Rising to the technological challenge: possibilities for integration of biotechnology in the Indian pharmaceutical industry

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Abstract: Presently the Indian pharmaceutical industry ranks 12th in the world and its market is conservatively estimated to be $2.5 billion. Tracing the evolution of this industry, the paper first shows that Indian firms over the years had invested in gaining knowledge of the chemical technology of creating bulk drugs, and the top tier firms had greatly 'learnt by doing', improving upon the process technology and bringing down their prices without investing in 'formal R&D centers'. These firms were then confronted with biotechnology, a set of techniques that was new and more complex to integrate. In this context the paper examines the variety of ways in which the Indian firms are strategically positioning themselves for the integration of biotechnology as dictated by their market objectives.

Keywords: India; pharmaceutical sector; strategic positioning; biotechnology; technology strategy.

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1 Introduction

India's pharmaceutical industry is the twelfth largest in the world today and the market accounts for $2.5 billion [1]. The pharmaceutical industry registered an average annual growth rate of 15% over 1990-1995 [2]. The real value of the industry's production should be deemed even higher in view of the fact that regulation on drug prices keeps prices artificially low in India [3]. The country is almost totally self sufficient in formulations and 80% self sufficient in bulk drugs [4].

The industry is a highly fragmented one with 3,153 firms in the organized sector and at least 13,000 firms in the 'unorganized' small scale sector [4]. However the economic liberalization measures of the Government of India, and the steady dismantling in recent years of the 'socialist pattern of society' that it had sought to promote for about four decades, are likely to result in the elimination of many small firms having very low profit margins. The organized sector includes most of the top pharmaceutical giants of Europe and some of the USA.

In the last decade, the global pharmaceutical industry has witnessed radical 'technological breakthroughs' through the employment of biotechnology. The product innovations created using biotechnology fall under two categories: diagnostics and therapeutics. Diagnostic kits consist of chemical products that can interact with body fluids, (blood, urine etc.), to reveal a particular biological condition. Therapeutics are basically curative and preventive medicines. Therapeutics are more sophisticated technologically, take a longer time to obtain regulatory approval, (since they have to be imbibed by humans), and have a much higher market value. All the therapeutics commercialized till now using biotechnology have been developed by small US companies and commercialized (mostly) by large US or European multinationals [5].

In the context of such developments, the issue of the Indian pharmaceutical industry's prospects in the ongoing 'technological race' is beginning to stimulate serious discussion, not unmixed with anxiety, in the government, research and business communities. The anxiety arises out of the fear that if India lags behind in key areas such as biotechnology, the economic and social uplifting of its people would slow down and a sort of neo-colonial dependency on advanced countries would result, with its attendant negative political implications.

What then is the present state of the Indian pharmaceutical industry and how prepared is it to meet the challenging task of integrating biotechnology for new product innovation and commercialization? Are Indian firms diversifying into biotechnology? What are the different technology strategies pursued to achieve this objective? These are the questions we attempt to answer in this paper. The paper is organized as follows. Section 1 takes a very brief look at the evolution of the Indian pharmaceutical sector over 1948-1995. Then Section 2 presents a typology of Indian firms in the pharmaceutical sector according to their learning trajectories. Explanations are proposed in Section 3. Finally conclusions are summarized in Section 4.

1.1 Evolution of the Indian pharmaceutical industry 1945-1972

When India attained its independence in 1947 it had only a pharmaceutical industry of very modest size with a market of about $28.5 million [6]. There were several Indian-owned firms in the field but their operations were on a much smaller scale than those of the foreign companies. In this paper we shall use the term 'Indian firm' for a company owned by Indians and 'multinational' or 'MNC' for a company owned by non-Indians. The production of pharmaceuticals involves two phases: the manufacture of basic ingredients that are called 'bulk drugs' and their subsequent 'formulation' for final use by consumers, in the form of tablets, capsules, syrups, injectibles, drops and sprays. No Indian company was a major factor in either field at the time of independence and there was heavy dependence on imported foreign drugs which were marketed either by MNCs already established in India or by local agents of other MNCs that did not have a local presence. In order to reduce the dependence on imports and on western MNCs, at least for vitally needed antibiotics, the Government of India undertook large investments to establish a network of public sector enterprises [7]. The most important among these were Hindustan Antibiotics Limited (HAL) and Indian Drugs and Pharmaceuticals Limited (IDPL). The move was useful and timely but it was not a comprehensive response to the country's healthcare needs.

The foreign multinationals formulated their drugs in India, importing the bulk drugs from their home countries. It was their contention that the locally available bulk drugs were not of the desired quality. This led to drug prices that were regarded as being too high by the consumers as well as by the government. Thus in 1965 the government pegged drug prices at levels that prevailed as on 1 April 1963. The 'drug price control' order of 1970 brought under price control a number of bulk drugs and selected formulations and also set a ceiling on the overall profits of companies in the pharmaceutical sector. The control regime was continually opposed by both MNCs and the fledgling Indian companies. They argued that high import duties were largely responsible for pushing up prices and that price controls discouraged the flow of investment into the industry by depressing the earnings of companies. Discouraged by what they regarded as low margins that could be made under the price control regime, MNCs became disinclined to increase their investment in their Indian subsidiaries or expand their manufacturing activities significantly. They evinced little interest in developing R&D activities based in India.

1.1.2 Rapid growth phase: the Indian patents law of 1972

Desirous of developing the indigenous pharmaceutical industry at a much faster pace, the Indian Government enacted the Indian Patents Law in 1972. The act ensured patent protection only to production processes and not to the products themselves. The provision left the way open for Indian companies to develop and market substitutes for MNC products by simply evolving some process variations. This expedient was not something invented by the Government of India. Japan, for instance had such a provision in place for several years in order to promote its own indigenous pharmaceutical industry [8]. The communist countries did not respect Western patents either. That the Government of India made its move a quarter of a century after the country attained its freedom testifies to its inadequate awareness and appreciation during earlier years of what countries like

Japan were doing, and of what Indian private enterprise might be capable of achieving in the pharmaceutical industry.

