Original Article

A structural change in the global pharmaceutical marketplace

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ABSTRACT **Asia is becoming a centre of gravity for global business. As a result of this, there is a growing interest in investment in this area, and pharmaceutical companies are not an exception. The old research and development investment model of the Western Big Pharma companies is starting to fall apart with the well-publicised reduction of new chemical entities productivity. Big Pharma is rethinking its business opportunities. Today, 88 per cent of the world's pharmaceuticals are shared between only 18 per cent of the world's population, which means that 82 per cent of the world's population has access to only 12 per cent of the world's pharmaceuticals. This presents a unique business opportunity for those that can seize the moment. Within this context, we are witnessing the use of different strategies by pharmaceutical companies. Some Big Pharma companies have a generic strategy, some have a developing world strategy, some have an outsource strategy and others have all three. The current mergers and acquisitions of pharmaceutical companies in India portray these structural profound changes.**
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> Oh East is East & West is West and never the twain shall meet. (Rudyard Kipling, *Ballad of East & West*, 1865–1936)

BIG PHARMA

The R&D investment model of the Western Big Pharma companies is starting to fall apart with the well-publicised reduction of new chemical entities (NCEs) productivity. Surprisingly, global R&D expenditures haven't changed much in spite of all the comments on downsizing by Big Pharma. However, there has been a rebalancing within the R&D numbers through outsourcing to Asia of R&D. At the same time, regulatory

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hurdles have risen with more questions being raised by Regulatory Authorities on submitted clinical data during the regulatory process on potential blockbusters as identified by the financial analysts. The hurdles to gaining reimbursement in the European marketplace have also risen. Altogether, this has put more pressure on the NCE pipeline.

While Brazil, Russia, India, China, South Africa (BRICS), 'generics' and 'developing countries' are well-known terms in the economic development of the global markets, IMS has now generated a new name for this Pharma sector called 'pharmerging'. The seven emerging markets of Brazil, China, India, Mexico, Russia, South Korea and Turkey are estimated to have contributed an unprecedented 51 per cent of global pharmaceutical growth in 2009. In contrast, the conventional mature markets of North America, Western Europe and Japan have accounted for just 16 per cent of global growth. This is in sharp contrast to 2001, when these so-called pharmerging markets accounted for only 7 per cent of global growth, compared to the 71 per cent share from mature markets. This growing sector has attracted the attention of Global CEOs and Chairmen of the Big Pharma companies. This high level of interest has yet to percolate down through the middle ranks of these Big Pharma companies, and is raising interesting management issues within these companies. For example, Pfizer calls its generic division an 'Established Products Unit' because it has to deal with probably five decades of anti-generic public relations.

Government authorities have also become more and more invasive. The European Union (EU) has organised four separate but related anti-trust raids on Pharma Companies in 2008/2009. In the United States, the anti-trust pendulum has swung both for and against Big Pharma generic deals, but today it is resisting such deals in spite of the legal uncertainty.

Corporate headquarters are looking to retain in-house added-value roles such as regulatory, clinical trial design, price negotiators and sales/marketing teams. The outsourcing to Asia continues with manufacturing, clinical trial and development, and is leading to an active Contract and Research Market Size (CRAMS) business segment.

The generic industry has become more and more skilful at finding its way around imperfect patents, and this has led to most Big Pharma companies facing major patent erosion, with some as high as 70 per cent. The major exception is Roche, which seems to have managed its pipeline well as a result of the Genentech acquisition. New generic companies are appearing every month from India and China as they enter the international markets.

This has led to restructuring of 15 of the top 18 Big Pharma companies in recent years and a consequent loss of jobs. In addition, some companies have gone for big mergers and acquisitions (M&A) mergers to camouflage these problems.

THE DEVELOPING WORLD

Economically, the West has started 2010 hoping for a better year and looking for upbeat post Christmas retail sales as a positive sign of future economic recovery. In Asia and India in particular, the GDP growths of 6, 7 or 8 per cent are being forecasted. Where there used to be areas of jungle there are now new shopping malls with Versace and Chanel being shouted from their shop windows. Corporate offices in downtown Delhi are sporting rooftop waterfalls and lawns for the first time ever.

The rise of China was the most read news story of the last decade, surpassing even 9/11 and the Iraq war. On the macro-economic front, Chinese non-performing loans are now a quarter of 2002 and the Reserve Bank of India has become a model central bank owing to its careful historical management of Indian debt.

