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Opportunities unfurling

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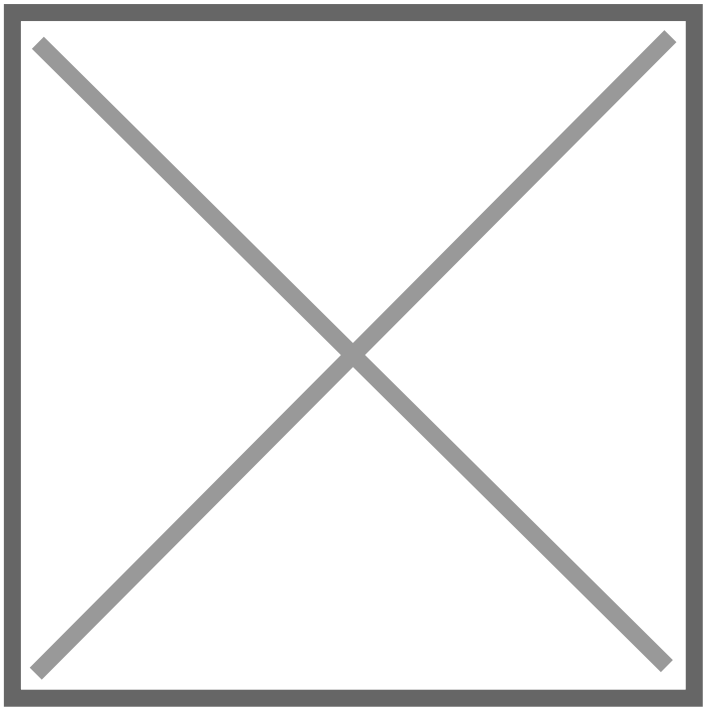

On 1 January 1995 India became a signatory to World Trade Organisation (WTO). India agreed to implement a product patent regime with effect from 1 January 2005. Since then, Indian pharma sector has gone through several remarkable changes in attitude and policies to prepare for the new patent regime. Some of these have been brought about through legislative action in the Union budgets in 2000 and 2001. The pharma industry was one of the major beneficiaries of budgetary allocations. The Government of India recognized it as a knowledge based industry.

The industry, which is witnessing the transition phase in preparation for the new WTO-induced regime, and currently demonstrates wide-ranging capabilities in the field of drug manufacture and technology.

Biopharma in India

Biopharmaceuticals contribute about 80 percent of the overall Indian biotech pie. This is comparable to the global scenario. A holistic view will bare the fact that a lot of back-end work in R&D is being pursued in India particularly in the academic institutions. Pioneers in the field like Shantha Biotechnics, which launched the country's first indigenous recombinant product, Hepatitis B vaccine in 1997, are focused more on applied basic research with the objective of commercializing products which are affordable to the masses.

Companies like Aventis, Dr Reddy's Lab, Nicholas Piramal, Smithkline Beecham, Bharat Biotech, Biocon India, and Wockhardt are the other key players in the biopharma sector. We find a strong base of biopharma in Ahmedabad, Mumbai, Bangalore, Hyderabad, and Pune. "The biopharma industry in India is still in its infancy. An overview of the market indicates a turnover of Rs 500 crore. However, over, 80 percent of this is hogged by imported products. This is the dichotomy. The concerned authorities on the one hand express their desire to encourage indigenous products but on the other hand also allow duty-free imports. There should be a level playing field. In several product categories, the installed capacities of indigenous manufacturers outstrip domestic demand, so where is the need to import? Moreover, Indian pharma companies have proved
beyond doubt that the quality of their products match international standards," says Varaprasad Reddy, managing director, Shantha Biotechnics Pvt Ltd.

The opportunity

India is in a unique position in terms of genetic resources. It has several ethnic populations that are valuable in providing information about disease predisposition and susceptibility, which in turn, will help drug discovery. In the drug discovery process, pharmaceutical or biotech companies need tremendous software support to write algorithms, develop software for existing algorithms, manage databases and for other key activities. The IT and pharmaceutical industries should team up with

researchers to harness India's natural competitive advantage and strength in this sector. The main investment opportunities in the pharma industry are in diagnostics, vaccines and recombinant therapeutic proteins.

