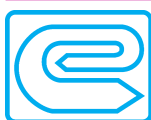


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Biotechnology Industry In India: Opportunities For Growth



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CURRENT STATUS

Revenue

Indian biotechnology industry has been growing at a CAGR of 31.5% during the period 2001-02 and 2008-09, to reach the level of Rs. 12137 crores. In dollar terms, the revenue of the Indian biotechnology industry is estimated to be over US \$ 2.6 billion, a share of around 3% in global biotech revenues. In terms of number of biotech firms, with about 325 firms engaged in this industry, India ranks 11th in the world, and fourth in Asia-Pacific region.

The domestic biotechnology market clocked revenues of Rs 4,985 crore, registering a 10% growth, accounting for a share of 41%. BioPharmaceuticals sector accounted for the largest chunk of the Indian biotech industry, having a share of 65% in total revenues. The BioServices and the BioAgriculture segments followed the BioPharmaceutical segment with a share of 16.9% and 12.3%, respectively in 2008-09. Segments like BioIndustrial and BioInformatics garnered a share of 3.9% and 1.8%, respectively, of the total revenue in 2008-09.

The very nature of the Indian biotech industry is export-driven. Exports in the year 2008-09 were valued at Rs. 7152 crores, a growth of 25% over the previous year, and accounting for 59% of the total business in 2008-09. Segments like BioPharma and BioServices have had a majority of their revenues coming from exports.

Segmentwise Performance

The biotech industry in India can be broadly categorised under five distinct segments - BioPharmaceutical, BioServices, BioAgriculture, BioIndustrial, and BioInformatics.

Segments	Revenue in Rs. Crores						
	2002 -03	2003 -04	2004 -05	2005 -06	2006 -07	2007 -08	2008 -09
BioPharma	1790	2752	3570	4708	5973	6899	7883
BioServices	135	275	425	720	1102	1572	2062
BioAgriculture	110	130	330	598	926	1201	1494
BioIndustrial	235	238	320	375	395	410	478
BioInformatics	75	80	100	120	145	190	220
Total	2345	3475	4745	6521	8541	10272	12137

Source: Biospectrum

BioPharmaceutical

BioPharmaceutical products are therapeutic or preventative medicines that are derived from materials naturally present in living organisms using recombinant DNA (rDNA) technology. According to a report by PriceWaterhouseCoopers, the growth in BioPharmaceutical drugs and biologics has outperformed the pharmaceutical market largely. The total BioPharmaceuticals segment in India, comprising vaccines, therapeutics and diagnostics have registered a 14.4% growth in 2008-09 over the previous year, in terms of total revenues. The segment has been the single largest contributor to the Indian biotech industry for many years. The total revenue from BioPharmaceuticals sector grew from Rs. 6890 crore in 2007-08 to Rs. 7883 crore in 2008-09. Exports In 2008-09 accounted for 62% of total BioPharmaceuticals revenue, while domestic sales accounted for the balance (38%).

BioServices

BioServices mainly include clinical research and contract research organizations (CRO) and to some extent custom manufacturing. The BioServices

sector, which accounted for about 17% in the total revenue of Indian biotechnology industry, has recorded a growth of 31% over the previous year. The BioServices revenue for 2008-09 was estimated at Rs 2062 crores. Exports dominate the BioServices sector with almost 95% of the total BioServices revenues in 2008-09, which amounted to Rs. 1964 crores.

BioAgriculture

BioAgriculture contributed around 12% of the total market value of biotechnology in India, in 2008-09, with a total revenue generation of Rs. 1494 crore; of which domestic revenues constituted around 96%. The domestic market potential, combined with scientific infrastructure in agriculture, rich bio-diversity and skilled human-power is poised to make India an important global base for BioAgriculture research. The surge in opportunities is expected to improve the agricultural productivity especially at a time when there is a diminishing per capita arable land and water resources.

BioIndustrial

The BioIndustrial segment predominantly consists of enzyme manufacturing and marketing companies. Although the use of enzymes in manufacturing of products such as detergents, textiles, food, leather, paper and pharmaceuticals, is still at a relatively

low level in India, there has been a growing awareness regarding the benefits of using enzymatic solutions in manufacture of such products to improve efficiency and quality. The BioIndustrial segment is estimated to have garnered revenues to the tune of Rs. 478 crore in 2008-09, a growth of 16.6% over the previous year. Almost 81% of the revenue in the year 2008-09 was generated from the domestic market alone; this sub segment constituted around 1% of the total biotechnology exports from the country in 2008-09.

