Four scenarios for the future of the pharmaceutical industry

Ron Bradfielda* and Hany El-Sayedb

aDepartment of Management, University of Strathclyde Business School, Glasgow, UK; bBristol-Myers Squibb Bahrain, PO Box 648, Manama, Bahrain

Pharmaceutical companies are facing several major interrelated challenges, the most strategic being the decline in R&D productivity resulting in empty product pipelines to replace products nearing patent expiry. A common response has been mergers and acquisition of competitors and biotechnology firms, but rather than resolving the problems, this has created new ones. While biotechnology promises to reshape the pharmaceutical industry, it too faces challenges: the industry as a whole is unprofitable and there is uncertainty regarding market acceptance of its products. This paper examines the current issues in the two industries, and describes a scenario process resulting in the development of a set of scenarios depicting four possible future paths along which the pharmaceutical industry may develop over the next 15 years.

Keywords: pharmaceutical industry; future; scenarios; new products

Introduction

There have been periods in history during which industries and their foundations have undergone profound mutations; the pharmaceutical industry may be on the verge of such a mutation brought about by the coalescence of various environment forces, including the emergence of a relatively new industry, biotechnology (biotech).

Pharmaceuticals are a global industry and the industry has traditionally been a high performance and highly profitable one, ‘elite in terms of outsized rewards and excessive profits’ (Trombetta 2005). The industry comprises hundreds of companies including biotech firms, generic drug manufacturers, researchers, wholesalers and retailers, but dominating the industry is a group of large multinational companies known colloquially as ‘big pharma’ whose combined sales accounted for more than half of the industry’s retail sales in 2004. Although highly competitive, the industry is fragmented with Pfizer, the largest player in the industry, accounting for less than 10% of global market share by value in 2004, and collectively the top 10 companies account for only 41.7% (Trombetta 2005; Anon 2007). The biotech industry meanwhile is a relatively new one and unusual by conventional business standards in that there are biotech firms with multi billion market capitalisations that are ‘not profitable companies, that do not have significant drugs in

*Corresponding author. Email: bradfield@pacific.net.sg

ISSN 0953-7325 print / ISSN 1465-3990 online
© 2009 Taylor & Francis
DOI: 10.1080/09537320802625280
http://www.informaworld.com
late stages of development, that don’t have fully worked out development engines’ (Anon 2004). Despite this, biotechnology is fundamentally reshaping the pharmaceutical industry.

Given the above, this paper sets out to examine issues currently facing the pharmaceutical and biotech industries, and to describe the development by a team of managers from a US-based pharmaceutical company, of four plausible scenarios depicting how the pharmaceutical industry may evolve over the next 15 years. The paper is divided into five sections, beginning with an overview of a commonly used scenario methodology. This is followed by presenting the background to the scenario project, which includes a discussion on the current realities facing the industries to provide the context for the scenarios developed. Details of the four scenarios are then given and the paper concludes with a discussion of the outcomes of the scenario workshop and conclusions.

Overview of the intuitive-logics scenario development model

The first widely documented use of scenarios in the context of business was the experience of the Royal Dutch Shell company (Shell) which adopted scenario planning as a permanent strategy in 1972 and along with the work of SRI (SRI International formerly known as Stanford Research Institute), gave rise to what is loosely known in the literature as the ‘Intuitive Logics’ methodology (Bradfield et al. 2006). Numerous variations of the intuitive logics model have since been published, leading to the observation that there are almost as many ways of developing scenarios, as there are practitioners in the field.

One of the attractions of the intuitive logics approach is that it can be tailored to suit the situation, short-cuts can be taken and stages of the process combined. This has led to criticism from researchers contending that ‘no generally accepted, theoretically and empirically sound scenario construction methodology exists’ (Jungermann 1985) and protocols for scenario development are ‘ad hoc and not very defensible’ (Bunn and Salo 1993). Despite this, most intuitive-logics scenario techniques described in the literature incorporate systematic and recognisable phases, which can be categorised into four distinct stages as indicated in Figure 1. Regardless of the methodology used, scenario development processes are generally undertaken in facilitated groups, are primarily creative and rely heavily on the subjective judgements of the group members.

Stage 1: Project orientation

The starting point of the orientation stage is to determine the purpose of engaging in a scenario project. As depicted in Figure 2, scenario projects can serve four main areas of purpose; all four have value but prior to embarking on a project, it is essential to clarify which purpose the project sets out achieve. The reason for this is that each of the four purposes will inevitably have different audiences and expectations, and will involve different process design, facilitation emphasis and resource requirements.

Having established the purpose underlying the scenario work, it is essential to determine precisely what strategic issues or topics the client organisation is trying to understand. Scenarios can be built around an infinite number of topics, but if they are to be of value to the client organisation, they must centre on those issues that concern the senior management of the organisation. An effective way of identifying these issues is through a series of in-depth interviews with the key senior members of the organisation involved in strategic decisions. Subsequent analysis of the interview data results in an understanding of the organisation and the dominant perspective of the management team as to what they regard as the major uncertainties in the business environment.
Stage 1: Project Orientation
- Establish the scenario purpose
- Identify the focal/strategic issues
- Surface potential scenario themes
- Establish the scenario horizon year

Stage 2: Environmental Exploration
- Identify the Driving Forces
- Segregate 'Uncertainties' from 'Predetermineds'
- Establish 'Critical Uncertainties'
- Identify linkages and causal relationships

Stage 3: Synthesis & Story Development
- Define the scenario 'logics'
- Create scenario 'end states'
- Construct scenario storylines
- Elaborate/embellish storylines to create narratives

Stage 4: Scenarios to Strategy
- Identify Early Warning Signs for each scenario
- Establish Implications across and within the scenarios
- Assess Strategic Fit and identify strategic options

Figure 1. A process framework for developing scenarios.