Diagnostics:

According to Confederation of Indian Industry (CII), the market for diagnostics in India was at about $200 million, by the end of 2002. It says that around 50 percent of the demand is met by imports. There is an increased consumption of diagnostic devices and tests in public hospitals. There are more than 11,500 hospitals and 14,000 diagnostic laboratories in India that consume large volumes of diagnostics.

Vaccines:

The Indian local vaccine market is currently in the region of $100 million and this is growing at the rate of more than 20 percent per year. The potential for these products is immense with the possible market for all types of diarrheal vaccines alone being about $200 million.

Vaccine	Estimated requirement (million doses)
DPT	114
DT	57
Tetanus toxoid	200
BCG	43
Oral polio	225
Measles	46
Measles, Mumps & Rubella (MMR)	7.50
Rabies - Sheep brain based - Cell culture based	 1.50 5
Hepatitis B - Plasma derived - Recombinant	 0.20 45
Typhoid (attenuated oral & injectable)	50
H. influenza type B	5
Meningitis	2
	Source -CII

Major multinational pharmaceutical companies active in the vaccine businesses in India include SmithKline Beecham, Hoechst, Glaxo Wellcome and the Serum Institute. In addition, Shantha Biotechnics manufactures a recombinant HBsAg vaccine (Shanvac B), at a cost of approximately $5 per dose. This is the first such genetically engineered product from any category in India.

Although vaccines against tetanus (T), diphtheria (D), pertussis (P) and their combinations (like DPT and DT), BCG and measles are produced in the country. Genetically engineered as well as human plasma derived from hepatitis B vaccines is still being imported. Human diploid cell culture based vaccines against measles, mumps and rubella (MMR) are being locally produced. Several other vaccines like attenuated oral as well as Vi antigen based injectable typhoid vaccine are also required in the country in large quantities.

Recombinant Therapeutic Proteins:

The Indian government has granted marketing licences for about 25 recombinant protein therapeutics. These include insulin, alpha interferon, hepatitis B surface antigen based vaccine, GM-CSF, G-CSF, blood clotting factor VIII, erythroproietin, streptokinase, human growth hormone and follicle stimulating factor. Of these, only hepatitis B surface antigen-based vaccine is produced in the country and all other products are imported. Recombinant insulin, human growth hormone, in terferon and hepatitis B vaccines enjoy larger market share. Medical proteins such as relaxin, rennin, the interleukins and tumor necrosis factor also offer market opportunities. Several companies, including Wockhardt, Piramal and Dabur are exploring the opportunities to manufacture bio-generics. In addition, Dabur India is developing plant medicines and is working on a natural substance-based immuno-modulator.

According to DA Prasanna, vice chairman, Wipro Ltd and executive officer, Wipro Health Sciences, "India should concentrate on two niche areas - drug discovery design system and clinical trials - in biotechnology both domestically and internationally. Locally, the country has to stress more on the drug discovery design system. And internationally, India has to look at clinical trials."

"We will find ample opportunities in Indian biopharma sector particularly in drug discovery and clinical trails. It is expected to capture about 60 percent of the IT spending of Rs 600 core in the coming years. Major pharma companies like Dr. Reddy's Laboratories, Ranbaxy and Shantha Biotechnics Pvt Ltd have already commenced activities in clinical trials," adds S Sabyasachi, manager, demand side research, IDC India.

The Government initiatives

In India, medical biotechnology has gained more importance with spectacular advances in biology. This is mainly due to a number of emerging and re-emerging infections requiring immediate attention for development of suitable diagnostics and therapeutics. Now biopharma has become an important component of the national economy.

