Healthcare biotechnology firms in India: Evolution, structure and growth*

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The Indian biotechnology industry, like its global counterpart, is dominated by the healthcare sector. The present article attempts to specifically highlight the important characteristics of Indian healthcare biotechnology firms by examining their evolution, structure and growth.

The study revealed that the growth of biotechnology companies gained momentum after 1990s, with a phenomenal growth being observed post-WTO (1995 onwards). Biotechnology healthcare firms are predominantly clustered in four states, namely Andhra Pradesh, Maharashtra, Karnataka and Delhi. R&D as well as alliances is a common feature of the firms having activity profile mainly concentrated in the domain of recombinant therapeutics, vaccines, diagnostics and antibodies. In recent years, the Indian biotechnology industry has come out with several generic products. Enormous opportunities exist for pharma and biotech firms to find innovative ways to harness the strengths in vaccine development, bioinformatics and traditional medicine to gain global presence and to bring a novel drug molecule for the country.

Keywords: Biotechnology, evolution and growth, firms, healthcare.

BIOTECHNOLOGY has emerged globally as a high growth sector with tremendous applications in the areas of human and animal healthcare, agriculture, environment and processing industry. In the pharmaceutical sector, advances in modern biotechnology have initiated a radical change in the nature of search processes for the creation of new drugs (i.e. creation by rational design rather than by trial and error methods). This has led to a radical change in the production of new or rare molecules and drugs with lower costs, novel means for quicker and more accurate diagnostic tests, and new and safer vaccines 1-4. Globally, the health sciences convergence with biotechnology and pharmaceutical companies are the most advanced. Biotechnology is leading the new health economy with around 30 of the top 200 selling medicines worldwide being developed by biotechnology companies alone or in partnership with pharmaceutical companies. Out of 30, 40% are top-selling biologics blockbusters⁵.

Currently, the global biotechnology market revenues are dominated by the US public traded companies with a share of 77% followed by Europe and Canada with a share of 16 and 4% respectively, and the remaining 3% being occupied by the Asia-Pacific. The Asia-Pacific, in terms

of descending order of number of biotechnology firms, is mainly comprised of Australia, China, India, Taiwan, Korea, Japan, New Zealand, Singapore, Malaysia, Philippines and Thailand⁵. It is interesting to note that developing countries like Cuba, Brazil and Argentina have also taken serious initiatives in the promotion of biotechnology^{6,7}.

India is making consistent efforts to emerge as a key player in biotechnology-related activities and investments endowed with the huge knowledge pool, rich biodiversity and vibrant pharmaceutical industry. Unlike in USA, Europe and Japan, in India the government largely dominates the biotechnology research investments. The government has invested more than Rs 1000 crores in various public research institutes since the creation of a separate Department of Biotechnology (DBT) in 1986 in the country⁸. In recent years, there has been active interest and involvement of industry in this area. India is among the top 12 countries in terms of number of biotechnology companies in the world.⁵ According to the latest official statistics9, biotechnology and drugs and pharmaceuticals are the dominating sectors accounting for 36% of the total industrial investment on R&D during 1998–99. According to CII estimate, biotechnology in India employs approximately 20,000 people and has a share of 2% in the global market. The Indian biotechnology industry, like its global counterparts, is dominated by the healthcare sector 10. The healthcare sector accounts for 60%, industrial application 25% and agricultural biotechnology 15%.

Prominent among India's notable achievements in modern biotechnology in the recent years is the development of a

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recombinant hepatitis B vaccine, human insulin, erythropoietin, granulocyte colony-stimulating factor, interferon, streptokinase, a world patent for solid state fermentation called pla factor, bioinformatics software like Avadis and Biosuite. The first indigenously developed recombinant hepatitis B vaccine by the Shantha Biotechnics, Hyderabad drastically brought down the cost (imported price) from US\$ 16 per dose to around 50 cents in India^{11,12}.