Figure 2. The purpose of scenario work.

With regard to long-term strategy development. The set of critical uncertainties elicited represent potential scenario themes and they are generally encapsulated in an organising or focal question which the scenarios will seek to address. This then serves as the agenda for the scenario exercise, determining areas to be examined in the exploration stage of the scenario process.

The final step of the orientation stage is to establish the horizon year for the scenarios, i.e. how far ahead should the scenarios foresee. This is not a trivial question, the time parameters for the scenarios need to be carefully considered as this will be a crucial factor in terms of the plausibility of the scenarios developed; for example, what may be possible in 15 years may not be plausible in the next five years.
Stage 2: Environmental exploration

The second stage of the scenario process begins with the scenario team considering the range of external environmental factors, or 'driving forces' that will impact the scenario agenda. Driving forces are the underlying and impacting elements in the contextual environment that set the pattern of events and determine outcomes in the business environment – the forces that make things happen, but which the organisation has no, or little control over.

At the heart of the process of surfacing driving forces are brainstorming techniques, and a wide range of protocols can be used. The objective is to push thinking to the limits using a structured analytical framework such as STEEP (Society, Technology, Environment, Economics, Politics) analysis or derivatives thereof that consider a wide range of factors relating to the contextual environment and that appear relevant to the scenario focal issue. In generating driving forces, care needs to be taken to ensure that (1) all of the ideas assembled represent driving forces rather than their outcomes; and (2) to segregate out those driving forces which may be 'predetermined' within the context of the focal question. Predetermineds constitute events that have already happened, or existing trends that will change slowly because of prevailing systemic relationships, and as such, will unfold in the same way with predictable outcomes in every scenario. The driving forces are then clustered to create a taxonomy of higher-level concepts, each cluster representing an interrelated set of uncertainties. At the same time, a key element within the clustering exercise is to develop an understanding of the causal relationship that links the individual elements within each cluster, and the clusters to the focal concern in a meaningful framework.

The final step in this stage is to identify which of the clusters are likely to have the highest impact on the client organisation, while simultaneously are the most uncertain in terms of their potential outcome. This is commonly achieved by positioning each of the clusters on a two-dimensional predictability/impact ranking matrix, with the continuum 'high/low' impact on one axis, and high 'certainty/uncertainty' on the other axis. At the end of the exercise those clusters in the high impact/high uncertainty quadrant of the matrix represent the 'critical uncertainties' and it is these that will form the foundation of the scenarios built in the synthesis stage which follows.

Stage 3: Synthesis and story development

As implied by the name, this stage is concerned with synthesising the data generated to create a viable logics framework around which a set of scenarios can be built. The first step is to select two clusters representing critical uncertainties which are independent of each other and which can be used as variables along a continuum; placing these across one another results in a two-dimensional matrix, providing the 'logics' framework for a set of four coherent scenarios as shown in Figure 3.

Having arrived at a framework for a scenario set, the next step is to develop the end states for each scenario, i.e. a snapshot of the state of the world in each scenario at the scenario horizon year. The final step is to create the storylines that describe how and why the situation moves from its current state, to the end state depicted in each scenario, and then elaborating and embellishing the storylines to create a compelling, plausible narrative for each scenario.

Stage 4: Scenarios to strategy

The final stage of the scenario process involves first, identifying the early warning signs for each scenario – the signals one might expect to see through subsequent environmental scanning, which provide forewarning of the situation moving in the direction of a particular scenario. Second, one
Four Scenarios for the Future of the Pharmaceutical Industry

<table>
<thead>
<tr>
<th>Individualistic/ Materialistic</th>
<th>“New Science”</th>
</tr>
</thead>
<tbody>
<tr>
<td>Advances in understanding of genetics results in innovative, customised and targeted treatment</td>
<td></td>
</tr>
<tr>
<td>Seamless integration of biotech and pharmaceutical processes/products</td>
<td></td>
</tr>
<tr>
<td>Lifestyle expectations leads to demand for new life enhancement medicines</td>
<td></td>
</tr>
<tr>
<td>Regulators struggle to cope with flood &amp; complexity of new drug applications</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>“Bitter Pill”</th>
</tr>
</thead>
<tbody>
<tr>
<td>New technology &amp; pharmacogenomics lower barriers to drug discovery</td>
</tr>
<tr>
<td>Exponential increase in biological targets significantly amplify R&amp;D costs</td>
</tr>
<tr>
<td>Growth of educated patient-consumer lobby demand value for money drugs</td>
</tr>
<tr>
<td>Regulators moralistic - demand cost effective medicines, technology transfer and relaxing of IPR</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>“Old Science”</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lack of fundamental innovation in pharmaceuticals - biotech fails to live up to expectations</td>
</tr>
<tr>
<td>Pharma shun biotech and focus R&amp;D on therapeutics for affluent markets</td>
</tr>
<tr>
<td>Shift in consumer demand for more self-medication for quality of life drugs</td>
</tr>
<tr>
<td>Governments/Regulators support laws against generics and patent intrusion</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>“Druggernauts Rule”</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharma and biotech muddle along in various relationship combinations</td>
</tr>
<tr>
<td>Demographics increases demand for medicines for ageing conditions</td>
</tr>
<tr>
<td>Activist pressures on stem cell drive biotech R&amp;D to developing countries</td>
</tr>
<tr>
<td>Regulatory decisions based on prevailing societal views and focus on controlling healthcare costs</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Communitarian/ Non-market</th>
</tr>
</thead>
</table>

Denotes current situation

Figure 3. The scenario logics matrix.

must establish the implications for the organisation inherent across the scenario set, and within each of the scenarios. The concluding step which completes the scenario exercise, is to determine how well the organisation’s current strategy(s) address the business environment depicted in each of the scenarios, and what options exist for the organisation in terms of improving the robustness of its strategy(s). The analogy often used to describe this particular step, is that of placing a model aircraft inside a wind tunnel, and then simulating various weather conditions to determine how well the aircraft performs in the conditions.