With the changing scenario, the government has announced a new Indian Pharmaceutical Policy 2002. It focuses on liberalization reducing number of drugs subject to price control and opening the market to foreign investment. The policy also stresses on setting up of a Pharmaceutical Research and Development Support Fund to boost R&D.

In addition to these efforts, several international biotech events are organised with the rise of the genomics era, stem cell research and bioinformatics. These have percolated down the national biotechnology scene with a large number of scientists galvanized to reap the benefits. The Department of Biotechnology (DBT) is making allefforts for the development of suitable diagnostics, vaccines, therapeutics and better drug delivery systems. The approach of multi-institutional projects and networking have paid rich dividends in terms of utilizing national expertise towards achieving welldefined aims.

The DBT has set up a Task Force under the chairmanship of Prof. H Sharat Chandra, director, center for human genetics, Jawaharla Nehru Center for Advanced Scientific Research, Bangalore to monitor the projects. The Task Force has been evaluating the projects. It is also meeting regularly in generating new projects for genomics, stem cell, biology, tuberculosis, HIV, cholera etc.

Further DBT has been supporting the projects taken up by the premier research centers in a contract mode for the last decade. As a result, various labs in the country have developed a number of prototype test systems. Some of these prototypes have already been transferred to industries for fine-tuning, upscaling and commercialization.

Technologies transferred and launched in the market		
Technology	**Developed by**	**Launched by**
Leprosy immunodulator	NII, New Delhi	Cadila Pharma, Ahmedabad
Leshmaniasis detention kit Western Blot for HIV- I &II	CDRI, Lucknow CRI, Mumbai	Span Diagnostics Ltd J Mitra &Co, New Delhi
Naked Eye agglutination system for HIV- I&II	University of Delhi , South Campus	Cadila Pharma, Ahmedabad
Hepatitis C Diagnostics ELISA based	ICGEB, New Delhi	Xcytron, Bangalore.

Tribulations before the sector

In biopharma sector, human resources are very critical. The educational institutions lack sophisticated instrumentation. A well-defined regulatory framework must be in place, preferably a single body for approvals on the lines of Center for Business and Economic Research (USA). Another problem is the Intellectual Property Rights (IPR) issue. It must be addressed, as the experts in this sector are few. More than 15 percent of the scientists in the US Pharma industry are of Indian origin. They must be motivated to return-reverse brain drain.

The skill sets of those emerging from colleges must be improved in terms of practical knowledge. As stated earlier the infrastructure needs to be strengthened and a well-defined regulatory framework must be in place. Practical skills need to be improved. The curriculum also should be upgraded to meet global standards. An expert committee must be set up for addressing these issues urgently. Strategic alliances between academic institutions and the industry and biotech-pharma must be encouraged. These will largely contribute towards making India a powerhouse in biopharmaceuticals.

Besides, the sector is facing other problems like lack of product patents and restrictive foreign exchange regulations, which led to poor MNC exposure in the country. Small scale industry exemptions led to proliferation of small formulation manufacturers and low cost manufacturers and price ceiling under Drug Price Control Order limited profit margins and shifted the focus onto cost control.

Reddy maintains, " There is a saying that India has been reduced to a dumping ground for overseas pharma companies. Recently it was brought to our notice that a leading MNC is indulging in unfair/unethical practices to promote one of its products, which could prove detrimental to the efforts of indigenous manufacturers. This is largely due to a loose regulatory framework which neither has the will nor the wherewithal to stop such practices."

Indian pharmaceutical market scenario

The Indian Pharmaceutical sector is highly fragmented with over 20,053 registered pharmaceutical manufacturers in the country. The leading 250 pharmaceutical companies control 70 percent of the market (FY 2000). The top 10 companies cover around 31percent of the pharma market. During FY 2000, production of formulations was around Rs 184 billion and of bulk drugs Rs 45 billion. India's pharmaceutical imports (including bulk drugs, formulations, intermediates, chemicals, solvents etc) are in the region of Rs 30 billion (Rs 22.65 billion bulk drugs and Rs 7.15 billion formulations), while exports are around Rs 87.30 billion. The industry provides direct employment to 460,000 people.

