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Transfer of Technology for Successful Integration into the Global Economy

A Case Study of the Pharmaceutical Industry in India

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United Nations

New York and Geneva 2002

Note

This paper is part of the series of case studies on Transfer of Technology for Successful Integration into the Global Economy carried out by the Investment Policy and Capacity Building Branch, DITE, under the UNCTAD/UNDP Global Programme on Globalization, Liberalization and Sustainable Human Development: Best Practices in Transfer of Technology. The work has been carried out under the direction of Assad Omer, assisted by Maria Susana Arano. Overall guidance was provided by Khalil Hamdani.

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Preface

The main objective of the studies carried out under the UNCTAD/UNDP Global Programme on Globalization, Liberalization and Sustainable Human Development: Best Practices in Transfer of Technology is to identify factors that could enable firms in developing countries to upgrade technologies or develop new technologies with a view to enhancing their productivity. The case studies focus on successful cases of technology transfer and integration into the world economy. They are thus expected to provide lessons, in terms of *best practices*, to other developing countries in the context of *technological capacity building.*

The project consists of three case studies[1] of sectors where the selected developing countries have demonstrated their ability to create new productive capacities and successfully participate in the world market. Each of the sectors represents an example of created comparative advantage; that is, where a country's factor endowments were modified through investment in physical capital, human resources and the building up of capacities to develop and use new technologies. Central to an understanding of the catch-up process and the building of technological capacity across countries is the identification of firm-level factors as well as government policies and institutions that enable firms to thrive, grow and compete in the world market. Therefore the case studies aim to identify conditions under which sectoral development, integration into the global economy, and sustainable human developments are all linked together.

[1] The three case studies are: *A Case Study of the Pharmaceutical Industry in India*; *A Case Study of the South African Automotive Industry*; and *A Case Study of Embraer in Brazil*. These three studies will also be part of a forthcoming publication under the UNCTAD/UNDP GLOBAL PROGRAMME ON GLOBALIZATION, LIBERALIZATION AND SUSTAINABLE HUMAN DEVELOPMENT, which will include an overview on the studies and on the international dimension of the national policies adopted in these cases.

INTRODUCTION

The decade of the 1990s has been significant for India in terms of the changes in policy orientation directed at its economy. From the relatively inward looking policies in place till the end of the 1980s, the policy regime adopted in 1991 sought to break down the walls of protection behind which Indian industry had developed in the past. The biggest challenge for Indian industry posed by the new regime arose from the need to adopt measures that would improve its competitive strength.

This study focuses on the performance of the pharmaceutical industry, a sector that has been able to meet the challenges posed by the new policy regime with a degree of success. The success that this industry experienced in the 1990s was, however, built on a foundation that was laid in the 1970s. During this phase, the Government provided a policy environment to the industry, which was defined through a mix of instruments. The prime objective of the policy framework was to develop a viable domestic industry with adequate participation of Indian entrepreneurs. A key instrument for the realization of this objective was the policy aimed at building up the technological sinews of the industry.

The impact of the policies adopted through the three decades covering the 1970s to the 1990s is analysed in this paper in three chapters. While the first two chapters present a broad overview of the performance of the industry, the third chapter provides a case study of the leading Indian enterprise in this industry, namely Ranbaxy Laboratories. The case of Ranbaxy Laboratories shows how the Indian pharmaceutical industry performed through the changing policy regime.

CHAPTER I

HISTORICAL OVERVIEW OF THE INDIAN PHARMACEUTICAL INDUSTRY

The pharmaceutical industry in India has evolved through three phases over the past 50 years. The first was the period prior to 1970, when the industry was relatively small in terms of production capacities. The second phase spanned the late 1970s to the early 1990s, a period during which the industry experienced policy-induced growth. In its third phase, during the 1990s, much of the regulatory structure that the Government had imposed during the previous two decades was dismantled.

Even as late as the mid-1970s, India had a relatively small pharmaceutical industry, with a total production of just over US$ 600 million. During the subsequent four years, the total output of the industry more than doubled, the major contribution being made by formulations, which accounted for 85 per cent of total production. Table 1.1 shows the production figures for the two broad segments of the industry: bulk drugs and formulations.

Table 1.1

Indian pharmaceutical industry in the 1970s: Production (US$ million)			
Years	Bulk drugs	Formulations	Total
1974/75	111.1	493.7	604.8
1975/76	155.2	668.6	823.8
1976/77	167.4	781.3	948.7
1977/78	187.7	1 029.9	1 217.6

Source: Based on GOI, Ministry of Chemicals and Fertilizers, *Annual Report* (various years).

An overwhelmingly large share of installed capacity in the Indian industry was in the small-scale sector, with approximately 2,400 of a total of 2,524 units belonging to this sector in the mid-1970s. Of the remaining units, 43 were affiliates of foreign firms in which the parent firms' share in equity holdings exceeded 40 per cent. These foreign affiliates were deemed to be “foreign-controlled” firms in accordance with the guidelines that were laid down by the Foreign Exchange Regulation Act of 1973 (commonly known as FERA). According to FERA, any firm registered in India was to be treated as “Indian” as long as its foreign equity holding did not exceed 40 per cent.

The 43 foreign firms in the Indian pharmaceutical industry had a disproportionately high share in total production in the mid-1970s. They produced 42 per cent of bulk drugs and

formulations put together and about 38 per cent of the bulk drugs produced by the Indian industry.[2]

1. The policy regime since the 1970s

The decade of the 1970s marked a turning point in the development of the Indian pharmaceutical industry as a result of three critical policy initiatives taken by the Government: the Drugs Price Control Order (DPCO), which was adopted in 1970; adoption of the new Patents Act, which became effective in 1972; and adoption of a new drug policy in 1978. The framework for the new drug policy was provided in the Report of the Committee on Drugs and Pharmaceutical Industry (commonly known as the Hathi Committee). Complementing these policy initiatives was yet another piece of legislation, the Foreign Exchange Regulation Act (FERA) of 1973, which aimed at reducing the share of foreign equity in enterprises registered in India. The above-mentioned policy initiatives were taken with two broad objectives in view: (i) to develop a strategy for the expansion of the domestic pharmaceutical industry by relying essentially on Indian enterprises, and (ii) to establish a structure for keeping the prices of drugs within affordable limits.

The first step towards evolving a comprehensive policy regime for the Indian pharmaceutical industry was taken by the setting up of the Hathi Committee in 1974. The Committee had an exhaustive mandate that aimed at the realization of the two broad objectives mentioned above. The Hathi Committee presented its recommendations in 1975.

2. The new drug policy of 1978

The new drug policy announced by the Government in 1978 had the following five broad objectives: (i) to develop a strong Indian sector with the public sector playing a leading role; (ii) to channel the activities of the foreign firms in accordance with the national priorities and objectives; (iii) to deepen the production base of the domestic industry by ensuring that the production of drugs took place from as basic a stage as possible; (iv) to encourage research and development and improve the technological sinews of the industry; and (v) to provide drugs to consumers at reasonable prices.

A. Expansion of capacities and the role of foreign firms

The 1978 Drug Policy guided the expansion of the Indian industry through two means: (i) by providing incentives to Indian drug manufacturers by relaxing the provisions of the licensing

[2] GOI, Drug Policy, 1978.

policy, and (ii) by imposing conditions on foreign-controlled firms to ensure that they created linkages within the economy.

Indian enterprises were given two major incentives. First, these enterprises were allowed to produce formulations up to 10 times the value of bulk drugs. The Indian drug manufacturers were thus allowed to produce a relatively higher proportion of non-basic drugs in a regime that laid emphasis on the production of bulk drugs. Further, to encourage consumption of indigenously produced bulk drugs, only such formulation capacity was sanctioned in which the formulation turnover was based on a ratio of 2:1 between indigenous bulk drugs and imported bulk drugs.

Foreign firms[3] on the other hand faced relatively tighter controls in respect of their expansion in production of formulations. Three conditions were imposed on the foreign drug firms intending to expand their operations in India. These were: (i) the ratio between production of bulk drugs and formulations allowed in their output mix was 1:5, as against 1:10 allowed to the Indian firms; (ii) licences to foreign firms were provided only if the firms agreed to supply 50 per cent of their production of bulk drugs to non-associated formulators; and (iii) foreign firms producing formulations based on imported bulk drugs and intermediates had to start manufacturing from the basic stage within two years. The policies in respect of the foreign firms were thus aimed at utilizing the strengths of these firms for creating linkages within the industry for fostering an increase in downstream capacities.

The Drug Policy of 1978 was adopted during the phase when the Government was implementing the Foreign Exchange Regulation Act (FERA) of 1973, which aimed at reducing foreign holding in enterprises that were not of strategic importance for the country. According to FERA, foreign holdings up to 40 per cent were allowed in any enterprise registered in India. The shadow of FERA fell on the pharmaceutical industry as well. The Drug Policy of 1978 provided that firms which did not use high technology while producing bulk drugs or formulations had to reduce their foreign holding to 40 per cent, if the share of foreign holding was higher.

B. Emphasis on technology and R&D

As regards technology, the new drug policy had two stated objectives: (i) to develop local R&D facilities, and (ii) to import technology wherever necessary.

The local R&D facilities were to be developed in two ways: first, by using the facilities available with the public-funded organizations, which included the public sector production units and national laboratories; and second, through obligations imposed on foreign firms. In the case of foreign firms that had a drugs turnover of more than US $ 6.2 million (Rs 50 million) a year, the Drug Policy imposed two obligations. These were: (i) to have R&D facilities in India in which the capital investment would be at least 20 per cent of their net block, and (ii) to spend at least 4 per cent of their sales turnover as recurring expenditure on R&D facilities.

[3] The Drug Policy of 1978 did not provide a clear definition of foreign firms. This category of firms presumably comprised those that had a majority foreign holding.

The public sector units were expected to develop a strong design and engineering component to bolster their R&D facilities, so that processes that they may have developed could be indigenously tested and scaled up with the necessary complement of indigenous design and engineering skills. The public sector units were also directed to set aside at least 5 per cent of their net turnovers for R&D activities.

Alongside development of indigenous capabilities, the new Drug Policy emphasized the role that technology imports could play in the technological upgrading of the pharmaceutical industry in India. With respect to agreements for technology transfer entered into by public sector units, the policy stated that efforts should be made to ensure that the import of technology would provide for horizontal transfer of technology. This emphasis on technological upgrading was crucial for an industry in which less than 40 of the firms engaged in production activities during the mid-1970s[4] had R&D units that were recognized by the Government.[5]

C. Price control regime

The pharmaceutical industry in India had been subjected to rigorous price controls since 1970 through the adoption of the Drugs Price Control Order or DPCO (henceforth DPCO ’70). DPCO '70 was aimed at fulfilling two objectives. The first and more obvious objective was to ensure that drugs were available at reasonable prices in India. The second was to create an incentive structure for the domestic producers so as to encourage them to produce new formulations and to use, as active ingredients, new drugs that were products of original research in India. Besides covering the above-mentioned formulations, DPCP ’70 also gave the Government the power to fix the minimum price of essential bulk drugs. The latter objective was in fact built into the larger policy framework evolved through the Drug Policy of 1978 as indicated earlier.

A modified DPCO was adopted in 1979 (henceforth DPCO ’79), which had three significant changes from DPCO ’70. These were: (i) the number of bulk drugs under price control was reduced from 347 to 163; (ii) non-essential formulations were excluded from price control; and (iii) all small-scale units with an annual turnover of less than US $ 1.22 million (Rs. 10 million) were exempted from the purview of price control. One of the major effects of DPCO ’79 can be seen from the manner in which the small-scale sector expanded in the Indian pharmaceutical industry.[6]

The policy regime for the pharmaceutical industry in India was revised during 1986/87. Although the broad parameters of policy, defined by the Drug Policy of 1986, remained largely unchanged, a new DPCO was introduced in 1987, which reduced the number of drugs under price control: the number of bulk drugs under price control was reduced to 145. Accordingly the new price control regime remained valid both for drugs that were used in the National Health

[4] In the mid-1970s, more than 2,500 firms were engaged in the production of pharmaceuticals.

[5] This information was obtained from R&D statistics produced by the Department of Science and Technology, Government of India.

[6] A recent estimate shows that there are more than 8,000 small-scale units in operation, see GOI, *Annual Report 1999-2000*: 2.

Programmes monitored by the Ministry of Health, and for other essential drugs that were identified by a group of experts.

3. Modifications to the drug policy

The changed orientation of the Indian economy since 1991, with emphasis by the policy makers on market forces, had implications for the drug policy. Modifications to the drug policy were adopted in 1994, followed by the adoption of the revised DPCO in 1995, which aimed at freeing the industry from the limitations imposed by government regulations. The following were the key elements of the new drug policy:

(i) The licensing requirement was abolished for all bulk drugs, with three exceptions: (a) identified bulk drugs which were the exclusive preserve of the public sector units, (b) bulk drugs produced by using recombinant DNA technology, and (c) bulk drugs requiring *in-vivo* use of nucleic acids;
(ii) Conditions stipulating mandatory supply of a percentage of bulk drug production to non-associated formulators were abolished;
(iii) Limitations on the use of imported bulk drugs were removed;[7]
(iv) Foreign holdings of up to 51 per cent of the total equity were allowed, as against the ceiling of 40 per cent earlier;
(v) New drugs, developed through indigenous R&D efforts were excluded from price control for 10 years from the commencement of commercial production; and
(vi) The scope of price control was limited to two categories of drugs: (i) those for which there were at least 5 bulk drug producers and 10 formulation producers, with none having a market share exceeding 40 per cent, and (ii) genetically engineered drugs produced by recombinant DNA technology.

The policy regime adopted for the pharmaceutical industry in India thus changed from one in which the industry was subjected to government controls in the 1970s to one that was almost completely guided by market forces two decades later. This changed scenario can be best understood by looking at the sharply declining number of bulk drugs under price control since 1970, the year in which the first DPCO was introduced in the country (see table 1.2).

[7] This in effect removed "local content regulation" in respect of the pharmaceutical industry.

Table 1.2

Bulk drugs under price control (1970 to 1995)	
Year of introduction of the Drug Price Control Order	Number of drugs under price control
1970	347
1979	163
1987	145
1995	74

Source: Indian Credit Rating Agency (ICRA), 1999.