In concluding the discussion on the scenario development process, several points are worth noting, these being that:

1. Although the scenario process has been described above as a linear one, it is generally an iterative one as teams invariably cycle back and forth between the various stages several times. The temptation is often to complete a scenario project as quickly as possible, and while this may be appropriate in some circumstances, experience shows that a well-founded scenario assignment typically takes 3–6 months. This extended period allows team members time to reflect critically on the process and content, to engage in discussions with one another, and to undertake focused research addressing knowledge gaps identified in the exploration and synthesis stages of the process.

2. It would appear that the scenario development process is relatively straightforward – constructing scenarios is simply a matter of progressing through a series of well-defined, sequential steps. However, anyone who has carefully observed the development process in detail will
quickly realise that it is not that simple, there is generally substantially more going on in the
process than is generally ascribed to in the literature on scenarios.

(3) Scenarios are not forecasts, although some form of prediction is inherent in any forward­
looking exercise; nor are they extrapolations of the past. Although there is no widely accepted
definition of the term scenarios, they are fundamentally plausible stories that examine the
principal drivers of change and associated uncertainties in the business environment, and
explore how they might play out to create alternative future states. The probability than the
future will unfold exactly as portrayed in a particular scenario is very small; however, it is
quite likely that the future will lie somewhere within the boundaries encapsulated in a set of
scenarios. Consequently, the value of engaging in a scenario exercise is not in the reliability
of the content or the accuracy of the projections of the scenarios, but the insights and learning
arising from the process itself.

Background to the pharmaceutical scenario workshop

In 2005, a scenario exercise was conducted with a team of twelve senior managers from the Asian
operations division of a well-established, US-based, global big pharma company. All had heard
of the term ‘scenarios’ with varying degrees of understanding, but had not previously participated
in a scenario workshop, and to their knowledge, the company had never formally undertaken a
scenario project.

The reason for commissioning the scenario workshop was that the Asian operations were in
the preliminary stages of preparing the next long-range strategic plan for their division, and
the Finance Director (FD) responsible for its coordination was keen for the team tasked with
developing the plan, to do some ‘out of the box thinking’. He had come across the work of Shell
in using scenario-based planning and thought it would be useful to give the planning team hands­
on experience of using the technique. Accordingly, the author was commissioned with designing
and facilitating, a five-day scenario workshop for the team.

The starting point of the workshop was to establish the scenario agenda. As it was not possible in
this case to arrive at this conventionally through interviewing managers across the organisation,
the agenda was developed with the participants at the start of the workshop, and summarised
in the focal question – what are the paths along which the pharmaceutical industry could evolve
over the next 15 years?

The workshop then progressed to examining at the macro level, the recent history of the pharma­
ceutical and biotech industries to arrive at a common understanding of the current realities facing
the industries. The rationale underlying this is that in order to understand how the future may
develop, it is first necessary to appreciate the current situation and how it came about. Although
all of the issues raised in this exercise are already well known to those familiar with the industry,
they have been detailed in the following section in order to provide the reader with the contextual
setting for the scenarios discussed in a later section of this paper.

The pharmaceutical industry – current realities

Angell (2004) suggests that while the pharmaceutical industry was ‘a good business’ from 1960 to
1980, from 1980 to 2000 it was ‘a stupendous one’ as prescription drug sales tripled and ‘profits
skyrocketed’. With hindsight 2000 may however, mark another turning point in the industry’s
history, the year that things began to go wrong as the industry began to face a convergence of
interrelated challenges, the most significant being the cost of R&D and the decline in R&D productivity, competition from generics, health care costs and product liability.

**Cost of research and development**

R&D is the lifeblood of the pharmaceutical industry as evidenced by data from CMR International which shows that the industry spent US$60 billion in 2006, up from US$35-40 billion in the 1990s (Anon 2007). There are several interrelated issues associated with this, the first being that R&D costs are high. It is estimated that the cost per new drug from discovery to Food and Drug Administration (FDA) approval has risen from an average of US$154 million in 1976, to approximately US$800 million in 2000 (European Federation of Pharmaceutical Industries and Association 2007; DiMasi, Hansen, and Grabowski 2003); although cost estimates vary widely in the literature and the figure of US$800 million is for bringing a new molecule entity (NME) to market rather than a incremental modification of an existing drug, it has been suggested that 'the era of the billion dollar new drug has arrived' (Anon 2007). The second issue is that R&D is high risk; on average from every 10,000 molecules synthesised in laboratories, 250 proceed to preclinical testing and only one or two eventually pass all approval stages to become a marketable medicine, with the majority of new drugs failing at clinical testing phases which constitute approximately 43% of R&D cost (European Federation of Pharmaceutical Industries and Association 2007). Consequently, of the new drugs that make it to market, on average only three out of 10 earn back the cost of the investment in R&D (European Federation of Pharmaceutical Industries and Association 2007; DiMasi, Hansen, and Grabowski 2003). The third point is that R&D is also time consuming, the median time from discovery to patent of a new substance now averaging 12 to 13 years (European Federation of Pharmaceutical Industries and Association 2007; DiMasi, Hansen, and Grabowski 2003).