BioInformatics

The share of BioInformatics in total revenue of Indian biotechnology sector is around 1.8% in 2008-09. This sub segment achieved a modest growth, increasing from Rs. 190 crore in 2007-08 to Rs. 220 crore in 2008-09, at 15.7%. The industry has been found to be more export oriented with around 77% of the total revenues coming from offshore markets, in the year 2008-09. BioInformatics uses computer software tools for database creation, data management, data warehousing, data mining, and global communication network. With the Indian IT industry eyeing for diversification of software applications, BioInformatics becomes one of the potential area for IT application. The Indian firms have been strategically devising tools so as to cater to the world requirements.

Emerging Areas in Biotechnology

Biosimilars

The expiry of patent protection and regulatory data protection for certain biotechnological medicines has led to the development of product groups that are called as biosimilars. As regulatory obstacles to biosimilars development is increasingly being resolved, opportunities are expected to be created for generic companies in the BioPharmaceutical market. According to Datamonitor, the Indian biosimilars market will grow to more than US\$ 2 billion by 2014, as patents for key drugs are likely to expire soon.

Nanotechnology

From an Indian context, nanotechnology is at a very nascent stage, but given the potential of the sector, it is expected to grow at a robust pace in the coming years. In fact, nanotechnology has the potential to revolutionize the Indian agricultural scenario. It is also predicted that nanotechnology will transform the entire food industry, changing the way food is produced, processed, packaged, transported, and consumed. Recent years

have also witnessed convergence of nanotechnology and biotechnology.

Stem Cell Research

Stem cell research is being touted as the next wave of biotechnology, not only in India but also across the world, which could potentially revolutionize treatment of diseases in the next couple of decades. According to a study by Frost & Sullivan, the global market for stem cell therapy is expected to be around US\$ 20 billion by 2010. The Stem Cell Research Forum India has predicted that India would have a market size of about US\$ 540 million by 2010 with an annual growth rate of 15%. The potential of stem cell technology to develop therapy for many untreatable diseases through cellular replacement or tissue engineering is being widely recognized.

CHALLENGES & STRATEGIES

Challenges

Skill Development

Despite mushrooming educational institutions, offering a range of courses in biotechnology, gap between the needs of the industry and skills taught at these institutions still remain, though the gap is being narrowed down. It has also been mentioned that most of these institutions have limited ability to provide the right pedagogy, or the requisite infrastructure. The challenge of bridging the gap between the needs of the industry and the curricula taught at various institutions should be collectively addressed by the Government, industry and academia.

Government Health Expenditure

Most Governments in developing countries usually finance programmes that support child immunization against various diseases as part of the basic public health package. Though India too has such immunization programme, because of relatively high birthrate and population, the share of Government health budget in total healthcare expenditure is relatively low (at 25%), according to the World Development Indicators – 2009. In comparison, other developing countries like Brazil, Russia, China and South Africa, portrays better ranking in Government healthcare system. It may also be noted that as a percentage of GDP, the total health expenditure in India is around 3.6%, far below than that of other emerging economies.

Basic Education & Health System

Amongst the most critical building blocks for biotechnology development and its success are good education and health system. India fares low in terms of both

these measures as reflected by the UN Human Development Index. India's ranking is 132 out of a total of 153 countries, and is also one of the lowest as compared to other competing countries in this sector.

Funding

The inherent characteristics of the biotechnology make the industry a high investment one with a long gestation period. Thus, funding plays a key role in ensuring the concept to develop into a product. Global financial crisis has affected the funding prospects of biotech companies, as risk aversion increased among the venture capitalists, angel investors, as also financing institutions.

Ethical Issues in Genetic Research

Biotechnology has been confronting the world with some ethical issues, which have raised numerous challenges with no definite solutions. Genetic research and its applications like genetic engineering, manipulation, testing, therapy, eugenics, selective abortion, GMOs, stem cell research, and cloning, opened significant ethical and consumer issues, the potential risks that may be impacting the environment. The issue of a genetically modified food appears to be of particular concern. A challenge for the Indian biotechnology industry will be to work and liaise widely with the community and earn its confidence and investors.

Concentration of IPRs

Intellectual property rights are intended to promote research and development by allowing researchers to generate revenue to meet the development costs. However, there are concerns that the current level of biotechnology IPRs are concentrated mainly at the hands of private sector. It is reported that, globally, few companies are responsible for the vast majority of agri-biotech research. These companies have focused on crops and traits (such as herbicide resistance) that are having commercial significance, and thus may not be willing to transfer to others. Globally, trends in mergers & acquisitions, among biotechnology companies, have also been on similar lines, encouraging the concentration of IPRs, which may affect the ability of developing countries, like India, to negotiate for access to proprietary technologies at a reasonable price.

Biosecurity

Biosecurity is another challenge with growing debate and discussions among the academic and policy spheres, with bioterrorism, biosafety, and emergence and re-emergence of infectious diseases as

concerns to the society as a whole. The threats associated with the misuse of biotechnology including proliferation of bio-weapons, affect the growth prospects of this sector, which otherwise present potential benefits for global priorities such as health, food and environment.