In the Indian context, empirical works have examined the R&D, knowledge base, market sales, commercialization and alliance of biopharmaceutical firms^{13–17}. Also using-industry-specific databases, the structure of biotechnology firms in general has been analysed in terms of parameters such as size, activity profile, product portfolio, R&D patterns, alliances, etc.^{18,19}, but all these empirical studies have been limited to only a few firms.

Realizing the importance of the healthcare sector, an attempt has been made to portray a more comprehensive dimension of the healthcare biotechnology firms. The article endeavours to uncover the current developments in healthcare biotechnology industry, i.e. post 2000 and correlate these with earlier activities. The overall trends and examination in various sub-periods highlighting the structural characteristics and growth of the firms in this emerging area of great public interest are also presented.

Methodology

The data for the analysis have been primarily derived from the latest available *Directory of Biotechnology Industries and Institutions in India 2003*, brought out by Biotech Consortium India Ltd (BCIL), Department of Biotechnology, New Delhi. The Directory contains alphabetically arranged list of biotechnology firms in India along with their brief profile. The profile contains details about the firm's operational sector, state, establishment year, products developed, alliances, etc.

The Directory information base 11 was suitably transformed according to the need of the study. In this regard, the healthcare firm records with details of parameters such as establishment year, state, activity domain, manpower, alliances, etc. were extracted and a separate core database of healthcare biotechnology firms was created using in-house software programs. An in-depth analysis of healthcare biotechnology firms was carried out using the core database with the help of appropriately developed software programs. The outcome of the analysis was further validated and supplemented with updated information from other relevant secondary sources like CII reports 20,21, Ernst and Young report⁵, newspaper reports^{22–25}, Chronicle Pharmabiz weekly reports²⁶, annual reports^{8,27}, websites^{24,28,29}, etc. to have a more informed picture of the healthcare biotechnology in India. Interaction meets on one-to-one basis with R&D chiefs of select biotechnology firms like Shantha Biotechnics; Panacea Biotech, New Delhi; Dabur Research Foundation, Ghaziabad; Biocon India Ltd, Bangalore and Strand Genomics, Bangalore were also held to get an in-depth insight of these firms and an overall view of the healthcare biotechnology industry^{30–35}.

Results

Distribution of biotechnology firms

An overall analysis of the directory database shows¹¹ the sectoral distribution of biotechnology firms in the country (Table 1).

The healthcare sector dominates the Indian biotechnology industry with 44% of firms followed by agriculture, 40%; industrial biotech and equipment, 11% each and the remaining 11% by bioinformatics, environment, etc. (Table 1).

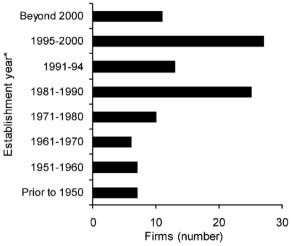
Characteristics of healthcare biotechnology firms

Healthcare biotechnology is an emerging industry with majority of the firms being established recently (Figure 1). About 72% of the firms were established after 1980s,

Table 1. Sector-wise distribution of biotechnology firms, 2003[†]

Sector	No. of firms	Percentage	
Healthcare	142	44	
Agriculture	130	40	
Industrial biotech	37	11	
Equipment	36	11	
Bioinformatics	20	6	
Environment	15	5	
Contract services	2	0.6	
Total	321	100	

[†]Firms may be operating in multiple sectors. Healthcare sector includes firms active in the area of human and animal healthcare.



*Establishment year as reported by firms

Figure 1. Healthcare firms by establishment year, 2003.

38% of the total firms were established during 1991–2000, while 11% got established after 2000.

Key firms established prior to 1980s like Wockhardt Ltd, Hindustan Antibiotics Ltd, Lupin Ltd, Gland Pharma, Venkatesawara Hatcheries, etc. were primarily active in pharmaceutical business and later got diversified into healthcare biotechnology. The last decade (beyond 1991) has seen the emergence of dedicated biotechnology firms (DBFs) like Shantha Biotechnics, Bharat Biotech, Xycton Diagnostics, Strand Genomics, Syngene International, etc. as well as the active participation of pharma majors like Ranbaxy, Cadila, Reddy Research Foundation, Dabur, etc. Interestingly, subsidiaries of MNCs like GlaxoSmithKline and Eli Lilly also emerged on the scene during the period.

