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Growth of Indian biotech companies, in the context of the international biotechnology industry

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Abstract

The paper discusses the evolution and growth of Indian biotech companies in recent years. It focuses on the alternative business models key players in the industry have adopted and highlights the activities and achievements of some of the globally competitive companies across various segments of the market. The paper also chronicles recent developments in the industry with respect to international alliances, product development and investment and expansion. Increasingly, India is being recognised as a country that combines low-cost research and manufacturing capabilities with a rapidly improving climate for intellectual property (IP) creation and protection. Efforts are being made by Indian companies to move up the value chain in niche areas within the biotechnology sector. There is indeed a clear opportunity for global players to leverage the India advantage by collaborating with Indian companies and exploring potential market opportunities.

Keywords: *India, biotechnology, evolution, biogenerics, bioservices, partnering*

INDIAN BIOTECH IS COMING OF AGE. . .

The Indian biotechnology industry finally seems to be coming into its own after a period of sustained support from the Indian Government for over 15 years. The Government's budgetary allocations to the Department of Biotechnology (DBT) increased from US$8.73m in 1987–88 to an estimated US$51m (at current prices) in 2002–03.[1] An analysis of events in recent years clearly indicates that Indian biotech companies are emerging beyond the lag phase and are getting their fundamentals firmly in place. Business models are become more mature, product commercialisation capabilities are rapidly improving and a bio-partnering model is being preferred to move up the value chain. Over the past few years, the industry has made considerable progress in terms of emergence of new growth companies, larger product pipelines, increased patent filings, higher number of alliances and several product launches.

India's position as a biotechnology hub in the Asia-Pacific is assuming greater eminence as it continues to build critical mass in terms of skills and capabilities. According to a Frost & Sullivan Asia-Pacific biotechnology report released in 2003,[2] India ranked fourth (one rank higher than China) in the attractiveness index of Asia-Pacific countries as a biotech investment destination. The attractiveness score has been arrived at by rating competing destinations on parameters such as industry competitiveness, regulations, private participation, infrastructure, investment climate, ease of market entry, domestic market potential, natural resources, personnel and Government support.

INDIAN BIOTECH SECTOR: A PREVIEW

Currently, the biotech industry in India, which includes the modern biotechnology the support and service businesses, is relatively small. Growth in the biotech sector in the country has been

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The Indian biotech sector, valued at US$705m in 2003–04, is estimated to generate annual revenues of US$5b and one million skilled jobs in 2010

dynamic. The sector grew by 39 per cent to reach a value of US$705m in fiscal 2003–04.[3] Industry estimates suggest that the biotechnology business in India has the potential to generate annual revenues of US$5bn and one million skilled jobs by 2010.[4]

According to the survey, the top 20 firms alone accounted for over US$493m in revenues (Table 1), constituting nearly 70 per cent of industry revenues. Biocon India Ltd, Bangalore, with US$108.4m, Serum Institute of India, Pune, with US$106.05m and Panacea Biotec Ltd, New Delhi, with about US$32.2m in revenues were the three largest firms in 2003–04. Biocon has become the first company to cross the US$100m mark in 2003–04. Biocon is India's oldest, largest and perhaps the first fully integrated biotech company. It started in 1978 by formulating industrial enzymes provided by an Irish company. The company has now turned its fermentation technology to the manufacture of biopharmaceuticals. It has recently developed human insulin, which is awaiting marketing approval. Biocon has also created contract drug discovery, clinical trials, genomics and chemistry research units through sister companies.

In terms of numbers, small and medium-sized enterprises (SMEs), however, dominate the Indian biotech sector. There are estimated to be in excess of 150 such SMEs that are working on a wide spectrum of biotech products and services. The industry is diverse and has several kinds of players from pure play to diversified companies. The companies here are manufacturing biopharmaceutical products, industrial enzymes, genetically modified (GM) seeds, diagnostic kits, biopesticides, biofertilisers, etc, and also providing custom services related to R&D and manufacturing