Initially the multinationals did not see the new patent act as a threat to their market position as they assumed that it would be beyond the technological competence of the Indian pharmaceutical companies to do 'reverse engineering' and formulate products equivalent to those of the MNCs [9]. The immediate impact was slight. As late as 1976, among the top 20 firms which held 57.19% of the pharmaceutical market, there were only four Indian firms (see Table 1). However the patent act opened up opportunities which in time some alert and aggressive Indian companies equipped themselves to exploit. Those that were unimaginative and timid were left behind. The MNCs had underestimated the capability of Indian technologists and the entrepreneurial skills of the Indian businessmen, and overestimated the appeal of their brand names for the price conscious consumer. The consumer was quite willing to go for a lower priced Indian product with its own brand name.

Table 1 Market share of drug sales of the 20 leading companies in India in 1976

Number	*Rank*	*Name of Company*	*Market share %*
1	1	Sarabhai	7.1
2	2	Glaxo (UK)	6.2
3	3	Pfizer (USA)	5.9
4	4	Allembic	4.2
5	5	Hoechst (Germany)	3.6
6	6	Lederle (USA)	2.5
7	7	Parke-Davis (USA)	2.3
8	7	Abbot (USA)	2.3
9	7	Ciba-Geigy (Swiss)	2.3
10	8	Sandoz (Swiss)	2.2
11	9	Burroughs-Wellcome (UK)	2.1
12	10	Boots (UK)	2.0
13	10	Suhrid	2.0
14	11	Unichem	1.9
15	11	E. Merck (USA)	1.9
16	11	John Wyeth (USA)	1.9
17	11	M&B (USA)	1.9
18	12	SKF (USA)	1.6
19	12	German Remedies	1.6
20	12	MSD	1.6

Among the companies that successfully took advantage of the patent law were some who had entered the field with bulk drugs, some others with formulations and the rest with both bulk drugs and formulations. As their business expanded the first group engaged in forward integration into formulations and the second undertook backward integration into bulk drugs. Many saw advantages in expanding their product range while some that achieved quick success with a particular product concentrated their efforts on increasing the production of that product in order to achieve economies of scale and reduce average costs.

Indian companies that had expanded production volume began to explore the prospects of overseas markets in order to sell the substitutes they had developed for products protected by patents in Western countries. They targeted countries that did not recognize Western patents or did not have restrictive local patent laws. The Soviet Union

became an early client for exports. The success achieved in that market encouraged Indian companies to further step up their production volume and to initiate attempts to penetrate markets in developing countries, especially in South-East Asia and Africa. As a necessary part of the effort the companies began adding requisite strength to their R&D capabilities in reverse engineering by inducting scientists and technologists to improve the quality of their products and to re-engineer additional products.

The major constraint in the overseas markets was establishing confidence among medical personnel and hospital and government administrators that the Indian products were of good quality; the major advantage was their ability to offer their products at considerably cheaper prices than those of the MNCs. Initially Indian companies lined up local distributors for their products. In time as business developed they saw the need to set up their own representative offices in the foreign countries to facilitate approval from local regulatory agencies, as well as to organize promotional activities.

Export sales soon came to be recognized as a means of increasing production volume and also of availing certain fiscal and customs duty concessions offered by the Government of India. Exports were also seen as a source of higher margins than in the Indian market with its price control regulations. The financial success achieved by the companies that were pioneers in exporting their products influenced several others to follow a similar course.

During the 1980s MNCs found themselves steadily pushed lower in rankings among the top pharmaceutical firms in the country. In 1976 the top position had been held by the Indian company Sarabhai with a market share of 7.1%. Sarabhai had earlier licensed technology in antibiotics from Squibb. Sarabhai's position as the top ranking company in terms of market share was to become seriously eroded as was that of Allembic, the other Indian company among the top five companies. On the other hand Ranbaxy, which had a lowly 16th rank in 1976, made its way to the top position in 1995 edging out the British MNC, Glaxo, which had occupied that rank for several years. In terms of market share in 1995 only seven MNCs, (including their subsidiaries), figured among the top twenty pharmaceutical companies in India and together they could claim only 15.1% of the total market, (see Table 2). Indian companies that had won a place in the 1995-1996 list ranked in order of their market share were: Ranbaxy, Lupin, Cipla, Dabur, SOL Pharma, Sarabhai, Torrent, Dr. Reddy's, Allembic, Kopran, Ipca and Cadilla. In addition, there were 38 other Indian owned pharmaceutical companies that were among the top fifty in terms of sales, ($22 million or more), during 1995-1996. Only 12 MNCs figured in the list, of whom only three made it to the top ten: Glaxo, Hoechst, and Pfizer.

Clearly, in order to compete against entrenched and popular MNC brands, the Indian substitutes had to become of comparable quality and cheaper in price. These requirements made it incumbent on Indian engineers and managers to pay continuing attention to cost reduction and quality control. Many of the companies in the top hundred, recognizing the opportunities afforded by the Indian Patent Law, made modest investments in R&D activities resulting in an enhancement of their technical capabilities in working out processes for the production of selected drugs identified by them as having good commercial prospects. However R&D expenditures as a percentage of sales still remained quite low compared to figures in the advanced countries, and companies generally tended to raise it to just the point needed for the production of the identified drugs. Ranbaxy the leader in the Indian pharmaceutical market spent only about 5% of its sales income on R&D. Most importantly, while successful Indian companies had demonstrated their

capabilities in bringing out very satisfactory substitutes for a number of patented Western products, and expanded their sales in India and in the overseas markets through lower prices, none of them had come up with a significant innovation in the form of a new drug based on indigenous R&D. The Indian pharmaceutical firms had their knowledge base firmly embedded in organic and synthetic chemistry. They had not made any efforts to integrate other scientific disciplines to create or re-engineer innovations. These firms were then confronted with biotechnology, a set of techniques based on recent developments in the life sciences that was new, different and much more complex to integrate requiring a multi-disciplinary team to create a product. They had to address the issue of where and how – or if at all – they should position themselves to respond to the emerging role of biotechnology.