Nearly 77% of the total firms were located in four states, namely Andhra Pradesh (AP), Maharashtra, Karnataka and Delhi (Table 2). Maharashtra and AP have the largest concentration of healthcare biotechnology firms, accounting for 27% each. It is interesting to observe that Maharashtra, being a traditional pharma hub, could integrate biotechnology in its activity domain to come at par with AP, being well recognized as an upcoming biopharma hub. In contrast, Gujarat being traditionally known for its large concentration of pharma majors like Torrent, Cadila and Alembic, has been quite slow in adopting biotechnology.

Majority of the healthcare biotechnology firms are operating in multiple segments like marketing, manufacturing as well as R&D of biotechnology products/processes. A few firms are also active in providing consultancy and services, like Avestha Gengrine Technologies, Biocon India Limited, Bharat Biotech International, Bhat Biotech India, BCIL, etc. In addition, biotechnology firms are working in the multifarious activity domain (Table 3). Nearly 60% of the firms are engaged in the specialized activity domain like recombinant drugs, DNA, proteins, hormones, micro-arrays, diagnostics and vaccines, having R&D as a prominent feature.

In terms of manpower profile, around 51% of the firms like RPG Life Sciences Ltd, Xcyton Diagnostics Ltd, Yashraj Biotechnology Ltd, etc. have less than 100 employ-

Table 2. State-wise distribution of healthcare biotechnology firms, 2003

	No. of firms	
State	No. of firms	
Andhra Pradesh	38 (27%)	_
Maharashtra	38 (27%)	
Karnataka	17 (12%)	
Delhi	16 (11%)	
Gujarat	12 (8%)	
Tamil Nadu	10 (10%)	
Uttar Pradesh	4 (3%)	
Haryana	2 (1%)	
West Bengal	2 (1%)	
Jharkhand	1 (1%)	
Kerala	1 (1%)	
Orissa	1 (1%)	
Total	142 (100%)	

ees. Nearly 31% of the firms like Biocon India Ltd, Panacea Biotech Ltd, Shanta Biotech, Nicholas Piramal India Ltd, Eli Lilly, etc. have a strength of more than 300 employees. In terms of technical personnel, 75% of the firms like Strand Genomics, Eli Lilly, Bharat Biotech, Bibcol, etc. have less than 100 employees. Firms having more than 300 technical personnel are Wyeth Lederle Ltd, Hindustan Antibiotics Ltd, Panacea Biotech Ltd, Biocon India Ltd, etc.

Alliances are a prominent feature among biotechnology firms irrespective of the year of establishment (Table 4). The alliances involved mainly contract research, contract manufacturing, marketing, technology transfer as well as joint R&D agreements. Indian biotechnology firms exhibited alliances with national institutions like JNU, Delhi; BARC, Mumbai; NCL, Pune; Bayer (India), IGIB, Delhi; IISc, Bangalore etc. and with international institutions like Austin Chemical Company, USA; Animal Research Institute, Australia, Institute of Animal Health, UK, Vetter Pharma, Germany, etc.

Table 3. Distribution of healthcare biotechnology firms by activity domain, 2003

Activity domain	Total no. of firms	Proportion of firms doing R&D (%)
Recombinant drugs, DNA, proteins, hormones, micro-arrays	32	81
Diagnostics	30	60
Vaccines	21	71
Antibodies	12	92
Therapeutics	10	80
Enzymes	10	80
Antibiotics	8	100
Equipment	6	67
Tissue culture	4	100
Bioinformatics	4	75
Clinical research trials	3	100
Consultancy	3	33
Others	32	69

Others include firms active in herbal, ayurveda, nutraceuticals, aquaculture, media reagents, etc.

