Chapter 4

THE INDIAN PHARMACEUTICAL INDUSTRY: An Overview

4.1 INTRODUCTION

This chapter presents an overview of the Indian pharmaceutical industry as it has developed over the last century. Our objective is to identify the different political economy forces that have shaped the structure of production, R&D and technology generation in the industry over time. This chapter will provide a bird’s eye view of the pharmaceutical industry as it stands now. Juxtaposing this industry overview against the theoretical and empirical literature on technology generation and diffusion discussed in chapters 2 and 3, we shall be able to raise the fundamental research questions of our study.

The inception of this industry in India can be traced back to the late 19th century but it has experienced phenomenal growth, post independence. The size of the pharmaceutical industry increased 2000-folds from Rs.10 crores in 1947 to Rs.20,000 crores in 2000. The development path of this industry not only reflects this quantitative expansion, but there also have been major structural changes in the quality of production and technology, especially in the last couple of decades. The industry, over the years, has been characterised by changing market-forms and ownership structure. These changes have been determined by a host of factors, exogenous (e.g. policy changes) and endogenous (e.g. technology and R&D).

In order to present an overview of the developmental path of the Indian pharmaceutical industry, we delineate four phases of its growth. In phase I, the pre-independence period (pre-1947), the evolution and growth of this industry was shaped primarily by the medicinal needs of the British Army working in tropical regions. In
phase II, the first two decades after independence (1947-1969), India’s overall development strategy of import substituting industrialisation was the key driving force behind the growth and expansion of the pharmaceutical industry. Phase III, spanning over 1970-1986, witnessed several important policy changes with the explicit objective of technological self-reliance. These were the Patent Act of 1970, Drug Price Control Orders (DPCO) 1970, 1979, Foreign Exchange Regulation Act (FERA) 1973, New Drug Policy 1978. Phase IV, 1987 onwards, begins with piecemeal attempts of economic liberalisation and globalisation which culminated in the formal launching of India’s comprehensive economic reforms programme in 1991. In the decade of the 1990s, the pharmaceutical industry has been undergoing major structural adjustments to cope with the newly emerging global orders.

Accordingly this chapter is divided into six sections. After this introduction, sections 4.2 to 4.5 will discuss the development of the pharmaceutical industry in India in its phases I to IV respectively. The final section (4.6) will conclude and raise the central research questions of our study.

4.2 PHASE I (Pre-1947)

The pharmaceutical industry was established in India primarily to cater to the requirements of the British Army suffering from tropical diseases. Accordingly, almost all the early pharmaceutical units in India engaged in production as well as research, focused exclusively on drugs/vaccines for infective tropical diseases like Malaria, Kalazar etc. Most of the pre-independence pharmaceutical companies were owned by the British, perhaps with the only exception of Bengal Chemical and Pharmaceutical Works established in 1901 by P.C.Ray.
Although the production of pharmaceuticals started in India since the late 19th century, India continued to remain import dependent and "an exclusive preserve for unloading the products of the British drug industry" till as late as 1939.\textsuperscript{1} In most cases, the British and other European manufacturers used to market their products either through their own Indian branches or through various trading companies.\textsuperscript{2}

The World War II gave a boost to the Indian pharmaceutical industry with respect to its size as well as product range. Besides vaccines for infective diseases, the industry started producing various other drugs including alkaloids, chemotherapeutic drugs and calcium preparations. The number of drug companies also went up. While in 1939 Indian production could meet only 13% of total drug requirements of the country, in 1943 the corresponding share rose to around 70%. The country became self-sufficient in the production of sera and vaccines.

Meanwhile, a number of native companies producing ayurvedic formulations also entered the Indian pharmaceutical market with proprietary preparations of tonics, cough syrups etc.

4.3 PHASE II (1947-1969)

This phase begins with India's independence and coincides with the period of therapeutic revolution\textsuperscript{3} in the global pharmaceutical industry. The two broad features of the therapeutic revolution have been the use of synthetic and semi-synthetic chemicals in the drug research and a shift in focus from preventive to curative medicines. With India's independence, the virtual monopoly of the British companies in India also came to a halt.

\textsuperscript{1} See Rangarao (1975).
\textsuperscript{2} To reduce dependence on imported drugs, several government medical stores were set up in India to produce pharmaceutical preparation as per the British pharmacopoeial standards at substantially lower costs.
Competition from other foreign companies increased. As a result of increased foreign competition in an era of therapeutic revolution, many Indian-owned private firms found it increasingly difficult to survive and consequently closed down. The industry became largely dominated by MNCs (wholly or partly owned subsidiaries), British as well as others. In fact, according to a Reserve Bank of India (RBI) survey for the period of 1964-70, the overall domination of the foreign firms was the highest in the pharmaceutical sector. 38 out of 197 companies in India with more than 50% foreign equity, and 8 of the 17 wholly owned foreign subsidiaries in India belonged to the pharmaceutical sector. The domination of MNCs in this sector was fostered by the existing patent regime with the Patent Act of 1911. This gave the MNCs protection against reverse engineering activities by domestic firms. As a result the latter could not flourish and the MNCs continued to dominate the Indian pharmaceutical market.

After independence India adopted an inward looking development strategy of import substituting industrialisation based on centralised planning. To this end, the newly independent government formulated several trade and industrial policies during this phase which determined the development of the manufacturing sector in general and the pharmaceutical industry in particular. The Industrial Policy Resolution of 1956 placed the pharmaceutical industry in schedule-B where both private and the public sector companies were allowed to operate.

The first public sector drug manufacturer, the Hindustan Antibiotic Limited, was established in 1954. Another public sector company Hindustan Organic Chemicals (HOC) also started operation about the same time. In 1958 Government of India entered into an agreement with the erstwhile Union of Soviet Socialist Republic (USSR) for the

3 During 1940-55, the world witnessed a remarkably high rate of discoveries in pharmaceuticals and the introduction of several new drugs like sulfonamides, penicillin, streptomycin, cortisteroids etc. primarily by US and Swiss drug companies.
The manufacture of antibiotic, synthetic drugs and surgical equipment with a Ruble 80 million loan. Accordingly the Indian Drugs and Pharmaceuticals Limited (IDPL) was started in 1962 with Soviet technical know-how. The establishment of these public sector units (HOC and IDPL in particular) initiated the process of backward integration of the pharmaceutical industry with the basic chemical industry. The objective was to reduce import dependence on raw materials. It may be noted that unlike many other countries, the establishment of the pharmaceutical industry in India preceded the establishment of basic chemicals industry. As a result, for a long period the pharmaceutical industry remained dependent on imports of chemical bulk drugs. However, reduction of import dependence has not been an easy task for the government. Several import restrictions in the form of tariff and non tariff barriers had to be introduced to curb imports across the board.

