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RIS
Research and Information System for the Non-Aligned and Other Developing Countries

Core IV-B, Fourth Floor
India Habitat Centre
Lodhi Road
New Delhi-110 003, India.
Ph. 91-11-24682177-80
Fax: 91-11-24682173-74-75
Email: dgoffice@ris.org.in
Website: http://www.ris.org.in

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Aradhna Aggarwal

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Research and Information System for the Non-Aligned and Other Developing Countries
Core IV-B, Fourth Floor, India Habitat Centre
Lodhi Road, New Delhi – 110 003 (India)
Tel: +91-11-2468 2177/2180; Fax: +91-11-2468 2173/74
Email: dgoffice@ris.org.in

Strategic Approach to Strengthening the International Competitiveness in Knowledge Based Industries: The Indian Pharmaceutical Industry

Aradhna Aggarwal*

Abstract: This paper identifies the factors that determine the export competitiveness of firms in the Indian pharmaceutical industry. The analysis is based on the primary survey data as well as the PROWESS database. Our findings suggest that the competitiveness of firms depends not only on firm specific advantages but also on government fiscal incentives. Among the firm specific factors own R&D efforts emerged as one of the prime factors influencing export competitiveness. Technology imports on the other hand did not play a significant export-enhancing role. Brand promotion and lower costs were other important determinants of the export competitiveness. The study also finds that the determinants of export-competitiveness differ across firms of different size and ownership. High transaction and production costs are found to be major constraints faced by Indian exporters. Based on the quantitative and qualitative analysis, the study draws useful policy implications to strengthen the export competitiveness of the industry.

I. Introduction

The Indian pharmaceutical industry is one of the most vibrant knowledge driven industries in India that has witnessed consistent growth over the past three decades. Currently, over 90 percent of the modern medicine consumed in India is produced locally. The industry manufactures almost the entire range of therapeutic products and is capable of producing raw materials for manufacturing a wide range of bulk drugs from the basic stage. The industry accounts for 8 per cent of world's production by volume and 1.5 per cent by value. India is among top five pharmaceutical producers worldwide in terms of volume and ranks

* Reader, Kirori Mal College, University of Delhi. Email: aradhna@aradhna.info

among 15 in value. It is one of the top 20 top exporters of bulk actives and dosage forms. Indian exports are destined to around 175 countries around the globe including highly regulated markets of US, Europe, Japan and Australia.

Rapid growth in this sector has largely been the result of the patent regime that had been pursued by the government of India since 1970. The ongoing process of liberalization and WTO's Intellectual property Rights Agreement have however made a major impact on this policy framework. Some fear that the post-TRIPs regime will discriminate against local firms in favour of foreign companies that can afford the enormous funding required for research and development and will harm the domestic industry while others suggest that this will result in a metamorphosis of the industry. They argue that the industry would make rapid strides in restructuring their business to meet global standards in R&D, manufacturing, product development and marketing as the traditional approaches of bypassing process patents will not be sufficient to get onto the market. The present paper however argues that the new policy regime will pose challenges for the industry. Indian firms would need to focus on the global marketing initiatives to tap *international markets of generic*s. This will allow the industry to continue to grow in the post TRIPs regime. The regulated developed country markets are now showing a definite shift towards generic drugs amid strident public demand for less expensive medicines. Furthermore, in the next five years a number of patented drugs are going off patent in the USA and Europe. This will open tremendous opportunities for the Indian firms to share additional global market to the tune of US $60 billion. Aside from this, evidence suggests that the drug sector is one of the ten fastest growing sectors in world trade. Drug exports grew at an average rate of 14.1 per cent over the 1990-95 period against the average export growth rate of 8.5 per cent for the total world manufactured exports (UNCTAD 1999). Focus therefore needs to be on major initiatives on the export front.

The Indian pharmaceutical industry has already made a firm mark on global markets. Pharmaceuticals' exports grew from Rs. 373.3 millions in 1973-74 to Rs. 119250 millions in the year 2003-2004. Some of the top India companies have export contribution of more than 50 per cent in their sales. Ranbaxy which is one of the world's largest manufacturers of cefaclor (the world's largest selling antibiotic at US$1bn a year) had the export share of 75 per cent in its total sales in 2003. Similarly, Lupin, the world's largest producer of ethambutol, an anti TB drug exported 35 per cent of its sales in overseas markets in 2002. Dr. Reddy's Lab, the second largest producer of ranitidine, an anti-ulcerant is