While the declining role played by the DPCO has been an important factor in the growth of the pharmaceutical industry, particularly in recent years, as the evidence provided below indicates the Patents Act of 1970 provided the initial impetus for the industry to take firm roots in India. This Act contained several provisions that were directly responsible for the development of the pharmaceutical industry in India.

4. The Indian patent system

In 1970, India adopted a new Patents Act (henceforth Patents Act, 1970), which became effective from 1972. The Patents Act, 1970 replaced the Patents and Designs Act of 1911. Its adoption marked more than two decades of intense debate amongst policy makers for evolving a patent regime that best suited India's development needs. The key issues figuring in this debate were high prices for drugs and the abuse of patent monopoly by foreign patent holders, especially in the case of pharmaceuticals. It was therefore not totally unexpected when the most important changes in the patent system ushered in by the Patents Act of 1970 were in respect of drug inventions.

There were three provisions in Act that affected the pharmaceutical industry. These were: (i) patents could be taken only for processes and not for products; (ii) the patent term was five years from its being granted or seven years from application, whichever was shorter;[8] and (iii) automatic licences of right could be issued three years after the granting of the patent. It could be argued that these three provisions had the combined effect of almost denying any patent rights to inventors seeking patent protection in India for their inventions involving pharmaceuticals. First, the process patent regime adopted by India encouraged reverse engineering and development of alternative processes for the products patented in other countries. Secondly, the reduction of the duration of the patent term, coupled with the fact that the Patents Office took on average four

[8] For all other inventions, the patent term was 14 years from the date of application.

years to grant a patent, meant that the patentee did not enjoy patent monopoly for more than a year. And, finally, the provision relating to automatic license of right meant that anyone interested in exploiting the patented process involving a drug could do so, of course after obtaining the concurrence of the patentee.

It was therefore quite clear that the Patents Act of 1970 was intended to restrict the rights of the patent holders especially in the area of pharmaceuticals. With a "weak" patent regime, the foreign inventors had very little incentive to take out patents in India. Consequently, there was a decline in the number of foreign drug patents in India after the Act became effective. This might have had a negative impact on technology transfer, but at the same time it also left the Indian firms free to produce alternative processes for the drugs that were not patented in India.

The process patent regime was adopted in keeping with the argument that such a regime would encourage innovations in India, which had limited technological capabilities and financial resources for carrying out R&D activities. Support for this view was provided by evidence from several developed countries, which had also adopted process patent regimes when their pharmaceutical industries were at the nascent stage.[9]

One of the most obvious indicators of success achieved by the Indian pharmaceutical industry in the period since the adoption of the Patents Act of 1970 has been the shortening of the time lag between the introduction of a drug in the global market by the inventor and the marketing of the same drug in the Indian market, as indicated in table 1.3**.**

The table shows that the Indian firms have been able to progressively shorten the time lag between the introduction of a drug by the inventor and its introduction in the Indian market. However, estimates of the share of patented drugs in the overall sales of the pharmaceutical industry vary widely. The Indian Drug Manufacturers' Association (IDMA) estimated the value of drugs marketed in India with valid United States patents for the period June 1990 to July 1991 at 21.47 per cent of the total pharmaceutical market (IDMA, 1992). Redwood (1994) estimated this, on the basis of 500 top selling brands whose patents were still effective in Europe, at 11 per cent for the year 1993.

The overall impact of this mix of policies was favourable for the industry. This is evident in the relative performance of the pharmaceutical industry in the industrial sector as a whole, and also by the performance of the pharmaceutical industry in the 1990s, when it had to face external competition in the liberalized policy regime adopted by the Government.

[9] Countries such as Japan and Italy moved from process to product patent regimes only in the 1970s.

Table 1.3

Time lag between introduction of a new drug in the world market and its introduction in India			
Drug	Introduced in (year)		Time lag before introduction in India (years)
	World market by the inventor	Indian market by domestic companies	
Ibuprofen	1967	1973	6
Salbutamol (anti-asthmatic)	1973	1977	4
Mebendazole (anti-helminthic)	1974	1978	4
Rifampicin (anti-TB)	1974	1980	6
Cimetidine	1976	1981	5
Naproxen (anit-rheumatic)	1978	1982	4
Bromhexin (anti-hypertensive)	1976	1982	6
Captopril (anti-hypertensive)	1981	1985	4
Ranitidine (anti-ulcer)	1981	1985	4
Norfloxacin (anti-bacterial)	1984	1988	4
Ciprofloxacin (anti-bacterial)	1985	1989	4
Acyclovix	1985	1988	3
Ciprofloxacin	1985	1989	4
Astemizole	1986	1988	2
Larazepam	1977	1978	1

Source: Keayla (1997).

CHAPTER II

IMPACT OF THE POLICY REGIME ON THE DEVELOPMENT OF THE PHARMACEUTICAL INDUSTRY

1. Effects of active policy intervention

The changes that took place in the Indian pharmaceutical industry in the phase following the adoption of active policy intervention by the Government were, in many ways, quite significant.

Two sets of figures are provided in tables 2.1 and 2.2. The first gives details of the production of bulk drugs and formulations by the pharmaceutical industry in India. The second pertains to the performance of the pharmaceutical industry as compared to the other major sectors of Indian industry considering their respective profitability ratios.

Table 2.1

Production performance of the Indian pharmaceutical industry during the 1980s (US$ million)

Years	Bulk drugs	Formulations	Total
1980/81	305.2	1 526.1	1 831.3
1981/82	333.8	1 656.1	1 989.9
1982/83	364.9	1 755.7	2 120.6
1983/84	351.5	1 742.7	2 094.2
1984/85	331.8	1 607.9	1 939.7
1985/86	336.3	1 572.5	1 908.8
1986/87	363.2	1 696.9	2 060.1
1987/88	370.3	1 813.0	2 183.3
1988/89	395.2	2 263.4	2 658.6
1989/90	394.4	2 107.7	2 502.1

Source: Organization of Pharmaceutical Producers of India (OPPI).

Table 2.1 shows that the pharmaceutical industry grew by a third in dollar terms during the 1980s. The impetus for growth during this period came from the formulations, the production of which went up by almost 40 per cent. Bulk drugs production, on the other hand, increased by

less than 30 per cent. The more important aspect of the increase in output of the industry was that it was more pronounced in the second half of the decade. While bulk drugs production increased twice as fast in the second half of the decade as compared to the first, production of formulations grew more than sixfold in the second half as compared to the first. Clearly, it was in the latter half of the 1980s that the pharmaceutical industry started consolidating. Another noteworthy point is that this take-off in bulk drugs production in the country was in keeping with the expectations of the Drug Policy of 1978.

Table 2.2 and figure 1 below show the relative profitability of the firms in the pharmaceutical industry. Two sets of data have been used to compare the relative profitability ratios. The first set of data is from the annual survey conducted by the Reserve Bank of India (RBI) using data from public limited companies. Table 2.2, and, more clearly, Figure 1, show that the firms belonging to the pharmaceutical industry in the sample used by the RBI have been registering profitability ratios consistently higher than the non-pharmaceutical firms in almost the entire period from 1970/71 to 1999/00. What is important is that while the non-pharmaceutical firms taken as a whole have experienced a declining trend in their profitability ratios (profits after tax to net worth) during the 1990s, the profitability ratios in the pharmaceutical industry have seen a rising trend.

Another set of data presented in table 2.3 along with the associated figure 2 compares the profitability ratios of the firms in the pharmaceutical industry with those in other major industrial sectors of the Indian economy during the 1990s. Unlike in the earlier exercise where the data for the non-pharmaceutical firms were presented in an aggregate manner, this exercise provides the data for the firms belonging to each of the larger segments of the Indian industry. Data for this exercise have been taken from a database comprising major firms in the Indian corporate sector.

The data compares the profitability ratios (defined as profits after tax as a percentage of the net worth) of the firms in the pharmaceutical industry with five of the largest sectors in Indian industry during the 1990s. Three of the sectors included in the data set faced declining rates of growth in the latter half of the decade, which turned negative in the closing years of the 1990s. The firms belonging to the pharmaceutical industry too faced a declining profitability ratio from the middle of the decade, but witnessed a turnaround in their profitability ratios in the last year of the decade.

Table 2.2

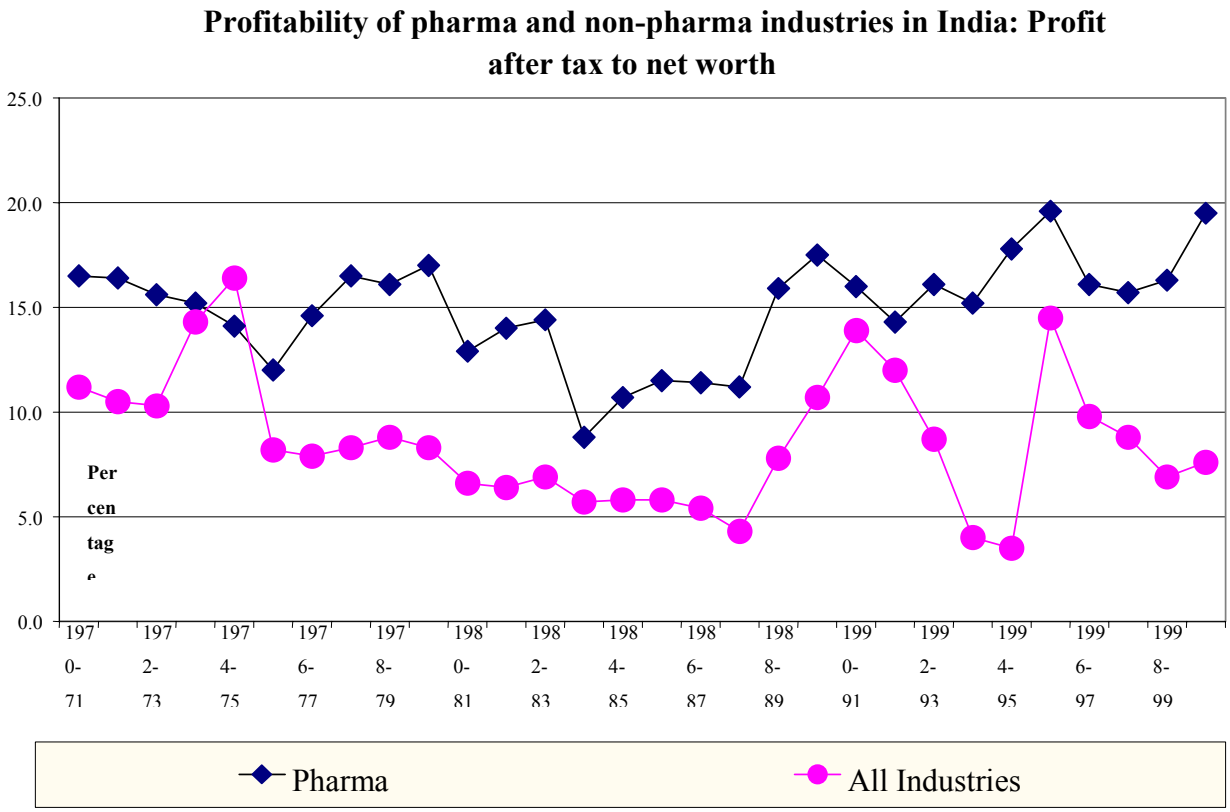
Profitability ratios of the drugs and pharmaceutical industries (percentage)[10]				
Years	Gross profits to sales		Profits after tax to net worth	
	Pharmaceutical	All industries	Pharmaceutical	All industries
1970/71	17.8	10.3	16.5	11.2
1971/72	16.2	10.0	16.4	10.5
1972/73	15.5	9.5	15.6	10.3
1973/74	14.9	12.0	15.2	14.3
1974/75	13.6	12.7	14.1	16.4
1975/76	13.0	9.2	12.0	8.2
1976/77	14.2	9.0	14.6	7.9
1977/78	14.2	9.0	16.5	8.3
1978/79	14.5	9.5	16.1	8.8
1979/80	13.5	10.1	17.0	8.3
1980/81	10.8	9.8	12.9	6.6
1981/82	10.4	9.3	14.0	6.4
1982/83	11.0	8.7	14.4	6.9
1983/84	9.7	7.9	8.8	5.7
1984/85	9.9	8.8	10.7	5.8
1985/86	9.0	8.8	11.5	5.8
1986/87	8.6	8.3	11.4	5.4
1987/88	8.3	8.6	11.2	4.3
1988/89	9.1	8.9	15.9	7.8
1989/90	9.6	10.2	17.5	10.7
1990/91	10.4	11.6	16.0	13.9
1991/92	9.9	11.9	14.3	12.0
1992/93	10.3	11.0	16.1	8.7
1993/94	11.3	11.9	15.2	4.0
1994/95	13.3	13.0	17.8	3.5
1995/96	11.5	14.3	19.6	14.5
1996/97	13.8	12.9	16.1	9.8
1997/98	13.9	13.0	15.7	8.8
1998/99	14.5	11.7	16.3	6.9
1999/00	16.2	11.8	19.5	7.6

Source: RBI, *Finances of Public Limited Companies*, various issues.

Note: (1) The number of companies varied from year to year. For instance, the number stood at 46 in 1970/71 while in 1997/98 the number of selected companies was 69.
2) The above ratio pertains to the financial performance of non-government, non-financial public limited companies based on the audited annual accounts of selected companies.
3) The selected companies for this study, for instance in 1997/98, accounted for 30.3 per cent in terms of paid-up capital.
4) It needs to be noted that while for most years the companies selected were mainly medium and large public limited companies, for some years a few small companies were also included.
5) Companies whose paid-up capital is about US $ 12,000 using the 1999/2000 exchange rate, or Rs.0.5 million or above, were included under medium and large public limited companies.

[10] Although the number of companies included in the survey has varied, there is no sampling bias in favour of any industry, and the data are therefore quite reliable for the purpose of this exercise.

Figure 1



Source: RBI, *Finances of Public Limited Companies,* various issues.