**Decline in R&D productivity**

Although global pharmaceutical R&D expenditure has increased by an annual average of 13% since the 1980s, the annual number of new chemical entities (NCEs) and NMEs recorded has declined since the 1960s from a high of about 100 to between 20 and 30 per year in the new millennium (Weisbach and Moos 1995; Calfee 2006). Although the decline in R&D productivity is a contentious one, recent reports by both the US Congressional Budget Office and the Government Accountability Office arrive at the same conclusion, namely that the productivity of research and development investments has declined since the mid-1990s (Congressional Budget Office 2006; US Government Accountability Office 2006).

Compounding the above is that few of the drugs launched in recent years have been therapeutic breakthroughs with only one third of them being regarded as 'first or second in class', the remainder being indistinguishable 'me too' products that essentially treat the same problem in similar ways as existing drugs (Bunn and Salo 1993; Angell 2004). Goozner (2004) for example, provides evidence purportedly showing that 50% of the pharmaceutical industry's R&D expenditure 'is spent on drugs that add nothing significant to physicians' armamentarium for fighting disease'.

Although the 'me-too' product phenomenon was established many years before the first 'Blockbuster' drug was recorded, the almost industry wide adoption of the blockbuster drug' strategy over the past 20 years has fuelled the situation. Given the cost, risk and time frames associated with R&D, big pharma have focused their efforts on the commercial attractiveness of big diseases markets; i.e. high prevalence, high incidence and chronic diseases, and developing blockbuster
drugs which address these. While this strategy stimulated the rapid growth of companies in the 1990s, blockbuster-fueled growth is fading; whereas 15 blockbusters were introduced in 1997, only four were in 2005 (Anon 2007; Anon 2004; Jackson 2003). Striving to develop a first in class drug with the expectation of it becoming a blockbuster does not automatically guarantee success; Lipitor for example, was the fifth comer to the cholesterol-lowering market but has since come to dominate the market and is the best-selling drug in the world with sales of US$13 billion in 2005 (Anon 2007). Meanwhile recent problems with Vioxx demonstrate that the blockbuster drug strategy can be a risky one.

**Competition from generics**

Aside from intense rivalry within the industry, pharmaceutical companies are facing increasing competition from generic medicines which have been aided by the 1984 Drug Price Competition & Patent Term Restoration Act (Hatch–Waxman) authorising the FDA to approve generics without additional extensive clinical testing. This is because generics have the same active ingredients, are absorbed and metabolised in the same way as their branded counterparts and do not therefore require additional extensive clinical trials to establish their safety and efficacy. As a result, the estimated cost of developing a generic drug is around US$1 million, a fraction of that of a branded drug; consequently they are sold at 20–80% below the price of equivalent branded drugs and regulatory agencies are increasingly encouraging their prescription (Trombetta 2005; Jackson 2003; Balaban et al. 2003). Meantime manufacturers of generics are becoming more aggressive as evidenced by recent challenges of the patents on Prozac (Eli Lilly) and Lipitor (Pfizer) by Barrs and Ranbaxy respectively.

Exacerbating the above is the fact that the patents of 80% of the global blockbusters in 2000 will expire by 2008, exposing an estimated US$50–70 billion to generic erosion and a projection that global sales for the top 10 selling drugs in 2004 will shrink by 82% in 2011 (Balaban et al. 2003; Hamilton 2005; Feki 2005). The generics market is worth US$60 billion and this will inevitably continue to rise (Hamilton 2005). The data varies in the literature, but the reported consequence of this is that branded drugs will lose between 15% and 30% of their market share after the first generic drugs reach the market, and 75–90% on subsequent generic launches. Recent evidence attesting to this comes from Bristol-Myers Squibb who in their third quarter earnings in 2006, note that the expiration of the patent on their cholesterol lowering drug Pravachol, resulted in a 46% decline in sales of the drug (Harrison 2006). The biggest challenges in this area comes from Indian drug companies such as Ranbaxy, Nicholas Piramal and Dr Reddy’s who with their modern facilities and pools of well educated chemical scientists, are able to develop, test and manufacture generics at a fraction of what it costs in the West (Trombetta 2005).

**Health care costs and price controls**

Worldwide healthcare expenditure is increasing annually and in the USA the cost of pharmaceuticals is the fastest growing component of healthcare. This is an evocative issue in the USA where health care expenditure is largely privately rather than government funded, and in 2004 reached an estimated US$1.8 trillion, of which US$200 billion represented the cost of prescription drugs (Feki 2005). The consequence is escalating pressure on the industry as governments seek to curb health care expenditure through price control regulation, cheaper substitutes, alternative medicines and the sale of more drugs OTC (over-the-counter). The USA is now the only major market in which there are no general government price controls on drugs and prices have continued to rise, whereas
in Japan and Europe prices have flattened or declined as governments have successively strengthened cost control and containment measures (US Government Accountability Office 2006).

**Product liability**

While product liability risk in the industry is not new, drug safety issues have heightened, testimony to which is that hormone replacement therapy which has been on the market for 60 years was classified as a carcinogen by the World Health Organization in 2005. At the same time there have been four recalls since 2000 of products that had been on the market for between 4 and 10 years (Bextra, Vioxx, Lipobay and Prepulsid). Aside from lost revenues, litigation associated with product liability is overwhelming. Merck for example, purportedly faces 11,500 lawsuits related to Vioxx resulting in potential payments approaching US$20 billion (Berenson 2006). Liability lawsuits are not however limited to recalled products, drugs such as Seroquel (AstraZeneca), Ortho-Evra (Johnson & Johnson), Pempro (Wyeth) and Fosamax (Merck) all of which are still in use with combined annual revenues of US$7 billion, are also reportedly facing liability litigation. Lawsuits in the USA over prescription drugs generally result in the highest financial settlements of all product liability litigation, witnessed to which Eli Lilly reportedly agreed to a US$700 million payout in settlement of 8000 lawsuits over Zyprexa, while Wyeth has allegedly spent US$15 billion in settlement of lawsuits over Fen-phen (Berenson 2006).