Table 2 Market share of drug sales of the 20 leading companies in India in 1995

Rank	*Name of Company*	*Market Share*
1	Ranbaxy	7.0
2	Glaxo India (subsidiary of British firm)	4.4
3	Lupin	3.0
4	Cipla	2.7
5	Hoechst India (subsidiary of German firm)	2.6
6	Dabur	2.4
7	Pfeizer (USA)	1.9
7	SOL Pharma	1.9
7	Ambalal Sarabhai	1.9
8	Torrent	1.8
8	Dr. Reddys	1.8
8	Allembic	1.8
9	Knoll (Germany)	1.7
9	HAL	n.a.
10	Kopran	1.6
10	Ipca	1.6
10	SmithKline-Beecham (USA-UK)	1.6
10	Burroughs-Wellcome (UK)	1.6
10	Cadila	n.a.
11	Parke-Davis (USA)	1.3

2 Strategic positioning of Indian firms

One of the main preoccupations of the technology management literature is to understand the relation between strategy, resource structure, and performance of firms and the market environment in which they operate. As a first step in this direction, in our study of the Indian pharmaceutical sector, we wanted to identify a typology of Indian firms according to their strategic positioning for the integration of biotechnology. An examination of the literature in mainstream economics and management journals revealed that the focus of the existing articles is on the R&D activities of manufacturing firms in the Indian economy as a whole, contributing to the debate on the relationships between resource structure and performance of the firm in developing countries. For instance a number of

articles examine the influence of factors such as firm size, imports, R&D expenditure as percentage of market sales etc. [10]. They mainly use panel data on public firms published by the Indian Government. Private firms have not been examined due to lack of data. With the exception of two, all the articles have dealt with the period before 1987, i.e. before the period of economic liberalization when the rules of the game were very different for firms in any sector. We thus could not use any of these articles to respond to the questions being posed in this paper.

In their paper 'Patterns of strategic choice in emerging firms: positioning for innovation in biotechnology', Hamilton, Vila and Dibner [11] analyse the innovation strategies of firms founded between 1971 and 1983 in the USA, in the biotechnology sectors, with respect to three features: focus of the innovation process, external alliances and timing of the innovation [11]. They examine if the focus is on research, development, production or marketing and whether the external network with other firms played a crucial role in the evolution. Then they present a typology of firms according to the above features and the timing of the innovation.

In the present work the above three features are studied under the unified concept of technological competence. By competence we mean the ability of the firm to exploit its resources, in the particular environment in which it functions, to satisfy its chosen objectives [12]. In particular technological competence is taken to be the ability of a firm to exploit its resources to create the particular technologies relevant to its needs. Since firms can engage in competence improvement without it being transformed into any activity related to innovations, by replacing innovation strategy as studied by Hamilton, Vila and Dibner [11] with firm strategy for the evolution of technological competence, we can include the 'influence of external networks' and 'impact of timing' in a broader picture of the evolution of the firm. .

We propose that in any market the evolution of technological competence, (or simply competence from now on), of firms can be one of two types: 'competence maintaining' or 'competence improving'. Under a 'competence maintaining' trajectory, firms do not invest in R&D and simply exploit a particular technology to manufacture a particular set of products or services without any change in terms of quality or variety. Any learning that occurs is through 'learning by doing', i.e. emerges as a side product of the activity of the firm. We then make two assumptions:

1 A1: Any firm that invests in R&D expenditure improves its competence.

2 A2: Any improvement in the quality, increase in the variety, and increase in the quantity of products manufactured by the firm indicates an improvement in the competence of the firm.

The first assumption asserts that R&D is a sufficient but not necessary condition for improving competence. This reflects the fact that R&D is essentially a search activity which generates knowledge and competence. A firm can also improve its competence through research contracts, purchase of technology or strategic alliances, which in turn can generate changes in the quality, variety or quantity of the set of commodities being produced by the firm. Hence the second assumption. Again by identifying firms whose competence has changed according to the above two criteria, our set of 'competence improving firms' may incorrectly exclude firms whose competence has improved without any R&D expenditure and without any change in the product portfolio. Nevertheless we

adopt this approach because we assume that in any high-tech sector the set of such firms being excluded incorrectly is negligible.

Competence improvement can be of two kinds: 'competence deepening' or 'competence widening'. Competence deepening occurs whenever a firm invests in R&D without there being any increase in the variety of the products being produced. In other words R&D expenditure of firms in this category is geared towards increasing the quantity or improving the quality of products already being produced. Competence widening occurs whenever there is any increase in the variety of products being produced by the firm.

We deliberately avoided taking into account patents obtained or publications originating from firms as indicators of competence improvement. This was because the central thrust of the innovative activity in India, like in many developing countries, is on the 'engineering side' of product development rather than on the basic scientific principles and techniques on which product development is based. Such knowledge is highly tacit and resides with individuals of technical competence. It cannot be codified and therefore patents and publications become irrelevant for firms [13].

Then our objective was to identify a typology of firms according to patterns of competence improvement. However, identifying the evolution of competence trajectories alone is inadequate to characterize the behaviour of firms without a clear understanding of the motivations of each group of firms in pursuing a particular trajectory. Thus we sought to identify 'strategic positioning' of Indian firms by referring to two indicators: the competence trajectory followed by the firm and the strategic objectives of the firm in following such a trajectory. However the present paper limits itself to the identification of strategic positioning of Indian firms without delving further into the relationships between resource structure, strategy and performance, (these are dealt with in an extension of the present paper referred to in [10]).