However, the pharmaceutical industry was largely dominated by MNCs during this phase. These firms continued to procure their bulk ingredients mostly from the respective parent companies abroad. Thus the industry remained import dependent. Moreover, this form of intra-firm trade led to widespread abuse of transfer pricing as a mode of profit repatriation raising the cost of the final product. Daniel (1986) points out that while the cost of import of Librium from parent bodies of a Swiss MNC was around Rs.5555 per kilo, a Delhi-based domestic firm had to pay only Rs.312 per kilo, when imported from open (international) market. Lanjouw (1999) points out that Theobromine was imported by an MNC subsidiary at Rs.2436/kg when international price in the open market was Rs.1088 per kilogram.

In this phase, the industry also remained heavily dependent on imported technical know-how, again due to the domination of MNCs. A RBI survey of 1968 indicated that

---

4 Chaudhury (1984) cites several instances where domestic firms (both public and private) were forced to stop production of bulk chemicals using reverse-engineered processes.
32 agreements of transfer of technology had taken place. It rose to 60 in the year 1970. The RBI survey 1968 also noted that for a production of Rs.394 billion, the 20 foreign subsidiaries imported raw materials worth Rs.38 million. The following table shows that majority of the technology transfer agreement was done through subsidiaries or companies with foreign participation.

**Table 4.1: Type of Technology Transfer in the Indian Pharmaceutical Industry**

<table>
<thead>
<tr>
<th>Type of Technology Transfer</th>
<th>Foreign subsidiaries</th>
<th>Minority participation</th>
<th>Technical collaboration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patent+Trade mark+KH*</td>
<td>7</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Patent+Trade mark</td>
<td>1</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>Patent+KH</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Trade mark+KH</td>
<td>5</td>
<td>5</td>
<td>0</td>
</tr>
<tr>
<td>Only patent</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Only trade mark</td>
<td>0</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Only KH</td>
<td>0</td>
<td>6</td>
<td>0</td>
</tr>
</tbody>
</table>

Source: RBI survey of foreign collaboration in the Indian industry, as quoted in Rangarao (1975), pp28. *KH=know-how

Thus 29 out of 32 agreements were through some kind of foreign participation. Trade mark was sold in 25 cases out of 32.

The in-house research and development was insignificant. According to Rahman et al (1970), the Indian pharmaceutical sector invested around 1.1% of its sales turnover on R&D in contrast with a global average of around 10%. Since the MNCs had ready access to technology and raw materials from their parent bodies, there was little inducement to undertake research activities in their Indian operations, or for that matter in any other LDCs. They also showed reluctance to develop production facilities for bulk drug.

---

5 See Lall (1980).
It was the public sector firms, which initiated some research activities in their own facilities. The Hindustan Antibiotic Limited consistently invested around 2% of its STO in developing fermentation technology for production of antibiotics. Two new antifungal antibiotics, namely Hamycin and Aureofungin, were developed.⁶

Control and rationalisation of drug prices constituted another important policy dimension. The origin of such price control initiatives can be traced back to the Kafeuver Committee Report of 1962, which revealed that drug prices in India were among the highest in the world. The control of drug prices under *Defence of India Act* was made effective from April 1, 1963. In 1966 a system of *selective increase* in prices was introduced under the *Essential Commodities Act of 1955*. A mark-up of upto 150% was allowed subject to approval of the government.⁷ The law was somewhat modified in the year 1968 and exempted drugs sold under pharmacopoeia names from this restrictions. New drugs, evolving out of original research were also excluded from the controlled list. In such cases manufacturer could fix prices after submitting necessary data to the government and it was open to the government to revise prices. Government received 521 applications for upward revisions of prices. The percentage increase allowed by the government varied from product to product.

**Table 4.2: Cases of Price revision**

<table>
<thead>
<tr>
<th>Percentage increase</th>
<th>Number of cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>Less than 10</td>
<td>124</td>
</tr>
<tr>
<td>10-19</td>
<td>205</td>
</tr>
<tr>
<td>20-29</td>
<td>107</td>
</tr>
<tr>
<td>30-39</td>
<td>41</td>
</tr>
<tr>
<td>40-49</td>
<td>44</td>
</tr>
</tbody>
</table>

*Source: Rangrao 1975, pp 18*

It is interesting to note that very few MNCs applied for upward price revision.

---

⁶ This may be regarded as an example of some sort of basic research in Indian industry during this period.

⁷ In the same year 18 essential drugs were identified and referred to the Tariff Commission for appropriate cost structure.
In sum, this period was characterised by the government’s initiative to create indigenous capacity in pharmaceutical production and R&D and to control and rationalise drug prices. These policy initiatives were at best partially successful. With the support of the patent regime, MNCs continued to play the predominant role with minimal attention towards either R&D or production of bulk drugs.

4.4 PHASE III (1970-1986)

1970 marked the beginning of new era in terms of a comprehensive attempt on the part of the government to attain self-reliance in the pharmaceutical sector, both in production and in technology. In this section, we first elaborate the policy initiatives of the government affecting the pharmaceutical industry. Next we discuss the performance of the industry during this phase in this policy environment.

The policy initiatives in this phase can be categorised into the following three groups:

(i) concerted effort to rationalise drug prices through various drug price control acts (DPCO) and to offer price incentives to promote the production of bulk drugs for self sufficiency,

(ii) regulation of foreign capital and foreign ownership with the introduction of Foreign Exchange Regulation Act (FERA), 1973 to reduce the domination of MNCs,

(iii) introduction of a weaker patent regime (Patent Act of 1970) to promote domestic technological activities with the objective of creating “know-why” capabilities through reverse engineering, and

Each of these acts and orders (DPCO, Patent Act, and FERA, MRTP) are discussed below.

**4.4.1 Drug Price Control Order (DPCO), 1970 & 1979**

*DPCO 1970:*

This is regarded as the first concerted rational effort to check the increasing spiral of drug prices in India. However, only 22 bulk drugs were subjected to such control. The order provided for two schemes of pricing: the general scheme and the alternative scheme. Under the general scheme, the retail price of a formulation was to be worked out after considering material cost, packaging cost, conversion cost and mark-up. The alternative scheme allowed some flexibility in price fixing mechanism. According to this scheme, price fixed by the formulator should not fetch an overall gross profit (before tax) of more than 15% of the sales turnover. It is interesting to note that 63 out of the 76 formulation units present at that time opted for the alternative scheme instead of the general scheme.

Under the general scheme, three categories of drugs were demarcated. Category I included drugs necessary for various national health programmes\(^8\), which were allowed an MAPE (i.e. *Maximum Allowable Post-manufacturing Expenses*) of 75%. Category II included mostly analgesic, antibiotic and cardiovascular drugs and were allowed a mark up of 150%. Category III covered new drugs and all other formulations including formulations made by the small-scale sector and were kept out of price control.