Table 2.3

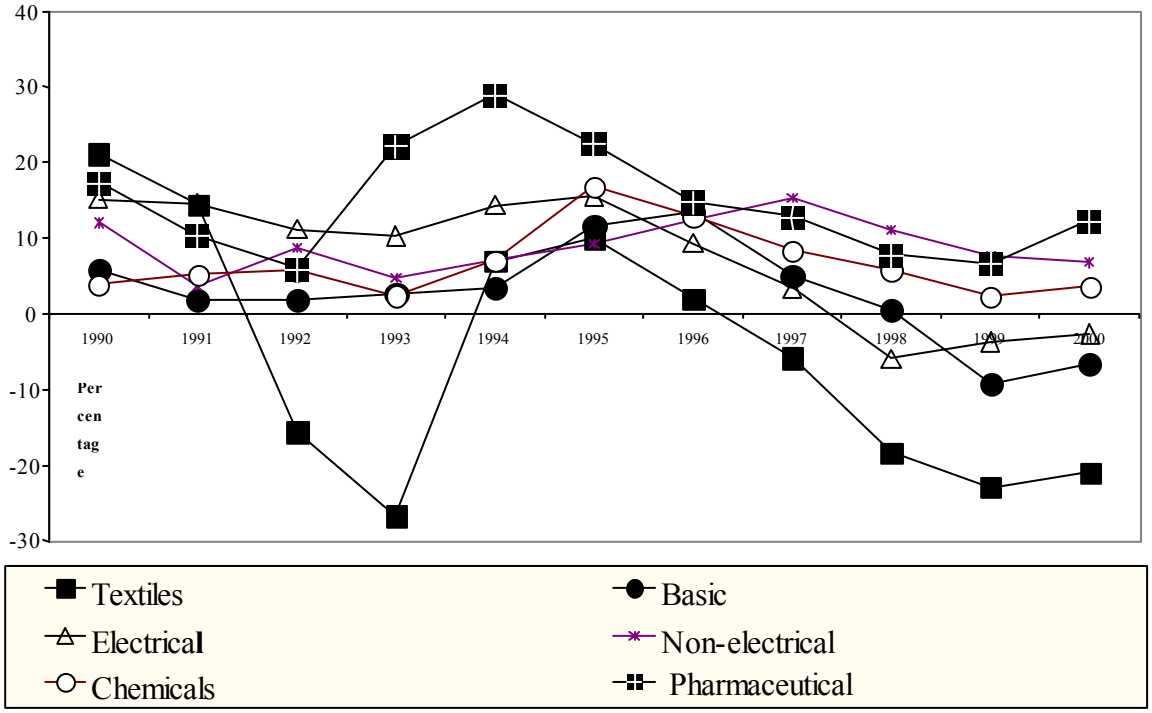
Profitability of industries in India (1989-2000)[11]														
Sectors	1989	1990	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	1990/ 1995	1996/ 2000
Profit after tax /net worth														
Textiles	-105.2	21.12	14.45	-15.6	-26.7	6.97	10.01	2.01	-5.8	-18.4	-22.9	-21	1.7	-13.2
Basic metals	225.31	5.79	1.86	1.73	2.62	3.47	11.64	13.46	5.03	0.6	-9.37	-6.6	4.5	0.6
Electrical equipment	60.3	15.12	14.51	11.15	10.33	14.37	15.6	9.32	3.37	-5.9	-3.67	-2.7	13.5	0.1
Non-electrical equipment	117.07	12.04	3.72	8.75	4.69	7.03	9.24	12.36	15.32	11.06	7.72	6.82	7.6	10.7
Chemicals	9.49	3.87	5.2	5.91	2.48	7.2	16.9	12.99	8.37	5.92	2.39	3.6	6.9	6.7
Pharmaceutical	30.68	17.35	10.39	6.01	22.22	28.96	22.55	14.81	12.89	7.85	6.66	12.3	17.9	10.9

Source: Centre for Monitoring Indian Economy (CMIE), Prowess Database (2000).

[11] As in the earlier data set, firms have been included in the data set with no explicit bias and hence the sample is quite reliable for the purpose of this study.

Figure 2

Comparative profitability of Indian industries



Source: Centre for Monitoring Indian Economy (CMIE), Prowess Database (2000).

2. Performance of the pharmaceutical industry during the 1990s

The 1990s witnessed the strongest performance of the Indian pharmaceutical industry on several fronts. Not only did the industry exceed its output expansion of the previous decades, but it actually became a net foreign exchange earner. This performance followed the change in the policy orientation of the Indian economy that took place in 1991. This industry thus took advantage of the unshackling of the industrial sector during the 1990s from the controls imposed by the Government. The rapid opening up of what had been largely an insulated economy to international trade and investment brought about a swift response from the leading firms in the pharmaceutical industry. The following discussion, as well as the case study of the largest Indian pharmaceutical firm, Ranbaxy Laboratories, highlights the key facets of the response of the industry to the changed economic environment.

A. Production

That the decade of the 1990s was the phase in which the Indian pharmaceutical industry took off is clearly evident from the production trends. Between 1990/91 and 1999/00, the industry grew twice as fast as it had during the preceding decade. Table 2.4 presents the annual production of bulk drugs and formulations.

Table 2.4

Production performance of the Indian pharmaceutical industry in the 1990s (US$ million)

Year	Bulk drugs	Formulations	Total	Share of the pharmaceutical industry in the manufacturing sector
1990/91	417.0	2 193.8	2 610.8	2.4
1991/92	395.7	2 110.6	2 506.4	2.8
1992/93	443.7	2 315.0	2 758.7	2.9
1993/94	432.9	2 262.8	2 695.7	3.2
1994/95	483.8	2 529.2	3 013.0	3.1
1995/96	561.9	2 814.0	3 375.9	2.8
1996/97	616.9	2 961.6	3 578.6	3.2
1997/98	722.3	3 323.3	4 045.7	3.0
1998/99	763.0	3 363.6	4 126.6	na
1999/00	877.3	3 706.9	4 584.1	na

Note: Totals may not add up because of rounding off of numbers
Sources: 1. Department of Chemicals and Petrochemicals, *Annual Report* (various years). 2. Organization of Pharmaceutical Producers of India (OPPI) and UNIDO, *International Yearbook of Industrial Statistics.*

The production of bulk drugs rose from US$ 417 million in 1990/91 to more than US$ 877 million in 1999/00, showing a compound growth rate of 8.6 per cent. The production of formulations, on the other hand, increased from nearly US$ 2,194 million to US$ 3,707 million during the same period, showing a growth rate of 6 per cent. The share of bulk drugs in total drug production increased from 16 per cent in 1990/91 to 19 per cent in 1999/00. If we divide the decade into two five-year periods, we find that in the first period the growth rate of bulk drugs production was less than 4 per cent, and this increased substantially to nearly 12 per cent in the second period. In the case of formulations production, while the growth rate for the first five-year period was 3.6 per cent, it was twice as much in the second five-year period.

The market structure of the Indian pharmaceutical industry can be characterized as "long tailed" (i.e. there are a small number of large firms and a large number of small firms).[12],[13] The Indian pharmaceutical industry consists of a large private sector, which can be further divided into the large Indian private sector, foreign-controlled companies (FCCs)[14] in India, and small private sector firms. There are also five public sector units in this industry. The public sector concentrates on the production of bulk drugs and has almost no presence in formulations. The Indian private sector is active both in the production of bulk drugs and formulations. The FCCs import most of their bulk drug requirements and formulations into the country, their focus being the domestic market. The small firms concentrate mainly on lower-end therapeutic drugs and formulations and depend on imports for meeting their bulk drug requirements, but there is a part of this category that produces bulk drugs.[15]

B. Exports

The Indian pharmaceutical industry turned into a net earner of foreign exchange on its trade account in 1988/89, and this surplus kept increasing throughout the 1990s. The export performance of the pharmaceutical industry is all the more remarkable given that it has been the only one amongst the major industrial sectors to have consistently generated trade surpluses in recent years, with total exports increasing from US$ 448.4 million in 1990/91 to US$ 1,540.1 million in 1999/00 (see table 2.5).

Total exports of pharmaceuticals showed a compound growth rate of nearly 15 per cent during the 1990s. This was built around an 18 per cent growth in the export of formulations and a 14 per cent growth of bulk drugs. A notable feature of the export performance of the two broad segments of the industry was that while exports of formulations performed relatively better in the first half of the decade, export of bulk drugs expanded rapidly during the second half, the period when growth in world trade had declined quite significantly.

The impressive growth in exports witnessed during the 1990s meant that an increasingly larger share of total production was being exported, particularly during the second half of the decade (see table 2.6). This is a particularly significant development in a country where the major industrial sectors have been largely inward looking.

[12] "There are about 250 large units and about 8,000 small scale units in operation…" in the pharmaceutical industry, Government of India (GOI), *Annual Report 1999-2000*: 2. The Reserve Bank of India defines a small firm as a firm with a paid-up capital of less than Rs. 500,000 (approximately US$ 150,000) and firms with more than this amount of paid-up capital are categorized as medium and large (RBI, 1995).

[13] In 1994, industrial licensing in this sector was abolished (GOI, *Annual Report, 1994-95*).

[14] FCCs were identified as firms having more than 25 per cent foreign equity holding.

[15] About 30 per cent of the total bulk drug production is accounted for by the small-scale sector. (GOI, *Annual Report, 1998-99*: 624).

Table 2.5

Indian pharmaceutical industry: Exports (US$ million)			
Years	Bulk drugs	Formulations	Total
1990/91	236.2	212.2	448.4
1991/92	317.7	245.6	563.3
1992/93	158.0	372.5	530.5
1993/94	174.1	429.9	603.9
1994/95	242.3	479.9	722.1
1995/96	349.4	630.6	980.0
1996/97	446.2	708.2	1 154.4
1997/98	598.4	875.7	1 474.1
1998/99	669.9	774.4	1 444.3
1999/00	na	na	1 540.1

Source: Department of Chemicals and Petrochemicals, *Annual Report;* and Organization of Pharmaceutical Producers of India (OPPI).

Table 2.6

Shares of exports in the total production of the pharmaceutical industry (1990/91 to 1999/00)			
Years	Total exports (US$ million)	Total production (US$ million)	Shares (percentage)
1990/91	448.4	2 610.8	17.2
1991/92	563.3	2 506.4	22.5
1992/93	530.5	2 758.7	19.2
1993/94	603.9	2 695.7	22.4
1994/95	722.1	3 013.0	24.0
1995/96	980.0	3 375.9	29.0
1996/97	1 154.4	3 578.6	32.3
1997/98	1 474.1	4 045.7	36.4
1998/99	1 444.3	4 126.6	35.0
1999/00	1 540.1	4 584.1	33.6

Note: Totals may not add up because numbers have been rounded off.
Source: Department of Chemicals and Petrochemicals, *Annual Report;* and Organization of Pharmaceutical Producers of India (OPPI).

The export performance of the pharmaceutical industry during the 1990s came after the industry experienced rapid expansion in exports during the 1980s. However, it should be pointed

out that the increase in exports during the earlier decade took place from a very low base.[16] A noteworthy feature of the exports of pharmaceuticals is the significant presence of bulk drugs (see table 2.7). The share of bulk drugs in the total exports of pharmaceuticals from India shows a rising trend from the mid-1990s, an indicator that the industry has been consolidating its production in the relatively higher technological segments. What is more, developed countries have been the major export destinations of bulk drugs while the export destination of formulations have been developing countries (Government of India, *Annual Report, 1992-93*: 4).

Table 2.7

Shares of bulk drugs and formulations in total exports (Percentage)		
Years	Bulk drugs	Formulations
1990/91	52.7	47.3
1991/92	56.4	43.6
1992/93	29.8	70.2
1993/94	28.8	71.2
1994/95	33.5	66.5
1995/96	35.6	64.3
1996/97	43.4	56.6
1997/98	40.6	59.4
1998/99	46.4	53.6

Source: Department of Chemicals and Petrochemicals, *Annual Report*; and Organization of Pharmaceutical Producers of India (OPPI)

The bulk drug exports from India are mostly in the generic category[17] (i.e. those drugs on which patents have expired).[18] Significant advantages are gained by being the first entrant in this market (Lanjouw, 1998:16). The Indian firms managed to gain experience in the production of generic drugs by the reverse engineering process and by acquiring production capabilities based on indigenously generated technologies,[19] activities that were possible because of the process patent regime adopted in the country. This is the principal reason for the growth of exports of generic bulk drugs from India during the 1990s. With their ability to develop generic drugs,

[16] Exports increased from about US$ 50 million in 1980/81 to close to US$ 410 million in 1988/89, Department of Chemicals and Petrochemicals/OPPI.

[17] In 1998 the generic market accounted for 47 per cent of the prescriptions market (CRISIL, 2000: 30).

[18] EXIM Bank (1991), discussing the exports of the bulk drugs, Ibuprofen, Ampicillin and Amoycillin Trihydrate, noted that the exports of these products took off after their patents expired.

[19] The Annual Report of the Department of Chemicals and Petrochemicals had this to say: "...Indian research has led to cost effective production of a wide range of products such as Myethyldopa, Paracetamol, Ibuprofen, Aspirin, Ampicillin, etc. and a host of other items. The process improvement achieved in these areas is internationally competitive, with the result that most of these products have found markets even in advanced countries like the USA, Germany, etc. May all of the Indian companies have the technology for cost effective production of a variety of items" (GOI, *Annual Report, 1993-94*: 2).

Indian firms had the opportunity to export drugs to the larger markets in the developed world when the patents on the products had expired.[20]

The expansion of the market for generic drugs in the United States that took place after the mid-1980s resulted directly from the enactment of the Waxman-Hatch Act in 1984.[21] The requirement for fresh clinical trials for generic drugs existing till then was replaced with the much simpler and less expensive "bio-equivalence" and "bio-availability" tests.[22] Consequently, the share of generic drugs increased from 18 per cent in 1984 to as much as 47 per cent in 1998 (CRISIL, 2000: 30). A firm can reap the full benefits of this growing popularity of generic drugs if it markets its drug formulations in the United States market. Only a few Indian firms are involved in this activity at present. These Indian firms have applied for about 60 Abbreviated New Drug Applications (ANDAs) (Does this have to be capitalized?) and have obtained marketing approval for some of them.