2.1 Data and methodology

Information on firms in the Indian pharmaceutical sector was mainly obtained from publications of the Center for Monitoring the Indian economy, Economic Intelligence service. Data on pharmaceutical firms was also acquired from the Directory of biotechnology industries and institutions in India 1994-1995, published by the Biotech Consortium India Ltd., Research profile of biotechnology activities in India 1993 published by the Department of Biotechnology (DBT), and annual reports of the Department of Biotechnology. These mainly gave addresses of the companies, their product focus, sometimes indicators of their financial assets and in a few rare instances indicators of R&D activity at a particular point in time, (or over two to three years). Panel data over a longer period of time was not available. For the firms that were public, annual reports were available. Even these mainly gave financial data and the product focus of the company and rarely concrete indicators of R&D activity.

Thus in order to know how and why the product portfolio of firms in the 'competence improving' category evolved during the last five years, we had to bolster our data base with postal questionnaires and direct interviews with firms. The response rate to the postal questionnaires was about 20%. We then interviewed about 15 firms in order to have detailed information on almost 50% of the firms in our sample of 'competence improving' firms. We also used information in business and trade journals as well as

extensive interviews with well known experts to gauge the nature of the innovative efforts of the remaining Indian pharmaceutical firms.

Next, the competence trajectory of a firm was identified on the basis of its R&D expenditure and the evolution of its product portfolio. Firms which spent less than 2% of their turnover on R&D and which had not changed their product portfolio during the period 1990-1995 were considered to be pursuing a 'competence maintaining' trajectory. Spending less than 2% of turnover was not considered significant, since most firms accounted for some marginal amount as R&D expenditure in order to avail of fiscal concessions and spent it on fixing day-to-day problems at the plant. Diversification of the product portfolio through mergers or buy-outs of other firms was excluded from the analysis.

Firms which spent more than 2% of their turnover on R&D but had not introduced any new product during the period 1985-1995 were considered to be pursuing a 'competence deepening' trajectory. Then firms which had introduced new products in the final product during the period 1985-1995 through any means other than purchase of a firm or a merger were considered to be 'competence widening'. R&D expenditure was not taken as a benchmark for the evolution of competence in this case, as some of the firms had pursued the 'competence widening' trajectory through tacit learning on the engineering side, a market transaction or a strategic alliance, that was not always reflected in the R&D expenditure. Then for each set of firms that had implemented a particular technology learning trajectory, the strategic objectives of the firm in the final market were identified. Then on the basis of the competence trajectory and the strategic objective different types of 'strategic positioning' were identified.

3 Results

3.1 Competence maintaining cluster

There are four types of firms that engage in little or no R&D whilst being technologically adequate for their overall objectives: small scale units, most of the mid-size and large firms that concentrate on their production and market strategy alone, public sector companies that have particular social targets to fulfil and foreign multinationals. At the most optimistic estimate, except for about a hundred or so firms, the rest of the pharmaceutical industry falls into this category.

3.1.1 Objective: to maintain market share

This cluster comprises the thousands of firms in the small scale sector that have neither the resources nor the incentive to invest in R&D. They survive because of reservation of certain drugs for the small scale sector and their lower cost of production owing to lower overheads and wages paid. These small units then sell their product to the medium size and large size firms. As intermediate sellers they have no incentive to invest in R&D and their survival strategy consists of maintaining their present buyers and seeking additional ones.

3.1.2 Objective: to increase market share through focus on production and marketing

Many of the medium sized and large companies which have substantially larger resources than the small scale sector stick to a strategy aimed at maintaining and increasing market share through expanding capacity for their profitable products, improving production efficiency, cutting down costs and improving their marketing practices. For instance, IPCA laboratories is among the top 20 firms in India in terms of market share while spending about 1/2% of its turnover on R&D. Its core competence lies in the production of anti malarial drugs in which it has 42% of the market share. Its substantial growth and market share are explained by the growth of its exports and its backward integration from formulation to bulk drugs.

3.1.3 Objective: to achieve social targets

This set comprises the network of public sector firms that had been created by the central and state governments during the 1950s in the course of implementing a social policy that called for import substitution and self-reliance in certain basic antibiotics, so that essential drugs could be made available to the public at reasonable prices. Commercial considerations and profit making did not figure significantly in the calculations of policy makers. Thus the public sector firms functioned to meet certain production targets fixed by the governments. There was little co-ordination between marketing, production, and whatever was depicted as 'R&D', and even less attention was bestowed on how to align such activities of the firm to improve its competitive position in the market. Inevitably, the results in terms of business performance were quite unsatisfactory [14]. Over the years the public sector pharmaceutical companies piled up enormous losses and serve today as standing monuments to all the errors that a government can possibly make in running a business establishment. At no point did the Government of India appear to have harboured any notion that its public sector firms should be transformed into launching pads for the promotion of advanced R&D and a quest for new drugs.

3.1.4 Objective: to market foreign biotechnology products

There are many firms that have diversified into biotechnology through selling a foreign product. Both public sector, (e.g. IDPL), and private sector companies, (Astro Drug, Lupin, Dr. Reddy's Labs), are marketing diagnostic kits made abroad. Margins in the pharmaceutical industry do not warrant commitment of a company's resources to R&D. It is more profitable for a firm to continue to make its range of bulk drugs and to seek alliances with suitable foreign partners in order to get access in the Indian market for their patented products. Often, an Indian company's criterion for entering into an international strategic alliance is access to the foreign company's patented drugs to be produced and marketed in India under its name, or access to the commercial network of the foreign company to export an Indian product abroad. In order to attract foreign companies as an outsourcing base, the Indian unit signals its quality through gaining regulatory approval of a western agency, (e.g. GMP or good manufacturing practices certificate from regulatory authorities of the USA). It can also offer the use of an extensive sales network to market the foreign product or a jointly created product.