**Other challenges and issues**

Two other matters gaining more prominence are public perception of and confidence in the pharmaceutical industry. Consumers are increasingly demanding more transparency and questioning the relationships between pharmaceutical firms and medical professionals. Despite concerted efforts by the industry to improve its public image, its reputation has fallen to an all time low; the *Wall Street Journal*/NBC News poll in January 2005 for example, found that ‘only 3% of people thought drug companies were working for the public good while 76% thought they were mostly interested in making profits’ (Agres 2005).

Concomitantly non-governmental organizations (NGOs) and patient-activists are confronting the drug pricing strategies of companies, asserting that the industry has little interest in non-profitable disease areas, notably tropical diseases such as Leishmaniasis and Schistosomiasis, and other diseases of the developing world (Agres 2005). Confirmation of this is that between 1975 and 1997, only 13 (1%) of the 1223 NCE registered were for the treatment of tropical disease, of which only four were developed by pharmaceutical companies (Hamilton 2005; Hoen 2002).

The backlash from African countries over high priced human immunodeficiency virus (HIV) anti-retrovirals and the Trade-related Intellectual Property Rights agreement, demonstrates that NGOs are increasingly focusing attention on the social responsibilities of the industry, declaring that high drug prices buttressed by rigorous patent protection are condemning millions of poor people in developing countries to death. Meanwhile the Thai government’s recent decision to issue compulsory licenses for two HIV/AIDS drugs (Abbot’s Kaletra and Merck & Dohme’s Stocrin) and a heart disease drug (Sanofi-Aventis’ Plavix) (Treerutkuarkul 2007) may foreshadow mounting pressure from developing countries to force big pharma to reduce the price of ‘essential medicines’, or risk these countries bypassing patents and purchasing generic versions of the drugs.

The second matter is that of the industry’s over-dependence on the US market. The pharmaceutical industry has traditionally focused on North America, Europe and Japan, which account for nearly 90% of the overall market, the largest market being the USA where prescription drug prices
are the highest and contributed almost half of the industry’s revenue in 2004 (Goozner 2004). While the USA is liable to continue as the dominant market for some time, the sustainability of premiums for branded drugs is doubtful given the rise of generics and pricing pressure to rein in healthcare expenditure. Meanwhile there are rapidly developing markets such as China, India and South America; with a growth rate exceeding 20% for the past three years (vs 7%+ for global growth), China is the fastest growing market and at current growth rates will overtake Germany and France in terms of market size within the next 10 years (Hamilton 2005).

Of the challenges and issues discussed above, the most pressing is that of the declining R&D productivity and the resultant lack of products in the pipeline to replace patent-expiring blockbusters. Capgemini for example, states that around 150 new NMEs will be required in the USA alone by 2007 to plug the drug pipeline shortfall (Capgemini 2004). How then has the pharmaceutical industry in general, responded?

Mergers & acquisitions – The most visible response has been merger and acquisition (M&A) activity and the number of M&A transactions has risen continuously from 10 in 1995 to 71 in 2004, giving rise to companies of an unprecedented size and scope in the industry (Feki 2005; Daemmrich and Bowden 2005). Declining R&D productivity is generally cited as one of the principal drivers of M&A within the industry, and recently several big pharma companies have been targeting the acquisition of smaller companies to fill specific gaps in their product pipelines.

While M&A have resulted in significant cost reductions, data from Pharmaceutical Executive indicates that 75% of large-scale mergers fail to create shareholder value exceeding industry averages, productivity declines by 50% following the announcement of a merger and leadership attrition rises to 47% within three years following a merger (Bogan and Symmers 2001). This, PricewaterhouseCoopers suggests, results from the fact that M&A activity magnifies the issue of inefficient processes and diminishes agility as companies struggle to integrate new operations (PricewaterhouseCoopers, nd). It is now commonly acknowledged within the industry that M&A does not necessarily solve issues such as declining R&D productivity, but may in fact exacerbate it, as the merged companies often drop innovative but less lucrative drug prospects. There is also the additional issue that the bigger the company, the bigger the need for new products to sustain it (Weisbach and Moos 1995).

Product lifecycle management – A second common approach has been for companies to commercialise their products and focus on product lifecycle management where added revenues have been extracted from blockbuster products within stagnant markets. This ‘relentless marketing’ of me-too drugs as Angell suggests, resulted in substantial increases in sales and marketing expenditures to the point where some pharmaceutical companies are now spending more on marketing and product promotion than R&D (research and development) (Angell 2004). Exacerbating the situation is that best-practice lifecycle strategies adopted by other industries, are either absent in the pharmaceutical industry, or are poorly implemented, antagonising stakeholders including regulators (Capgemini 2004). Critics of the growing expenditures on direct-to-consumer advertising of drugs in the USA claim that this has not only increased the cost of drugs, it has also prompted demand for the latest drugs in favour of older and less expensive, but often equally effective medications.

Partnering with biotech companies – The third response of pharmaceutical companies has been to seek alliances with, invest in and or acquire biotech companies in order to shift their drug discovery programs from conventional models based on costly, long haul clinical trials, to a better
predictive model based on the information gathered from genomics. While not a new phenomenon, this strategy will likely escalate as this form of drug discovery proves to be faster, more precise and ultimately more cost effective.

Despite all of the above, a report by Accenture (2006) reports that the biopharmaceutical industry 'remains remarkably robust. Companies are profitable and flush with cash'. However more importantly, it also notes that between 2000 and 2005, the 14 largest companies in the industry 'lost US$500 billion in value. More worrying still, future value expectations for these same companies have plummeted – by an astonishing US$1 trillion.' Failure to manage issues such as innovation and R&D, and determining which products and markets offer the greatest future growth potential, will the report warns, 'continue to jeopardise future value' (Accenture 2006).