Table 4. Distribution of firms by type of alliances by establishment years, 2003

Establishment year		No. of alliances		
	No. of firms	Indian	Foreign	Total
Prior to 1950	7	3	4	7
1951-1960	7	4	5	9
1961-1970	6	2	4	6
1971-1980	10	3	5	8
1981-1990	25	7	8	15
1991-2000	40	13	17	30
Beyond 2000	11	5	6	11
Total	106	37	49	86

Some of the firms revealed having multiple alliances.

Growth of healthcare biotechnology industry

Today, the Indian biotech sector has attained a critical mass in manufacturing as well as research services and has slowly built a market for biotech products and services estimated at US\$ 700 million. This is expected to reach US\$ 1 billion by 2005 and further to US\$ 5 billion by 2010, along with the creation of more than 1 million jobs^{5,28}. A major chunk of the biotech business has been exports accounting for 56%, while the domestic consumption accounts for 44%. Our consumption of biotechnology products is estimated to increase from Rs 87 billion in 1999 to Rs 94 billion in 2005, while the projected demand for 2010 is around Rs 233 billion. Around 40% of the consumption comprises human and animal healthcare products^{28,36,37}.

Biopharmaceuticals

The Indian biopharmaceuticals alone have the potential to reach US\$ 2 billion market size²⁸ by 2010. In 2003–04, biopharmaceuticals occupied the largest market share of 76% of the total biotechnology business in the country, amounting to Rs 2480 crores^{28,36}. Biopharmaceutical products fall under four broad categories, namely vaccines, therapeutics, diagnostics and others, like statins. The vaccine business is the largest contributor, accounting for 47% of the market share, therapeutics 17%, diagnostics 10%; the rest 26% is accounted by others, primarily statins business. Biopharmaceuticals account for 75% of the total exports dominated by vaccines and statins^{29,36,37}.

The domestic vaccine market is currently of the order of US\$ 100 million and is growing at the rate of 20% per year³⁸. The key players in the vaccine segment are: Shantha Biotechnics, Bharat Biotech, Biological Evans, Cadila, GlaxoSmithKline, Haffkine Bio Pharmaceuticals, Panacea Biotech, Serum Institute, Wockhardt, Indian Immunologicals, Venkateswara Hatcheries, etc. These companies are selling DPT, DT, tetanus, rubella, hepaptitis B vaccine, rabies (tissue culture-based), typhoid vaccines, new generation vaccines, etc. In the pipeline are the vaccines for protection against hepatitis E, malaria, HIV, tuberculosis, leishmaniasis, etc. There are also opportunities for developing recombinant viral vector vaccines and DNA vaccines.

The therapeutic products are largely consumed in the domestic market and the major players in this segment are: Shantha Biotechnics, Eli Lilly, Bharat Biotech International, Cadila Healthcare, Cadila Pharmaceuticals, Intas Pharmaceuticals, Nicholas Piramal, Novo Nordisk, Wockhardt, Biocon, Dabur Research Foundation, etc. These companies are working on diseases like diabetes, tuberculosis, HIV, malaria, cancer, cholera, heart diseases, etc.

The market for diagnostics is around US\$ 100 million and nearly 50% of the demand is met by imports³⁸. In the diagnostics segment, there is a handful of companies, namely Xcyton Diagnostics, Accurex Biomedical, Reametrix, Beacon Diagnostics, Bhat Biotech, Bio-systems Diagnostics, Monozyme India, Span Diagnostics, etc. These compa-

nies are selling kits in areas such as pregnancy, ovulation, estimation of T3, T4 and TSH, HIV infection, HBV infection, HCV infection, rheumatoid diseases and disorders, cancer (cervix, colon, prostate, lungs, mouth, etc.), kidney and liver function tests.

Monoclonal and polyclonal antibodies for disease immunodiagnosis, tissue typing, clinical assays and research constitute a huge portion of the market. Key industry players in this space include Lupin Labs, Cadila, Dr Reddy's, Ranbaxy, etc. The animal health biotech market is yet another expanding field. It is expected³⁸ to touch US\$ 200 million by the 2011. MNCs and large companies with animal health divisions based on India include Bayer, Aventis Pharma, Pfizer, GlaxoSmithKline, Wyeth, Wockhardt, Ranbaxy and Alembic.