According to Rangarao (1975), some downward price revision took place after DPCO 1970 ranging from around 83% for antibiotics to 35% for antiseptics.

To summarise, DPCO made an effort to check the price spiral of the essential drugs. The degree of the control was however lucid, and the scope of ‘alternative pricing

\(^8\) For instance, anti-leprosy drugs, anti-tuberculosis drugs etc.
rule' made the situation even more volatile. Due to the presence of this rule government could not address the problem of transfer pricing by MNCs which enabled them to inflate the cost of raw material imported from their parent firms and continue to charge high prices under the alternative scheme.

**DPCO 1979:**

In its 1979 revised version, the DPCO expanded the coverage stipulating ceiling prices for controlled categories of bulk drugs and their formulation. In fixing the prices, the Government continued to advocate profitability ceiling. In case of bulk drugs, this was done by imposing a limit on the company's return on networth (14%) or capital employed (22%). In case of formulations, the retail prices of controlled products were decided by applying the concept of MAPE (Maximum Allowable Post-manufacturing Expenses) as before, which is akin to a mark-up on ex-factory costs provided to cover all selling and distribution costs including trade margins. DPCO 1979 put 370 drugs under price control. The government also modified the drug categories and their permissible MAPE or mark-ups. The mark-up for Category I drugs was reduced to 40% from the earlier 75%. For Category II drugs MAPE was reduced to 55%. Category III drugs, hitherto out of control, were also made subject to price control with a mark-up of 100%. The Government also introduced a Category IV with 60% MAPE to include some drugs from Category III (such as Vitamins etc.) to reduce the margins in these products. With DPCO 1979 around 80% of the Indian pharmaceutical industry (in value terms) was brought under price regulations.

**4.4.2 The Patent Act, 1970**

Among developing countries, India was the first to grant patent rights way back in 1885 when it enacted the protection of inventions act along the lines of the British Patent Law of 1852. In 1872, The Patents and Designs Protection Act came into force globally.
This act was modified 16 years later into the Inventions and Designs Act. The Indian patents and Design act was passed in 1911. On August 15, 1947, with the birth of free India, the Indian Patents and Designs Act came into force. However, the first independent attempt to formulate a patent bill started only in the late 1960s. The Patent Bill was first introduced in the Parliament in 1967 but the Patent Act 1970 came into force only in 1972.

The Patent Act, 1911 had several weaknesses and limitations in so far as the promotion and acquisition of domestic technological capability is concerned. It provided product as well as process patent protection up to a period of 10 years. This limit could also be extended for a maximum of another 6 years if it was established that the innovator could not fetch satisfactory profits during the first 10 years. Moreover, according to this Act, the process specifications could be mentioned in sufficiently vague terms to deter any imitator to obtain any clue for reverse engineering. Although the basic objective of the Act might have been to protect the innovator's interest, it was misused by large MNCs to prevent domestic firms from manufacturing drugs with indigenous processes even when no clear evidence of infringement was found.⁹

It is in this context that the Patent Act, 1970 may be viewed as a radical departure from the earlier Act. The primary objective of the 1970 Act was to facilitate the creation of indigenous technological capability. The pharmaceutical industry was targeted to be a prime beneficiary. The 1970 Patent Act had the following salient features:

- In contrast with the earlier one, it granted only process patent for chemical substances including pharmaceuticals.

---

⁹ See Chaudhuri (1984) for detail about various legal cases between MNC and Indian domestic firms.
• The duration of patent was reduced from 10 (extendable up to 16 years) years to 7 years from the date of filing the patent or 5 years from the date of sealing the patent whichever is lower.

• Only new substances manufactured in India were entitled to patent protection thus excluding imported substances from the domain of intellectual property rights protection.

• The law also provided relief to domestic firms by putting the burden of proof on the plaintiff, in case of infringement of the patent.

In order to prevent the abuse of patents (in the form of sleeping patent) two types of licensing agreements were sought: Compulsory Licensing and Licensing of Right. Any interested producer can apply for Compulsory Licensing after 3 years of the granting the patent if either the innovation is unavailable in the country (sleeping patent), or unavailable at a reasonable price or its production by the patentee has not been able to meet the demand. The License of Right is somewhat automatic after 3 years of the granting of patent. Any interested producer can obtain this license from the patentee on mutually agreed terms and conditions. The objective of this license was to ensure the availability of these substances at reasonable prices either by the patentee or by a third party.

The patent Act of 1970 provided a framework, which encouraged reverse engineering activities, thus creating know-why oriented technological capability. By limiting the duration of patent protection only for a maximum of 7 years it sought to increase competition and thereby check the rise in drug prices. The licensing of right led to the entry of a large number of producers, most of them in the small-scale sector. However, the launching of new drugs by MNCs was perhaps discouraged within such a framework.
Indeed, as reported by the Hathi committee (1975) MNCs in India had transferred old technologies to their Indian subsidiaries often with a lag of 15-20 years. Accordingly, it recommended that all MNCs be ‘taken over’ and the use of foreign brand names be completely banned. Generally, the Hathi Committee (1975) recommendations formed the backbone of the New Drug Policy (1978).

4.4.3 Foreign Exchange Regulation Act (FERA), 1973

FERA was perhaps the first policy initiative that extended discriminatory treatment between Indian firms and multinationals. The section 29 of the FERA (1973) mentions that the permission of RBI is essential for all the non-banking foreign branch companies and companies with foreign equity greater than 40% to carry on, establish, purchase shares of, or, acquire wholly or partly, any undertakings engaged in commercial trading or industrial activities.

Industrial units engaged either in high-priority industries requiring sophisticated technology as identified by the government or in pre-dominantly export activities were, however, given an exemption from the above requirement in terms of allowing up to 74% of foreign share. Since the pharmaceutical industry was identified as high priority, FERA companies having more than 40% foreign share holding in this sector was restricted to high technology bulk and formulation manufacturing. Moreover, these companies had to satisfy two additional criteria, namely (1) 50% of the bulk must be supplied to non-associated formulators, and (2) the share of the value of own bulk drug in total formulation should not exceed 1:5 and thereby restricting the practice of captive consumption.