3.1.5 Foreign multinationals: to maximize sales through aggressive marketing

Most of the major US and European pharmaceutical companies have subsidiaries in India. Some like Glaxo have been in India even before the end of British rule. Despite their vast turnover and R&D outlays, their commitment to new product innovation through India based R&D has been insignificant. MNCs in India basically serve as retail outlets for the commodities developed in their home country. Their objective is to maximize their profit through developing an efficient production base and distribution network. They put into good use the accumulated knowledge generated through their international operations. Their positive contribution to the development of industrial competence in India is through the quality of their product, its packaging and its marketing, setting the benchmark in the market towards which the Indian companies are forced to move. In biotechnology, Hoechst and Ciba-Geigy do research in India. All recombinant products are still imported into India, and thus we find companies like NovoNordisk, Hoechst, Eli Lily and Boehringer marketing in India, recombinant products produced in their home country.

3.1.6 Competence improving cluster

In order to identify firms in the competence improving cluster we considered as candidates firms that either had the financial resources or the proven scientific competence to create innovations. Thus we considered the top twenty firms according to net profits [15]. We also included the fastest growing Indian pharmaceutical firm, Wockhardt, (during 1990-1995), and 31 firms that were not in the above list but were mentioned as being active in research according to the latest Directory of Biotechnology Industries and Institutions in India 1994-1995 published by the Biotech Consortium India Ltd. We also included three newly formed dedicated biotechnology firms that had escaped mention in the directory such as Shantha Biotechnics, Transgene, and Avra labs, to form our sample of analysis of 55 firms.

3.2 Competence deepening cluster

This cluster comprises incumbent firms in the pharmaceutical sector that do not plan to integrate modern biotechnology, but nevertheless strive to improve their competence in the traditional 'chemical technology' underlying the production system of the pharmaceutical industry. With respect to new firms founded on biotechnology, this cluster refers to firms that systematically invest in R&D to improve upon their competencies. However, since the variety of products is left untouched, the learning objectives of firms in this cluster, are centered on 'development' or 'production' targets or on marketing the superior products of another firm rather than 'creation' of innovations.

3.2.1 Objective to exploit knowledge of a narrow and sophisticated technology

These refer to a few (four to our knowledge) dedicated biotechnology firms, mostly created by former public laboratory researchers to do contract research or contract production for other firms. They have shown themselves to be competent and knowledgeable in a few specific areas of science. A typical example in this category is Avra Labs. Avra labs was created by A.V. Rama Rao, former director of the Indian

Institute of Chemical Technology with the financial support of the Daichi group and a renowned US scientist. The company has received contracts from US companies active in biotechnology such as Monsanto, Cytomid and Chantel.

3.2.2 Objective: to produce biotechnology products through strategic alliances

There are also dedicated biotechnology firms which have been created with foreign collaboration. For instance, the company Transgene Vaccine, is developing a hepatitis B vaccine in India with imported technology from the German company Braun Biotech. Another firm, Reproductive Biotechnologies is developing a contraceptive vaccine in collaboration with a US company Zonagen using the patented technology of the latter [16].

3.3 Competence widening cluster

This set includes firms that have introduced new products either through in-house R&D, market transactions or strategic alliances with universities or other firms.

3.3.1 Objective: to develop competitive advantage through improvement of existing products

These refer to a set of medium sized companies whose competitive advantage lies in their ability to do 'reverse-engineering' and develop process modifications to produce acceptable substitutes for drugs already discovered, patented and marketed by western firms. In the Indian bulk drugs market, the prices of certain commodities systematically fall following 'sprints' in the technological race. For instance, a competent Indian bulk drug manufacturer may discover how to make an already discovered western drug. By bringing the price down and being the first to sell on the market, the innovating firm rakes a winner's margin. This puts into motion an intense race among other technologically competent firms and the prices fall further as more and more bulk drug manufacturers copy the process. Therefore the companies which manage to innovate in the second or third rounds obtain lower margins. Thus, speed of introduction of a 'me too' version is crucial to a firm's success. Companies in this category evolve their strategy taking this phenomenon into account.

Several top ranking Indian pharmaceutical firms owe their success to the effective implementation of such a strategy. Cipla, holding the 4th largest market share in the Indian market, produces among other drugs 'vincristine', an anti cancer drug. India used to export dried leaves of vinca rosea and Eli Lily that was used to make vincristine in capsule form. The capsules sold in India for $2.28 each. Cipla improved and scaled up this known process to make tablets costing less than a dollar and also exported the drug to some foreign countries.

Another example of a company that has successfully developed its own processes to produce drugs patented in the west is SOL pharmaceuticals. It was the first in India to take up commercial production of some of the new molecules like Astemizole and Fluconazole. SOL also copied some new molecules like Lomefloxacin, Lansoprazole, and Amlodipine, reducing their prices by half [17].

Another firm that has been attracting praise for its enterprise and dynamism is Dr. Reddy's Laboratories. It developed new processes for certain drugs that were initially

discovered and sold by foreign multinationals, forcing them to lower their prices as it developed cheaper substitutes. Among its successful products are Quinolone, an antibacterial drug, Ciprofloxacin, an antityphoid drug, Enam, a blood pressure lowering drug, and Omex, an anti ulcer drug.

These firms have not shown a willingness at this stage to integrate biotechnology in their R&D efforts. The most technologically competent firms among them take note of the fact that an intense technological race is ahead of them to replicate about 40 western drugs with a present market value of more than $15 billion that are going off patents in the next five years [18]. They are gearing themselves for the race by strengthening their R&D centres, expanding their production capacities, and formulating marketing strategies for the domestic market and markets in other countries that do not present patent constraints.

These firms have not thus far diversified into biotechnology because their core competence is in organic and synthetic chemistry and not molecular biology. They perceive the costs of diversifying and developing core competence in biotechnology to be too high, and their short term strategy is to tap the tremendous market potential of replicating the already discovered drugs based on chemical technology that will go off patents. They may consider integrating biotechnology once the opportunities for making quick and high profit from processing already known drugs are exhausted.