Table 1: Top 20 biotech companies in India

Rank	Company	Biotech sales (US$m)
1	Biocon	108.42
2	Serum Institute of India	106.05
3	Panacea Biotech	32.18
4	Nicholas Piramal	28.08
5	Novo Nordisk	23.76
6	Venkateshwara Hatcheries	19.01
7	Wockhardt	18.14
8	GlaxoSmithKline	17.28
9	Bharat Serums	17.21
10	Eli Lilly and Company	14.56
11	Novozymes	14.04
12	Quintiles Spectral	13.51
13	Krebs Biochemicals	12.29
14	Indian Immunologicals	12.25
15	Zydus Cadila	11.88
16	Mahyco Monsanto	11.66
17	Shantha Biotechnics	8.64
18	Syngene International	8.31
19	Biological E	8.29
20	Span Diagnostics	7.69

Source: Biospectrum-ABLE Survey 2004.

THE BIOTECH INDUSTRY'S EVOLUTION IN INDIA

If one were to trace the evolution of the biotechnology industry in the USA and Europe, it could be directly linked with the ability of scientists in academia to translate their research into marketable products and the support of R&D institutions in spinning off entrepreneurial ventures, assisted, of course, by the easy availability of venture capital as well as public markets allowing exit options for investors.

The biotech industry has evolved quite differently in India. Companies have entered the biotech sector in India primarily through four distinct routes. The early entrants were large industrial/pharmaceutical companies which identified biotechnology as a growth engine for the future (Biocon, Wockhardt, Nicholas Piramal); thereafter the pure play biotech start-ups focused on production of recombinant drugs, bioinformatics and custom services (Shantha Biotech, Bharat Biotech, Strand Genomics, Syngene), Software companies which grafted biology branches onto strong IT stems (Wipro, TCS, Satyam) and more recently industrial conglomerates which have diversified into biotechnology (Reliance Industries, others).

The start-ups in India have been those

The response to limited availability of venture capital, most new entrants in the Indian biotech sector have opted for a services model

that were willing to take early risks and either had good institutional support or were able to mobilise capital from within. Some of India's leading biotech companies such as Shantha Biotechnics and Bharat Biotech International received early support from government-funding agencies such as the Technology Development Board (TDB). Shantha, for instance, took shelter at the Center for Cellular and Molecular Biology (CCMB), Hyderabad, before it had its own R&D facility.

The absence of venture capital in the early days and the onset of risk-averse venture funding today has compelled most Indian biotech start-ups to pursue a revenue-earning business model from inception. Consequently, many companies have adopted a services model much along the lines of the early days in the Indian information technology (IT) sector. Others have pursued a product-based business model where vaccines and biogenerics have dominated.

A CROSS-SEGMENT PERSPECTIVE

Bio-services

Indian contract research organisations are rapidly moving towards ICH/GCP compliance

Custom research is a services model that has been extremely popular with biotech start-ups in India as it enables them to earn early revenues to fund infrastructure and scientists' salaries. Syngene International, a company promoted by Biocon, was the first such custom research company set up in 1994. Aurigene, another leading player and part of the laboratories of the leading Indian pharma major Dr Reddy, focuses on drug discovery centred on the structure-based drug design platform. It has built several capabilities along the drug discovery value chain that translate into cutting edge services. Genotypic Technology, Chembiotek, Cytogenomics and Jubilant Biosys are other good examples of such service-based biotech companies. Other companies such as Avesthagen and Bangalore Genei have opted for custom research services as a secondary business to generate revenues to support existing business lines. The custom research segment of India's biotech industry is expected to reach revenue levels in excess of US$1bn by 2010.[5]

Indian contract research organisations (CROs) have emerged to take advantage of the huge clinical research opportunity that is opening up. These include some major players such as SIRO Clinpharm, Clinigene, Lambda Labs and Lotus Labs. Clinigene is a CRO that offers global biotechnology and pharmaceutical majors strong clinical trial, regulatory and laboratory capabilities for drug development. Established in 2000 as a Biocon subsidiary, Clinigene is believed to be India's first CAP (College of American Pathologists) accredited Central Reference Laboratory with clinical specialisations in biochemistry, haematology, histopathology and microbiology. Apart from Phase II to IV trials, Indian companies have a large commercial opportunity in preclinical and proof of concept studies. The real opportunity lies in shortening time lines by speedy patient enrolments, made possible by the large patient populations that also lend themselves to sub-segmentation and statistically superior data. Most Indian CROs are moving towards ICH/GCP (International Conference on Harmonisation/good clinical practice) compliance norms to find international acceptance for their services. This sector is expected to play a major role in India's biotech future. International CROs and several big pharma companies have already recognised this opportunity and have set up operations in anticipation of policy changes that will enable early phase clinical trials to be carried out concurrently in India.