However, the definition of ‘high technology’ remained sketchy at best. A committee was set up in 1978, which suggested 12 criteria for ‘high technology’.
Accordingly, 97 out of 207 bulk drugs produced by these FERA companies passed these criteria. Interestingly, many domestic private companies (supposedly technologically backward) also could produce those bulk without any foreign collaboration.\(^\text{10}\)

**4.4.4 Monopolies and Restrictive Trade Practices Act, 1969**

India’s industrialisation policy of this period also had the objective of controlling monopoly and industrial concentration. The Monopoly and Restrictive Trade Practices Act 1969, required prior license to enter or expand any line of production for the firms with assets above a threshold limit or a dominant market share (known as the MRTP firms).\(^\text{11}\) The thresholds were fixed in nominal terms as a result of which they became increasingly restrictive with inflation. However, the policy was criticised because of the bureaucratic hassles it involved, which delayed the process of approval by several years. According to Joshi and Little (1994) the policy prevented firms from realising economies of scale, and thereby affected the growth of R&D thrust of the industry. In their opinion, the policy has, in fact, reduced competition rather than increasing it.

**4.4.5 The New Drug Policy (1978)**

The drug policy of 1978 was, in a sense, sequel to the earlier policies of this phase affecting the drug industry. The policy was designed with a three-fold objective:

- self-reliance in technology
- self-sufficiency in drugs
- easy and cheap availability of quality drugs.

The policy abolished brand name for five drugs, namely Analgin, Aspirin, Chloromycine, Ferropsulphate, and Piperozine. In order to promote R&D activities by

---

\(^{10}\) See Daniel (1986) for detail.

\(^{11}\) These MRTP firms were restricted to core sectors like pharmaceuticals. They could enter other sectors only if certain very restrictive export and/or locational clauses were met.
MNCs in their Indian subsidiaries the New Drug Policy'78 stipulated that every MNC with an annual STO of Rs.5 crores is required to have an R&D set up with a capital investment of at least 20% of their net sales. These MNCs should also spend at least 4% of their STO as recurring R&D expenditure. Furthermore, multinational firms were asked to extend their quality testing facilities to small-scale firms on a no-profit-no-loss basis. The policy also demarcated the areas of operation for various ownership groups. It reserved 25 items for the public sector, another 23 for the private sector and around 66 items were kept open to all.

To summarise the policy regime during this phase, all the policies had the common objective of encouraging efforts to acquire domestic technological capability. It was attempted to keep drug prices under control through direct price-intervention and through restricting monopolistic and oligopolistic practices. However, the private sector continued to be the predominant force in this industry, although foreign ownership got somewhat diluted.

4.4.6 Performance of the Industry

Production and Trade

Within the framework of the above policy environment, with its clear thrust on import substitution, self reliance and domestic technological capability in process engineering, the production of bulk drugs received a major boost during this phase as reflected in table 4.3. In terms of annual growth, the bulk drug industry grew at a rate of 21% per annum during 1970-79, and 11% during 1980-87.12

Table 4.3: Production of bulk drug in the 1980s

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Sales Rs Cr</td>
<td>240</td>
<td>289</td>
<td>385</td>
<td>355</td>
<td>375</td>
<td>416</td>
<td>458</td>
<td>550</td>
<td>580</td>
<td>640</td>
</tr>
</tbody>
</table>

Source: Key Statistics, OPPI

The increase in output of bulk drug also resulted in bulk drug exports, which were essentially surplus of production over domestic consumption. In fact, the total pharmaceutical exports registered a phenomenal increase from Rs 46.38 crores in 1980-81 to Rs 664.7 in 1989-90. The share of bulk drug in total pharmaceutical export during the same period increased from 24% in 1980-81 to 53% in 1989-90 after attaining a peak at 61% in 1988-89.\(^\text{13}\)

The formulation industry also had shown impressive growth rate, although in terms of annual rate of growth, its performance was marginally poorer than the bulk drug industry. Its growth rate was 13% and 10% per annum during 1970-79 and 1980-87 period respectively.

**Table 4.4: The production of formulation in the 1980s**

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Sales</td>
<td>1200</td>
<td>1434</td>
<td>1660</td>
<td>1760</td>
<td>1827</td>
<td>1945</td>
<td>2140</td>
<td>2350</td>
<td>3150</td>
<td>3420</td>
</tr>
<tr>
<td>Rs Cr</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The formulation exports continued to grow in value terms, but its share in total export declined from 76% in 1980-81 to 47% in 1989-90. The destination of exports of both bulk as well as formulations were mostly other developing countries, particularly in Africa and Commonwealth of Independent States (CIS) countries.

On the import front, the growth of import of both bulk as well as formulation was moderate. The share of import in total formulation consumption was 7% during 1970-79, and 10% during 1980-87. During the same period the share of imports in total bulk consumption was 5% and 10% respectively.

*Industry's R&D thrust*

There was a marked increase in the research and development expenditure of the industry during this period. Prior to 1970, only about 1% of the industry's STO was spent

---

\(^{13}\) Source: INFAC (1998), vol I, pp.7.
on R&D. In 1986-87, R&D expenditure stood at Rs 50 crores, 2% of the industry’s STO. The increase in R&D expenditure is perhaps a reflection of increased activities on reverse engineering and know-why capability building effort, primarily by the domestic firms.

*Prices and Profitability*

All the policy controls, the DPCOs in particular, were somewhat successful in containing the high profitability trend of the industry. In fact, OPPI report¹⁴ shows that profitability of the industry had declined from 16% of STO in the year 1969-70 to only about 4% in 1986-87.

*Quality of Drugs*

Another striking feature of the industry has been its large multiplicity of formulations. Rangarao (1975) points out that 8,400 formulations were sold by 289 units. This number phenomenally increased during next 10 years. Daniel (1986) gives a comparable figure of 60,000 formulations after 10 years. This had two-fold implications. On one hand, large number of formulations made the drug industry crucially dependent on the marketing practices as it was impossible for any physician to remember and choose a medicine from this long list for his/her prescription. The problem was multiplied by the fly-by-night operators who used to imitate even the package and name of relatively reputed producers. A second, though somewhat related problem was to maintain and check the quality of these drugs. In fact, it was estimated that among these 60,000 formulations available in the market, only 5,000 were useful, and another 25,000 were marginally useful. This puts the share of hazardous and irrational drugs as high as 50% of total available drugs.¹⁵ The problem of quality monitoring by the state was compounded due to the lack of adequate manpower to keep vigilance on such large number of drugs.

¹⁴ See website: www.indiaoppi.com
¹⁵ See Daniel (1986) for details.
Table 4.5: Manpower in Quality Control Department

<table>
<thead>
<tr>
<th>State</th>
<th>Personnel available</th>
<th>Personnel required</th>
</tr>
</thead>
<tbody>
<tr>
<td>Andhra Pradesh</td>
<td>29</td>
<td>151</td>
</tr>
<tr>
<td>Gujarat</td>
<td>30</td>
<td>113</td>
</tr>
<tr>
<td>Karnataka</td>
<td>35</td>
<td>95</td>
</tr>
<tr>
<td>Maharashtra</td>
<td>95</td>
<td>402</td>
</tr>
<tr>
<td>Tamilnadu</td>
<td>53</td>
<td>173</td>
</tr>
<tr>
<td>West Bengal</td>
<td>58</td>
<td>359</td>
</tr>
</tbody>
</table>

Source: Daniel (1986).