The successful entry of Indian firms into developed country markets is also because of the advantage they have of low production costs (Lanjouw, 1998: 17); in the competitive market for generic drugs, low costs are a distinct advantage. The Indian firms have also started paying attention to good manufacturing practices, and their production facilities have been approved by the Food and Drug Administration (FDA) of the United States and the Medicines Control Agency (MCA) of the United Kingdom (ICRA, 1999).

C. Imports

Total imports of drugs and pharmaceuticals rose from US$ 335 million in 1990/91 to US$ 799 million in 1999/00. Bulk drugs and formulations were imported in the ratio of 6:1 at the beginning of the decade. By the end of the decade, the ratio had declined to 4:1, as seen in table 2.8.

Imports of intermediates and bulk drugs rose from US$ 296.5 million in 1990/91 to US$ 641.3 million in 1999/00, showing a compound growth rate of 8.9 per cent. Imports of formulations increased from US$ 48.5 million to US$ 157.9 million during the same period, showing a growth rate of 14 per cent. The share of intermediates and bulk drugs in total drug imports declined from 85.9 per cent in 1990/91 to 80.2 percent in 1999/00, the average being 86.3 per cent for the whole period.

[20] Between 1991 and 1995, 19 of the top 50 pharmaceutical products lost their patent protection (EXIM Bank, 1991); As Jayaram, Venugopal and Bhagat (2000) have noted, these are "… drugs that accounted for sales of nearly US$ 90 billion in 1995. An unprecedented number of drug patents are set to expire between 2002 and 2005."

[21] See Grabowski and Vernon (1986).

[22] "Bio-equivalence tests refer to the tests conducted on a sample of persons to test the similarity between the original drug and the re-engineered drug. Bio-availability tests are also aimed at testing the similarity, but here the similarity is examined in terms of the presence of the drug in the bloodstream after different time intervals. Since the bio-equivalence and bio-availability tests are conducted on a relatively smaller number of persons and against a lesser number of parameters, the total cost and time involved are considerably less than in the case of the original drug trials" (ICRA, 1999: 133).

Table 2.8

Indian pharmaceutical industry: Imports (US$ million)			
Year	Intermediates and bulk drugs	Formulations	Total
1990/91	296.5	48.5	345.0
1991/92	312.8	42.3	355.0
1992/93	392.7	46.1	438.8
1993/94	337.2	45.4	382.6
1994/95	381.1	55.1	436.3
1995/96	658.4	83.3	741.7
1996/97	638.0	97.4	735.3
1997/98	671.4	118.4	789.8
1998/99	627.3	130.9	758.1
1999/00	641.3	157.9	799.2

Note: Totals may not add up because numbers have been rounded off
Source: Organization of Pharmaceutical Producers of India (OPPI).

D. Research and development

The pharmaceutical industry is a technology-intensive, science-based industry, with biotechnology playing an ever-increasing role in its development – a feature of the industry that has grown in importance in recent years.

Ballance, Pogany and Forstner (1992) have presented a typology of the world's pharmaceutical industries. They identified 10 countries (all of them developed) as "countries with a sophisticated pharmaceutical industry and a significant research base". The next group of 17 countries was identified as "countries with innovative capabilities". India is one of the countries in this group. While these countries are not active in discovering new molecular entities they have the technological capability to either develop innovative processes or improved formulations of already discovered drugs.

Although India has been attempting to develop new drugs, its record is far from impressive. For example, during the period 1956 to 1987 there were only 13 cases of invention of new chemical entities in India (Mehrotra, 1989:1061). In the late 1990s there were some new molecular discoveries by the private sector firms, Ranbaxy and Dr. Reddy's (CRISIL, 2000: 40).[23] The other area where the Indian firms seem to have succeeded is in new drug delivery systems (NDDS). This research involves "modifying an existing molecule to develop more user

[23] Ranbaxy had discovered a new molecule for benign prostatic hypertrophy and another one for asthma. Dr. Reddy's had discovered a new molecule for anti-diabetics. Wockhardt is reported to have applied for three patents for new chemical entities in the area of anti-infectives (*Financial Express*, March 8, 2000).

friendly dosage forms of medicines" (CRISIL, 2000: 21). Ranbaxy has developed an NDDS for ciprofloxacin (see chapter III, below) and the firm Wockhardt is reported to have applied for three patents for new drug delivery systems. Apart from this, Indian firms are active in developing new processes for known molecules. Again Ranbaxy is the most successful firm in this area and was granted 24 new process patents in the United States between 1990 and 2000; Dr. Reddy's and Cadila are other Indian firms with patents in the United States.

Internationally, the pharmaceutical industry has gone through two stages in the pre-molecular biology era. These can be broadly classified as "random drug discovery" (this approach entails screening of natural or chemically derived compounds for possible therapeutic activity) and "drugs by design" (resulting from advances in knowledge, such as in pharmacology and cell biology, which led to more sensitive screening mechanisms).[24] The Indian pharmaceutical industry does not seem to have progressed beyond the "random drug discovery" mode in whatever new drug discoveries it has made.[25]

The Indian pharmaceutical industry spends about 1.8 per cent, on average, of its sales on R&D (see table 2.9). This is higher than the average for Indian industry, which is around 0.7 per cent. The reported R&D expenditure by pharmaceutical firms grew at a compound growth rate of 6.7 per cent during the period 1990/91 to 1999/00.

A key aspect of technological change in the pharmaceutical sector in India is the close interaction between private sector firms and publicly funded laboratories of the Council for Scientific and Industrial Research (CSIR). The three laboratories that are most active in drugs research are the National Chemical Laboratory (NCL) located in Pune; the Central Drug Research Institute (CDRI) located in Lucknow; and the Indian Institute of Chemical Technology (IICT) located in Hyderabad.

The Government offers various incentives in the form of tax concessions and exemptions of specific products from the purview of price controls to encourage firms to engage in R&D. The pharmaceutical industry is eligible for weighted deduction for R&D expenses up to 150 per cent. Three categories of drugs are exempt from price controls for specific periods. These are: (a) drugs using processes developed through indigenous R&D effort, for a period of five years; (b) drugs using a new drug delivery system developed indigenously and approved for marketing, for a period of five years (GOI, *Annual Report, 1993-94*); and (c) new products developed in India, for a period of 10 years (GOI, *Annual Report, 1994-95*).

[24] Henderson, Orsenigo and Pisano (1999).

[25] Henderson, Orsenigo and Pisano (1999), while studying the impact of molecular biology on the pharmaceutical industries in the United States, Europe and Japan come to the conclusion that firms, which have graduated from "random drug discovery" to "drugs by design" were found to move on to molecular biology more often than firms that did not. The Indian pharmaceutical firms, if they are into drug invention, seem to be in the "random drug discovery" mode.

Table 2.9

Reported R&D expenditure by Indian pharmaceutical firms (1990/91 to 1999/00)[26]		
Year	US$ million	R&D expenditure as percentage of sales
1990/91	36.5	1.30
1991/92	29.4	1.40
1992/93	37.0	1.50
1993/94	39.8	1.90
1994/95	44.6	2.00
1995/96	45.5	1.80
1996/97	51.5	1.90
1997/98	56.0	1.90
1998/99	61.2	2.00
1999/00	73.6	1.90

Source: Department of Science and Technology *Research and Development in Industry*; and Organization of Pharmaceutical Producers of India (OPPI).

With a view to furthering the industry-government linkages in R&D activities, the Government appointed a Pharmaceutical Research and Development Committee, which submitted its report in November 2000. The Committee explored the possibility of developing institutional linkages in the pharmaceutical sector in order to improve the capacity of Indian industry to develop new drug molecules. In what appears to be a rather ambitious target, the Committee recommended that 20 new molecules, capable of being patented in the United States, should be developed by the pharmaceutical industry by the year 2005 (GOI, 2000).

E. Knowledge partnerships

In the transition from process development to applied and basic research, there has been a growing realization in the Government and industry that India must seek to leverage collective wisdom. Such leveraging implies intense networking between academia, government and industry. Such networking allows the funnelling of intellectual and other resources towards significant incremental progress.

This objective led to the creation of a world-class training and research institute, the National Institute of Pharmaceutical Education and Research (NIPER) at Chandigarh. The idea was mooted by the industry to create a world-class infrastructure for pharmacy education and

[26] This data is based on a survey of all the in-house R&D centres that are registered with the Department of Scientific and Industrial Research. The overall response rate is not reported, but it seems to be around 60 per cent. As no adjustment is made for non-reporting, and as the number of firms registering their in-house R&D units increases from year to year, this data is not strictly comparable over time; but it can be taken as indicative.

research. The institute has been set up with government funds along with contributions from the industry. Today, apart from its regular activities of running academic courses at the masters, doctoral and post-doctoral levels, NIPER is interacting with several Indian companies, transnational corporations (TNCs) and international organizations such as the World Health Organization (WHO), Tropical Prevention of Conception and Disease, Rush University, Chicago. (TOPCAD), the World Bank and the United Nations Industrial Development Organization (UNIDO). It is also conducting training programmes for drug regulators from various parts of the world and for members of the Indian industry.

The other dimension of this partnership among academia, government and industry is the alliance between industry and national laboratories/universities. It is believed that, on the one hand companies should educate themselves on scientific research and, on the other, the scientists should become familiar with the world of business. Laboratories such as the Central Drug Research Institute (CDRI), National Botanical Research Institute (NBRI) and Centre for Indian Medicinal and Aromatic Plants (CIMAP) have been in existence for several years. However, until recently, each laboratory or institute worked in isolation. Only in the 1990s, was it recognized that significant results could be achieved by welding together the individual capabilities of these institutions in specific, time-bound projects and programmes. Companies are now collaborating not only with Indian laboratories and universities, but also with foreign universities. For instance, Ranbaxy Laboratories has collaborated with the University of Bath for a Gastro-Retentive drug delivery system. This collaboration has helped Ranbaxy file two United States patents. Similarly, Indian companies, such as Dr. Reddy's Laboratories, are partnering with TNCs such as Novartis and Novo Nordisk for co-developing drugs.

The Government has launched several schemes for promoting this networking. These include:

a) *The Drugs and Pharmaceuticals Research Programme*. Initiated in 1994/95 by the Department of Science and Technology, Government of India, this programme aims to promote R&D in the drugs and pharmaceuticals sector. The scheme intends to enhance the capabilities of the Indian drugs and pharmaceuticals industry in the development of new drugs by synergizing the strengths of national institutions and the drug industry. Under this programme, R&D in all systems of medicine is promoted including *Ayurvedic* (herbal), *Unani & Siddha*, which are all indigenous systems of health care. It has three fields of activities: (i) bringing together the scientific expertise existing in the country's research institutions and industry on a joint platform through projects; (ii) establishment of mechanisms and linkages to facilitate the development of new drugs by Indian industry and research institutions; and (iii) creating state-of-the-art infrastructure facilities at par with international standards for the benefit of the Indian industry and other users. The programme is jointly funded by the industry and the Government.

A list of the firms and institutions participating in this programme is provided in table 2.10.

b) *Technology Development Board*. With a view to encouraging the development and commercialization of indigenous technologies and adaptation of imported technology for wider applications, the Government constituted the Technology Development Board (TDB) in

September 1996. The Board provides equity and/or soft loans to industrial units and private research institutions. Since its formation, the Board has signed 67 agreements for providing financial assistance amounting to a total of US $ 71.62 million. Important TDB-financed projects relating to drugs and pharmaceuticals financed are listed in table 2.11.

c) *Programme aimed at Technological Self-Reliance (PATSER).* This is a scheme implemented by the Department of Scientific and Industrial Research (DSIR), whereby networking among the scientific facilities available at the National Laboratories and the industry is promoted through partial financial assistance. It has been in operation for about a decade. So far over 80 projects have been supported under this scheme including some projects concerning R&D in the field of drugs and pharmaceuticals. Table 2.12 provides a summary of these projects.

d) *New Millennium Indian Technology Leadership Initiative (NMITLI)*. This is another successful example of a public-private partnership for technology development. The initiative involves about 100 institutions, and the projects under NMITLI were selected keeping in view the Indian pharmaceutical industry's strengths and weaknesses. For instance, the drug development project for combating tuberculosis (TB) has been initiated because TB is not only a challenge for developing countries, including India, but also because India has the potential to emerge as a leader in drug development in this area. The project is being implemented through inter-institutional collaboration with special areas of focus in each of these: the Centre of DNA Fingerprinting in Hyderabad and the Bose Institute in Kolkata have developed targets for the disease (a part of the organism that the drug can attack); the Central Drug Research Institute (CDRI), Lucknow, will screen these targets for drugs; the Indian Institute of Science (IIS), Bangalore, is developing a model for testing the drug for latent tuberculosis, a stage in the onset of the disease when there are no symptoms; the National Institute of Immunology, Delhi, is developing a delivery system for the drug; and the Regional Research Laboratory in Jammu is examining whether its bio-enhancer (a drug that enhances the effect of another) can be used for tuberculosis. Lupin, with its long-term interest in tuberculosis, is the industrial partner that will take the drug to the market.

The above analysis reveals that “knowledge partnerships” are increasingly considered efficient, sustainable and reliable in the pharmaceutical sector in India.

However, as is evident from the tables (tables 2.10, 2.11 and 2.12), even in India[27] R&D efforts are largely concentrated on diseases like cancer, diabetes and cardiovascular problems. Only a handful of projects are being implemented for fighting tropical diseases and TB. This is one of the major concerns of the Indian Government.

[27] India accounts for nearly one-third of the global TB burden and every year there are more than 2 million new TB cases. Approximately 500,000 people die from this disease each year, more than 1,000 every day and one every minute. The spread of HIV/AIDS would increase the number of TB cases and deaths.

Table 2.10

Industry/Institutional Alliance

Industries:

1. Spic Pharma
2. Dr Reddy's Foundations
3. Ranbaxy Laboratory Ltd
4. Dabur Research Foundation
5. Zandu Pharmaceuticals Works Ltd.
6. Recon Ltd.
7. Bharat Biotech International Ltd.
8. Cadila Healthcare Ltd.
9. Indian Herbs Research and Supply Co. Ltd.
10. Arya Vaidya Sala
11. Cadila Pharmaceutical Ltd.
12. Glenmark Pharmaceuticals Ltd.
13. Alembic Ltd.
14. Lupin Laboratories Ltd.