The value of the pharma market in India was $3.8 billion in 2000. Indian pharmaceuticals account for 1percent of global sales in terms of value and 8percent in terms of volume. Globally it ranks fourth in volume terms and thirteenth in value.

Pharmaceutical industry domestic sales were around Rs170 billion in 2001. Of this, formulations account for 81.5percent with the remaining 18.5percent in bulk drugs.

(Ref: Organisation of Pharmaceutical Producers of India (OPPI) Pharmaceutical Compendium 2001).

Fast forward

With intense demand for low-cost R&D to fuel innovation, India's developing skills and infrastructure in the R&D phases of drug development are providing an enticing proposition for both the global pharmaceutical companies and investors. India's skills in technical computing, bioinformatics and cheminformatics, data integration have the ability to resolve issues surrounding. The Singapore-based International Data Corporation (IDC), Asia/Pacific, believes that India will become an ideal center for outsourcing R&D and drug development processes, which will surely entice new businesses to develop and attract much private investor attention. "Once India develops a genuine global reputation in life sciences
innovation, it will be attracting investor attention in its own Intellectual Property", the IDC report says.
Even the Union Health Minister Shatrughan Sinha's announcement on the increase in budget allocation for health research will definitely boost the sector in the coming years.

"Biopharma is going to be a highest growing area. Today therapeutic protein and monoclonal antibodies are becoming the most powerful pharmaceutical agents for some of our deadliest of diseases. Whether it is any genetically linked disease or cancer, these are the molecules that are able to do something about it," says Kiran Mazumdar Shaw, chairperson and managing director, Biocon India Group.

1960's	**Milestones in pharma industry** Government of India laid the foundation for the domestic pharma industry by promoting Hindustan Antibiotics Ltd and Indian Drugs and Pharmaceuticals Ltd for the manufacture of bulk drugs.
1970	Government introduces Indian Patent Act (IPA) and Drugs Price Control Order (DPCO)
1994	Syngene International, country's first Contract Research Center (promoted by Biocon India Group) to offer R &D services in drug discovery based on modern biology.
1997	Shantha Biotechnics launches India's first recombinant product, Hepatitis B vaccine Government sets up an independent body of experts called National Pharmaceutical Pricing Authority
2000	Genomed, country's first joint venture between institute (CBT) and Industry (Nicholas Piramal) to pursue pharmaco Ã¢â?¬â??genomics
2001	Genetic Engineering Approval Committee (GEAC) approves Wockhardt's EPO Drug authority implements GCP guidelines for clinical trials
2002	Government introduces Indian Pharmaceutical Policy 2002, based on the recommendations made by the Pharmaceutical Research and Development Committee

"Indian biopharma is still in an immature stage as far as data driven drug discovery and development are concerned. About 80 percent of action in biopharma, at present, is taking place from the US. Hence Strand Genomics, the first Bioinformatics company in India has been offering services to the US companies to improve efficiencies of drug discovery and development. These are not valuable at this stage to Indian biopharma," says Prof. Vijay Chandru, chairman, Strand Genomics.

" India has a strong pharma base as well as the necessary skills in this field. Thus the market for biopharma products will see an exponential growth. This when coupled with our strength in IT will provide cost-effective solutions to drug discovery efforts. However the infrastructure needs to be strengthened and the cost of inputs like power, need to reduce. A strong regulatory framework should be in place. In future, the world may witness India being a hub for drug discovery efforts," adds Reddy.

Abraham Thomas, managing director, IBM India Ltd, believes, "The Indian Pharmaceutical market shows positive signs. The Indian Government through DBT has been promoting the growth in this industry. The DBT and the Indian Council of Agricultural Research (ICAR) have stressed the importance of R&D for biotechnology. The Indian life sciences market has the potential, which we would be looking at tapping, in keeping with IBM's global focus on Life Sciences. "

Narayan Kulkarni