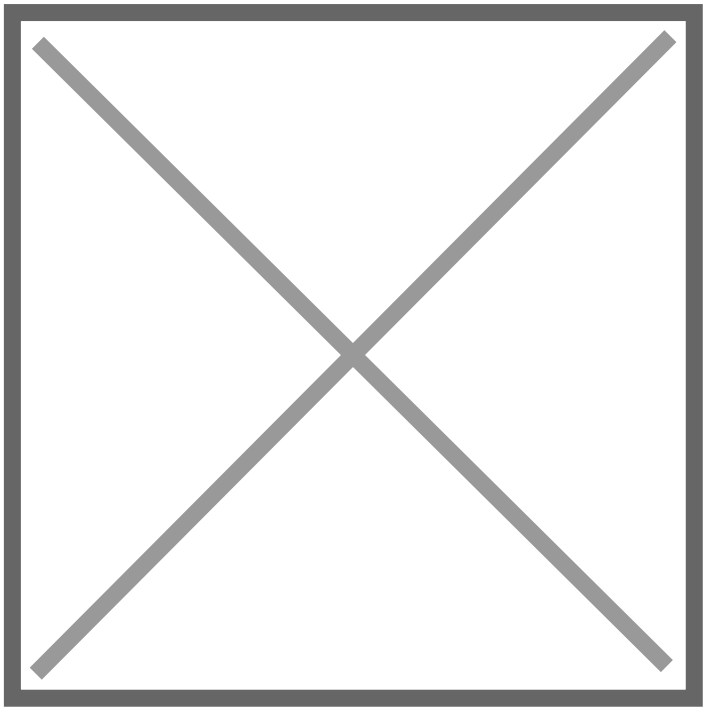
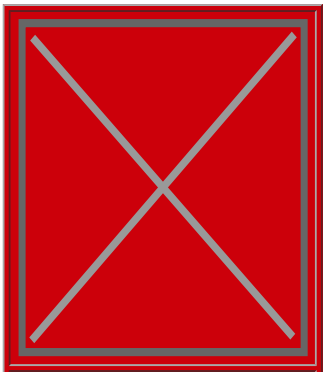
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Crucial decade for Indian biotech

10 March 2005 | News





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A revolution is taking place in the knowledge base of biotechnology, opening up enormous applications and opportunities in health care, agriculture and food products. This is in addition to stimulating research that are being conducted in the academic research centers. The knowledge base in biotechnology globally has resulted in the advancement of disciplines like genomic, proteomic, pharmagenomic, protein engineering, tissue engineering, nanotechnology, microarray technology, human and humanized monoclonal therapeutic antibodies, cell based therapies and novel vaccines.

The overall growth of biotechnology can be grouped in three generations. The first generation of biotechnology, also known as "conventional biotechnology", included the art of crossing plants, animals, using yeast to make bread and ferment alcohol. The description in "Rigeveda" on the use of beverages produced by fermenting grapes, suggested that we in India had the knowledge to use biotechnology processes for our daily needs even 8,000 years ago. The second generation of biotechnology included systematic attempt to understand role of microbes isolated from natural environment. During this phase several antibiotics (eg. Penicillin), enzymes and other fermentation products such as Bt(bacillus thuringiensis) biopesticides have been generated. The third generation of biotechnology - "Modern era of Biotechnology" is only about 30 years old. Innovations during 1970 resulted in developing recombinant DNA/genetic engineering and hybridoma technologies, which in turn ignite revolutions that are being experienced as a result of use of modern biotechnology tools. Though the investments are heavy on developing biotech products through modern biotech tools, returns are also higher.

A modest investment in biotechnology capacity building and sound bioindustry offers excellent business development opportunities for national and international biotechnology research and commerce. Even though biotech industry in the country is facing tremendous challenges in developing novel products from indigenous research and technology, the biotech

industry is vibrant. The total biotech sector market size during 2002-03 was $420 million in India, which grew by 39 percent in the fiscal year, 2003-04 (BioSpectrum-ABLE estimates). Biotechnology business in India has the potential to generate annual revenues of $5 billion and a million skilled jobs by 2010. Investment in this sector during fiscal year 2003-04 stood as over $137 million, which was 26 percent higher than during the 2002-03. The pharmaceutical segment consisting of products like therapeutic, vaccines, diagnostic etc. has major (76 percent) market share. This was followed by the bioservices segment (8.42 percent) comprising of manufacturing and clinical trials, bioindustrial segment (7.7 percent) consisting primarily of enzymes market and bio-agri (5.5 percent) and bioinformatics (2.4 percent) segments.