Biogenerics

Biogenerics is another approach that is being pursued by Indian biotech companies as a business opportunity. Shantha Biotechnics paved the way for this business segment by developing the country's first recombinant hepatitis B

vaccine based on *Pichia* (a kind of yeast) expression system in 1997. Other companies, Wockhardt (using the *Hansenula* expression system), Bharat Biotech (using *Saccharomyces*), Panacea (*Pichia*), and Serum Institute have also entered the international market with their own recombinant hepatitis B vaccines. The recombinant market had so far been dominated by imports of established global brands. India is one of the few countries in the world to approve human vaccines based on the *Pichia* and *Hansenula* expression systems. *Pichia*, a methylotropic yeast, is recognised as a powerful expression host for recombinant proteins and hence is a low-cost producer. Neither the USA nor Europe has approved a human therapeutic based on this host. The world has slowly begun to recognise Indian vaccine manufacturers as the ones who have the ability to fill the gap left by multinational companies who no longer find the mass market of paediatric vaccines profitable to operate in.

Some of the small to mid-sized Indian biotech companies such as Bharat Biotech and Shantha Biotechnics have proved that they can be shaped into global companies. For instance, Bharat Biotech has one of the largest bio-manufacturing facilities in Asia-Pacific with over 27,800 m^2 (300,000 sq ft) of clean room facility, conforming to cGMP/USFDA/UKMCA (clinical good manufacturing process/US Food and Drug Administration/UK Medicines Control Agency). It is the world's first company to produce a caesium-free hepatitis B vaccine (REVAC-B) and also to have a global patent for a new biotech molecule – Lysostaphin to fight staphylococcal infection. Over 35 million doses of REVAC-B have been sold so far in India, Africa and Latin America. The company has teamed up with the Indo US Vaccine Action Group to produce test dosages of oral rotavirus vaccine and to conduct clinical trials in India.

Similarly, Shantha Biotech's capacity for manufacturing recombinant hepatitis B vaccine is at about 100 million (0.5 ml doses) doses per year. Shantha's first indigenous development of recombinant hepatitis B vaccine enabled India to join the select club of five countries to have the know-how to produce hepatitis B vaccine. Its r-DNA hepatitis B vaccine product, Shanvac-B, was India's first indigenously developed recombinant human healthcare product. In June 2002, Shanvac-B was pre-qualified for purchase by UN agencies and is now being exported to ten countries. In 2002, Shantha also came out with Shanferon, the world's first recombinant human interferon alpha 2b expressed in *Pichia pastoris*. Both Shantha and Bharat have grants from the Bill & Melinda Gates Foundation's Program for Appropriate Technologies for Health.

Another major player in the biogenerics segment is Wockhardt. Wockhardt is among the few leading Indian pharmaceutical companies that has focused strongly on biotechnology as an engine for future growth. With close to a decade of experience in biotech research, the company has built considerable expertise in the development and manufacture of recombinant biopharmaceuticals The manufacturing facility for its recombinant biotech product conforms to USFDA/EMEA (European Medicines Evaluation Agency) norms. The Company's pioneering efforts in biotechnology have led to three successful brands – Biovac-B (hepatitis B) vaccine, Wepox (erythropoietin) and Wosulin (rDNA human insulin).

India's biogenerics business will gain an early advantage in terms of *Pichia*- and *Hansenula*-based recombinant production technologies on a commercial scale

India's biogenerics business will gain an early advantage in terms of *Pichia*- and *Hansenula*-based recombinant protein production technologies on a commercial scale supported by a regulatory regime that will generate significant clinical data on a statistically relevant population base.