Some companies have developed biotech products or entered into tie-ups with global leaders to market biotech products in the country. India today boasts of being the world's largest producer of recombinant hepatitis B vaccine due to the combined strength of Shantha Biotechnics, Bharat Biotech, Panacea Biotech, Wockhardt and Serum Institute. India is also emerging as a global player in recombinant human insulin, where companies like Biocon and Wockhardt are the lead runners. Follow-on biologics like streptokinase, GCSF, interferon and erythropoietin are all set to gain market share in the near future. The total biopharma business is expected to grow by about 35–40% in the coming years³⁶.

Bioinformatics

The Indian bioinformatics sector³⁸ is gradually trying to garner a good share of the global revenues and is expected to grow to US\$ 6 billion by 2005. It is a promising sector for Indian enterprenuers and the developments are going beyond the genomics and proteomics zones. The bioinformatics industry is mushrooming around IT services centres. As a result, a lot of companies are based in the southern part of India, viz. Bangalore, Hyderabad and Chennai vis-à-vis few companies in the north. Some of the major players in the south are: Jalaja Technologies, Infosys, Kshema Technologies, IBM India, Strand Genomics, TCS, GVK Biosciences, etc. In the north, companies active in this area are Mascon, Labvantage Solutions, SAS India, V Life Sciences Technologies, etc. The two successful products in this area are TCS, Biosuite and Strand Genomics, Avadis, which was successfully licensed to Abgenix, and a co-distribution agreement has also been signed with a Japanese company³⁶.

Investments and expansion

Spurred by the state and national government support, a series of investment and expansion activities have been initiated by the industry: Biocon plans to invest around US\$ 113.5 million over the next three years to expand its

statins facility and to increase the number of scientists in its contract research organization, Syngene. Ranbaxy, India's largest pharma company is planning to enter the biotech segment with investments of around US\$ 50–60 million. Lupin is expanding into biotechnology via acquisitions, while Intas Pharma is also making a foray in this segment. MNC Roche Scientific India plans to invest US\$ 7.5 million in India for conducting clinical research operations. India is already a centre for conducting regional trials for Roche interferon cancer drug 'Pegasys'. In addition, successful attempts have been made by various biotechnology companies such as Wockhardt, Nicholas Piramal, and Strand Genomics to mobilize foreign investments for their expansion and R&D activities^{39,40}.

As a result of the 2005 global patent agreement, Indian companies are driven to innovative research and are establishing their own niche areas: Reliance Life Sciences is planning to launch genetically engineered skin; Avesthagen has won a US patent for multiple use genetic modification technology; GlaxoSmithKline Biologicals has plans to launch a number of vaccines like new-generation DTP, rotavirus and cervical cancer for its global portfolio. Similarly, Xcyton, a small biotech diagnostic kit-maker has made its presence felt in the global and domestic diagnostics market^{5,22}. Several biotech medicines are due to come off patent in the next few years, and pharma majors are looking at India for contracting research and manufacturing of biologic generics. India is becoming a talented and cost-competitive destination for biotechnology research, product development, toxicity studies and clinical trials and has positioned itself to take advantage of moves by governments in the US and Europe to create a regulatory framework for approving generic versions^{5,24}.

Conclusion

The Indian biotechnology industry like its global counterparts is dominated by the healthcare sector. The present article attempts to highlight the important characteristics of Indian healthcare biotechnology firms by examining their evolution, structure and growth.

The results have shown that the evolution/growth of healthcare biotechnology firms has its roots in the pharmaceuticals industry, which reflects the phenomenon taking place globally. Key pharmaceutical firms established in pre-80s in the country like Wockhardt Ltd, Hindustan Antibiotics Ltd, Lupin Ltd, Gland Pharma Ltd, etc. have ventured or adopted at a later stage the biotechnology in manufacturing, marketing and also research. Majority of the biotechnology companies were established after 1980s and this period incidentally coincides with the initiatives started by the government during the Sixth Five Year Plan (1980–85) to set up a dedicated Department of Biotechnology and to nurture and promote biotechnology.