Institutions:

1. Indian Institute of Chemical Technology
2. Central Drug Research Institute
3. Centre for Biotechnology
4. Regional Research Laboratory
5. Regional Research Laboratory
6. National Chemical Laboratory
7. Indian Institute of Chemical Biology
8. Centre for Cellular & Molecular Biology

Academia:

1. Indian Institute of Science
2. University of Hyderabad
3. University Department of Chemical Technology
4. All India Institute of Medical Sciences
5. Tamil Nadu Veterinary & Animal Science University
6. Delhi University
7. Indian Institute of Technology
8. Seth G.S. Medical College & KEM Hospital

Note: A large number of these projects are on Anti-cancer agents, Anti-infectives agents and new Anti-virals.

Source: Ministry of Science and Technology, Department of Science and Technology, December 2000

Table 2.11

Drug and pharmaceutical project financed by the Technology Development Board

S.No (1)	Company (2)	Product (3)	Field of application (4)	Total Project Cost (US$ m) (5)	TDB support (US$ m) (6)
1.	M/s Shantha Biotechnics Private Ltd.	Hepatitis B Vaccine	Hepatitis B control	5.05	1.7
2.	M/s Shantha Biotechnics Private Ltd.	Interferron alfa-2	Treatment of viral Hepatitis C	4.88	0.24
3.	M/s Bharat Biotechnic International Ltd.	Recombinant vaccine for Hepatitis B	Hepatitis A control	2.44	0.65
4.	M/s Bharat Biotechnic International Ltd.	Streptokinase through recombinant route	Activator for Myocardial infraction	4.7	2.2
5.	M/s Alpha Amines Private Ltd.	DL-2 Amino Butanol	Intermediate for manufacture of ethambutol – an anti-TB drug	1.04	0.5
6.	M/s Ranbaxy Laboratories Ltd.	Development of *Cefuroxime Axetil*	Anti infective drug	0.62	0.23
7.	JKDPL	4th generation *cephalosporins* antibiotics-*cefixime*	Respiratory and other infections	0.64	0.3
8.	Manukirti Biogems Private Ltd.	Reagent for detection of bacterial endotoxin	Detection of bacterial contamination	0.13	0.06
9.	Mark Medicines Private Ltd.	Concentrate of living lactic acid bacteria	Suppressing development of pathogenic flora in intestine	5.31	1.4
10.	Shantha Marine Biotechnology Private Ltd.	Extraction of *beta-carotene*	Natural source of vitamin A	0.01	0.7
11.	Medicorp Technologies India Ltd.	Manufacture of *fluconazole, enalapril maleate*, *itraconazole and omeprazole*	Anti-fungal, anti-hypertension and anti-ulcer drugs	3.40	1.06
12.	ACL Chemicals Ltd.	Extraction of *beta-carotene* from algae	Vitamin A precursor	0.57	0.18
13.	Gland Pharma Ltd.	Manufacture of *enoxaparin*	Anti-coagulant in bypass and other surgeries	1.54	0.7

Source: Department of Science and Technology

Table 2.12

Drug and Pharmaceutical R&D Projects under PATSER

S.No.	Project item	Executing agencies	Total project cost (US$ m)	DSIR's share (US$ m)
1.	Development of a process of manufacturing *Pyrazinamide* – an anti-T.B. drug	SPIC, and IICT	1.04	0.43
2.	Scale up process for development of *Lyposonal Amphotericin B* used for *Kala Azar*	Lifecare Innovations Private Ltd.	0.29	0.1
3.	Development of novel resins for use in solid phase organic synthesis and combinatorial chemistry	M/s Bharavi Industries Pvt. Ltd.	0.13	0.04
4.	Controlled released formulation of *Nimesulide*	M/s Ajanta Pharma Ltd., Mumbai	0.29	0.12
5.	Pilot scale manufacture of hyaluronic acid formulations	M/s Gland pharma Ltd., Hyderabad	0.27	0.09
6.	Development of technologies for 3-*Chloro methyl-D3-Cepham Ester* from *Pen-G*	M/s SPIC and CECRI	0.29	0.13

Source: Technology Development Board (TDB), Annual Report, 2000-2001 and Technology Development Board-Enabling Commercialisation.

F. Technology transfer

During the 1990s policies relating to transfer of technology have been liberalized in the form of easier procedures, removal of restrictions on royalty or technical fee payments, removal of restrictions on inclusion of restrictive clauses in arrangements, and no scrutiny for repeated imports, among others. However, all these measures have failed to increase the number of collaboration agreements in the Indian pharmaceutical industry. According to Narsalay (2000), there were a total of 187 technical collaboration approvals in the drug industry during 1991-1999, which constituted 3.1 per cent of all the technical collaboration agreements approved during that period. This is a very small figure for such a technology-intensive sector.

Foreign technical collaboration has not been as important for the export market as for the domestic market; many small and medium firms enter into technical collaboration with foreign firms to cater mainly to the domestic market. One of the reasons ascribed to this low level of transfer of technology in the Indian pharmaceutical industry is the relatively weak patent system that currently exists in India in respect of pharmaceuticals. As mentioned earlier, the Indian Patents Act, 1970, follows a process patent regime, which is due to be dismantled in 2005, in

keeping with India's commitments under the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). It is only when a product patent regime is in place that its impact on the number of technical collaboration agreements can be assessed.

G. Foreign direct investment

Controls over the operations of foreign enterprises that were imposed largely through the Foreign Exchange Regulation Act (FERA) in 1973, were rapidly reduced through the 1990s.

In 1994 the Government allowed foreigners to hold up to 51 per cent of the equity capital of enterprises registered in India. This change in policy led many firms, which had reduced their foreign shareholdings in the 1970s to 40 per cent or less to meet the requirements of FERA, to increase the foreign share to 51 per cent (for a list of firms which increased their foreign equity to 51 per cent, see GOI *Annual Report, 1993-94*).[28] However, apart from the increase in foreign stakes of some of the major firms operating in India, the pharmaceutical sector was not among the major beneficiaries of FDI inflows during the 1990s; it accounted for only 0.4 per cent of total FDI approvals during the period 1991-1999, amounting US$ 260 million (Narsalay, 2000).[29]

It has often been contended that India's failure to attract FDI is due to its relatively weak patent regime. According to Tancer and Josyla (1999), the 10-year transition period that India has opted for in order to introduce product patents in fulfilment of its obligations under TRIPS has affected the inflow of FDI in the pharmaceutical sector. The real interest of foreign firms in the Indian market will be better assessed only after India starts giving product patents in pharmaceuticals from 2005. Reporting on disinvestments in the pharmaceutical sector by the firms, Nicholas, Merind, Roche, and Searle, the GOI *Annual Report, 1993-94* gives the following reasons: "... the pricing system, lack of patent protection, advantages in entering into licensing arrangements with local India firms rather than direct investment..." (p. 4).

The above discussion shows the benefits for the Indian pharmaceutical industry resulting from the policy environment since the beginning of the 1970s. It is clear that the instruments of policy introduced by the Government during this phase suited the industry, a fact borne out by its performance over time. While the more protected environment in the 1970s and 1980s helped the domestic enterprises to establish their presence in the industry, the adoption of an open economy framework in the 1990s encouraged the leading firms to expand their overseas operations. The latter aspect can be best understood by analysing the performance of the leading firms in the industry. The next chapter therefore presents a case study of the success of Ranbaxy Laboratories, the largest of the wholly Indian-owned enterprises.

[28] These are Glaxo, E Merck, Reckitt & Colman, Procter & Gamble and Hoechst.
[29] This figure is obtained by using the average rupee-dollar exchange rate for the period.

CHAPTER III

THE SUCCESS OF RANBAXY LABORATORIES

Ranbaxy Laboratories has been one of the best performers in the Indian pharmaceutical industry during the past decade, a period that has witnessed an opening up of the Indian economy to external competition. The firm, which was established in 1961, has emerged as the largest enterprise among the wholly Indian-owned pharmaceutical firms in terms of sales turnover. In more recent years, the overall performance of the firm has been even more impressive. This is corroborated by an annual survey of the leading firms in the Indian corporate sector. According to the most recent edition of the survey, which covered 266 firms, Ranbaxy Laboratories ranked the highest among the pharmaceutical firms included in the sample (see table 3.1).

Table 3.1

Ranking of the leading pharmaceutical firms among the best performing firms in India		
Company	Rank in 2000	Rank in 1999
Ranbaxy Laboratories	18	26
Novartis India Ltd	43	92
Cipla Ltd	46	70
Dabur India Ltd	54	65
Glaxo India Ltd	68	93
Aurobindo Pharma Ltd	74	147
Wockhardt Ltd	79	na
Rallis India	83	134
Sun Pharmaceuticals	92	na
Dr Reddy's Laboratories Ltd	100	118
Hoechst Marion Roussel Ltd	105	150
Torrent Pharmaceuticals Ltd	130	167
Bayer India Ltd	169	203
Cadila Healthcare Ltd	176	na
Orchid Chemicals and Pharmaceuticals Ltd	198	154
Smithkline Beecham Pharmaceuticals India	205	185

Note: The ranking was based on parameters: net sales, earnings before interest, depreciation, tax and amortization, net fixed assets, market capitalization, return on capital, number of employees, and sales to net fixed assets.
Source: *Business India*, 27 November to 10 December 2000.

The performance of Ranbaxy Laboratories can be better understood by analysing the changes observed in three sets of variables since the beginning of the 1990s. The first pertains to the size of the enterprise and includes variables such as equity capital and assets. The second set includes variables that provide an idea of the magnitude of the operations of the enterprise. And finally, the third set of variables helps explain the foreign exchange transactions of the enterprise during the past decade.[30]

1. Performance of the firm in the 1990s

A. Growth in size

The following three variables are considered for assessing the growth of the enterprise during the 1990s: (i) equity capital, (ii) net worth, and (iii) gross fixed assets. In addition to using more commonly used variables for commenting on the size of an enterprise (i.e. equity capital and fixed assets), net worth has also been taken into account. Net worth includes the undistributed profits of an enterprise and provides an indication of its growth potential.

Table 3.2 presents the figures for the above-mentioned variables over the past decade. From a modest US$ 5.3 million in 1990 the equity base of the company had increased to more than US$ 27 million by the end of the decade. Measured in constant dollar value,[31] the equity base of the firm increased more than 5 times, its gross fixed assets increased more than 6 times, and its net worth rose almost 14 times.

The performance of Ranbaxy Laboratories over the past decade can be divided into two distinct phases, 1990-1994 and 1995-1999. The first four-year phase was one in which the firm experienced phenomenally high rates of growth in all spheres. The second phase, although marked by a considerable slowing down of expansion, can be considered the period of consolidation for the firm. Thus the size of the firm increased at widely varying rates in the two halves of the 1990s. The compound rates of growth of the three variables are shown in table 3.3.

[30] The data used for the analysis were taken from the Prowess Database on the Indian corporate sector, which has been developed by the Centre for Monitoring Indian Economy (CMIE) as well as from the Annual Reports of Ranbaxy Laboratories. Additional information was obtained from discussions held with the firm's senior managers.
[31] US$ 1was Rs. 19 in 1990 and Rs. 42 in 1999.

Table 3.2

Size of Ranbaxy Laboratories (1989/90 to 1999) (US$ million)			
Year	Gross fixed assets	Equity capital	Net worth
1989/90	29.0	5.3	23.9
1990/91	36.8	5.0	27.9
1991/92	38.3	5.9	24.4
1992/93	60.4	8.3	47.5
1993/94	65.3	11.0	63.8
1994/95	94.8	13.7	204.8
1995/96	126.2	12.6	231.0
1996/97	152.3	13.8	317.3
1997/98	168.7	13.7	320.1
1999*	183.5	27.3	331.2

Note: Until 1998, Ranbaxy followed the accounting year April to March. After 1997/98, the accounting year was changed to the calendar year.
Source: Centre for Monitoring Indian Economy (CMIE), Prowess Database 2000

Table 3.3

Compound rates of growth in size of Ranbaxy Laboratories during the 1990s (Percentage)			
Years	Gross fixed assets	Equity capital	Net worth
1990-1994	22.5	20.0	27.8
1995-1999	18.0	18.8	12.8

Source: Centre for Monitoring Indian Economy (CMIE), Prowess Database 2000

B. Growth in the size of operations

The size of operations of Ranbaxy can be measured using four variables: total income, sales, value added and profits. While for total income, sales and value added the gross figures are taken, for profits the figures taken are net of taxes and depreciation. Table 3.4 presents the trends observed in these variables during the 1990s.

Of the three indicators of performance included in the table, profits have registered the most impressive increase over the period. While total income and sales of the firm increased by a factor of 3 and the gross value added increased by a factor of 4, the profits of the firm increased more than 16 times.

Table 3.4

Size of operations of Ranbaxy Laboratories (1989/90 to 1999) (US$ million)				
Year	Total income	Sales	Profits after tax	Gross value added
1989/90	150.0	116.6	2.8	23.7
1990/91	169.3	137.3	6.7	26.7
1991/92	162.7	129.5	6.3	25.6
1992/93	219.1	175.8	13.4	40.6
1993/94	223.0	189.0	20.2	47.8
1994/95	282.1	226.8	35.1	71.5
1995/96	309.9	248.2	40.0	83.8
1996/97	352.7	319.8	44.7	109.9
1997/98	386.6	339.3	44.3	109.9
1999	472.5	367.0	45.5	104.6

Source: Centre for Monitoring Indian Economy (CMIE), Prowess Database 2000

The four sets of variables taken together make the analysis of the performance of Ranbaxy Laboratories quite interesting. The comparable increases in total income and sales of the firm during the period under consideration indicate that the manufacturing activities remained as important for the firm at the end of the period as they were at the beginning of the period. The higher increase in gross value added of the firm as compared to that in the total sales implies a deepening of the production process internally as well as an improvement in the utilization of its production facilities. It can further be inferred from table 3.4 that the growth of value added observed through the 1990s was reflected in the increase in net profits recorded by the firm.

A better understanding of the performance of Ranbaxy Laboratories described above can be had by looking at the compound growth rates of the above-mentioned variables in the two halves of the decade (see table 3.5).