exporting 60 per cent of its sales. Firms have also begun to diversify their export markets from developing countries and CIS countries to capture new markets in Europe and the US. Some of the companies have highly diversified export markets. Alembic (35 export markets), Arti drugs (56 markets), Neuland Pharma (72 markets) , Wockhardt (61 markets) are some such examples. The number of Indian firms having foreign operations has grown over the year. Aside from Ranbaxy and Dr. Reddy's Lab, there are several other firms that have set up joint ventures abroad. These are for instance, Ajanta, Glenmark, Himalaya, Aurobindo, Orchid, J.B.Chemicals, Nicholas Piramal, Torrent and Wockhardt. This raises an important question: what drives Indian firms' competitiveness in this knowledge based industry? The present paper attempts to address this question and analyses the determinants of export performance in this industry. While doing so, it uses both the primary survey based data and secondary data.

The paper begins with an overview of the evolution of the Indian pharmaceutical industry in Section II. Section III examines the patterns of various indicators related to the structure, conduct and performance of the industry. Section IV focuses on the analysis of the export competitiveness of firms. It begins by analysing the inter-firm variation in the export performance. It then provides analytical framework for explaining inter-firm variations in the export performance, examines the determinants of export competitiveness of the industry using the primary survey data, provides quantitative analysis of the secondary data and discusses major constraints faced by Indian firms in their exporting activity. Finally, Section VI draws policy implications.

II. Evolution of the Indian Pharmaceutical Industry

The establishment of a modern Indian pharmaceutical industry commenced with the setting up of Bengal chemicals by Acharya PC Ray in Calcutta in 1901. Later, Alembic chemicals was set up in Baroda by B.D.Amin. The British also set up a few pharmaceutical research institutes for tropical diseases. These included Haffkine Institute in Bombay, the King Institute of Preventive Medicine, Madras, in 1904, the Central Drug Research Institute Kasauli in 1905 and the Pasteur Institute Conoor in 1907. During the First world war the industry grew as local demand increased and imports cut off. However, after the war was over, production in this industry fell again. During the second world war, India began to produce conventional medicines, serums and vaccines. Manufacturing of synthetic drugs for dysentry and leprosy also began. Still the industry remained dependent largely on the United Kingdom, France and Germany for medicines until independence.

Since independence in 1947, the Indian pharmaceutical industry has shown tremendous progress in terms of infrastructure development, technology base creation and a wide range of production. There are three distinct phases in the evolution of the Indian pharmaceutical industry : the period from independence to the late 1960s; the period from the late 1960s through to the mid 1980s and the period from 1985 onward. Following is an overview of the evolution of this industry through these three phases.

II.1 The phase of heavy reliance on multinationals : 1947-1970

In 1947 total pharmaceutical production was just Rs. 100 millions. Pharmaceutics were largely imported whereas local production remained minimal. The colonial patent law the Patent and Design Act,1911 had secured the Indian market to British industry. Under this Act India had product patent regime for all inventions. Since MNCs were the patents holders, they dominated the markets. They were operating in India as trading companies with small investment. They imported drug formulations in finished form and marketed them locally.

After the attainment of independence, the first Industrial policy resolution was announced in 1948. The government included the pharmaceutical industry in the list of basic industries and subjected it to central controls. In the 1956 Industrial Policy Resolution, this sector was included in Schedule B which comprised of industries in which the State was to establish new undertakings, but where private enterprises was also given an opportunity to develop. During this crucial period, the role that science would play in the development of the country was also recognised and institutions like the National Chemical Laboratory at Pune and the Central Drug Research Institute at Lucknow were established. However, the industry had little domestic technological base to start local production of modern drugs. To initiate production in the industry therefore, FDI was invited. Foreign investors responded to liberal FDI policies of the government. In the 1950s alone, fifteen major foreign subsidiaries were established in India. However they did not make substantial investment in the country to extend productive capacity here. Instead, they imported bulk drugs and processed them into formulations. Between 1947-57, 99 per cent of the 1704 drugs and pharmaceutical patents in India were held by foreign MNCs, which controlled 80 per cent of the market. Patent law protection, hold on technology, financial resources and foreign brand names gave them distinct monopolistic advantages in India. They made high profits while drug prices in India were amongst the highest in the world (Nayar 1983).

Government attempted to give a fillip to the industry by setting up public undertakings. In 1954, the first public sector drug company Hindustan Antibiotic Limited was established with the help of WHO and UNICEF. In 1961, the Indian Drugs and Pharmaceutical Limited was established with the help from the Soviet Union. These undertakings did boost production and helped in training manpower but the national sector remained very small. It was estimated at less than 25 per cent of the domestic pharmaceutical market (Redwood, 1994). Of the top ten firms by retail sales in 1970, only two (Alembic and Sarabhai) were Indian firms and the rest were subsidiaries of multinationals. Much of the country's pharmaceutical consumption was met by imports.