In the past, the Chinese and Indian share of the world population has stood at around 37 per cent, although representing only 14 per cent of the global world wealth. By contrast, the United States and EU hold only 17 per cent of global population but with a massive 55 per cent of global wealth. Today, a part of the world has substantial historical wealth and the other has dynamic GDP economic growth that is building a new era of middle classes. Investment bankers see a great opportunity here for synergising this wealth and this growth through alliances and M&A.

McKinsey has forecast that with a consistent 7 per cent GDP growth in India the middle-class population in 2015 will grow to 281 million and in 2025 will rise to 600 million. These numbers overshadow the current size of the US middle class.

One of the driving forces of all this growth is the high regard in Asia for education and science. India has increased its science and technology budget from US$4 billion in 2004/2005 to $6 billion in 2008/2009. This contrasts with the recent announcement in the United Kingdom of the Chancellor's decision in December 2009 to cut $1 billion from the countries' science and technology base. It is generally accepted that India is particularly strong in Chemistry and Maths, with China seen as much stronger in Biology. There are now a dozen internationally ranked business schools (including Duke) being set up in the Delhi area. The Lancaster University Management School already has 1000 students at the Goenka World Institute in Gurgaon. However, China has quietly become the second source of scientific knowledge, surpassed only by the United States. In 2006, China's research output was 83 000 articles per year, overtaking Germany, the United Kingdom and Japan at 80 000. In 2009, China reached 120 000 articles per annum, compared to the United States at 350 000 per annum. China now produces 20 per cent of the new scientific knowledge in material sciences. While quantity is not the same as quality, 9 per cent of Chinese papers do have a US-based co-author.

Many private equity health-care investors are attracted by the Asian sector, and some private equity executives in London believe that India is the only place worth visiting each month. The CEO of HSBC's relocation from London to Hong Kong in October 2009 is symptomatic of the movement in the business centre of gravity. While vehicle sales in the West have been held back by the recession, the unit sales of Maruti Suzuki motor vehicles grew by 51 per cent in December 2009 and 32 per cent for the 9 months to December 2009. There are also rumours in Delhi that Disney is buying land nearby. The Asian Developing World business is going forward in top gear.

Most developing world generic markets are called branded generic markets. They are also going forward in top gear, and, more importantly, continue to be highly profitable. These markets contrast with the low-profit commodity generic markets of Western Europe. This profit element is part of the reason why Big Pharma is attracted to this sector.

RECENT CHANGES IN INDIA

A merger between the sense of order of the Japanese and the intrinsic entrepreneurship of Indians should be a winning combination. The Singh family decision to divest their interests in Ranbaxy has led to a number of dramatic changes in perception in India.

First, Ranbaxy should now be able to move to the next level, having gained a new owner with very deep pockets. It should be easier to make those difficult launch decisions at the board level when it comes to launching a possible 'at-risk' highly profitable generic on the US market.

Second, the decision enabled the Singh family to spread their wealth across a wider space. Such a move was unheard of in India during the last decade. Nobody would have ever considered divesting the family jewels or businesses. It was a very brave decision made with great secrecy and executed well.

Third, many Indian promoters with hindsight can now see the common sense and opportunity in such a strategic move. As a consequence of this deal, many promoter families are involved in such conversations. What is the best way of distributing the family wealth? Even the sudden demise of Satyam has stirred the thoughts of these families. Young members of the promoter families are also reviewing their career prospects. Not everybody wants to join the pharmaceuticals industry and its strange scientific language. What was in the past a non-subject that could never be voiced is now a part of strategic planning for such business families. This should lead to more balanced decision-making, as all the options to refocus family wealth are now fair game. With the positive economic dynamics in India, one can see the multitude of opportunities if there is a pile of cash available. This is what the Singh family divestment has now let loose in India.

As expected, the new intellectual property regime has slowly reduced the generic new product pipeline available to Indian companies on the Indian domestic market. Although the local market grew at 15 per cent in 2009 with 40 per cent of the sales going for export a new domestic era is approaching for Indian CEOs and promoter families. There are currently a large number of Big Pharma CEOs and Indian CEOs in strategic discussions either directly or through consultants or Indian Mergers and Acquisitions (MA) boutiques.

WHERE DOES THIS LEAVE BIG PHARMA?

The failure of the old R&D model in the Pharma space has led many Big Pharma companies to reconsider their strategy and widen their vision.

Big Pharma have become intrigued by the fact that 88 per cent of the world's pharmaceuticals is shared among only 18 per cent of the world's population. More significantly, 82 per cent of the world's population shares only 12 per cent of the world's pharmaceuticals. Here lies a business opportunity. This is strategically reflected in many ways. Some Big Pharma companies have a generic strategy, some have a developing world strategy, some have an outsourcing strategy and some have all three. In addition, some have a parallel strategy of expanding in vaccines, consumer/over the counter (OTC) and healthcare venture capital investments. The Chinese domestic vaccine market is said to be worth \$1b in 2012, growing at 25 per cent per annum with 40 domestic companies.