The growth of healthcare biotechnology companies gained momentum in post-1990s, with phenomenal growth

being observed in the post-WTO period, i.e. 1995 onwards. This period has seen the emergence of DBF or start-ups, large pharmaceutical firms adopting BT, spin-offs from the established pharma majors like Dabur, Ranbaxy, Reddy, Cadila, etc. as well as biotechnology majors like Biocon and Shantha Biotechnics. The first successfully established spin-off company from the Indian Institute of Science (IISc), Strand Genomics, also emerged in this period³⁵. Majority of the healthcare biotechnology companies established in post-1990s are private limited companies. Interestingly, MNC subsidiaries like Eli Lilly, GlaxoSmith-Kline, Pfizer, etc. also gained entry during this period²³. The reasons for the active participation by MNCs during this period could possibly be the signing of the WTO treaty by India, coupled with the comparative advantages the country offers like cost, skilled manpower, etc. in the healthcare domain.

The growth of healthcare biotechnology firms has largely taken place in clusters. The results showed a large concentration of companies in four states, namely Andhra Pradesh, Maharashtra, Karnataka and Delhi. The state governments are giving a special thrust for the promotion of biotechnology cluster development by evolving liberal/favourable policies, including tax and excise concessions as well as the much needed venture capital support^{25,41}. This has resulted in an upsurge of new biotechnology firms, especially in states like AP and Karnataka. 'Baddi' in Himachal Pradesh is a recent witness of this phenomena^{5,26,31}. Perhaps this could be one of the reasons that Gujarat, despite being recognized as a traditional pharma hub along with Maharashtra is yet to catch up with other states in adopting biotechnology.

The firms that are active in the healthcare sector mainly comprised of medium sized and newly dedicated biotechnology firms. The activity profile of these firms though quite diverse, is mainly concentrated in the domain of recombinant therapeutics, vaccines, diagnostics and antibodies. Biotechnology is a knowledge or research-intensive industry; the results portend that biotechnology firms, irrespective of their size, are engaged in multi-disciplinary R&D activities. Thus there is a realization by the firms to carry out innovative research for achieving growth by bringing out new products in the post-WTO era^{42,43}.

Globally, the growth of biotechnology has been characterized by large alliances or networks of learning^{44–46}. Indian BT firms have exhibited alliances both with national and international organizations. A study on Indian biopharmaceuticals also supports this assertion¹⁷. Foreign collaboration dominated among the firms, thereby reflecting their tendency to catch up with the new or cutting-edge technology or align with the global research network for higher growth ^{30,31,47}.

The R&D efforts of Indian biotechnology firms are substantially lower than those of global counterparts. One of the prime reasons for this is the lack of research infrastructure compared to that of other developing countries like Brazil, Taiwan, China and Israel. In India, the govern-

ment has played a key role in building capacities and capabilities in terms of research infrastructure, human resources, fiscal support and R&D incentives, apart from synergizing the various actors through new initiatives and programmes such as PRDSF (DST), NIMTLI (CSIR) etc. aimed at utilizing the results of the public research institutions for commercialization^{25,27,48,49}. The National Biotechnology Policy (National Biotechnology Development Strategy, Draft 2005) announced recently by the government is a step forward in encouraging innovative enterprises and addresses appropriately issues such as quality of manpower, regulatory environment, effect of WTO, etc. for the growth of biotechnology in India²⁸.

Though there has been a slow transition to product model by Indian biotechnology companies, India is still a generic market. To achieve global presence, Indian firms need to have product focus and should come up with blockbuster drugs^{20,21}. There exist boundless opportunities for pharma and biotech firms to find innovative ways of working together by leveraging the committed government support. According to Padmanaban³⁷, 'India has just crossed the lag phase of the biotechnology growth and is at the beginning of the log phase of growth'. India's advantages lie in vaccine development, traditional herbal medicine as the cheapest mode of protecting health as well as bioinformatics, because of strong capabilities in software, and for these areas India should aim for global leadership^{12,34,50}.

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