Table 3.5

Compound rates of growth in the operations of Ranbaxy Laboratories in the two halves of the 1990s (Percentage)				
Years	Total Income	Sales	Profit after tax	Gross value added
1990-1994	10.4	12.8	63.9	19.2
1995-1999	13.7	12.8	6.7	10.0

Source: Centre for Monitoring Indian Economy (CMIE), Prowess Database 2000

Table 3.5 reveals that in the two halves of the 1990s the performance of Ranbaxy Laboratories was a study in contrast. The contrast in the growth of profits of the firm is particularly striking. Net profits of the firm increased more than sevenfold during the first phase (1990-1994), which was reflected in a compound growth rate of nearly 64 per cent, as shown in the table. The second phase (1995-1999) on the other hand, saw profits register only a modest increase. Consequently, the growth of net profits was less than 7 per cent. Although this rate can be considered quite impressive, given the overall performance of the industrial sector in India, the high standards set by the firm in the early 1990s makes this performance look rather ordinary.

The growth of gross value added of the firm during the two halves of the 1990s also showed considerable variation which, in the period 1990-1994, increased annually by 19 per cent, while in the second half of the 1990s, compound growth dropped to about 10 per cent.

Two factors could have contributed to these striking contrasts in the annual growth rates of Ranbaxy Laboratories in the two halves of the 1990s. The first is that both net profits and gross value added started moving upwards from relatively small bases at the beginning of the decade. This was particularly so for net profits which were a mere US$ 3 million in 1989/90. The second factor that could explain the slowing down of the firm towards the end of the decade was the process of consolidation that was under way. This in part could be explained by the fact that the total income or sales of the firm did not slow down as sharply as did the net profits. The latter argument can be further supported by the external transactions of the firm, which had improved consistently throughout the decade.

C. Foreign exchange transactions

The successful forays made by the larger firms like Ranbaxy Laboratories in the international market was the key factor behind the rapid growth of exports of the pharmaceutical industry, particularly during the 1990s. Throughout this decade Ranbaxy Laboratories maintained a steady increase in its net foreign exchange earnings (see table 3.6).

The single most important aspect of the foreign exchange transactions of Ranbaxy Laboratories is the remarkable turnaround that the firm experienced after the early 1990s when its net foreign exchange earnings were negative. The rise in net foreign exchange earnings was mainly due to the firm's ability to maintain a consistently high rate of increase in foreign exchange earnings. Thus even though the foreign exchange spending of the firm was growing at a reasonable rate, its increase in foreign exchange earnings was able to more than compensate for the growth in foreign exchange spending. Table 3.7 shows the broad composition of foreign exchange earnings of the firm.

Table 3.6

Ranbaxy's foreign exchange transactions (US$ million)			
Year	Foreign exchange earnings	Foreign exchange spending	Net foreign exchange earnings
1989/90	22.3	24.7	-2.4
1990/91	32.7	34.0	-1.3
1991/92	36.6	35.2	1.4
1992/93	53.6	45.5	8.1
1993/94	70.6	45.2	25.4
1994/95	97.1	69.2	27.9
1995/96	120.2	94.8	25.4
1996/97	146.1	90.9	55.2
1997/98	150.4	98.8	51.6
1999	191.5	96.7	94.8

Source: Centre for Monitoring Indian Economy (CMIE), Prowess Database 2000

Table 3.7

Composition of Ranbaxy's foreign exchange earnings (US$ million)			
Year	Goods exports	Services	Total earnings
1989/90	21.7	0.5	22.2
1990/91	31.9	0.9	32.8
1991/92	35.7	0.9	36.6
1992/93	52.2	1.4	53.6
1993/94	69.1	1.4	70.5
1994/95	94.4	2.7	97.1
1995/96	113.8	6.4	120.2
1996/97	141.5	4.6	146.1
1997/98	n.a	n.a.	n.a.
1999	170.9	20.6	191.5

Source: Centre for Monitoring Indian Economy (CMIE), Prowess Database 2000

The composition of foreign exchange earnings of Ranbaxy Laboratories shows an interesting pattern. Although export of goods was an overwhelmingly large component of its foreign exchange earnings throughout the decade, its export of services increased quite

significantly in the later years. This was mainly because of the firm's entry into the market for technology. In 1999 there was evidence of the firm's potential in this market when it registered a phenomenal growth in its services exports. This was primarily because of the licensing agreement that Ranbaxy Laboratories entered into with Bayer AG for a new drug delivery system involving the blockbuster antibiotic *ciprofloxacin*.

Ranbaxy Laboratories looked increasingly to the international market for expansion of its operations. Representing the strongest segment existing in the Indian pharmaceutical industry, Ranbaxy Laboratories undertook international expansion during the 1990s, clearly a response to the policy changes that the Government introduced from the beginning of the decade. This can be better understood by looking at the percentage of the domestic market sales and exports in each of the major product groups of the firm in the most recent year for which the data are available (see table 3.8).

Table 3.8

Ranbaxy Laboratories: Market distribution of products of different therapeutic groups in 1999 (US$ Million)

Therapeutic groups	Domestic sales	Exports	Total	Share of exports (percentage)
Anti-infectives/antibiotics	84.9	40.8	125.6	32.4
Gastrointestinal tract	12.2	8.8	21.0	41.8
Nutritionals/multivitamins/haematinics	12.9	6.9	19.8	34.8
Analgaesics	11.5	3.8	15.3	24.8
Dermatologicals	12.6	0.1	12.7	0.9
Cardiovasculars	6.8	1.1	7.8	13.6
Orthopaedics	6.8	0.0	6.8	0.2
Central nervous system	5.2	0.3	5.4	4.7
Others	7.3	8.8	16.1	54.7
Total	160.1	70.5	230.6	30.6

Source: Ranbaxy Laboratories, *Annual Report 1999*.

Almost a third of the major products of Ranbaxy Laboratories have been marketed internationally. This figure can be considered quite significant in view of two objective realities that face the firm. First, the domestic market is itself very large, and second, the increasing exports have not been as motivating a factor for the Indian firms given that the overall orientation of policy has remained essentially inward looking for a considerable period of time.

2. The technology factor in the performance of Ranbaxy Laboratories

The initial forays of Ranbaxy Laboratories into R&D activities began in the late 1970s. However, it was not until the late 1980s that the firm made some progress in this area through the development of a novel process for Cefaclor. One of the major advantages that Ranbaxy had as it sought to build its R&D base was the favourable policy environment provided by the Patents Act of 1970.

Eli Lilly owned the drug, Cefaclor, through a patent that the firm had obtained in 1979. This antibiotic was one of the best selling drugs in 1980s. Ranbaxy started work on developing a new seven-stage process for the production of Cefaclor in 1989. After spending nearly US$ 1.1 million (Rs.20 million) on a three-year project, Ranbaxy emerged as the only other manufacturer of Cefaclor besides the patent holder, Eli Lilly. Not only did Ranbaxy produce the product successfully; but it also managed to obtain high yields from its process. In 1993, Eli Lilly and Ranbaxy Laboratories agreed to set up two joint ventures in India. One was to conduct research in India and the other, to market Eli Lilly's products in the South Asian market. These joint ventures had yet another significance – it was the first time in its 30-year existence that Ranbaxy Laboratories entered into a joint venture with a foreign firm.

Ranbaxy Laboratories has a clearly articulated strategy to compete in the global markets, the key element of which is technology. There are two facets of this strategy. In the first instance the firm has made optimum use of its own R&D capabilities built up over the past two decades. The second facet is the strategic alliances it has tried to build with other firms in the pharmaceutical industry, both of foreign and Indian origin. The R&D structure built by the firm has four dimensions. These are: (i) development of abbreviated new drug applications, (ii) novel drug delivery systems, (iii) development of new processes, and (iv) new drug discovery and research. In the following sections the R&D expenditures of the firm during the decade of the 1990s and the main features of its R&D activities are discussed.

A. Growth of in-house R&D activities in the 1990s

Table 3.9 presents the R&D expenditures of Ranbaxy Laboratories from 1992/93 to 1999.

The two kinds of expenditure of Ranbaxy Laboratories during the 1990s, as shown in the above table, indicate contrasting tendencies. In the earlier years, capital expenditure was relatively greater, which is a pointer to the establishment of R&D facilities by the firm. However, since the middle of the decade, capital expenditure has declined quite significantly. Such has been the magnitude of the decline, that in 1999 capital expenditure on R&D was no more than a fourth of the level of spending in 1993/94. In sharp contrast, current expenditure on R&D has increased rapidly and at a rate far exceeding that of the decline in capital expenditure. Between 1992/93 and 1999, current expenditure on R&D increased more than four times.

Table 3.9

R&D expenditures of Ranbaxy Laboratories (1992/93 to 1999) (US$ million)			
Year	Capital expenditure	Current expenditure	Total
1992/93	3.4	2.6	6.0
1993/94	8.2	2.9	11.1
1994/95	5.7	5.9	11.6
1995/96	5.8	7.2	13.0
1996/97	4.3	9.6	13.9
1997/98	3.2	10.1	13.3
1999	1.7	11.4	13.1

Source: Centre for Monitoring Indian Economy (CMIE), Prowess Database 2000

The increase in the R&D expenditure can be seen more clearly from table 3.10, which shows the contrasting growth rates of the three components of such expenditure by the firm.

Table 3.10

Growth rates of the three components of R&D expenditure by Ranbaxy Laboratories			
Years	Capital Expenditure	Current expenditure	Total expenditure
1992/93 to 1999	Negative	27.9	13.9

Source: Centre for Monitoring Indian Economy (CMIE), Prowess Database 2000

A better picture of the R&D expenditure of the firm can be had by looking at this expenditure in conjunction with the sales turnover figures (see table 3.11). The R&D intensity of the firm through the 1990s has been showing a somewhat mixed picture. While the ratio of current spending as a percentage of sales turnover has been registering a steady increase, the ratio of total spending on R&D to sales has been declining since the middle of the decade. Interestingly, the highest ratio of total R&D spending to sales was registered in 1993/94, which was during the period when the firm started to use R&D spending as a strategy to meet the challenges posed by the new policies adopted by the Government in India. The R&D spending of the firm in the later years, however, indicates that the initial thrust appears to be wearing out. This is a pointer to the fact that the firm needs to give more attention to its R&D activities if it is to remain true to the epithet of a research-oriented firm.

Table 3.11

R&D intensity of Ranbaxy Laboratories		
Year	Current expenditure/sales (percentage)	Total expenditure/sales (percentage)
1992/93	1.5	3.4
1993/94	1.5	5.9
1994/95	2.6	5.1
1995/96	2.9	5.3
1996/97	3.0	4.3
1997/98	3.0	3.9
1999	3.1	3.6

Source: Centre for Monitoring Indian Economy (CMIE), Prowess Database 2000

B. Areas of R&D spending of Ranbaxy Laboratories

Among the four dimensions of R&D activities that Ranbaxy Laboratories has focused on, two have been quite prominent in terms of the results obtained. These are: (i) development of abbreviated new drug applications, and (ii) development of new processes. However, in more recent years, the two other areas have also shown considerable promise.

(i) Abbreviated new drug applications

By focusing its activities in this area, the firm has been able to make the maximum use of its position as a leading generic drug producer in an ever-growing Indian market. Utilization of this core competence of the firm has resulted in the development of several formulations and alternative processes. More importantly, the firm has obtained approvals for its products as abbreviated new drug applications (ANDAs) in the United States (see annex table I for details). The development has taken place alongside the steps taken by the firm to obtain patents for the novel processes it has generated

The ANDAs were the creation of legislative action in the United States through the Drug Price Competition and Patent Restoration Act of 1984 (more commonly known as the Waxman-Hatch Act). Under this Act, a generic product needed only to be shown to be a "bio-equivalent" to a patented drug in order to obtain marketing approval after the original patent, and the market exclusivity granted therein, had expired. The Waxman-Hatch Act provides that a generic drug can be considered as a bio-equivalent if the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the patented drug.

In the past two years, there has been a quantum jump in approvals for ANDAs received by the firm. Three ANDA approvals were obtained by the firm in the first half of 1999. The

products that were approved belonged to the antibiotics therapeutic group, the traditional area of strength of the firm. By the first quarter of 2000, Ranbaxy Laboratories was seeking approvals for 26 ANDAs and had received approval for eight molecules. Among the products that received approval during this period was Ranitidine, one of the largest selling anti-ulcer drugs in the world market.

(ii) Development of new processes

This is an area where Ranbaxy Laboratories has developed considerable expertise, given the patent regime in India that allowed patenting of process patents in the area of chemicals, including pharmaceuticals. However, despite the fact that the present Indian Patents Act was adopted in 1970, it was not until the late 1980s that Ranbaxy Laboratories started applying for patents. The first patent was applied in the United States in 1988, followed by patent filing under the European Patent Convention; the firm did not file for patents in India before 1990.

The patenting activity of the firm has started increasing in recent years (see annex tables II to V). Data for the Indian filings were not available before 1995, but from 1996 to 1999 the firm filed 40 patent applications in India.

(iii) Novel drug delivery systems

The activities of Ranbaxy Laboratories centering on the development of novel drug delivery systems (NDDS) received a significant fillip as a result of a tie-up in 1999 with Bayer AG, the Germany pharmaceutical giant, involving one of the new generation antibiotics, *ciprofloxacin*. The firm was able to improve on the product, which was developed by Bayer AG and is under patent protection until 2003. Instead of the multiple-dose-a-day therapy that the Bayer formulation was offering, Ranbaxy Laboratories was able to produce a one-a-day formulation. This product improvement promised greater patient compliance, and was therefore considered to be a major step forward. The significance of this improvement was reflected in the terms of the licensing agreement between Ranbaxy Laboratories and Bayer AG. Under the agreement, Ranbaxy Laboratories was to receive US$ 65 million from Bayer over a four-year period, with an initial payment of US$ 10 million. The agreement allowed Bayer AG to have the worldwide marketing rights for *ciprofloxacin*, except in India and the countries of the Commonwealth of Independent States (CIS) where Ranbaxy Laboratories would have the marketing rights. The product is due to undergo phase III of clinical trials in the United States to be marketed there from 2002..

