BioSpectrum the business of Bio & Health Sciences

Handshake, a Must

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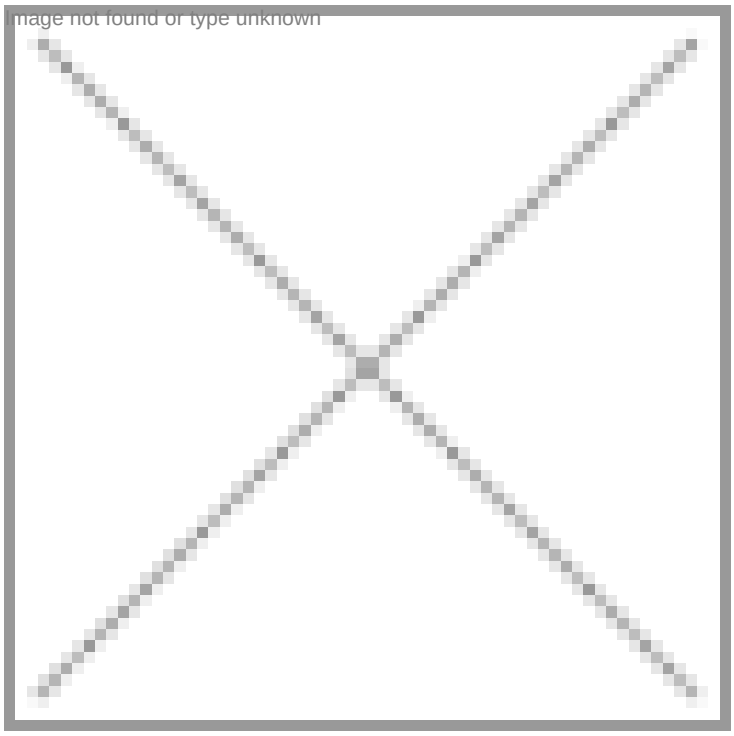

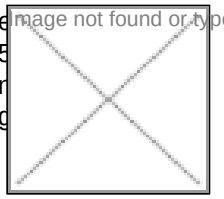

The Indian pharma and biotech sectors are poised for an explosive growth over the next decade. The combined size of these two can grow five-fold by the year 2010 to reach $25 billion from the present $5 billion. This is to quote a comment made by Sankar Krishnan, partner to McKinsey & Co., in a well-known publication recently in Mumbai. The growth is likely to take place against the backdrop of a fast-changing global pharmaceutical scenario.

The present trends suggest that more and more pharma companies are diversifying into the biotech sector. India is becoming a key source and market for biopharma. When several big drugs go off patent in the coming years, pharma companies from all over will be getting into this market quickly through the biotech mode. The bio-generic drugs are estimated to replace 70 percent of the conventional therapies by 2025.

The recent major structural shift in the pharma industry has resulted in new challenges for Indian companies. The ever-increasing size of drug companies resulting from continuing merger proposals is giving rise to unprecedented R&D budget for various multinationals. Unfortunately, many of the biotech companies are small and fragmented unlike the pharma industry. Mergers may lead them to outsource their R&D. It is time that Indian pharma companies in the country invest in productive R&D partnerships with biotech companies where original discoveries become viable products. The vast potential of the Indian herbal drug industry languishes due to the disinterest shown by the Indian pharma companies in the multitude of opportunities.

The biopharma sector is undergoing a major transition, perhaps the greatest since it began. The global biopharmaceuticals

market is estimated at Rs 33,000 crore and is said to be growing at the rate of 15 percent annually, in a scene dominated by global majors. This sector is very dynamic and for those companies willing to adapt flexible strategies, there are many opportunities ahead. Strategic tie-ups between big pharma companies and small biotech start-ups are already happening for contract research and manufacturing.

With over 350 biotech drug products in the pipeline across the world, this is also the chance for Indian pharma biotech companies. By 2005, the Indian market for recombinant medicine is also tipped to grow from Rs 535 crore to Rs 958 crore. Investments into biodrugs are also expected to grow to Rs 500 crore. Currently, four companies are into making the hepatitis B vaccine and several pharma companies have active biotech plans.

It would be wise to have synergy between the pharma and biotech companies to avoid cannibalisation and killing of effective products. The pharma industry should not lose focus at the market place.

"Learning" processes and the ability to change approaches and objectives to exploit new opportunities are the essential strategies. Companies like Bharat Biotech need to base themselves on the highest scientific skills that they can gather. Excellence in science alone, however, is not enough. It also needs entrepreneurial technology management and marketing coupled with entrepreneurial fund raising.