3.3.2 Objective: to create diagnostic kits

Diagnostics are the easiest types of biotechnology product innovations to commercialize in the pharmaceutical sector. They are subject to much less stringent regulatory rules since they only involve tests with body fluids without being imbibed by humans. Thus the smaller size of their market is compensated by the smaller time required for commercialization. The major thrust of the Indian Government's program in healthcare is research in immunodiagnostics and this has resulted in the creation of diagnostic kits by a number of public laboratories. These have then been transferred to private sector companies making this sector distinct for its successful record of transfer of technology from public laboratories to private firms. Further progress in this sector is however hindered by the availability of imported kits in the market bearing the names of reputed foreign companies which many Indian doctors tend to prefer.

Ranbaxy, the number one Indian company in the pharmaceutical market, is part of a small set of firms which are trying to create diagnostic kits through in-house R&D, (as well as through transfers from public laboratories and market transactions with foreign companies). It has developed a high class in-house R&D division which, in earlier years, had enabled the company to launch several products through reverse engineering. Ranbaxy attracted attention in the global market by developing a process for an advanced cephalosporin, and getting it patented in the USA though Eli Lilly had patented several stages in the process of the drug. The success of Ranbaxy's product based on quality and price had led Eli Lilly to make an agreement with Ranbaxy for joint R&D and a joint venture. Confident of its strength in traditional organic chemistry, Ranbaxy publicly made known its determination to commit funds for research in biotechnology that could lead to innovations. Ranbaxy is preparing to launch its own diagnostic kits for blood grouping, pregnancy tests, AIDS and stem cell based therapy.

Lupin, which has the third largest market share in India, also holds 60% of the global market for the anti-TB drug ethambutol and even the original discoverer Lederle is buying the bulk drug from Lupin. It has developed some products from technology transferred from Indian research institutes. Lupin's biotech division has launched an indigenous diagnostic kit for AIDS and is working on diagnostic kits for TB and hepatitis. Lupin will also be marketing similar kits made by the Italian firm, Sorin.

3.3.3 Objective: to create new chemical entities

Another product innovation for which the cost of commercialization is relatively low is new chemical entities. Among those that seek to create new chemical entities, there are not only big firms renowned for their technological capabilities like Dr. Reddy's Labs, but also a handful of lesser-known technological innovators. For instance, Bangalore Genei was formed by T. Babu who had been an associate professor at the Tata Institute of Fundamental research. It produces speciality chemicals for Indian and foreign laboratories at its sophisticated R&D center. Its first catalogue of products for sale in 1990 was five pages long, whilst their 1996-1997 catalogue of speciality chemicals is over 20 pages long, exhibiting a great increase in the variety of products produced. Another success story is that of a relatively little known enterprise named Malladi Drugs and Pharmaceuticals, which is stated to be one of only two major producers in the world of ephedrine, the other being Knolls AG of Germany. Established only in 1980 by a research minded entrepreneur, Malladi owes its success to its R&D capability that had been systematically developed since its founding. Currently with the help of the National Research Development Corporation, it is engaged in the developmental and clinical studies of a drug that could dissolve blood clots in about one tenth of the time taken by the two foreign drugs that are currently in use. If clinical trials are successful and if the multinationals do not come up earlier with a blockbuster, Malladi Drugs hopes to become the first Indian pharmaceutical company to have an important life saving innovation with a market of about $700 million.

3.3.4 Objective: to create therapeutics for developing countries

Kopran, the 15th ranking company in the Indian market, is the largest producer of the antibiotic amoxycillin trihydrate in Asia. It achieved this position through the development and improvement of its final product. Though its turnover in 1994 was $57 million, it has only recently invested about $2.8 million in a research facility. The main objective of its R&D unit is the creation of new molecules of therapeutic value for tropical and water borne diseases for which a large market exists in the third world.

3.3.5 Objective: to jump onto the biotech bandwagon anyhow

A number of established pharmaceutical companies also seek to integrate biotechnology through diversification into a non-healthcare biotechnology sector that is expected to yield quick returns. For instance Cadilla laboratories, among the top 20 pharmaceutical firms, has recently diversified into biotechnology. But the biotechnology application is in tissue culture, (with Dutch collaboration), and aquaculture. Its R&D center however intends to engage in basic research in biotechnology and immuno suppressants.

To summarize the results of this section we present Table 3.

Table 3 Configuration of Indian companies according to their competence trajectory

	Name of Company	*Trajectory*
1	Ranbaxy	CW
2	Glaxo India (subsidiary of British firm)	CM (M)
3	Lupin	CW
4	Cipla	CW
5	Hoechst India (subsidiary of German firm)	CM (M)
6	Dabur	CM
7	Pfeizer (USA)	CM (M)
8	SOL Pharma	CW
9	Ambalal Sarabhai	CW*
10	Torrent	CW
11	Dr. Reddys	CW
12	Allembic	CW*
13	Knoll (Germany)	CM (M)
14	HAL	CM (P)
15	Kopran	CM
16	Ipca	CM
17	SmithKline-Beecham (USA-UK)	CM (M)
18	Burroughs-Wellcome (UK)	CM (M)
19	Cadilla	CW
20	Parke-Davis (USA)	CM
21	Wockhart	CW
22	Anglo French Drugs Ltd	CW*
23	Anil Starch products	CW
24	Atul products	CW*
25	Avra laboratories	CD
26	Bangalore Genei	CD
27	Bharat Immunologicals & Biologicals Corp. Ltd	CM (P)
28	Bharat Serums & Vaccines Ltd.	CW*
29	Bengal Immunity	CM (P)
30	Biotech International Ltd.	CW*
31	Biotech R&D Laboratories	n.a.
32	Boehringer Mannheim India Ltd.	CM (M)
33	Chemtech Laboratories Ltd.	CW
34	Cynamid India	CM (M)
35	FDC	n.a.
36	Indian Herbs Research and Suppy co. Pvt.	CW
37	Indian Vaccines Corp. Ltd.	CM (P)
38	Indian Petro Chemicals Corp Ltd	CM (P, Mi)
39	Infar	CW*
40	J.K. Pharmaceuticals	CW*
41	Karnataka Antibiotics and Pharmaceuticals. Ltd.	CM (P)
42	Malladi Drugs and Pharmaceuticals Ltd.	CW
43	Merind Ltd.	CW*

