Prozac, through Medco, was 80% in just one week, far higher than the market as a whole (CSFB 2001a).

For marketing to physicians, the solution has always been to throw more sales reps at doctors with each new drug launched (CSFB 2001b). The Accenture survey referred to above indicates that the skills and motivation of the sales force is the single largest factor (33%) driving sales and marketing performance. Accordingly perhaps, the number of sales reps has been rising rapidly, at 20%, compared with physicians at only 3%. The time each rep spends with a physician is now only 100 – 300 seconds (AstraZeneca 2001). The 'doctor channel' is 'blocked'. Pharmaceutical companies are seeking ways around the doctor channel such as direct-to-customer (DTC) and various forms of the Internet delivery.

The impact of IT on the industry is the subject of another paper in this project in which these issues are discussed in more detail (see Houghton 2002). It is suffice to outline here the trends with particular implications for industry structure.

A number of marketing strategies are being tested. DTC techniques include special purpose Internet sites providing information to both physicians and patients about a particular drug. Each expected major drug is now launched with its own dot.com site. In addition to attracting the attention of doctors, the objective is to alert potential patients to the attributes of the drug and encourage them to seek prescription from their physician. Increasingly media, including TV advertising, is being used to announce the arrival of new drugs. The challenge of DTC for pharmaceutical companies is that patients need a

script from a physician to obtain the drug. They are not (except for OTC drugs) able to buy directly.

Some Internet sites have been established to give physicians the opportunity to call highly qualified sales reps and discuss the drug attributes via live video conference. This so called eDetailing has been found to be an effective way of raising product awareness amongst doctors, with, for one company, 93% of the calls being doctor initiated (AstraZeneca 2001).

Another AstraZeneca initiative is LinkMedica which uses the Internet to provide a personalised asthma monitoring and information service for patients and medical staff. It enables AstraZeneca to 'get closer' to their customers and gain valuable understanding of asthma patients. Interacting with customers electronically is regarded as a key part of managing customer information which in turn is one of the most significant factors in sales out performance (George and Perrone 2001; Blumberg and Perrone 2001).

Implications for Industry Structure

These new trends in sales and marketing while currently in their early stages will assume greater importance if medicine becomes more personalised. Currently the implications of the blockbuster model is to focus attention on mass patient markets. The impact of genomics and other technological advances outlined in Kim Sweeny's paper (Sweeny 2002) seems likely to make possible a level of quite targeted customised medicine. In particular the mapping of the human genome has introduced the possibility of personalised drugs to suit each patient's genetic makeup.

> One day, everyone will have their own genomes mapped out and stored in memory chips, and doctors will look at the information in those chips, and prescribe accordingly. (Mark Levin, CEO, Millenium Pharmaceuticals)[1]

Personalised medicine seems likely to be one component of high quality health care to be demanded by an aging population seeking longer but still comfortable lives. There are many components to high quality health care of which pharmaceutical products is but one. Medical and hospital services form another highly related component. It is readily acknowledged that early prescription of drugs can sometimes substitute for later acute care. While funders of pharmaceuticals (e.g. PBMs) may be less inclined to endorse early preventative use of drugs, patients are increasingly likely to demand this type of integrated care and institutions will change over time to reflect the economies of such an approach – for example the emergence of HMOs incorporating PBMs.

The thread likely to hold together an integrated approach to health care is the ready availability of sophisticated individualised health information systems – databases of medical information, devices for monitoring health conditions and drug dosages. These

[1] Champion (2001).

systems would offer early diagnosis with automated delivery of preventitive health care tailored to the genetic and other requirements of the individual patient (PWC 1999).

The delivery of such a service implies a radical realignment of the organisations and businesses currently providing health care. Suggestions to date involve the development of a complex web of networks, alliances and equity partnerships (PWC 1999). This is an easier 'call' than to forecast how the disparate pieces of the puzzle might shake down into new organisations, internalising certain parts of the 'value chain' and outsourcing others. Doubtless the new world will have elements of new organisational structures as well as new network alignments.

The role of pharmaceutical companies in such a realignment is difficult to predict. The implications of personalised medicine for pharmaceutical companies focused on mass market blockbusters appear to be fairly dramatic. Changes would be required at most parts of the value chain, from discovery, through the development phases to distribution. New technologies would be required through the discovery and development process and distribution of personalised medicine would be very different.

It has been suggested that the role of the pharmaceutical firms will change and that some of the trends already apparent will be accentuated. These include:

- an increasing reliance on specialist bio tech and other research companies to provide new compounds under licensing and equity share arrangements. ;
- increasing provision of new research technologies by specialist firms;
- business process reengineering of clinical trials and other drug development functions; and
- new alliances with health care companies for the distribution of drugs.

In this world pharmaceutical companies would focus on the co-ordination and financing of these functions. This view is reinforced by the seeming unsustainability of the blockbuster model – the rising costs of R&D, the very small number of potential blockbusters and the forces reducing the returns on those drugs.

A recent announcement by Merck, a company with the second largest global pharmaceutical sales in 2000, that sales of several of its blockbusters would be lower than expected and that there was a gap of 12 months in the blockbuster pipeline, was enough to immediately cut almost 15% from its share price. This type of severe market reaction to seemingly marginal adjustments in expectations illustrates the pressures under which the large pharmaceutical companies operate.

Further concentration of the large pharmaceutical companies is still consistent with a model in which these companies coordinate and manage a complex web of alliances, partnerships etc but their strategies would be very different to those currently pursued.

Although the forces of change, both technological and demand generated, appear overwhelming, it is a common mistake to predict prematurely, the dinosaur like death of large corporations. It was suggested for instance in the 1990s, that the profitability of

large banks, which were undergoing massive change resulting from deregulation and implementation of new technologies, would be eaten away by specialist 'cherry pickers' to such an extent that survival was problematic. Instead big banks have not only survived but probably strengthened their position in the financial services market and many of the would-be 'cherry pickers' have retired from the scene.

Accordingly whatever the structure of the pharmaceutical industry or indeed the health care industry it seems likely that large pharma will have a significant role in determining that structure. If that is the case what are the implications for Australia.

Implications for Australia

At this stage of the project, we are only beginning the process of reviewing the capabilities of the Australian pharmaceutical industry so these views are heavily qualified.

It has been generally acknowledged that Australian biological research is of world standard and with the current emphasis on blockbusters there is every prospect of global pharmaceutical companies entering into research contracts and licensing arrangements to develop that research into new and ultimately marketable drugs. It was clear from discussions in the United States however that the 'tyranny of distance' would limit global pharmaceutical company interest in Australia. In an environment in which most advances are incremental, new developments in Australia would need to meet higher thresholds than similar developments, in say the United States, unless very actively marketed. This is the case despite the seeming high demand for new leads.

In this environment the best option for Australian organisations is to form alliances with global pharmacetical and biotech firms or provide specialised services to these firms. If in their emerging strategies the global pharmaceutical companies seek to outsource many more of their functions to companies that can offer economies, arising from specialisation or unique knowledge, over in house solutions, then the likelihood of Australian firms having some greater value added role in the total drug production process is increased. Expansion of the role of Lilly's clinical trial data centre in Australia is one example of a non-research specialisation that could be globally competitive.

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