Diagnostics

In this sector companies such as xCyton, Span Diagnostics and J. Mitra & Co. have a fair presence – xCyton today has the complete infrastructure for ELISA

(enzyme-linked immunosorbent assay) kit manufacture, state-of-the-art peptide synthesis and purification systems. It is supplying kits to conduct about four million tests in the country. With a strong foothold in ELISA kits, it is now moving towards the development of rapid tests and polymerase chain reaction (PCR) kits. J. Mitra is among the pioneers in production and marketing of medical diagnostic kits in India. It is believed to be the first Indian company to get a drug manufacturing licence for hepatitis C Rapid and ELISA tests and also the first one to introduce HIV TRI-DOT, which has separate dots for HIV-1 and HIV-2. It is probably the only company in Asia to manufacture the confirmatory test for HIV.

Bioinformatics

India's bioinformatics segment offers tremendous opportunities for designing new drug molecules, mining novel bio-markers and new pharmacogenomic data

India's globally recognised software skills provide a natural advantage in bioinformatics. The opportunities are diverse and stretch across the value chain from mining of genomic and proteomic data in a discovery mode to clinical data management services. Bioinformatics is a segment that perhaps offers the most attractive innovation and discovery opportunities for Indian biotech companies in designing new drug molecules, mining novel bio-markers, new pharmacogenomic data and high-value medical information based on phenotypic and genotypic data. India has the largest human biodiversity in the world with close to 600 well-defined ethnic groups in the subcontinent. Indian companies are in a unique position to harness this opportunity through researching its vast and varied disease populations in conjunction with its human diversity. Indications already exist in Indian gene pools to provide new information on breast and colon cancer, asthma, diabetes and a host of other disease segments. Several companies have already taken initiatives to harness this opportunity. Biocon is working with Surromed Inc. (Palo Alto, CA) to identify biomarkers for diabetes in the Indian population. Nicholas Piramal India has formed a partnership with the Government's Institute of Genomics & Integrative Biology (IGIB) to conduct genomic research with the nation's diverse populations and to explore India's traditional medicines.

Strand Genomics is the first and one of the most successful firms in bioinformatics. Its success is based on a service delivery model relying on data management and development of customised data mining software for customers. Strand has also developed several proprietary mining software products, which have been licensed to some of the US biotech companies. Other major companies providing services in bioinformatics include Bigtec, Institute of Bioinformatics, Jubilant Biosys, Mascon Life Sciences, Molecular Connections, Ocimum Biosolutions, Scinova and SysArris. Software companies such as Infosys Technologies, Wipro Health Sciences, Tata Consultancy Services, Kshema Technologies and Satyam are also exploring the opportunities in the data management sector. An emerging player in this segment is the Bangalore-based Institute of Bioinformatics (IOB), which is engaged in high-end research in genomics and proteomics. It has recently completed its first international project on the creation of Human Protein Reference Database. The company is in the final stages of completing another resource, a cancer microarray database called Oncomine in collaboration with scientists at the University of Michigan, Ann Arbor, in the USA.

BioAgri sector

Agricultural biotechnology has been another area where there has been increased activity. MetaHelix is one of the leading players in this sector. With an employee strength of 30, the main business objectives of MetaHelix are gene discovery for agronomic and nutritional enhancement of food and commercial crops. MetaHelix has an alliance with ViaLactia Biosciences, a New Zealand-

based dairy biotechnology firm to test plant genes. The deal gives MetaHelix (with the infrastructure to test 200 genes a year) an entry into the US$50–100m market for validating new genes.

With the approval of Bt cotton for commercial cultivation, several other transgenic agricultural products are expected to follow suit

In 2002 a joint venture between Mahyco and Monsanto called Mahyco-Monsanto Biotech Ltd received approval from the Government of India for the commercial production and sale of Bt cotton (Bollgard) in six southern states. With the approval of Bt cotton for commercial cultivation in April 2002, more and more seed companies are seeking technologies such as genetic modification for insect protection. Increasing the shelf-life of fruits and vegetables is another big area of opportunity (especially in a country such as India, which is the world's largest producer of fruits and second largest vegetable producer, but only has about 1 per cent export market due to large post-harvest handling losses[6]). It is expected that, within a few years, several genetically engineered agricultural products including transgenic canola, potato, soybean and tomato will be commonplace in the Indian market. The demand for biopesticides and biofertilisers is also increasing rapidly.