Table 3 Configuration of Indian companies according to their competence trajectory (continued)

	Name of Company	*Trajectory*

44	National Research Development Corp.	CM (P)
45	Novo-Nordisk	CM (M)
46	Pfimex International Ltd.	n.a.
47	Rallis India. Ltd.	CM**(Mi)
48	Reckon Diagnostics Private Ltd.	CW
49	SS Clonatech Private Ltd.	CD
50	Shantha Biotech	CW
51	Span Diagnostics	CW
52	Transgene	CD
53	Wipro Biomed	CM**(Mi)
54	Venkateshwara Hatcheries	CM**(Mi)
55	Waters India Private Ltd.	CM**(Mi)

* signifies competence widening through reverse engineering.

** signifies competence maintaining while marketing foreign biotech products

CM=competence maintaining, CD=competence deepening, CW=competence widening, P=public sector firm, M=multinational, Mi=minor player i.e. principal activity of firm is not pharmaceuticals.

4 Prospects the integration of biotechnology in the Indian pharmaceutical sector

The previous section reveals that in spite of the existence of scientific competence, and the fact that most of the firms in our sample are continually improving their competence, integration of biotechnology is very marginal. Firms among the top twenty in terms of profit have diversified into biotechnology through marketing, and in a few cases, actual production of diagnostics. A handful of dedicated biotechnology firms have been created by researchers, sustaining themselves substantially through contracts. Thus, even though technological competence is essential both for medium term and long term survival in the Indian pharmaceutical industry, neither the market structure nor the market competition, have been significantly affected by the integration of biotechnology, which in itself has been quite feeble.

Three reasons are proposed for the above phenomenon of slow progress in the integration of biotechnology despite the availability of scientific talent at a cost lower than in advanced countries: Cultural heritage of Indian firms, inadequate financial resources, and impact of government strategy.

4.1 Cultural heritage of Indian firms

In terms of formulation of technology strategy, the Indian firms did not inherit any tradition of creation of incremental or radical innovations through public or private research. Certain cultural traits of Indian businessmen, many of whose firms are family run, manifest themselves in the form of a quest for quick and assured profits through copying the products of the West and a certain lack of confidence in their capability to create innovations of their own. Though the reasons for this are better studied by a social historian, it must be noted that the very many years of foreign rule probably retarded the creation of a culture of research or technological entrepreneurship because of the associated problems of appropriation of the fruits of innovations. Then after India

obtained independence in 1947, for about 30 years, the Indian Government was obsessed with ideological concerns like emphasizing the public sector and controlling profiteering by the private sector through rules and regulations. Under such an environment the efforts of top management came to be concentrated more on securing fiscal and tariff concessions, permits and licenses, and other such favours from the government rather than in seeking substantial support from the government for research activities for innovation. Thus while the pharmaceutical giants of Europe and the USA examined the possibilities of integrating biotechnology in the context of their established research centers and their tradition of investing in R&D to try to create technological innovations in the medium run, Indian firms started from the position of using R&D as a means of promoting their competitiveness in the very short run.

Indian firms are also distinct from their Western counterparts in developing their technological competence in-house. The phenomenon of strategic alliances between firms of various sizes and competencies for pre-competitive R&D or the commercialization of innovations, which so marks the biotechnology sectors in developed countries is thus far absent here. Indian firms are more likely to have strategic alliances with foreign firms than with other Indian firms but these links are for co-production of an existing product or distribution of a foreign product, never for pre-competitive research. Without requisite financial resources, alternatives to sharing risk and costs through financial markets, government programs or strategic alliances for R&D, integration of biotechnology in the Indian pharmaceutical industry cannot gather momentum.

4.2 Reality of financial constraints: 'no deep pockets'

Major drug companies, even in the advanced countries, were slower than newly formed biotechnology companies in moving into modern biotechnology. This was because they tended to equate the 'uncertainty' inherent in committing funds and personnel for creating an innovation with the 'risk' of effort turning out to be wholly or even largely infructuous. Business enterprises tend to weigh with great care the prospect of high-payback opportunities resulting within a reasonable period of time from any decision to commit substantial investment of funds and R&D resources in what is perceived to be a high risk area. Such considerations influence to a far greater extent even the most successful among the Indian companies. They are far more 'profit-driven' than their counterparts in the advanced countries and far less research-driven. They tend to rush out for the penny that can be picked up quickly rather than reach out for the dollar through long term efforts. Such a risk-averse attitude can in part be explained by the fact that very few Indian firms can command the financial resources necessary to invest in R&D. This is clearly reflected in Table 4, which gives the turnover and R&D outlays of the biggest US and European pharmaceutical firms (in terms of market share), US and European new biotechnology firms (NBFs) and the leading Indian firm Ranbaxy. Thus even as the Indian companies are seeking to overcome their ingrained reluctance to increase expenditure on R&D, they are constrained by the fact that their financial resources are quite small as compared to those of the global majors. The companies face a tough choice: How much of their financial and R&D resources should they continue to utilize for reverse engineering of patented products as also products that would go off patents before the year 2005? How much of their resources could be diverted to R&D in biotechnology techniques for the

discovery of new molecules? It is a scenario of the bird in the hand against two in the bush.

Table 4 Comparison of US, European and Indian pharmaceutical firms*

	Sales in $million	*R&D expenditure in $million*	*Number of employees*	*Sales per employee*	*R&D expenditure per unit of sales*
Merck (USA)	15947.4	1311.8	47500	.336	.34
Hoffman-LaRoche (France)	13673.8	2161.6	61381	.223	.169
Amgen (NBF-USA)	1652	345.8	3546	.466	.21
Elan (NBF-Ireland)	203	30.1	926	.219	.15
Ranbaxy (India)	264	6.94	4778	.055	.05

* Ernst & Young (1996), *European Biotech 96: Volatility and Value*, Ernst & Young's third annual report on the European biotechnology Industry, p.10 and answers to postal questionnaire by Ranbaxy.