From an Indian perspective and from someone who has lived in Delhi for the last decade there seem to be three groups of Big Pharma companies. First, there are those that stayed in India when the company shareholding laws changed 37 years ago. The Foreign Exchange Regulatory Act of 1973 limited the overseas parent's shareholding to 40 per cent. Second, there are those that pulled out of India totally. The third group is the Swiss. One should never underestimate the impact of those lost years when certain companies departed from India. Those companies that stayed have corporate headquarters that have become very comfortable with India, have built good relationships and have management teams they trust. The same is true in major fast-moving consumer goods companies like Unilever and infrastructure companies like General Electric (GE). One in four of GE's global headcount of technologists is now in India. Those Pharma companies that left have been trying to catch up with those that stayed for the last decade, and this is an interesting observation on the long-term impact of exiting a country during times of acute financial turbulence. I remember Sir Paul Girolami, ex-Chairman of Glaxo, explaining to me why it didn't make sense for Glaxo to exit Bangladesh in spite of years of losses because there were only a limited number of countries in the world and eventually one would return. In general terms, the Swiss Big Pharma companies are more focussed on China than India, and have put their major focus and strategy in that direction. The other international multinational Pharma Companies have attempted to look for the best synergy from both India and China. There is a certain learning curve in the United States on India (as opposed to China), as it is estimated that only 20 per cent of the top 100 American companies have a legal presence in India.

Ultimately, Big Pharma will expand greatly in Asia and the developing world and present a pharmerging face to the world alongside their mature markets face. With the new generation of global CEOs with young open minds, in my view a new global deal on IP will be cut with two levels of IP protection: one for the mature markets and the other for the pharmerging markets. The first signs are already there with the dual pricing policy being followed by some Big Pharma companies in Africa and South East Asia.

WHAT HAS HAPPENED SO FAR

In the generic space, Indian Drug Master Files (DMFs) continue to represent 50 per cent of US filings, compared to only 10 per cent for Chinese sourced DMFs. In addition, Indian sourced Abbreviated New Drug Application (ANDAs) have now reached 50 per cent. Chinese labour costs continue to be lower than those in India – although in Taiwan there are pressures from rising salaries. Chinese energy costs are also competitive, and will attract investment in fermentation-type facilities. The ready availability of inexpensive nuclear power in India will be an important step in competing with China in this respect. There are some signs of chemical industry overcapacity in China, with some chemicals running at 30–60 per cent capacity utilization, but this will probably balance itself out within the current dramatic domestic growth.

The vibrant economic strength of China and India is pulling along the South East Asian and Oceanic economies as their supply chains are integrated into adjacent countries, particularly Taiwan, Japan, Australia and South Korea.

Over 200 international companies have R&D innovation centres in India, with 40 per cent located around Bangalore. The $ spent per ounce of innovation is said to make a dramatic difference when various R&D facilities are compared.

The CRAMS is forecast to become $76 billion in 2010. What is surprising is that India and China each represent only a few percent of this marketplace. India itself has only a 4 per cent share. The potential for expanding this share is huge, and explains why the investment community sees this sector as a vibrant one in the Indian situation. Indeed, Pfizer is forecasting that 30 per cent of its manufacturing will be outsourced by 2010.

So far, Pfizer has acquired Vetnex and is forming supply arrangements with Cipla, Aurobindo, Claris and Strides Arcolab. Glaxo Smith Kline (GSK) is linking up with Aspen and DRL and acquiring assets in Egypt. Sanofi Aventis has acquired 80 per cent of Shanta Biotech and acquired generic assets in Mexico, Brazil, Turkey and the Czech Republic. Perrigo has bought Vedants, Lonza has acquired Simbiosys Biowares, Lanxess (Germany) has absorbed Gwalior, and Mylan has tied up with Biocon for Biosimilars.

Some of these are very unusual partnerships based on history. In this East-West dialogue, what has happened to date will probably be overshadowed by what is yet to happen in the light of the many discussions taking place today.

CONCLUSIONS

The old R&D model of Big Pharma is no longer working.

A developing world strategy is a top agenda item for Big Pharma.

The branded generic markets of the developing world continue to be very profitable.

Asia is becoming the centre of gravity for global business.

India promoter families are reviewing their strategic plans and their wealth profiles.

There are today many conversations between Big Pharma CEOs and Indian promoter families.

A structural change in the global international market is taking place.

Is it a fashion? Will it last? Or did Rudyard Kipling get it right?