Proper quality control was particularly lacking in small scale manufacturing units. The 1970 Patent Act, DPCO, and New Drug Policy (1978) encouraged small manufacturing units, but due to the lack of proper quality control facility and adequate number of technical personnel in these small units, they were incapable of producing and supplying high quality and effective drugs. One should also note that lower drug quality in India was not just a result of the deviation from the prescribed quality norms. The quality norm itself was kept at a low level by the regulatory authority. Test assays were specified in such a way that small producers also could bear the cost of quality testing. As a result there was a marked difference between the quality parameters of Indian drugs with that of drugs produced in the developed world.

4.5 PHASE IV: 1987 Onwards

From late 1980s Indian policy regime changed gears from a path of control and intervention to a more liberalised economic system with greater integration with the world economy. This triggered-off a process of restructuring and adjustment in the entire manufacturing sector, the pharmaceutical sector being no exception. In fact, the New Drug Policy of 1986 and DPCO of 1987 gave a clear indication of increased liberalisation in the drug industry. We discuss the changes in the policy regime at the outset. The policy statements can broadly be classified into two groups. First, there are overall policy
changes affecting the entire manufacturing sector. Second, there are policies specific to
the pharmaceutical sector, in particular.

4.5.1 General Policy Environment

The whole gamut of policy changes during this phase pertain to the following areas:

A. Trade Reforms
B. Exchange Rate Policies
C. Industrial Reforms: Licensing, Public Sector Policy, MRTP.
D. Foreign Investment and Foreign Technology Agreements
E. Patent Policies

The policy changes in all these dimensions reflected a major shift in India's
overall philosophy of industrialisation and development strategy.

India's liberalisation process started with the *trade reforms*. Reduction and
rationalisation in tariff rates and tariff structure, abolition of export and import licenses,
and removal of quantitative restrictions and non-tariff barriers have formed the backbone
of India's trade sector reforms. Transferring items from the *negative* list of import to
Open General List of import eliminated potential production bottlenecks arising out of
non-availability of domestic raw material and capital goods. However, import restrictions
were maintained for some life saving drugs.

In line with trade reforms, India moved into a system of *floating exchange rate
and current and capital account (partially) convertibility*. The current account
convertibility allowed foreign exchange transaction through authorised dealers and
therefore was intended to reduce the bottleneck in processing export receipts and import

---

16 Rangarao (1975) quotes “Focus on Pharmaceuticals” to state that 100 large units employed 6,000
technical personnel in 1970. However, no comparable figure was found for the 2,149 small units. He
however noted that this number was 1,611 for 1,643 units.
payments. The capital account convertibility was expected to improve prospects of investment (portfolio) both within and outside India.

The *Industrial Reforms* abolished the system of licensing for setting up, and expansion of industrial units, except for a few industries because of strategic reasons. The import of raw material and equipment was made automatic, if certain conditions are met. The MRTP Act was amended to *remove* the threshold limits of assets in respect of MRTP companies and dominant undertakings, thus eliminating the requirement of prior approval of the government for establishment of new undertakings, expansion of undertakings, merger, amalgamation, takeovers and appointment of Directors under certain circumstances. Policy changes towards public sector industries were directed to end the hegemony of the public sector in the process of industrialisation. However, the monopoly of public sectors was maintained only if there were overriding strategic and security considerations (Railways, Atomic Energy etc).

The policies of *foreign investment and foreign technology* promised to expedite the granting of 51% foreign ownership for the *high priority* industries and trading companies primarily engaged in the export activities, provided that the foreign equity covered the foreign exchange requirements of capital goods import. Although the monitoring of payments for imported raw material, and technical know-how was deregulated, RBI retained the monitoring authority of the dividend payment. Accordingly, the FERA (1973) was modified to Foreign Exchange Management Act (1999) which allowed the pharmaceutical MNCs to hike their stakes in India up to 74%. Automatic approval was granted for foreign technology agreements in *high priority industries* up to a lump sum payment of Rs.10 m, or if the royalty is less than 5% of domestic sales or 8% of exports. This is subject to a maximum total payment of 8% of sales over a period of 10 years from the date of agreement or 7 years from the commencement of production. For
other *non-high priority industries* automatic permission will be given according to the same guidelines *if no free foreign exchange is required for any payments.*

The **Patent Bill of 1999** has been a direct fallout of the WTO agreements. With the systematic and continued attempt to integrate the Indian economy with ongoing global order of liberalisation, the government sought to replace the 1970 Patent Act by a WTO compatible product patent regime. The salient features of the forthcoming patent regime are summerised below.

- Product patents will be allowed in all fields of technology with a uniform duration of 20 years in pharmaceuticals, food products and agrochemical from the date of application.
- Compulsory licenses will be given by the government *only* on the merit of each case, and would be granted in case of national emergency. However, the patent holder will be given a hearing and an opportunity to present his case for intellectual protection.
- There will be no discrimination between imported and domestic goods in so far as intellectual property protection is concerned as per the national treatment clause in WTO.
- For process patents, the burden of proof will rest with the party that infringes. This is in contrast with the requirement of the earlier patent regime. In Patent Act 1970 burden of proof was on the original innovator.

The enactment of this law would prohibit know-why oriented reverse engineering on patented molecules. However, reverse engineering on off-patented molecules may continue. But this strong product regime is expected to encourage basic and frontier research in the industry, eventually leading to the discovery of new molecules in India.

---

17 WWW: The India Information Inc. (1995)
The forthcoming patent regime allows for the patenting of discoveries as well as inventions. This covers the claims on products of nature and living beings including micro-organisms and animals. They also allow for patenting of new uses and new combinations of known drugs with insignificant changes in strengths but virtually having the same therapeutic effects.

The new policy environment, by reducing and eliminating policy interventions in the areas of industrial investment, trade, exchange rate, foreign investment and technology transfer, is expected to promote efficiency and productivity in the Indian manufacturing sector and bring about major changes in industrial technology and R&D activities.

4.5.2 Specific Policies towards the Pharmaceutical Industry

The policy shift towards liberalisation also started to become evident from the specific policy initiatives towards the pharmaceutical industry in this phase. The early signs of liberalisation can be traced to the Drug Policy of 1986, and the Drug Price Control Order of 1987.

Drug Policy of 1986 and 1994

The main objectives of the New Drug Policy (1986) can be summerised as

- ensuring abundant availability, at reasonable prices of essential and life saving and prophylactic medicines of good quality,
- strengthening the system of quality control over drug production and promoting the rational use of drugs in the country,
- creating an environment conducive to channelising new investment into the pharmaceutical industry to encouraging cost-effective production with economic sizes and to introducing new technologies and new drugs,
- strengthening indigenous capability for production of drugs.  