(iv) New drug discovery

Ranbaxy Laboratories has recently entered the most challenging area for pharmaceutical firms, that of new drug discovery. The firm has discovered three molecules, which are at various stages of development. The first product, discovered in 1998, is at the clinical trial stage; the second molecule was discovered in 2000 and went into clinical trials by the end of that year; and the third molecule is at an advanced stage of development. Having developed these molecules, the firm has now planned for the development of at least one new molecule every 12 to 18 months.

The R&D activities of Ranbaxy Laboratories show a distinct trend towards improvement of the company's technological intensity of operations. While emphasis in the earlier phase was on development of generics, in more recent years it has been on the development of new chemical entities. This transition to developing new chemical entities has two advantages. First, the Indian industry should look to better infusion of technology and an enhanced rate of introduction of new drugs. Secondly, and more importantly, this leading firm in Indian industry looks better prepared to face the challenges posed by the post-TRIPS patent regime.

CONCLUDING REMARKS

The production and export performance of the Indian pharmaceutical industry during the 1980s, and especially during the 1990s, has been impressive. The industry has carved a niche for itself in the international market as a supplier of low-cost and good quality generic bulk drugs. The foundations for a competitive pharmaceutical industry were laid during the 1970s in the policy regime, which encouraged the growth of domestic pharmaceutical firms. The other major objective of the policy regime was to keep prices low.

The Patent Act, 1970 played a major role in the development of the technological capability of Indian firms. By reducing the patent term, granting only process patents for drug inventions and bringing these inventions under automatic compulsory licences, it became unattractive for foreign firms to take patents in India, as evidenced in the lower number of foreign patent applications in the pharmaceutical sector. This gave the Indian firms the opportunity to copy technology and first cater to the domestic market, and later, when the patent expired, to export. This might have had a negative impact on technology transfer, but the Act became a useful tool for enabling Indian enterprises to make an entry into previously uncharted territory.

The process patent regime was adopted with a view to encouraging innovations in a country like India, which had limited technological capability and financial resources to devote to R&D. The shorter patent term was adopted to keep a "softer" monopoly in an area like drugs, which are essential for human life. In a similar vein, the provision relating to licences of right was introduced to encourage competition in the pharmaceutical industry.

Because of the fact that the patents law in force grants only process patents in the case of pharmaceuticals and a relatively short patent term, the Indian firms could gain experience through a reverse engineering process, acquiring production capabilities based on indigenously generated technologies. This gave Indian firms the opportunity to export drugs to the larger markets in the developed countries when the patent on the products had expired. This is the principal reason for the growth of exports of generic bulk drugs from India during the 1990s.

The policy regime for the pharmaceutical industry in India shifted from subjecting the industry to strict government control in the 1970s to freeing it almost completely to allow market forces to guide it in the 1990s. The major policies applied since the 1970s have gradually moved towards greater accordance with new international rules that entered into force in the mid-1990s.

India has chosen to opt for introducing a product patent regime in pharmaceuticals only from 2005. The Indian Patent Regime adopted in the 1970s would have been inconsistent with the WTO TRIPS Agreement. Under this agreement, patents are required not only for processes but also for products. Moreover, the terms of protection available shall not end before 20 years from the filing date. Additionally, the TRIPS Agreement establishes detailed conditions for

compulsory licensing or government use of patents without the authorization of the patent owner[32].

Regarding R&D, the Government has offered incentives to firms that engage in R&D. The incentives have taken the form of tax concessions and exemption from the purview of price controls. Although the WTO Agreement on Subsidies and Countervailing Measures (SCM Agreement) identified assistance for R&D as non-actionable subsidies, under certain circumstance these provisions applied only for a period of five years, beginning from the date of entry into force of the Agreement; thus they now fall under the category of actionable subsidies.

Moreover, until 1994, the drug policy provided that firms which did not use high technology while producing bulk drugs or formulations had to bring down their foreign holding to 40 per cent to be considered Indian firms. On the basis of that regulation, foreign firms faced a relatively tighter regime as regards production of formulations; they were also obliged to have R&D facilities in the country and to spend at least 4 per cent of their sales turnover as recurring expenditure on R&D facilities. Those requirements could have been inconsistent with the obligation of national treatment of regulations under Article III of the GATT 1994.

Technological change in the pharmaceutical sector in India also benefited from institutional support. The publicly funded laboratories of the Council for Scientific and Industrial Research (CSIR) were active in drugs research and had close links with private sector firms, thereby overcoming the common problem of non-interaction with industry. In particular, "knowledge partnerships" funnelled intellectual resources towards incremental progress.

However, the overall impact of this mix of policies was favourable for the industry. This is evident in the relative performance of the pharmaceutical industry in the industrial sector as a whole, and of the performance of the pharmaceutical industry in the 1990s, when it surpassed that of all other major industrial sectors in India. In a phase where most industries were devising strategies to meet the challenges posed by the opening up of the Indian economy, the pharmaceutical industry was in a league of its own. Since the 1970s, government policy initiatives were aimed at increasing the production of bulk drugs in India from as basic a stage as possible. This objective had been largely achieved by the year 2000. Presently, India is self-sufficient in up to 70 per cent of bulk drugs and almost all formulations.

The proactive government policies and the global developments in the pharmaceutical sector helped change the mindset of Indian drug manufacturers. Moreover, the contribution of industry visionaries[33] also greatly helped the development of the pharmaceutical sector.

[32] See for more details UNCTAD (1996).

[33] Persons such as Dr. Parvinder Singh of Ranbaxy and Dr. Anji Reddy of Reddy's Laboratories have been path breakers for the Indian pharmaceutical industry. When most Indian companies were content with production based on reverse engineering, Dr. Singh and Dr. Reddy had the foresight to recognize that the future of the industry lay in greater emphasis on R&D. They realized the necessity for untying this industry from the protectionist regime that had condemned it to low levels of competitiveness.

A new pharmaceutical policy announced in February 2000 aims at preparing the industry for the post 2005 period, when a new patent regime would come into force in the country. The new policy seeks to strengthen indigenous research, calls for better quality assurance, aims to ensure abundant availability of essential drugs and seeks to create a framework for the drug industry to promote new investment and encourage the development of new technologies.

The following are the key changes introduced in the new policy:

a) Industrial licensing for all bulk drugs, their intermediates and formulations is abolished except in the case of bulk drugs produced by the use of recombinant DNA technology, bulk drugs requiring *in-vivo* use of nucleic acids as the active principles, and specific cell-/tissue- targeted formulations.
b) Foreign investment of up to 100 per cent is permitted through the automatic route except for those items requiring industrial licensing.
c) Automatic approval of foreign technology agreements is given except for the drugs requiring industrial licensing.
d) The Pharmaceutical Research and Development Support Fund (PRDSF) is established.
e) The scope of price control is limited to only two categories of drugs: (i) those that have a turnover of a value of more than US $ 5 million and a market share greater than 50 per cent, and (ii) those that have a turnover of US $ 2 to 5 million and a market share greater than 90 per cent. This means, with respect to turnover, that 17 per cent of the total bulk drug market will be under price control, down from 38-40 per cent earlier.

The policy reflects the Indian Government's intentions to reorient this sector, enabling it to meet the challenges and harness the opportunities arising from the liberalization of the economy and the impending advent of the product patent regime.

In the medium term, the growth prospects for Indian firms are very encouraging. With a number of important drugs going off patent in the next decade, there will be enough room for the Indian pharmaceutical industry to expand. In comparison, long-term prospects are uncertain; they depend on the capacity of the Indian pharmaceutical industry to direct resources into R&D and discover and develop new molecular entities, and on how fast the industry can introduce molecular biology into its research programme.

The strategy adopted by the leading firms, such as Ranbaxy Laboratories, offers some hope for the industry. Particularly significant from the long-term point of view has been the growing presence of this firm in the larger markets, a presence built on the technological strength of the firm that was initially developed through joint ventures. Over the years, the joint ventures have given way to strategic alliances with some of the leading firms in the global market, which holds promise for the future of the industry.

REFERENCES

Ballance R, Pogany J and Forstner H (1992). *The World's Pharmaceutical Industries: An International Comparative Study*, Aldershot, Edward Elgar.

Centre for Monitoring Indian Economy (CMIE): < http://www.cmie.com >

The Credit Rating Information Services (CRISIL). *CRISIL Sector View: Pharmaceuticals*. Mumbai, CRISIL (2000): <http://www.crisil.com>

EXIM Bank (1991) *Pharmaceuticals: A Sector Study*. Mumbai, EXIM Bank: <http://www.eximbankindia.com>

Government of India (GOI), Ministry of Chemicals and Fertilizers, Department of Chemicals and Petrochemicals (various years). *Annual Report*. New Delhi: <http://chemicals.nic.in>

Government of India, Ministry of Chemicals and Fertilizers, Department of Chemicals and Petrochemicals (2000). Transforming India into a knowledge power. Report of the Pharmaceutical Research and Development Committee. New Delhi: <http://chemicals.nic.in>

Government of India, Ministry of Science and Technology: <http://mst.nic.in>. Department of Science and Technology (various years). *Research and Development in Industry*. New Delhi: <http://dst.gov.in>

Grabowski H and Vernon J (1986). Longer patents for lower imitation barriers: the 1984 Drug Act. *American Economic Review*, 76 (2): 195-198, May.

Henderson R, Orsenigo L and Pisano GP (1999). The pharmaceutical industry and the revolution in molecular biology: interaction among scientific, institutional, and organizational change. In: Mowery DC and Nelson RR (eds.), *Sources of Industrial Leadership: Studies of Seven Industries*, Cambridge, Cambridge University Press: 267-311.

Indian Credit Rating Agency (ICRA) (1999). *The Indian Pharmaceutical Industry*, ICRA, New Delhi: <http:// www.icraindia.com>

Indian Drugs Manufacturers Association (IDMA) (1992). *Intellectual Property Rights and Patent Protection*. Bombay, Indian Drugs Manufacturers Association.

INFAC India Group - International Property Development Company - (1998). *Pharmaceuticals*, New Delhi, CRISIL: <http://www.infacindiagroup.com>

Jayaram G, Venugopal K and Bhagat R (2000). *A Prognosis for the Indian Pharmaceutical Industry: Significant Change and Substantial Opportunity*. Mumbai, The Boston Consulting Group-India.

Keayla BK (1997). *TRIPS Agreement on Patent Laws: Impact on Pharmaceuticals and Health for All*. New Delhi, Centre for Study of Global Trading System and Development.

Lanjouw JO (1998). *The Introduction of Pharmaceutical Product Patents in India: Heartless Exploitation of the Poor and Suffering?* Working Paper No. 6366, National Bureau of Economic Research, Cambridge, MA.

McNeil Jr D (2000). Selling cheap "generic" drugs: India's copycats irk industry. *New York Times*, December 1.

Mehrotra NN (1989). Patents Act and technological self-reliance: the indian pharmaceutical industry. *Economic and Political Weekly*, 24 (19): 1060-1064, May 13.

Narsalay R (2000). *Pharmaceuticals*. Paper presented at the Seminar on Cross-border M&As and Sustained Competitiveness in Asia: Trends, Impacts and Policy Implications, Bangkok, March 9-10.

Organization of Pharmaceutical Producers of India (OPPI): <www.indiaoppi.com>

Rao C Niranjan (forthcoming). Patents and technological progress in developing countries: A case study of India. Ph.D. thesis, Jawaharlal Nehru University, New Delhi, India.

Reserve Bank of India (RBI) (1995). Financial performance of private corporate business sector, 1994-95. *Reserve Bank of India Bulletin*, 49 (7), July.

Redwood H (1999). *New Horizons in India: The Consequences of Pharmaceutical Patent Protection*. Felixtowe, Oldwicks Press.

Tancer R and Josyla S (1999). *Investing in the Indian Pharmaceutical Industry*. Thunderbird - The American Graduate School of International Management. - Glendale, Arizona, US: <http://www.t-bird.edu>

Technology Development Board (TDB): <http://www.nic.in/tdb>

United Nations Conference on Trade and Development (UNCTAD) (1996), *The TRIPS Agreement and Developing Countries* (Geneva and New York: United Nations) United Nations publications, Sales No.E.96.II.D.10

ANNEX

Table I. Approvals for abbreviated new drug applications obtained by Ranbaxy Laboratories in the United States

Appl No	Active Ingredient	Dosage Form Route	Strength
074975	ACYCLOVIR	Capsule; Oral	200MG
074980	ACYCLOVIR	Tablet; Oral	400MG
074980	ACYCLOVIR	Tablet; Oral	800MG
065016	AMOXICILLIN	Capsule; Oral	250MG
065016	AMOXICILLIN	Capsule; Oral	500MG
065021	AMOXICILLIN	Tablet, Chewable; Oral	125MG
065060	AMOXICILLIN	Tablet, Chewable; Oral	200MG
065021	AMOXICILLIN	Tablet, Chewable; Oral	250MG
065060	AMOXICILLIN	Tablet, Chewable; Oral	400MG
065059	AMOXICILLIN	Tablet; Oral	500MG
065059	AMOXICILLIN	Tablet; Oral	875MG
064156	CEFACLOR	Capsule; Oral	EQ 250MG BASE
064156	CEFACLOR	Capsule; Oral	EQ 500MG BASE
064166	CEFACLOR	Powder For Reconstitution; Oral	EQ 125MG BASE/5ML
064165	CEFACLOR	Powder For Reconstitution; Oral	EQ 187MG BASE/5ML
064164	CEFACLOR	Powder For Reconstitution; Oral	EQ 250MG BASE/5ML
064155	CEFACLOR	Powder For Reconstitution; Oral	EQ 375MG BASE/5ML
065018	CEFADROXIL/CEFADROXIL HEMIHYDRATE	Tablet; Oral	EQ 1GM BASE
065007	CEPHALEXIN	Capsule; Oral	EQ 250MG BASE
065007	CEPHALEXIN	Capsule; Oral	EQ 500MG BASE
065053	DOXYCYCLINE	Capsule; Oral	EQ 100MG BASE
065053	DOXYCYCLINE	Capsule; Oral	EQ 50MG BASE
075556	ENALAPRIL MALEATE	Tablet; Oral	10MG
075556	ENALAPRIL MALEATE	Tablet; Oral	2.5MG
075556	ENALAPRIL MALEATE	Tablet; Oral	20MG
075556	ENALAPRIL MALEATE	Tablet; Oral	5MG
075226	ETODOLAC	Tablet; Oral	400MG
075226	ETODOLAC	Tablet; Oral	500MG
065062	MINOCYCLINE HYDROCHLORIDE	Capsule; Oral	EQ 100MG BASE
065062	MINOCYCLINE HYDROCHLORIDE	Capsule; Oral	EQ 50MG BASE
065062	MINOCYCLINE HYDROCHLORIDE	Capsule; Oral	EQ 75MG BASE
075523	NALOXONE HYDROCHLORIDE; PENTAZOCINE HYDROCHLORIDE	Tablet; Oral	EQ 0.5MG BASE; EQ 50MG BASE
075439	RANITIDINE HYDROCHLORIDE	Tablet; Oral	EQ 150MG BASE
075439	RANITIDINE HYDROCHLORIDE	Tablet; Oral	EQ 300MG BASE
075000	RANITIDINE HYDROCHLORIDE	Tablet; Oral	EQ 150MG BASE
075000	RANITIDINE HYDROCHLORIDE	Tablet; Oral	EQ 300MG BASE