The medical biotechnology industry – current realities

Today biotech is the fastest growing sector in the drug industry with annual growth rates almost double that of the overall drug industry average; in 2005 revenues of publicly traded biotech companies in the USA totalled US$63 billion and are projected to reach of US$250 billion by 2015 (Farrugia 2004; Carr 2003). The 1500 biotech companies comprising the industry in the USA range from small start-ups to multi-billion dollar firms such as Amgen and Genentech who focus on delivering 'end-to-end product solutions', however the industry largely comprises small players carrying out highly specialised activities, most of whom have not posted profit from inception.

The advantages biotech companies offer over pharmaceuticals are that first, they have rich product pipelines and, second, they enjoy a relatively high success rate. While an average of 34% of biotech products will pass clinical trials and reach the market, only 8% of pharmaceutical products do so (Farrugia 2004; Carr 2003). Finally, the duration of their development process is quickening, much of this being due to significant progress in recent years in drug screening and discovery attributable to advances in combinatorial chemistry and high throughput screening (HTS). The disadvantage of biotech medicines is that cell culture methods require significant upfront investments in capital and labour and producing biotech drugs is complicated and time-consuming, which combine to translate into the first fundamental issue in the industry – that of sourcing capital investment funds.

Capital investment funding

As with pharmaceuticals, biotechs rely heavily on breakthrough scientific achievements and government approval, both of which require substantial front-end investment in R&D. While product development cycles are quickening, many of the biotech drugs now appearing on the market represent the accumulation of research over a period of 15–20 years. As in pharmaceuticals, R&D alone does not guarantee success; even the best of the products in the pipelines do not always produce results. The problem as Booz Allen Hamilton have noted, is that 'there is no statistical relationship between R&D spending and almost all primary measures of economic or corporate success'; what matters is not how much you spend on R&D, but how you spend it (Jaruzelsky, Denhoff, and Borda 2006).

In most cases, the biotech industry is poor in revenue generation and the industry as a whole remains unprofitable largely because commercialising a biotech product is a long, costly process. Although market capitalisation continues to rise in the industry, securing a steady stream of capital has proved difficult for most companies because of a so-called 'fundamental timing mismatch' in that while bringing a new biotech drug to market can take up to 20 years, the investment community
generally have much shorter investment horizons. This, along with the legacy of the dot.com bust, has made the investment community more cautious and as a result, investment-financing cycles in the biotech industry have been extremely volatile, and this presents significant risks to the industry, particularly to small companies perennially in need of capital (Carr 2003).

In broad terms, the industry as a whole has responded to this through strategic alliances, namely:

(1) **Alliances with big pharma** – The most obvious response to their funding problems has been for biotech companies to seek alliances with big pharma companies to the point where they are becoming the ‘discovery arm of the pharmaceutical industry’ (Carr 2003; Rabino 1998). The benefits of these alliances are supposedly mutual; biotechs whose organisational structures are generally better suited to creativity, leverage on the clinical research facilities, regulatory, and sales and marketing expertise of the pharmaceutical companies who in return, gain access to innovative biopharmaceuticals to strengthen their product pipelines. However a limiting factor in this is that the overall production cost of biotech-based drugs is considerably higher than it is for conventional drugs, and much of the pharmaceutical industry lack the infrastructure to manufacture biopharmaceuticals as they are geared towards production of small molecule drugs.

(2) **Alliances with academic research centres** – Another common response has been to build alliances with academic researchers in university research centres. Many biotech firms trace their origins to academic institutions, and it is largely academic researchers who have advanced the biotech field rather than large corporate R&D efforts (Carr 2003). The problems with this is that first, it has inevitably focused research away from pure science towards areas that offer the best prospects for patentable results that can be commercialised. The concern with this is that it will, in the long term, erode the quality and volume of basic science research with consequence affects on the next generation of biotech research. Second, studies (Rabino 1998; Blumenthal et al. 1996) have shown that commercialisation of research leads to a reduction in scientific dialogue and sharing of research results and insights, both essential for science to progress.

**Public attitude towards biotech**

The second major issue facing the biotech industry is that of the public attitude to biotech, in particular, recombinant DNA technology colloquially known as genetic engineering, and the resultant high degree of uncertainty regarding the eventual market acceptance of their products. There has been much societal confusion and mistrust over the science itself and its potential applications; issues such as cloning and stem cell research have aroused fear in segments of the public, and have led to much controversy, activist pressure and litigation. The issues are divisive and present moral and ethical dilemmas to which there are no easy answers, and have spawned a new field known as bioethics. The problem as Rabino (1998) points out is that public opinion is not only the driving force behind government funding, but also legislation and regulation. Additionally, dealing with the social, legal and ethical implications related to biotech experiments is costly, diverting scarce funds away from R&D efforts. It is unsurprising therefore that the industry has not been able to resolve this issue, and is unlikely to be able to do so in the near future.

With a clear understanding of the current realities, the team then progressed to developing scenarios, beginning with an exploration of the contextual environment and culminating in the development of four scenarios, as described in the following section.
The pharmaceutical industry scenarios

In thinking about the next 15 years, the team developed an initial list of over 150 'driving forces'; after removing duplications of ideas and identifying which of the forces were essentially predetermined (see Table I), this was reduced to around 100.

In subsequently clustering and ranking the uncertainties in terms of their predictability and impact, the team determined that there were a number of critical uncertainties, including the state of the global economy, terrorism and regional conflicts, the impact of the BRIC economies (Brazil, Russia, India and China) and the changing world political order, societal values and technological change. Possible polar extremes of each of the uncertainties were postulated (e.g. global economy continues to grow at one end of the continuum, global recession at the other), and pairs of uncertainties were juxtaposed across each in various combinations to form a potential set of four scenarios. In reviewing each of the potential sets, the team concluded that the most interesting and challenging uncertainties were 'the future path of technology development' and 'the dominant social values that organize society'.