\textsuperscript{18} Draft, Drug Policy (1986), see www.nic.in/cpc
This policy has been subsequently changed in 1994 to make it compatible with new liberalised environment and industrial licensing.

"Industrial Licensing for all bulk drugs cleared by Drug Controller (India) and all their intermediates will be abolished, except in the cases of

(i) 5 identified bulk drugs which are to continue to be exclusively reserved for the Public Sector
(ii) bulk drugs produced by the use of recombinant DNA technology and
(iii) bulk drugs requiring in-vivo use of nucleic acids as the active principles

Conditions stipulating mandatory supply of a percentage of bulk drug production to Non-associated Formulators will be abolished. Licensing shall be abolished for formulations except in cases of specific cell/tissue targeted formulations."

Thus restrictions on import of bulk drug were largely removed. The earlier policy to avoid captive consumption of bulk was reversed. These policies, however, acknowledged the need to focus on quality control and on the adverse impact of hazardous drugs. Consequently the government has resumed the authority to issue licenses for a limited number of drugs. Moreover, the concept of Good Manufacturing Practices (GMP) is made mandatory for every manufacturing unit.

*Mashelkar Committee Report (1993)*

According to this report, low profits and small firm-size acted as the principal deterrents to in-house R&D expenditure. The Committee's vision for Indian pharmaceutical R&D is "to provide intellectual capital to make available safe, cost-effective, contemporary, quality therapeutics to the people of India to help reduce percentage of mortality and morbidity and to emerge as a significant player in the global

---

19 Policy Draft (1994)
20 These include (i) large volume parenterals, (ii) Sera and Vaccines and (iii) whole Human Blood and Blood Products.
21 This argument has been put forward by the MNCs for the last two decades. Dunning (1988) also attributed the low price and excessive control as one main reason behind the low R&D by the MNCs in the French pharmaceutical industry.
market place." The committee suggested several ways to increase the production, investment and export of the industry. The committee proposed to prioritise R&D by exploiting the current research strength of the industry according to the need of the population. In line with current global resurgence on the issue of quality and efficacy, the Committee proposed to establish a monitoring authority to operationalise Good Laboratory Practices and Good Manufacturing Practices.

It also proposed to amend the existing legal structure regarding contract research, import of animals etc. in order to make India a global center for clinical trials. Committee has also recommended a professionally managed and efficient regulatory mechanism under the Central Drugs Standard Control Organisation.

On the funding of R&D, the Committee proposed several fiscal and non-fiscal measures. To attract R&D towards the high-cost-low-return areas the Committee recommended mandatory collection and contribution of 1% of MRP of all formulations sold within the country to a fund called ‘Pharmaceutical R&D Support Fund’ to be administered by the Drug Development Promotion Foundation. This may be taken as an acknowledgement of the constraints faced by private firms to engage in such high risk R&D activities.

Drugs Price Control Orders of 1987 and 1995

The DPCO 1987 drastically reduced the number of drugs under price control from 370 to 143. Also, the number of controlled categories were reduced to 2 allowing higher Maximum Allowable Post Manufacturing Expenses (MAPE) to both. Category I drugs were allowed 75% MAPE, while Category II drugs were allowed to fix price in such a way whereby a maximum of 100% MAPE can be obtained. While a large number of drugs were decontrolled, the rest moved up in terms of MAPE granted to their

---

22 Mashelker Committee Report (1993)
formulations. The 40% and 55% MAPE categories got enhanced MAPE of 75%, while those under 60% MAPE category got higher MAPE of 100%. Even new drugs brought under price control had a relatively liberal MAPE of 75%. Around 75% of the pharmaceutical industry remained under price control.

DPCO 1987 was followed by DPCO 1995, which further reduced the number of drugs under control from 143 to 74. The DPCO 1995 also marks a major departure from the earlier DPCO with respect to the stated principle for controlling drugs. While, earlier the objective was to make available necessary drugs at affordable prices, the DPCO 1995 clearly stated that the objective of drug price control was mainly to prevent monopoly in any market segment. Another major departure in DPCO 1995 was perhaps the inclusion of products manufactured by small-scale producers in the price control list.

The single criterion for a drug to be included in the price control list is that it should have an annual turnover of at least Rs.4 crores. A drug with a lower turnover can also be brought under price control if the following two conditions are satisfied:

1. The turnover is in excess of Rs.1 crore and
2. A single formulator has more than 90% of the market share

Similarly, a drug (irrespective of the turnover criteria) can be exempted from price control if there are at least five manufacturers supplying it. For calculating the maximum price that can be fixed for particular drug or formulation, the DPCO 1995 had clear directives. The maximum sales price of a bulk drug may be fixed so as to yield a post tax return of 14% on the net worth or 22% on the capital employed. Manufacturers can choose between any of these two parameters. In case of a new plant, an internal rate of return of 12% on long term marginal costing may be allowed. For determining the retail price of formulations prepared from bulk drugs under price control, the DPCO 1995
allows the manufacturer to charge MAPE at the rate of 100% on factory cost for all category I formulations.

Under Section 10 B of the Drug Price Control Order 1995, the government has however been given power to review the prices of decontrolled products in the interest of the public. If there is evidence of over pricing, the government may choose to fix a price or profitability ceiling on the decontrolled products.

To bring about more transparency in price mechanism as well as selection of drugs to be controlled, a committee called National Pharmaceutical Pricing Authority (NPPA) has been constituted. Earlier, the pharmaceutical industry was under the supervision of three different bodies supported by the state agencies – the Ministry of Chemicals and Petrochemicals23, Ministry of Chemicals and Fertilizers, and the Drug Prices Liability Review Committee (DPLRC). The NPPA replaced the DPLRC in September 1997 as the official body to administer DPCO. In addition to this, the NPPA is entrusted with the responsibility of ensuring adherence to price regulations, fixing fines for violation of price regulations, collection of fines, etc. The NPPA was established with the view to facilitate the process of drug price administration.

