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The changing paradigm

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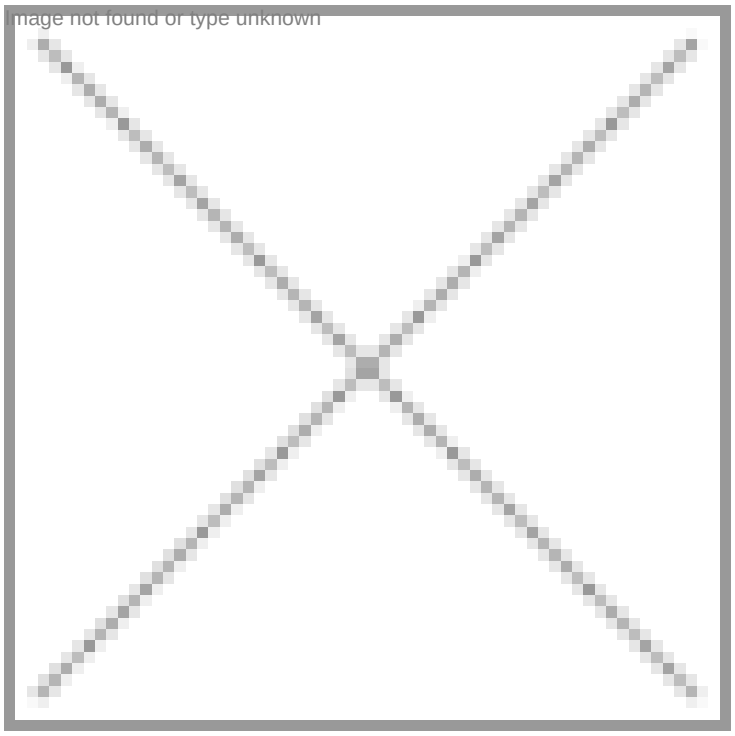

The changing paradigm

The pharma industry is changing from its traditional ways of investing in research and conducting business.

Diminishing returns on R&D investments is a growing concern for the global pharmaceutical industry. As an illustration of this point, the combined spending on drug discovery-research for the major North American pharmaceutical firms rose from slightly over $15 billion in 1995 to just under $45 billion in 2006; however, the new drug approvals every year fell from over 50 to just over 20 in the same period. This trend is forcing the industry to change from its traditional ways of investing in research and conducting
business.

First, placing big bets on a few small molecules, in the hope that these would become blockbuster drugs that would be the primary prop for the company, would no longer be a sustainable model. It is becoming increasingly clear that "big" drugs like say, Lipitor, the cholesterol drug made by Pfizer, which has been selling annually for well over $10 billion, are becoming almost impossible to discover. An analysis of recent drug launches suggest that the pipeline is shifting towards targeted therapies, though drugs for the general management of chronic diseases like high blood pressure and diabetes may still be important.

Another notable shift in focus is from treatment to prevention. According to a WHO report, only 3 percent of healthcare spending in wealthy countries is used for prevention, even though 80 percent of heart diseases, stroke and diabetes and 40 percent of cancer could be prevented. Preventive medicine offers the next growth area for pharma companies with vase opportunities in the realms of health management, wellness programs, compliance monitoring, vaccination and other value-added services. The market for just pure vaccines and combination vaccines is estimated to grow as much as $42 billion by 2015. Indian companies, which have proven strengths in this area, are well placed to capitalize on this opportunity.

Technology will be the other big driver of change in pharmaceutical innovation. The unraveling of the human genome sequence has opened up new opportunities for molecular science in health care and novel approaches in identifying drug targets. The promise of gene-based diagnostics for several physiological and pathological conditions is getting increasingly realized. Personalized medicine will become the order of the day.

The big pharma companies can no longer bank on the "cash-cows" in their product portfolios for sustaining their top and bottom lines. Drugs are fast going out of patents, and new innovations are not keeping pace for keeping the value of the company's Intellectual property from diminishing. It has been estimated that since

2001, the average annual value erosion to pharmaceutical firms, through expiry of patents, is over $15 billion. We are now in a phase of particularly accelerated intellectual property attrition; in the next 4 years, over $150 billion of global drug sales will stand exposed to generic competition. This could be a windfall for the Indian drug manufacturers, who have already emerged as leaders in the generic drug business.

In recent years, cutting costs for new drug development has been the primary focus in the R&D strategies for pharma companies. Rapidly emerging diseases like the avian flu also necessitate the need for shortening the drug development life cycle.

Both these objectives can be eminently addressed by discovering new uses for existing drugs. As approved drugs have known pharmacokinetics and safety profiles, any newly identified use can be rapidly evaluated in phase II clinical trials, thus bypassing almost 40 percent of the overall drug development cost and saving considerable time in bringing the drug (for a new use) to the market. According to a recent commentary in Nature, there are approximately 9,990 drugs known to clinical medicine. Of these, 8850 are unique and are worth screening for novel therapeutic uses. However, the availability of a comprehensive collection of these molecules and existing patent restrictions could be challenges to this approach.

Another means of reducing drug development costs is through outsourcing of discovery research to low-cost destinations like India. A study by Technomark, a UK-based organization that tracks the global market for research outsourcing, the pharmaceutical contract research market, which is currently just under $15 billion is growing at 15 percent per annum, twice the rate at which the pharma business is growing. India is today an attractive destination primarily because of the lower people cost; however, this situation is fast changing with rising salary levels for qualified scientists. The way things are developing, it appears that the window for cost arbitrage would remain open only for the next 10 years or less. We would do well to take full advantage of this short-term opportunity by improving the intellectual property protection regime and implementing some quick-fix approaches to generate more quality man power for technology management. The latter could be achieved through short-term specialized courses like a finishing school for graduates and post-graduates in the country. Attracting the well-trained Indian talent from abroad is another option; the looming economic recession in the US could be a spur for this "home-coming". Indian firms should open-up and provide the right working conditions for this to happen at an accelerated pace.

The global pharma market is predicted to be more than double in value at $1.3 trillion by 2020, according to a recent Pricewaterhouse Coopers study. India and China together, which will have almost 40 percent of the world's population by then, would also account for a major chunk of this market. The Indian pharmaceutical industry is well placed to capitalize on the changing paradigm in drug discovery and could well spearhead the transformation in the global health care business.

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