Partnerships and alliances are becoming the life-blood of the Indian biotech sector

KEY DEVELOPMENTS IN THE INDIAN BIOTECH INDUSTRY (2003)

Partnering and alliances

In the developed biotech markets of the USA and Europe, bio-partnering between industry and academia is a highly evolved model. In India, these linkages, which were hitherto weak or missing, have received a major thrust in recent years (Table 2). This has been on account of the Government's proactive initiatives to support the sector, which envisages a greater role of national R&D institutions in shaping the sector's development and enhanced bilateral ties with other countries for technology transfer. There exists an opportunity for biotech companies in the USA and Europe to forward-integrate their drug development programmes at lower cost and shorter time-lines in India. Alternatively, the monetary risk could be shared with an Indian partner who is keenly seeking to backward-integrate into research and discovery. An example of this model is a joint venture between Biocon and a Cuban institute, CIMAB, which has developed a humanised monoclonal antibody for head and neck cancers. The Indian partner will conduct clinical trials

Table 2: Foreign alliances in 2003

Company	Foreign partner	Collaboration objective
Biocon India	Hannah Research Institute, Scotland	Developing oral insulin based on Hannah's proprietary technology
Bharat Biotech Ltd	Wyeth Lederle	Contract manufacturing tie-up for pneumonia vaccine
Kee Biogenetics	Heber Biotech, Cuba	Marketing a range of biotech products in India
Transgene Biotek	Undisclosed US company	AIDS drug using recombinant fusion protein
Strand Genomics	Affymetrix, USA	Providing microarray platform
Bharat Biotech Ltd	Mvelaphanda, South Africa	Joint venture for setting up a biotech facility in Johannesburg
Emcure Pharma	Dragon Pharmaceuticals, Canada	Manufacture of erythropoietin based on technology from Dragon
Strand Genomics	United Bioinformatics Inc., Canada	Distribution agreement for Strand's product Acuris
Nicholas Piramal	Biogen IDEC	Market Avonex for multiple sclerosis in India
Sterling Biotech	Croda Colloids, UK	Setting up unit for gelatin manufacture
Ocimum Biosolutions	Labronica Inc., USA	Global marketing of Biotracker-LIMS
	United Bioinformatics Inc., Canada	Marketing rights for Gencheck and Biotracker
	Hospital for Joint Diseases Orthopaedic Institute (HJD), New York	Research into musculoskeletal disease using analytical tools developed by Ocimum

Source: industry news, compiled by Ernst & Young.

Collaborative arrangements, involving IP sharing, are expected to become the mainstay for the industry in the long run

of the Cuban monoclonal antibody and will invest in a manufacturing facility in India to produce it on a commercial scale.

Several Indian biotech companies have managed to cross intellectual property (IP) related hurdles to work with international partners through confidentiality and non-disclosure agreements. These collaborative arrangements reflect a growing trend, which could prove to be the mainstay for the industry over the long run. The alliances are of a varied nature and included contract research, contract manufacturing, marketing tie-ups, technology transfer and joint research. The most prominent of these alliances in 2003 was the five-year strategic alliance between Nicholas Piramal and US-based Biogen Idec to market in India the latter's 'Avonex', a therapy for multiple sclerosis with annual sales of US$1bn.[7]

Entry, expansion and investments

The domestic market for biotherapeutics and vaccines has become fiercely competitve

Spurred by proactive government support in the form of favourable policies and fiscal incentives, a host of investment and expansion activities were initiated industry-wide in 2003 (Table 3). There were also a few instances where existing biotech companies ventured into new segments and pharmaceutical companies, hitherto having no presence in the sector, made their foray. The industry has invested heavily last year in biotech activities.