Bio-hacking

With the fall in the cost of equipments capable of manipulating DNA, the threat of growing number of bio-hackers is significant. The work raises fears that people could create a deadly microbe on purpose, just as computer hackers have unleashed crippling viruses or hacking into various websites. Such a scenario may lead to "bio-spam, bio-spyware, bio-adware" and other bio-nuisances.

Patenting of Microorganisms

Another associated challenge to the industry is patenting of microorganisms and associated biosafety requirements, as strict biosafety norms have to be followed while handling microorganisms. The regulations for accessing strains from a depository have to be carefully worked out to ensure that these do not land into wrong and / or technically incompetent hands. India too needs to bring in suitable patent law for protecting microorganisms and rules for accessing strains from a depository.

Strategies

Public-Private Partnerships

Public-Private Partnership may be encouraged and supported in areas that are vital to the national development, from a scientific, economic or social perspective, and focused on technology and product development. India has a wide network of universities, departments and specialized institutions that have been promoted by various authorities providing numerous specialised science degrees at the post-graduate level. These institutions also provide an effective network of research laboratories. Efforts should be made to bring in a seamless transfer of knowledge and people among these universities, institutes, and corporate for a better coordination among themselves, and to share their research-based information on a continuous basis.

Need for enhancing Venture Capital funding in India

One of the biggest challenges for the Indian biotech industry is attracting investment through venture capital mode. With the corporate sector being risk averse to investing in biotechnology projects, especially in their gestation and early phases, the need of VC funding becomes critical for the growth of the biotech

industry in India. Venture capital firms typically source majority of their funding from large investment institutions such as pension funds and financial institutions, who like to invest long term only with assurance of high returns. Thus, venture capitalists make careful investment decisions, which leads to high risk aversion rates. Instead, India may consider promoting venture capital investment on the lines of Russian model. Russia has been boosting venture capital sector from scratch, by seeding funds with Government support, through the Russian Venture Company (RVC). Israel has also adopted similar approach of state-backed venture capital model to boost the investments in knowledge based industry.

Strategy to Move to a Higher Value Chain

Indian biotechnology industry, over the years, has developed a number of biotech products, but has been found to perform tremendously well in the vaccine segment. The players in this industry as well as the research institutions should increasingly focus upon moving up the value chain by enhancing strengths in new products and applications, and by offering R&D solutions in drug discovery and validation based on genomics, proteomics, pathway analysis (determining how toxic or radioactive substances reach humans), and clinical trials on humans. Drug discovery and innovations in drug delivery, especially in areas like diabetes, cancer, and inflammatory ailments could take the industry into greater heights. Indian biotech industry should also look forward to moving up the value chain in terms of geographies so that India is present in more premium markets.

Enhancing Biotech Applications

Modern research finds application of biotechnology in various economic segments, and thereby add value to the products and processes of such segments, including agriculture, forestry, marine resources, environmental management, pest management, and management of human and animal healthcare. To capitalize on the potential benefits and to ensure international competitiveness, it is important to promote speedy and widespread diffusion of biotechnology applications to the broader economic community, while maintaining responsible and sustainable use.

Lucrative Domestic Market

The domestic biotech market is expected to post robust growth with rising income levels, improving living standards,

improved medical infrastructure, growing health-insurance penetration, enabling regulatory framework and institutional infrastructure, and the growing number of organized pharma-retail chains. For example, in a country like India it is certain to find a market for products like insulin or new drug delivery solutions to combat diabetes. With more and more people leading a sedentary lifestyle, there may be further opportunities for the Indian biotech industry.

Biotech Skill Development

Biotechnology industry is highly R&D intensive. In order to remain globally competitive, the industry requires a pool of highly skilled manpower. India has already made its mark in scientific research in the world, with a large pool of scientific manpower. However, with the changing composition of economic growth there is an emerging trend of students not preferring science stream for career opportunities. This may lead to shortage of qualified manpower in highly research oriented activities such as biotechnology. Thus, it is important to devise policies that would attract more students to the science stream.

Reversing Brain Drain

Shortage of manpower due to brain-drain is another challenge faced by the Indian biotech industry. The shortage of scientists / skilled professionals in OECD countries may enhance the brain-drain from India in the coming years unless suitable policy measures are taken to reverse the trend. There is an urgent need to expand the current research programmes with attractive compensation package in order to attract world-class talent. Through the Ramalingaswamy Fellowship Programme, the Government of India is attempting to attract Indian scientific talent back into the country; but the scheme appears to be less attractive. In this context, it may be mentioned that China Academy of Sciences (CAS) has established programmes, such as Specially Hired Foreign Research Fellows, and Young Foreign Scientist Project, through which the country would attract over 600 Chinese scientists working abroad, annually; each returning scientist would receive funding of around US \$ 300,000 per annum.