4.3 Impact of government strategy

In a developing country like India the government has to consider the tradeoffs between allocating funds to meet immediate problems like feeding the population, developing basic infrastructure, establishing key industries and providing for defense needs, and, long term objectives of building technological competence. Attention to biotechnology is a recent development and this is reflected in the outlays for it by the Indian Government [19]. Total expenditure on biotechnology research in India increased from $13 million in 1988 to $28 million in 1994, with the government contributing about 85%. In contrast, the annual budget for biotech R&D in the US for 1994 exceeded $5 billion with the industry contributing over 80%.

The strategy of the Indian Government has been to restrict its attention to the two ends of the spectrum of the commercialization process leaving a lacuna in the middle. It has concentrated its efforts on the creation of scientific competence through subventions to the network of public laboratories and universities at one end, and regulation of the final market for pharmaceutical products at the other end. While press releases on plans and projects have been plentiful, a clear strategy for the transformation of scientific competence into industrial competence, and for ensuring accountability for performance on the part of publicly funded institutions has not been discernible [20]. Unlike in advanced countries the government has not recognized any responsibility for promoting collaborations between the public sector laboratories and the private sector firms. While this indispensable intermediate exercise was largely skipped, the government concerned itself with maintaining the public research establishment and intervening in the final market through fiscal measures such as price control and distribution schemes to benefit the common people.

It must be noted that price control of drugs is necessary in a country like India because unlike in Europe, there is no system of state funded health care. Virtually all consumers of drugs have to bear the cost of drugs by themselves. A small segment of the population comprising of government and public sector employees, workers in the organized sector, and employees of large companies, covered by schemes of health care, is the exception to this situation. Because of the social and political cost of drug prices

that the bulk of the population consider high, the government has to maintain a drug price regime. In 1987 the government introduced price control for 143 'notified' drugs constituting 72% of the output of the organized sector that were deemed essential. While the number of drugs under price control has been substantially reduced following the economic liberalization measures, 76 drugs are still subject to price control. These drugs cover 50% of the drugs produced by the organized sector. Pharmaceutical companies have long been complaining that such price controls lead to low gross profit margins of about 4-7% against the international margin of 11-14% and leave little for reinvestment into R&D [21].

Finally, the main thrust of government strategy is on agriculture rather than health care, because of the former's intrinsic importance to the economy and the existence of a good record of indigenous research accomplishment. The meager research output of pharmaceutical enterprises and the minor role of pharmaceuticals related research in the large government supported research establishment had their inevitable impact on the resources made available to the pharmaceutical industry.

5 Conclusions

The central objective of this paper was to explore if India had any chance of developing technological competence in biotechnology and creating a world class pharmaceutical industry in the foreseeable future. Such a scenario is not implausible considering that in certain other high tech areas, India though a 'latecomer' is seen to have made impressive progress. A review of Indian technology in the US journal *IEEE Spectrum* [22] noted that in several strategically important areas like nuclear science, telecommunications, satellite technology, parallel computers, and in certain industrial chemical processes and software operating systems, "India's achievements are unmatched anywhere else in the developing world." [22]

Thus in this paper we first of all briefly traced the evolution of the Indian pharmaceutical industry since 1948. We showed that Indian firms over the years had invested in gaining knowledge of the chemical technology of creating bulk drugs, and the top tier firms had greatly 'learnt by doing', improving upon the process technology and bringing down their prices without investing in 'formal R&D centres'. These firms were then confronted with biotechnology, a set of techniques that was new and more complex to integrate. Examining the variety of ways in which the Indian firms are strategically positioning themselves for the integration of biotechnology as dictated by their market objectives, we inferred that such integration in the R&D and production activities was marginal. Though a number of Indian pharmaceutical companies have been claiming to be active players in the global market on the basis of growing exports to several developing countries, they do appear to be rather daunted by the high costs and uncertain commercial returns of venturing into biotechnology. If however the environment in which they currently operate becomes more propitious some progress can be made, and then, as in some of the other high technology areas referred to, the process may gather a momentum of its own.

The availability of technically competent manpower is not a constraint; the most serious bottleneck is the financial constraint both for the Indian Government and for the Indian companies. No specific figures are available for the percentages of R&D

investment by the government or companies that go into biotechnology research relevant to the pharmaceutical industry, but the amounts are likely to be much lower than that spent by any one of the major MNCs in their home countries [23]. This situation makes it necessary for India to narrow down carefully a few areas on which its human and financial resources can be concentrated.

The second major problem is the virtual absence of networking among the actors of the biotechnology sector: the government, public research laboratories, firms and financial institutions. Without requisite financial resources and alternatives to sharing risk and costs through financial markets, self-organized or government engineered strategic alliances between firms and between firms and universities are necessary for the integration of biotechnology. Such a problem can be expedited if the government plays a constructive role by identifying a few essential and promising areas for the integration of biotechnology by the pharmaceutical industry, and providing appropriate subventions for research consortiums set up by designated companies of proven competence. As of now no goal of creating a world class pharmaceutical industry appears to have been set by Indian policy makers. The Japanese experience in fostering consortia of carefully selected companies for pre-competitive research collaboration, and the French experience in implementing various national programs for the creation of industrial competence in the biotechnology sectors, may offer lessons of considerable value to the Indian parties. There may be an element of complacency on the part of the Indian Government and the affluent segments of the population because of their belief that anyhow the MNCs will sell the radical innovations developed in their countries, in India, at a price that the Indian consumer can afford. But in the long run, such an attitude will encourage the under utilization of scientific and technical talent, especially since the MNCs are unlikely to commit themselves to the promotion of India-based biotechnology research.

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