4.5.3 Performance of the Industry

Production and Trade

Post-1991, following the introduction of increasingly liberal issue of licenses to set up new capacities and an eventual dismantling of all entry barriers, a plethora of pharmaceutical companies invaded the capital market. Total investment as of 1996 stood at Rs.1600 crores and is estimated to become Rs.2800 crores by 2002, the terminal year of the ninth plan. While the production of bulk drug increased from Rs.730 crores in 1990-91 to Rs.3777 crores in 1999-2000, formulations output rose even more sharply

23 This body defined the drugs to be included into or excluded from the price control. It also facilitated decisions on Indian pharmaceutical exports
from Rs.3840 crores to Rs.15960 crores during the same period. Liberalisation of import, particularly of raw materials, however, resulted in a sharp increase in the import content of the industry. Total imports increased from Rs.604 crores in 1990-91 to Rs.3441 crores in the year 1999-2000. Within this growing import share, the share of bulk drug in total import increased from around 50% to nearly 60% during the same period. The share of bulk drug in total exports of pharmaceuticals has however, shown a downward trend. From an all time high of 61% in 1989-90 it has come down to 29% in the year 1993-94. It stood at 46% in the year 1998-99. But the policy framework favouring exports has, however, been successful in increasing the volume of total pharmaceutical exports by nearly 300% in last 4 years. The total exports stood at Rs.6631 crores in 1999-2000.  

Notwithstanding this major expansion of the Indian pharmaceutical industry during this phase with respect to production and trade, many of the MNCs are, downsizing their operations in India. Hoechst, for instance, closed down its manufacturing plant and R&D facilities at Mulund in India. Glaxo has reduced the size of its employment by an estimated 25%. Pfizer closed down its plants at Kalyani (West Bengal), downsized production at Thane, and sold out its modern Ankeleshwar plant. It is now opting for outsourcing and subcontracting its activities to remain cost competitive. There has also been an increasing trend among MNCs to replace permanent labor by casual (contractual) labor to reduce production costs.

This contraction of MNC operations in India should be viewed as a part of their global restructuring in recent years. This trend is perhaps in conflict with the stated objectives of the policy reforms of this phase (patent reforms and decontrolling of prices, in particular). The regime was expected to bring about a surge in MNC activities in terms of bringing in superior technology and initiating greater R&D in India to take advantage

of increased profitability and flexibility in operation. In fact, the budget of 2000 has allowed MNCs to hike their stakes in the Indian pharmaceutical affiliates to 74%. This automatic approval is expected to encourage MNCs to introduce their new innovation in Indian market.

**Prices and Profitability**

As a result of price-decontrol, both prices of the pharmaceutical products and the profitability of this sector seemed to have increased. OPPI data shows profitability as a percentage of STO as 8% in the year 1998-99. We are giving below the prices (in rupee terms) of twelve essential drugs before the liberal decontrol of DPCO in 1995 and later in 1998.

**Table 4.6: Price fluctuation of decontrolled Drugs in the 1990s**

<table>
<thead>
<tr>
<th>Name of Drugs</th>
<th>Therapeutic area</th>
<th>Packing</th>
<th>1995</th>
<th>1998</th>
<th>Percentage increase</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diazepam</td>
<td>Depression</td>
<td>10</td>
<td>3.13</td>
<td>9.50</td>
<td>204%</td>
</tr>
<tr>
<td>Ampicillin</td>
<td>Antibiotic</td>
<td>4</td>
<td>12.85</td>
<td>23.15</td>
<td>80%</td>
</tr>
<tr>
<td>Cephalexin</td>
<td>Antibiotic</td>
<td>10</td>
<td>45.07</td>
<td>113.15</td>
<td>151%</td>
</tr>
<tr>
<td>Ethambutol</td>
<td>Anti T.B.drugs</td>
<td>10</td>
<td>5.92</td>
<td>33.00</td>
<td>457%</td>
</tr>
<tr>
<td>Rifampicin</td>
<td>-do-</td>
<td>10</td>
<td>24.00</td>
<td>64.00</td>
<td>167%</td>
</tr>
<tr>
<td>Pirazinamide</td>
<td>-do-</td>
<td>10</td>
<td>17.01</td>
<td>46.95</td>
<td>176%</td>
</tr>
<tr>
<td>Lignocaine Hcl</td>
<td>Anaesthetic</td>
<td>30 ml.</td>
<td>4.16</td>
<td>12.40</td>
<td>198%</td>
</tr>
<tr>
<td>Promethazine Hcl</td>
<td>Anti allergic</td>
<td>10</td>
<td>1.25</td>
<td>3.23</td>
<td>158%</td>
</tr>
<tr>
<td>Antacid liq.</td>
<td>Gastritis</td>
<td>200 ml.</td>
<td>13.00</td>
<td>23.00</td>
<td>77%</td>
</tr>
<tr>
<td>Oxefedrine Hcl</td>
<td>Angina pectoris</td>
<td>10</td>
<td>10.44</td>
<td>21.41</td>
<td>105%</td>
</tr>
<tr>
<td>Discopyramide Phosp. hate</td>
<td>Cardiac problems</td>
<td>10</td>
<td>16.50</td>
<td>50.46</td>
<td>206%</td>
</tr>
<tr>
<td>Dipyridamole</td>
<td>Anti angina</td>
<td>10</td>
<td>2.00</td>
<td>4.73</td>
<td>137%</td>
</tr>
</tbody>
</table>

Source: Dubey (1999).

**R&D thrust**

Apart from the expansion of this sector since the 1990s, there also has been a sign of major restructuring of the Indian pharmaceutical industry both with respect to
production and as well as R&D activities. Firms like Dr. Reddy’s Laboratory, Ranbaxy, Lupin, Sun Pharma have made a serious attempt to move towards the new drug discovery research and have projected to increase their R&D spending to 4-5% of their STO. A detailed analysis of issues relating to changing profile of R&D will be discussed in chapter 7.

Quality

With the implementation of Good Manufacturing Practices, some of the major Indian players are trying to match the quality of their products with the norms of international standards. To this effect they are updating their manufacturing facilities according to the standards specified by United States Food and Drug Administration (USFDA) and other international bodies.

Table 4.7: FDA approved manufacturing plants in India

<table>
<thead>
<tr>
<th>Name of the company</th>
<th>Number of approved sites</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cheminor Drugs</td>
<td>1</td>
</tr>
<tr>
<td>Cipla</td>
<td>2</td>
</tr>
<tr>
<td>Dr Reddy’s Lab</td>
<td>2</td>
</tr>
<tr>
<td>IPCA</td>
<td>1</td>
</tr>
<tr>
<td>Kopran</td>
<td>1</td>
</tr>
<tr>
<td>Lupin Chemicals</td>
<td>1</td>
</tr>
<tr>
<td>Lupin Laboratories</td>
<td>3</td>
</tr>
<tr>
<td>M J Pharma</td>
<td>1</td>
</tr>
<tr>
<td>Neuland</td>
<td>1</td>
</tr>
<tr>
<td>Ranbaxi Laboratories</td>
<td>1</td>
</tr>
<tr>
<td>Wockhardt</td>
<td>1</td>
</tr>
</tbody>
</table>

Source: INFAC (1998) data base
Note: The list is not exhaustive
Ranbaxy and some other firms are also trying to export their formulations to the generic markets of developed countries like USA, UK, Australia and others. The modalities for this type of exports have also undergone a change. These companies are now setting up collaborative ventures in these countries to market their formulations. As revealed in table 4.8, there are inter-firm differences in the mode of arrangement. Very few companies have established a subsidiary in these countries. Most of them rely on suppliers' arrangement and marketing joint ventures, and few on manufacturing joint ventures.