Corporate entities too may get involved by providing adequate exposure to the budding talents through training and placements. This would also provide the Indian biotechnology industry a tremendous competitive manpower advantage.

Symbiotic Relationship between Pharmaceutical and Biotech Sectors

Use of organisms for the improvement of biotech processes constitutes one of the major business segments of the biotechnology industry. This provides significant opportunities for pharmaceutical firms also. In general, biotech firms would concentrate their business models in covering a part of the product development value chain. Since, the biotech firms are not often engaged in entire product development value chain, due to shortage of funds and necessary know-how, pharmaceutical firms could complement the biotech players through their knowledge and financial power.

Strengthening North-South Collaborations

Many Indian firms use services contracts with foreign firms to fund their operations, develop commercialization capabilities and access valuable international technology and expertise. Services provided include R&D, clinical trials and manufacturing. MNCs are increasingly conducting clinical trials in India and rely on Indian contract research organizations to manage these trials. It will be vital for the Indian biotech firms to expand their capabilities in clinical trial management, and pay close attention not only to good clinical practice guidelines, but also to bioethical principles, to provide a high level of care, and assure protection of patent rights.

Encouragement to Innovative Funding Models

Encouraging innovative funding models in the biotech industry is essential given the financial constraints of the industry. For example, pharma/biotech firms may set up Special Purpose Vehicles, which shall be contracted by the parent firms for product development work, which may have high initial product development costs, and which are non-infringing process, based on regulatory compliances. Such funding models may not stretch the balance sheets of the parent companies, nor equity dilution. An agreed percentage of revenues from the SPV funded projects could be returned back to the parent company or funding bank towards the investment. In the case of institutional financing, once the funding bank recovers its investment or IRR, the ownership of the products would flow back to the company without any complications what so ever.

Emerging Biosimilar Market

Biotechnology industry in India has a well-developed foundation with strong pharmaceutical and bio-supplier sectors. The global market for generics are expected to grow significantly in the next few years as several 'blockbuster' drugs lose patent protection. A record number of drug patents expire over the next few years, which should lead to stiff competition from generics, and significant fall in prices. In such a situation Indian companies appear to be well positioned to leverage upon their cost-effective manufacturing capabilities to compete on a global scale and garner some of this market.

In the context of patent expiry on BioPharmaceuticals, it may be noted that USA would emerge as one of the largest bio-similar markets after the approval of Waxman Biosimilar Bill, providing opportunities for Indian firms. According to industry sources, there are at least 75 proteins and peptide therapeutics identified in the US as potential profitable targets for new products. Most of these were approved as New Drug Applications to facilitate BioPharma companies to develop biosimilar products.

Catalysing Coherence in Clusters

Cluster development is a key strategy to promote innovation, accelerate technology transfer and facilitate product development. Biotechnology, being interdisciplinary in nature requires enabling infrastructure for promoting and nurturing innovation, and thereby building successful enterprises. The clustering concept maximises synergy and efficiency of firms located in the cluster. Efforts could also be made to set up clusters around existing institutions of excellence, and to integrate them deeply into the economic, entrepreneurial and social fabric of the region.

Leveraging International Partnerships

Biotechnology requires strong international partnership, both at the levels of research institutions, and at corporate front. International cooperation can be leveraged to achieve global best practices in the country's science and technological efforts, for joint intellectual property generation, harmonization of regulatory processes, smooth cross border movement of biological materials, and access to global markets for the country's products and processes. Such an approach

would not only bring in better technical know-how but would also help in enhancing India's research and development resulting in quicker and faster outcomes.

Biotechnology Usage in Biofuels

Biotechnology could also be one of the most effective and innovative tools to make sustainable use of biofuel, reducing the adverse environmental impacts of GHG emissions, and limiting the diversion of land from food crops to fuel crops.

SUM UP

India is already being reckoned as a frontrunner in the biotechnology industry. The vast population of India helps not only in creating significant domestic demand, but also in providing biotech research companies with a vast gene pool. The institutional infrastructure in the country offers a strong foundation to tap the global business opportunities. Indian firms could focus on acquiring overseas biotechnology units in countries like the US, which have seen plunging valuations due to the global meltdown. Though India has a long way to go in terms of innovations in processes, instruments, and funding, the future looks bright for the industry with India poised to become one of the global leaders in the biotechnology industry.

The contents of the publication are based on information available with Export-Import Bank of India and on primary and desk research through published information of various agencies. Due care has been taken to ensure that the information provided in the publication is correct. However, Export-Import Bank of India accepts no responsibility for the authenticity, accuracy or completeness of such information.

Note: Indian Rupee are referred in crore and lakhs:
1 crore : 10 million
1 lakh : 100 thousand

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