In terms of technology development, the populist view is that geometric increases in computing power, communications, sensors and so on, would result in innovative and integrative technology development over the next 15 years. This, the team decided, is not predetermined, however; current advances in sequencing the human genome and breakthroughs in the 'omics' have taken 30 years and are revolutionary and disruptive rather than evolutionary innovations. As already complex technological systems become more complex by virtue of changing underlying technology and changing versions of software, an equally plausible contrasting view is that technological

<table>
<thead>
<tr>
<th>Table 1. Summary of predetermined elements.</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Ageing population and continued global population growth</td>
</tr>
<tr>
<td>• Growth of chronic and degenerative illnesses and spread of old (and new) contagious diseases</td>
</tr>
<tr>
<td>• More educated, demanding and increasingly vocal consumer-patients</td>
</tr>
<tr>
<td>• Regulatory pressure will increase rather than decrease</td>
</tr>
<tr>
<td>• Continuing pressure to reduce healthcare costs resulting in more:</td>
</tr>
<tr>
<td>- price controls</td>
</tr>
<tr>
<td>- 'authorised generics' as drugs near patent expiration</td>
</tr>
<tr>
<td>- shifts to OTC as patents expire</td>
</tr>
<tr>
<td>• Continuing erosion of premiums on branded health care drugs (in the US) results in more cost cutting and search for efficiencies:</td>
</tr>
<tr>
<td>- outsourcing/shifting of manufacturing to developing countries with established pharmaceutical/life sciences experience and trained scientists</td>
</tr>
<tr>
<td>- shift of development work including clinical trials to developing countries</td>
</tr>
<tr>
<td>• Increasing role and influence of NGOs and activist groups at both the national and international level and demand for:</td>
</tr>
<tr>
<td>- more transparency</td>
</tr>
<tr>
<td>- affordable therapeutics and technology transfer</td>
</tr>
<tr>
<td>• Asia becomes new competitive force (and market) in pharmaceuticals and biotech:</td>
</tr>
<tr>
<td>- more aggressive challenges to patents</td>
</tr>
<tr>
<td>- increasing acquisitions of western companies</td>
</tr>
<tr>
<td>• Debate over the ethics of biotech applications will not be resolved in 15 years</td>
</tr>
<tr>
<td>• Biotechs will increasingly develop their own facilities and expertise in clinical trials, regulation, distribution and sales and marketing</td>
</tr>
<tr>
<td>• Fragmentation of the industries, R&amp;D cost/timelines and empty pipelines will result in further rounds of consolidations</td>
</tr>
</tbody>
</table>
developments could stagnate, exacerbated by the emergence of a Luddite counter culture, united in concerns over the potential for catastrophic technological downsides and threats to human survival. Thus, while technology will continue to develop, progress would be incremental and fragmented.

Although the nature of societal values is not an independent or easily definable concept, the team decided that they are a critical uncertainty in that they essentially determine how society views healthcare, thereby influencing public healthcare policy, regulation and demand for healthcare products, and they key into many contemporary social debates. At one end of the spectrum were values dominated by the drive to private consumption and personal freedom as economies became more open and competitive through globalisation. While it would appear that this was the direction the world is currently heading in, the team determined that it was not predetermined that the trend would continue. It is equally feasible that disenchantment with consumerism could result in values becoming more communitarian and non-market oriented, shaped by a concern for the common good.

Juxtaposing the dimensions of these technology and values uncertainties across each other resulted in four scenarios with the salient features distinguishing and defining each of the scenarios shown on the matrix in Figure 3.

In discussing the scenarios, the team considered that at the point in time of the workshop, the Druggernauts Rule scenario was fundamentally a ‘business as usual’ scenario in that it largely represented the current situation. Going forward, there would be some changes – there were already discernable signs that society, particularly in countries such as China and India, was becoming increasingly materialistic, but there would be no large-scale technology integration, and the pharmaceutical industry would continued to ‘muddle along’ for the next 15 years. Inherent in this scenario were that there would be further consolidation of the industry and the focus would be on cost and efficiency-oriented strategies to combat competition from generics and socio-political price pressures. By the end of the scenario period, health care systems in the USA and parts of the EU would reach the point of financial collapse.

In the Old Science scenario, both biotech and technology fail to deliver to expectations and pharmaceutical companies shed their biotech investments and concentrate R&D on commercially attractive therapeutics targeted at affluent populations and markets. The majority of therapies continue to centre around the treatment of symptoms, but with an increasing focus on therapeutics and quality of life drugs for affluent, niche markets. Intrinsic to this scenario is that pharmaceutical companies favour the traditionally successful vertically integrated business model, and as with the Druggernauts scenario, cost and competitive pressures continue to dominate the industry.

The New Science scenario represents somewhat of an ideal state, albeit in this scenario markets would likely be hyper-competitive. Revolutionary changes in technology result in breakthroughs in mapping the fundamentals of genetic-based diseases, and along with further optimisation of molecules, results in a plethora of new, innovative and customised treatments. The consequence is substantial delays are encountered as regulators struggle to deal with the number and complexity of applications. Although more and more illnesses become treatable, pharmaceutical companies concentrate on the lucrative life enhancing medicine market and specialty drugs to combat targeted conditions such as obesity, rather than chronic diseases.