Source: US, Federal Drug Agency Orange Book <http://www.fda.gov>

Table II. Patent applications made in India by Ranbaxy Laboratories

Date of filing	Gazette Notification	Title
July 30, 1996	March 15, 1997	A novel process for manufacturing a key intermediate of simvastatin
June 13, 1996	March 15, 1997	A novel process for the preparation of 8-chloro-6-(2-fluoro-phenyl)-1-methyl-4h-imidazo (1 5a) (1 4) benzodiazepine (midazolam)
April 9, 1997	Dec. 5, 1998	A novel process for the preparation of cefpodoxime acid
March 4, 1999	June 12, 1999	A novel process for the preparation of cephem compounds
November 13, 1997	Jan. 2, 1999	A process for the synthesis of 1-(4-arylpiperazine-1-yl)-(i)-(2 5-dixopipedidin-1-y1) alkanes as a adrenoreceptor blockers useful for hypertension and benign prostatic hyperplasia (bph)
November 13, 1997	Jan. 2, 1999	A process for the synthesis of 1-(4-arylpiperazine-1-yl)-(i)-(2 6-dixopipedidin-1-y1) alkanes as a adrenoreceptor blockers useful for hypertension and benign prostatic hyperplasia (bph)
May 23, 1997	Dec. 5, 1998	A process for the preparation of a stable oral pharmaceutical composition
September 14, 1998	Feb. 27, 1999	A process for the preparation of a controlled drug delivery system containing pseudoephedrine and a long acting antihistamine
March 19, 1999	June 12, 1999	A process for the preparation of a novel coating composition
September 14, 1998	Feb. 27, 1999	A process for the preparation of a once-a- day pharmacokinetic profile of ciprofloxacin
Dec. 29, 1997	Jan. 2, 1999	A process for the preparation of a stable oral pharmaceutical composition containing a substituted pyridysulfinyl benzimidazole
May 13, 1997	Dec. 5, 1998	A process for the preparation of an oral pharmaceutical composition containing quinolone antibacterial agents.
September 29, 1997	Jan. 2, 1999	A process for the preparation of cefuroxime axetil in an amorphous form
June 6, 1997	Dec. 5, 1998	A process for the preparation of ranitidine capsules
October 22, 1998	March 20, 1999	A process for the synthesis of derivatives of monosaccharides as novel cell adhesion inhibitors
Jan. 15, 1999	June 5, 1999	A process for the synthesis of derivatives of monosaccharides as novel cell adhesion inhibitors
Jan. 25, 1999	June 12, 1999	An improved process for the preparation of cephem sulphoxides
October 28, 1997	Jan. 2, 1999	An improved process for the preparation of statins from their corresponding acids
October 28, 1997	Jan. 2, 1999	An improved process for the preparation of statins from their corresponding acids
May 2, 1997	Dec. 5, 1998	An improved process for the preparation of z-phenylacetamido desacetoxycephalosporanic acid

Table II (continued)

Jan. 25, 1999	June 12, 1999	Derivativers of monosaccharides as novel cell adhesion inhibitors
Dec. 4, 1998	March 27, 1999	I- (4arypiperazin-1-y1) -a-(n (a w dicorboximididoi-alkanel useful as uro-selective a adrenocept or blockers
April 25, 1997	Dec. 5, 1998	Improved process for the preparation of lovastatin
June 5, 1997	Dec. 5, 1998	Improved process for the preparation of mevinolinic acid or its salt
July 31, 1998	Feb. 20, 1999	Process for preparing a highly pure, predominantly amorphous form of cefuroxime axetil
March 18, 1996	Jan. 18, 1997	Process for producing cephalosporin antibiotics
May 6, 1997	Dec. 5, 1998	Process for the manufacture of ranitidine hydrochloride form i
March 19, 1999	June 12, 1999	Process for the preparation of a bioavailable oral dosage form of cefuroxime axetil
November 13, 1995	July 27, 1996	Process for the preparation of a pharmaceutical composition in the form of a layered tablet containing two active ingredients with different release profiles.
Jan. 12, 1998	Jan. 9, 1999	Process for the preparation of cephalexin hydrochloride monohydrate in an amorphous form
March 30, 1998	Feb. 6, 1999	Process for the preparation of ceruroxime from ceruroxime axetil
Jan. 21, 1997	Dec. 5, 1998	Process for the preparation of controlled release drug formulation containing diltiazem
June 1, 1998	Feb. 20, 1999	Process for the preparation of crystalline (z)-2-(2-tert butoxycarbonylprop-2-oxyimino)-2-association with n, n-dimethylformamide
Jan. 10, 1996	Jan. 4, 1997	Process for the preparation of modified release matrix formulation of cefaclor/cephalexin
November 22, 1995	July 27, 1996	Process for the preparation of novel pharmaceutical composition in effervescent form.
September 19, 1997	Jan. 2, 1999	Process for the preparation of oral controlled drug delivery system containing gas generating components
November 13, 1996	July 27, 1996	Process for the preparation of pharmaceutical tablet comprising rabutudube as core coated with a polymeric film.
Jan. 21, 1997	Dec. 5, 1998	Process for the preparation of simvastatin from lovastatin or mevinolinic acid
Dec. 4, 1998	March 27, 1999	Process for the preparation of stafies solid pharmaceutical compositions containing enalapril maleate.
May 8, 1998	Feb. 6, 1999	Process for the preparation cefpodoxime acid

Source: Technology Information, Forecasting and Assessment Council (TIFAC), Ekaswa-Database on Patent Applications.

Table III. Patents granted to Ranbaxy Laboratories in the United States

Date of Filing	Date of Issue	Patent Number	Title
Oct. 28, 1988	Feb. 20, 1990	US4902447	Process for the production of alpha-6-deoxytetracyclines and hydrogenation catalyst useful therein
Oct. 28, 1988	Nov. 27, 1990	US4973719	Process for the production of alpha-6-deoxytetracyclines
Feb. 9, 1990	Feb. 5, 1991	US4990636	Process for the production of alpha-6-deoxytetracyclines and hydrogenation catalyst
April 13, 1989	March 5, 1991	US4997959	Process for the production of alpha-6-deoxytetracyclines
March 7, 1990	Dec. 3, 1991	US5070195	Ring-opening process for preparation of 2-chlorosulfinyl azetidinones
May 6, 1991	Oct. 27, 1992	US5159071	Process for the manufacture of 7-amino-3-exomethylene-3-cepham-4-carboxylic acid
Feb. 18, 1993	April 25, 1995	US5347000	Process for the preparation of 2-chlorosulfinylazetidinone
April 21, 1993	Sept. 13, 1994	US5410044	Process for preparing Z and E-rotamers of 3-hydroxy cephem derivatives
June 24, 1994	April 15, 1997	US5536830	Process for P-nitrobenzyl ester cleavage in cephalosporin
June 24, 1994	Dec. 9, 1997	US5621120	Process for the manufacture of form 1 ranitidine hydrochloride
May 30, 1995	July 16, 1996	US5696275	Process for the manufacture of pharmaceutical grade ranitidine base
May 1, 1996	Feb. 9, 1999	US5728401	Effervescent ranitidine formulations
Oct. 9, 1996	May 26, 1998	US5756729	Process for the manufacture of 8-chloro-6 (2-fluorophenyl)-1 methyl-4H-imidazo [1,5a] [1,4] benzodiazepine (midazolam)
March 13, 1997	June 9, 1998	US5763646	Process for manufacturing simvastatin from lovastatin or mevinolinic acid
March 13, 1997	June 9, 1998	US5763653	Key intermediates in the manufacture of simvastatin
April 16, 1997	March 17,1998	US5792874	Process for the manufacture of 8-chloro-6-(2-flourophenyl)-1-methyl-4H-imidazo[1,5A][1,4] benzodiazepine
Aug. 26, 1997	Aug. 11, 1998	US5869649	Process for producing cephalosporin antibiotics
Dec. 17, 1997	Sept. 7, 1999	US5917058	Process of lactonization in the preparation of statins
April 6, 1998	Aug. 17, 1999	US5939564	Process of lactonization in the preparation of statins
April 22, 1998	June 29, 1999	US5948440	Modified release matrix formulation of cefaclor and cephalexin
May 9, 2000	June 17, 1998	US6060599	Process for the preparation of cefuroxime axetil in an amorphous form
June 13, 2000	Dec. 4, 1997	US6074669	Controlled drug delivery system for diltiazem
July 4, 2000	July 21, 1998	US6083950	1-(4-arylpiperazin-1-yl)-.omega.-[n-(alpha,omega.-dicarboximido)]-alka nes useful as uro-selective .alpha.1-adrenoceptor blockers
July 18, 2000	Dec. 2, 1998	US6090809	1-(4-arylpiperazin-1-yl)-.omega.-[n-(.alpha...omega.-dicarboximido)]-alkanes useful as uro-selective .alpha.1 -adrenoceptor blockers

Source: Delphion Intellectual Property Network: <http://www.delphion.com>

Table IV. Applications made under the European Patent Convention (EPC) by Ranbaxy Laboratories

Date of Filing	Date of Issue	Patent Number	Title
Oct. 27, 1989	April 3, 1991	EP366565A3	Process for the production of alpha-6-deoxytetracyclines and hydrogenationcatalyst useful therein
April 3, 1989	Oct. 16, 1991	EP391005B1	Process for the production of alpha-6-deoxytetracyclines
May 11, 1995	Aug. 19, 1998	EP694540B1	Process for the manufacture of form 1 ranitidine hydrochloride
May 11, 1995	July 1, 1998	EP697411B1	Process for the manufacture of pharmaceutical grade ranitidine base
March 13,1996	Dec. 2, 1998	EP745603B1	Process for p-nitrobenzyl ester cleavage in cephalosporin
March 13,1997	Nov. 12, 1997	EP806424A1	Process for producing cephalosporin antibiotics
June 13, 1997	April 15, 1998	EP835874A2	A process for the manufacture of 8-chloro-6-(2-fluorophenyl)-1-methyl-4h-imidazo 1,5a)(1,4) benzodiazepine (midazolam)
June 13, 1997	June 10, 1998	EP835874A3	A process for the manufacture of 8-chloro-6-(2-fluorophenyl)-1-methyl-4h-imidazo (1,5a)(1,4) benzodiazepine (midazolam)
April 29, 1997	Sept. 16, 1998	EP864560A1	Key intermediates in the manufacture of sinvastatin
July 4, 1997	Sept. 16, 1998	EP864569A1	Process for manufacturing simvastatin from lovastatin or mevinolinic acid
Feb. 28, 1997	March 24, 1999	EP902681A1	Inhibition of selectin binding (See WO09731625)
March 30, 1998	June 23, 1999	EP923934A1	Modified release matrix formulation of cefaclor and cephalexin
Dec. 7, 1998	Nov. 10, 1999	EP955297A1	An improved process of lactonization in the preparation of statins
Dec. 7, 1998	Dec. 1, 1999	EP960620A1	A stable oral pharmaceutical composition containing a substituted pyridylsulfinyl

Source: Delphion Intellectual Property Network: <http://www.delphion.com>

Table V. Applications made under the Patent Cooperation Treaty (PCT) by Ranbaxy Laboratories

Date of Filing	Date of Issue	Patent Number	Title
July 16, 1999	Feb. 3, 2000	WO005205A1	Arylpiperazine derivatives useful as uroselective alpha1-adrenoceptor blockers
Jan. 26, 1999	Feb. 3, 2000	WO005206A1	Arylpiperazine derivatives useful as uro-selective alpha-1-adrenoceptor blockers
Jan. 10, 2000	July 20, 2000	WO042053A1	Derivatives of monosaccharides as cell adhesion inhibitors
Jan. 10, 2000	July 20, 2000	WO042054A1	2,3-o-isopropylidene derivatives of monosaccharides as cell adhesion inhibitors
March 8, 2000	Sept. 14, 2000	WO053609A1	Process for the preparation of cefuroxime
Oct. 26, 1999	Sept. 28, 2000	WO056266A2	Taste masking coating compositions
March 17, 2000	Sept. 28, 2000	WO056286A1	Process for the preparation of a bioavailable oral dosage form of cefuroxime axetil
May 3, 2000	Nov. 9, 2000	WO066116A2	Stable solid pharmaceutical compositions containing enalapril maleate
May 5, 2000	Nov. 16, 2000	WO068234A2	Process for the preparation of cefpodoxime acid
June 7, 2000	Dec. 21, 2000	WO076479A1	Taste masked compositions
June 7, 2000	Dec. 21, 2000	WO077006A1	Process for the preparation of 1,8-disubstituted-1, 3, 4, 9-tetrahydropyrano (3,4-b)-indole-1-acetic acid esters in a hydroxylic solvent
June 7, 2000	Dec. 21, 2000	WO077017A1	Novel amorphous form of clarithromycin
Feb. 28, 1997	Sept. 4, 1997	WO9731625A1	Inhibition of selectin binding
Jan. 26, 1999	Dec. 2, 1999	WO9961022A1	A stable oral pharmaceutical composition containing a substituted pyridylsulfinyl benzimidazole
Jan. 27, 1999	Dec. 23, 1999	WO9965919A1	Process for the preparation of cefuroxime axetil in an amorphous form

Source: Delphion Intellectual Property Network: <http://www.delphion.com>