**Table 4.8: Extent and type of internationalisation of Domestic Firms**

<table>
<thead>
<tr>
<th>Company</th>
<th>Presence in countries (No.)</th>
<th>Type*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ranbaxy</td>
<td>15 Subsidiary, MMJVMJV, BO, SA</td>
<td></td>
</tr>
<tr>
<td>Cipla</td>
<td>6 MMJVMJV, SA</td>
<td></td>
</tr>
<tr>
<td>Dr Reddy's Lab</td>
<td>9 Subsidiary, MMJVMJV, BO</td>
<td></td>
</tr>
<tr>
<td>Lupin</td>
<td>14 BO, MMJVMJV, SA</td>
<td></td>
</tr>
<tr>
<td>IPCA</td>
<td>3 SA, BO</td>
<td></td>
</tr>
<tr>
<td>Wockhardt</td>
<td>6 Subsidiary, MMJVMJV, BO</td>
<td></td>
</tr>
</tbody>
</table>

*SA=Suppliers Arrangement, BO=Branch Office, MJV=Marketing Joint Venture, MMJV=Manufacturing and Marketing Joint Venture.

**4.6 CONCLUSION AND THE CENTRAL RESEARCH QUESTIONS**

This chapter has documented clear evidence of the industry showing signs of growth and maturity both in terms of volume of production as well as research capability, especially by LDC standards. There is little doubt that the country has acquired substantial technological capability in this sector. However, if the industry is audited on the basis of its primary role, which is to engage not only in the development and production of drugs needed for prophylaxis, diagnosis, and therapy, but also in their discovery and distribution, then the emergent picture portrays a need for introspection. Unfortunately enough, the distribution of modern medicine reaches barely 30 percent of the country's population. This means there is no coverage for 600 million people, a number more than the population of United States and...
The primary objective of the present thesis is to examine the nature of technological capability acquired by the Indian pharmaceutical industry, the process of acquisition of this capability and its implications. In particular, we propose to address the following research questions in our study:

1. In chapters 2 and 3, we have identified three levels of technological capability in the context of industrial R&D in developing economies: know-how capabilities to begin with, followed by know-why oriented capabilities and finally culminating in basic research capabilities (from elementary to advanced). An obvious and key research question that arises is: What has been the trajectory of technological development of the Indian pharmaceutical industry? We shall attempt to answer this question by analysing the optimum path of technological capability acquisition both theoretically and empirically.

2. A second question pertains to the determinants of technological capability acquired by the industry (its nature, level and complexity). We have already discussed that it depends not only on formal research effort but also on a host of other factors like learning, ownership, size and most importantly, institutional factors like the patent regime.

3. Accumulation of technological capability, even if it is "minor" in nature, can have far-reaching economic implications for a less developed economy. This is particularly true for a technologically aggressive and dynamic industry like the pharmaceuticals, where the global technological frontier is moving fast. In so far as the implications of technology development are concerned, we limit our study to the following sub-questions.

---

all of Europe put together. Diseases like tuberculosis, malaria, leprosy, plague, AIDS, dengue fever, rheumatic fever, and rheumatic heart diseases continue to pose serious problems and take millions of lives each year. As argued by De Souza (1998), the concentration of efforts is on developing the world market.
a. It is pertinent to ask *what has been the contribution of technological capability in increasing the export competitiveness of the Indian pharmaceutical industry.*

b. *The new international economic order emerging out of the WTO framework is resulting in substantial strategic readjustment in this industry.* Indeed drug quality is emerging as an important determinant of the trajectory of technological development and overall growth path of this industry in this new policy environment. We attempt to examine *what has been the exact nature of this readjustment process.*

c. Following the Schumpeterian tradition, the relationship between technological development and market structure has been a most extensively researched question in both theoretical and applied economic literature. This is a particularly contentious issue in the context of less developed economies. Unequal income and asset distribution has been a source of major concern for policy makers in LDCs prompting many of them (including India) to restrict the growth of large business houses. The government encouraged the growth of small scale pharmaceutical firms with the objectives of employment generation and widespread diffusion of technologies to ensure availability of drugs at a low price to a large segment of the population. Against the backdrop of this policy concern, the question that arises is *what kind of market structure is emerging in this sector as a result of its technological development in a new international economic order.*

We shall attempt to address the above research questions at different levels of economic analysis. We shall begin with generalisations based on micro theoretic and

---

*rather than on meeting the needs of the Indian population. This trend is particularly alarming in the context of divergent disease pattern prevailing in India and in developed countries.*
micro-econometric analyses in Part III. We shall construct and develop theoretical and econometric models in chapters 5 and 6 respectively to arrive at a few generalised results. However, such generalisations often fail to capture some of the specific dimensions of the process of technology development of this industry and its implications. This can only be explored through a micro-micro analysis of firm-level case studies, which we shall attempt in Part IV. The precise themes of analyses at these different levels are outlined below.

Part III, chapter 5 on micro-theoretic generalisations will present the following models:

1. A model of optimal path of technology acquisition of a firm with regard to its relative emphasis on know-how versus know-why over time.
2. A strategic interaction model between firm(s) and the government to capture the role of IPR regime in determining the level and nature of technological capability.
3. A strategic interaction model of foreign and domestic firms to understand the process and time length of diffusion of new drugs in India for a given level of technological capability of reverse engineering.

Part III, chapter 6 on econometric models will contain the following themes:

1. Estimation of a research production function to capture the role of learning, spillover, ownership, firm-size and technology import in determining the level of R&D effort and technological capability.
2. The same exercise with a distinction between know-how and know-why types of research outputs with the objective of a further refinement of the level, nature and complexity of technological capability.
3. Estimation of an export function to investigate the consequence of technological capability in terms of export competitiveness of the Indian pharmaceutical firms.

Finally the micro-micro analysis of Part IV (chapters 7 & 8) will raise the following issues:

1. The path of technological evolution of the Indian pharmaceutical firms and explore the inter-firm differences in this evolution trajectory.

2. The role of research networking and manufacturing linkages in the acquisition of technological capability and diffusion of knowledge.

3. The consequences of technological capability for the evolving market structure and changing export profile.

4. An overview of the broad strategic options, not only limited to the technological practices but also including an overall corporate philosophy and policy, of the Indian pharmaceutical firms under the newly emerging global order.

5. An analysis of the political economy forces underlying a new conceptualisation of quality, the resultant structural changes and its consequences.