Meanwhile the final scenario, Bitter Pill, is a mixed blessing scenario in that while innovative and integrative technology development results in many new possibilities, more altruistic and communitarian societal values limit the profit potential of the possibilities. On the positive side, new technology and pharmacogenomics open up endless new targeted drug discovery
opportunities in this scenario. On the negative side, regulators play a decisive role in the strategies of the pharmaceutical companies, demanding cost effective medicines, forcing technology transfer and minimising IPR (intellectual property rights) protection and enforcement for existing and emerging infectious, epidemic diseases, minimising the profitability of pharmaceutical companies.

Discussion

In terms of the scenario process, the team expressed two points of learning. The first was that many of the driving forces initially identified represented 'predetermineds'. For example, as reflected in Table 1, the team concluded that given the fragmented state of the industries, the cost and long lead times of R&D, and the empty product pipelines of most pharmaceutical companies, further rounds of M&A consolidation in the industries were inevitable over the next few years.

The second learning point was that few of the forces identified were truly standalones; most were interrelated at some level. As van der Heijden et al. (2002) has noted, there is a growing awareness of the fact that everything in life is 'part of a wider, non-linear, self-organising and interconnected milieu; what appear as seemingly discrete activities and happenings are in fact all part of interacting systems which combine to form complex global systems'. It is only by investigating how the connecting 'loops and linkages' comprising the system work to balance and reinforce elements, that a systemic understanding of situations and insights as to the possible ways they may evolve is arrived at (van der Heijden et al. 2002).

The conclusion of the team at the end of the workshop was that the fundamental economics that have driven the traditional business models for the industries are changing; both industries are in a transition phase. This being the case, if their company was to better position itself to survive the future, it had to begin to think about the future in a structured way in order to determine what lay ahead and how the company should start to prepare for this. This is best encapsulated in the comments below from one of the senior workshop group members:

I look at all the post-its we have on the walls ... there are a lot of them ... but there is nothing earth-shatteringly new in them. In the 10 years that I've been with the company we have probably discussed most of these. The problem is that we have always discussed them individually [one issue at a time], this is the first time I have been in a group where we looked at these things in a coherent way, how they work together and can create different futures, what we know for sure will happen and what we just cannot forecast. When you do this, you start to see the big picture ... and when you do, you start to realise that a lot of the things we do in the company are a waste ... like spending more money on advertising, because it doesn't really address the big picture. As you said earlier, it's a case of rearranging the deck chairs on the Titanic ... but we even hire consultants to help us rearrange them. We [as a company and the industry] cannot continue to muddle along down this path, it's just not believable. If we don't start to really think about the future in the way that we have done in this workshop, we are doomed to failure ... the writing is on the wall.

Having undertaken a scenario exercise with one division of the company, albeit a short 'mini' scenario exercise rather than a comprehensive scenario project, the question is – did it lead to any measurable results in terms of strategy development in the company? In recently discussing this with the FD who commissioned the scenario workshop, the answer was:

No. We prepared the strategic plan following corporate guidelines, attached the scenarios to the plan, and suggested that we would like to take the work we had done and expand it by doing some research
and some additional thinking. The answer from the corporate planning people was – there is a lot going on in the company right now, we can talk about this later. 18 months have gone by and nothing has happened, and it is now obvious that nothing is going to happen – we are still locked inside those old mental models we talked about at the workshop.

Conclusions

It has been said that we live in an age of uncertainty, an age of turbulence and structural discontinuities and as Drucker (2005) reminds us, the greatest danger in times of turbulence is not the turbulence, but to act with yesterday’s logic. The current turbulence being witnessed in both the pharmaceutical and biotech industries is not a temporary aberration; it should be expected that there will be continued and unrelenting pressures in the next 15 years from a growing range of stakeholders, along with increasing competitive forces from Asia and other regions. This being the case, traditional industry recipes that have worked well in the past are unlikely to lead to sustained success in the future (Hamel 2000).

How well prepared is the pharmaceutical industry to meet the inevitable changes arising from this turbulence? The answer according to Fuld (2004) is ‘not very’. There is he contends, ‘a large gap in competitive preparedness. Nearly every manager sees one or more looming threats just over the horizon, yet only a small fraction have done anything to see around the corner’. The reason for this is ‘self-induced competitive blindness’.

One way of overcoming this ‘blindness’ is to engage in scenario thinking which is a powerful mechanism for learning and change in organisations. In this case while the scenario workshop may have been successful at overcoming the blindness in the scenario team of a division of the company, with the consequent realisation that their strategy was largely a ‘traditional recipe’ that only worked well in a ‘business as usual’ scenario, it apparently failed to achieve anything outside of the division. One possible explanation for this is the comment from the FD stating that the management of the company were ‘locked inside old mental models’. As Wright et al. (2004) note, managers in locked-in organisations may regard scenario interventions as unnecessary because ‘the increased stress of a misfit between strategy and the environment may either have not been experienced because of the dominance of out-dated mental models, or have been reduced to tolerable levels by psychological coping mechanisms’.

The above being the case, the timing of a scenario intervention is therefore crucial and the apt timing for the intervention is ‘after there is recognition that the environmental threat to current strategy is high, but before the psychological processes inherent in coping behaviour are engaged’ (Wright et al. 2004). In terms of the scenario workshop discussed in this paper, it may be the case therefore, that it failed to lead to any follow-up action in terms of strategy development because among other things, the timing of the intervention was inappropriate.

Notes on contributors

Ron Bradfield is a lecturer in management, and director of Strathclyde University Business School’s campuses in the UAE. Resident in Abu Dhabi since 2005, he is responsible for the operations and development of the Strathclyde Business School’s campuses in the United Arab Emirates.

Hany El-Sayed is Territory Manager – Gulf and East Mediterranean at Bristol Myers Squibb Bahrain.
Four Scenarios for the Future of the Pharmaceutical Industry

References