Product development and innovation

India's major biopharmaceutical companies are accelerating efforts to get bioequivalent versions of patented well-characterised recombinant proteins onto the market before the window closes in 2005, when the new product patent regime comes into force in India on 1st January (Table 4). Two of the major product launches in 2003 were recombinant human insulin by Wockhardt and recombinant streptokinase by Bharat Biotech. The domestic market for biotherapeutics and vaccines has become fiercely competitive and price wars are common after a product launch. Some Indian biotech companies are accelerating efforts towards developing high-end biotech products and technologies. Reliance Life Sciences is planning to launch genetically

Table 3: Investment in the domestic biotech sector in 2003

Company	Investment (US$m)	Area
Biocon India Ltd	10.83	Expansion – facility for production of monoclonal antibodies
Transgene Biotek	6.5	Expansion – manufacturing facility
Shantha Biotechnics	4.3	Expansion – facility for combined vaccine and vaccine filling plant
Biocon India Ltd	0.11	Expansion – various projects over the next three years
Sterling Biotech	0.06	Doubling capacity of Baroda facility
Intas Pharma	0.03	Plasma fractionation facility
Aktiva Biotech	–	GMP production facility at SP Biotech Park
KCP Biotech	1.08	Initial project cost for facility at biotech park
Reliance Life Sciences	–	Exporting aloe vera to Europe and Japan
Bharat Biotech	4.33	Setting up a CRO
Ranbaxy Laboratories	50–60	Biotechnology research
Siri Technologies	–	Setting up a new centre for biotechnology
Emcure Pharmaceuticals	16.25	Facility at biotech park and export facility
Venkateshwara Hatcheries	6.5	Greenfield vaccine facility
Avesthagen	–	Entry in biopharmaceuticals segment
Intas Pharma	–	Entry into biopharmaceuticals segment
Lupin Labs	–	Proposed entry into biotech via acquisitions of research firms in Europe and USA

Source: industry news, compiled by Ernst & Young.

Table 4: Products launched in 2003

Company	Product
Bharat Biotech	Typbar – typhoid vaccine Indikinase – recombinant streptokinase
Shantha Biotechnics	Shanviv (natural beta-carotene product)
Wockhardt	Wosulin – recombinant human insulin
Cadila Healthcare	Complex typhoid vaccine
TCS (in collaboration with CSIR, DBT)	'Biosuit' – bioinformatics software

Source: industry news, compiled by Ernst & Young.

engineered skin and Avesthagen has won a US patent for a multiple use GM technology (Table 5).

With the post-2005 patent norms just round the corner, small biotech companies are being driven to do innovative research and are picking niches where there is less competition. For instance, Xcyton, a small biotech diagnostics kit-maker, has benefited from an IP-driven model, which respects IP creation and protection. Despite technology barriers, it has made inroads into medical diagnostics market both global and domestic, with WHO approval for its kits. Other players benefiting from an IP-driven model by entering into licensing arrangements are bioinformatics companies such as Strand Genomics and Molecular Connections (Table 6).

Several biotech companies are finding niches and benefiting from licensing arrangements

CONCLUSION

The Indian biotechnology sector has come a long way from the mid-1980s when the Department of Biotechnology was formed and the sector came into public consciousness for the first time. Indian biotechnology companies have evolved over time and have emerged as globally competitive players. Product

Table 5: Products under development in 2003

Company	Products	Stage
Reliance Life Sciences	Genetically engineered skin products	Advanced stage of development, pending clinical trials
Shantha Biotechnics	Shanferon (recombinant interferon for treating chronic myeloid leukaemia)	Patent application
	Filgrastim	Advanced stage of development, pending clinical trials
Avesthagen	Multiple use GM technology	US Patent Grant
Shantha Biotechnics	Shankinase	Awaiting approval
Sami Labs	3 active pharmaceutical ingredients – tetra-hydro curcuminoids (THC), coleus oil, ZeaLutein®	International Patent Grant

Table 6: Products out-licensed in 2003

Company	Licensee	Product
Strand Genomics	Bioprocessing Technology Institute, Lilly Systems Biology (Singapore)	Soochika (microarray data mining and management product)
Molecular Connections	Lio Bioscience Research Inc.	NetPro – proprietary protein interaction database
	Avalon Pharmaceuticals, USA	DM-CHIPS

Source: industry news, compiled by Ernst & Young.

Indian biotechnology companies are emerging as 'Partners of Choice' for the global life-sciences industry

development and IP creation are being widely recognised as key to sustainable development and this is evident in more companies adopting this path. Correspondingly, Indian companies are becoming more attractive globally as collaborating partners for biotechnology activities across the value chain.

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