Concerns and Issues

One of the key concerns is about R&D. Many of our scientific leaders like Dr RA Mashelkar, Dr Manju Sharma and Dr VS Ramamurthy are all visualizing India to be the hub for R&D in the region. Indian biotechnology should leverage the IT strength displayed by the Indian software industries. Further due to the availability of human genome project data, India is in a position to develop new products that are globally acceptable. Keeping this in mind, biotechnology in India is now focussing on knowledge creation and retention. A think tank comprising of visionary groups from academia and industry to strategize the work plan for next five years is also being contemplated.

R&D alliances of various types are increasingly becoming a fact of life in the biotech industry. Underlying this trend is the general understanding that now a days no company or organization holds all the pieces of the complex jigsaw that together make up the picture of new profitable products. Increasingly, business success depends upon the ability of bioentrepreneurs to bring all these pieces together and to use them collectively to make profitable products.

An important feature of alliances is that they are often task-bound. The significance of this feature is not that partners eventually fallout with each other and go their separate ways, but rather that partners come together because they have some shared interest and complimentary resources and competencies. In other words, each partner holds part of the jigsaw. Once a specific problem is solved or a product developed and commercialised there is no binding reason for the alliance to continue. The skill of a bio-entrepreneur is to be able to draw all these pieces together for just long enough to achieve a goal and then to reconstruct new alliances around new problems or opportunities as they arise. An important aspect of this being that research may need to change direction and this may require a reassessment of the resources and competencies that may be needed in future. Patterns of partners can change.

There is a common perception that intellectual property rights (IPR) are a major concern in R&D alliances. While It is true that contractual agreements need to be concluded before R&D alliance or manufacturing alliances can start, but the criticality of formal IPR agreement in my experience is that technology is advancing so quickly that going for watertight IPR protection, particularly of technology processes is often simply not feasible. In most successful R&D alliances, more often than not, trust was the worthy substitute for formal IPR protection. In unsuccessful alliances, IPR protection alone did not protect the companies.

IPR and emerging patent problems in India

Many processes and gene components used in biotechnology are subject to intellectual property claims through patenting and plant variety rights. Dr RA Mashelkar, Director General, Council of Scientific Industrial Research, reiterated the importance of IPR in the context of WTO and gave a strong wake-up call to the ignoramii of IPR's importance. His awareness program has brought about a change in the mindset of our scientific community. Some western companies do not want to share technology with developing countries like India due to IPR protection. This type of intellectual isolation will hurt equal opportunities in the global society. Restriction of this kind will tempt entrepreneurs of developing countries to seek alternative methods. It is wise that companies from developed and developing world work together, thus safeguarding IPR for benefit of the society. In a controversial move some US companies whose patents are expiring are trying to extend the patent life. TRIPS does not respect the extension of patents in healthcare though.

Regulatory issues

India is undergoing the learning curve in regulatory issues. Unfortunately, biotech industries face five central ministries, six state ministries and 14 committees of both centre and state governments. This results in inordinate time-delays. In addition, the committees are not being stringent. This is resulting in lack of transparency in discussing the technical issues. The Indian Government should think of setting up a national level organisation independent of the government consisting of a think tank of academicians and industrialists to frame guidelines, policies and strategies for promoting research, development and production of biologicals. The organization can follow the model of CBER under US-FDA.

Bioentrepreneurship

Setting up and running a company requires teamwork and trust. In the last 25 years, science has metamorphosed into a viable business. While I was a graduate student at the University of Wisconsin-Madison, the business aspect was initially viewed with curiosity and doubt. After the introduction of the concept of incubator/science or research parks, the universities saw the emergence of bioentrepreneurs. This bioentrepreneurship changed the way science has been thought of in the US. It is gratifying that similar opportunities are gradually emerging in India.

Trends

Some of the leading Indian pharma players will make the transition to large globally successful companies. In addition, mid-size but high value research focused companies will emerge. Others may be forced to play a low value game to survive.

Innovation-led businesses in India consisting of new drug discovery, R&D services, will be as large as $5-7 billion by 2010. India's current base of the domestic market, global bulk and generics will present an $18-19 billion opportunity by 2010, up from $6-7 billion currently.

The forthcoming years will belong to bio-drugs like the human insulin, Streptokinase, recombinant hepatitis B, vaccines and diagnostics. Major investments will go into bio-engineered drugs for diseases from diabetes and cancer to HIV/AIDS, malaria and tuberculosis.

(Dr Krishna M Ella is the Chairman and Managing Director of Bharat Biotech International Ltd (BBIL), one of the leading research-based firms in India. BBIL was established with the objective of providing affordable solutions to health problems in developing countries.)

Dr.Krishna M.Ella