Although the biotech industry in India is at the crossroads, there is a vast scope for growth and opportunities. There are about 200 registered biotech companies of which about 60 are in the modern biotech sector. Biotech industry is expected to grow by 26 percent annually with investment close to $27 million in the next couple of years. Although it has being projected that what has been achieved for information technology, the same would be repeated for biotech industry. This appears to be bit out of socket since biotechnology is a hardware-intensive sector requiring highly skilled intellectual scientists along with high investment. There is always pretty longish incubation period before returns on the heavy investment can be realized. Three elements namely, innovative ideas, strong gut feelings and strong shoulders to carry forward are essential for any success story in biotechnology. Although biogeneric approach would provide immediate business, profit and affordable biotech products, this may not be a strong business model in the long run. The biocomparic and bioimprovic biotech products do require a longish regulatory approvals and challenges. However, such a business model will also be a success in the short term only.

For the growth of biotechnology industry, conditions that support the creation of knowledge network are innovative ideas, availability of high quality skills, strong public support and perception of opportunities. The multinational biotech companies and Indian companies have deep commitment for developing new products. With the changed economic scenario and the TRIPS-compliant patent regime, Indian biotech companies would be required to compete with multinational biotech companies in R&D, innovation and patenting & products affordability.

The lessons so far learned in the growth of biotechnology industry in India are as follows:

1. Firms that have grown rapidly are the ones that have identified good windows of opportunity.

2. Industrial firms that link opportunities and learning are rapidly evolving.

3. Venture capital has been a major link that facilitated the evolution of innovative biotechnology set up, especially starts-ups.

4. Biotechnology clusters have evolved where there is strong links with academia.

With the changes that are taking place in India, biotech industry will soon merge the separating line between discovery, development and market place. All these can amount to breather - reduction in the time and cost of making new medicines. This could also reduces time from target identification to launch, boost success rates from first human dose to market and a significant reduction in the pre-launch investment per drug to about $200 million Ã¢â?¬â?? a cost advantage that Indian industry has been advocating. The partnerships, alliances, joint ventures, co-development & co-marketing biotech products along with generation of new products based on ownership IPR would be essential ingredients for success of biotechnology industry. The current decade is likely to be crucial for biotechnology business.

Here is a set of suggestions to boost the biotech sector:

a. To be a leading biotech unit in a global scenario, newer and innovative products based on IPR ownership is most crucial. An innovative R&D at industrial level is a key issue. It would, however take a couple of years, before products based on IPR ownership will be made available. In order to shorten the delays in bringing innovative products in market, there is an urgent need to device better and effective means to usher close interactions between academia and biotech industry.

b. We still do not have sufficient well trained physicians, who are aware and can conduct clinical trials as per the requirements of GCP. We also do not have scientists who can manage the trial sites and manage the clinical data appropriately. This situation is needed to be improved at the earliest.

c. Although limited world class infrastructure in terms of GMP manufacturing facilities, conforming to US FDA or EU requirements are available, the biotech industry is alive to this situation and efforts are being made to improve existing infrastructure.

d. The government, of late, has devised industry-friendly policies without compromising safety aspects of biotech products. Incentives like custom duty exemption on equipments and consumables required for modern biotechnologies tools will further boost infrastructure capability of Indian biotech industry.

e. Adequate venture capital funds are still not available to young entrepreneurs, scientists or biotech industry to conduct studies to provide "proof to the concept' i.e. is to evaluate early leads. Such funds to conduct R&D on early leads would go in a long way to generate new IPR based products. In addition, research grants to industrial R&D setup would yield rich dividends to the development of globally competitive biotechnology sector.

f. Many Indian biotech industries are gearing to be major players of "contract manufacturing". The facilities would be required to be have US FDA or EU approved production plants.