II.2 The phase of emphasis on self reliance : 1970-1985

The landscape of the pharmaceutical sector was transformed during this period, largely as a result of some important policy initiatives undertaken by the government. The government put into place a series of policies aimed at breaking away India's dependence on MNCs for the production of bulk drugs and formulations and moving the country towards self-sufficiency in medicines. Major policy measures adopted by the government during this period are as under.

The patent act 1970 : The introduction of the Patent act 1970 was perhaps the single most significant policy initiative taken by the government that laid the foundation of the modern pharmaceutical industry. The patent system was first introduced in India in 1856 through the Exclusive Priviledge Act 1856. Later, the Indian Patent and Design Act 1911 replaced the previous Act although the main clauses remained the same. This Act provided exclusive right to the patent holder for a period of 14 years. This act conferred monopolistic advantages to MNCs as they were the main patent holders. With a view to breaking their monopolies and encouraging the Indian pharmaceutical industry the Government introduced a new system of patents through the Patent Act 1970. This Act, which is prevalent till date, does not allow product patents on medicines, agricultural products and atomic energy. For these, only process patents can be registered. The basic philosophy has been to disallow monopoly and encourage research to help in overall growth in these sectors. In general, India provides patent protection only for 14 years, but in case of food, chemicals, pharmaceuticals and agro chemicals, the patent period is only 5 years from the date of sealing or 7 years from the date of patent, whichever is lesser. The patent act also has provisions relating to compulsory licensing. On the completion of 3 years from the date of sealing, any person interested in working the patented

invention may apply for compulsory license with respect to the invention on the grounds of public benefit. The controller of patents may direct the patent holder to grant such a license upon the terms as may be deemed fit. In addition, the Patent act 1970 includes a provision of 'license of right' where the central government can after the expiry of three years of the sealing of patent apply for compulsory licensing on the grounds of public benefits.

This act enabled Indian companies to develop skills in reverse engineering and to produce alternate processes for drugs. Exempt from paying for licenses and royalties, Indian companies could now access the newest molecules from all over the world and reformulate them for sale in the domestic market. As a result, after 1970, many new drug firms were set up. These companies developed R&D base, which was later leveraged by them to move up the R&D value chain.

Drug Price Control Order 1970*:* Price controls in Indian pharmaceutical industry were introduced in 1962 when Drug (Display of prices) Order 1962 came into force. Later these controls were modified through Drugs (control of prices) Order 1963, and Drugs (Display and Control) order 1966. In 1966, the government requested the Tariff Commission to examine the prices of 18 bulk drugs and their single ingredient formulation. Following the submission of the Tariff Commission Report in 1968, the government introduced a price regulatory policy better known as the Drug Price Control Order (DPCO) 1970 (Kumar and Pradhan 2002). The objective was to protect the interests of consumers and ensure a restricted but reasonable return to producers. The government brought 18 essential bulk drugs under the purview of DPCO 1970. These drugs accounted for less than 9 percent of total value of drugs marketed. The sale prices of other bulk drugs were frozen at the level prevailing immediately before the issue of the Order. The policy was subsequently revised in 1979,1987 and 1995.

Priority Status*:* Policies towards foreign capital and foreign technologies were tightened during this period. The 'Foreign Exchange Regulation Act (1973)' imposed numerous restrictions on foreign equity participation and on the growth and expansion of foreign companies. The entry of foreign firms was restricted to certain priority industries in which little technological progress had been made in the country. These industries were listed in Appendix I of the Industrial Licensing Policy (1973). Appendix 1 specified industries where products were not being produced in India or where the local sector was being dominated by a single (usually foreign) company. MNCs could retain upto 74 per cent ownership against the general limit of 40 per cent on maximum foreign

shareholding permissible. A priority status was accorded to the drug industry by including it in Appendix I. Most foreign pharmaceutical companies present in India, prior to the enactment of FERA, chose to continue with their Indian operations and settled for reduced equity holdings. However, the Drug Policy 1978 announced some stringent measures against MNCs and attempted to consolidate the position of the domestic firms.

Drug Policy 1978: In the mid 1970s, the government appointed a Parliamentary committee better known as the Hathi Committee. This committee reported that in the year 1976-77 there were 45 foreign drug companies operating in India accounting for roughly 42 per cent of the total production. The committee examined various aspects of foreign and domestic companies' functioning. It was observed that foreign companies had far lower ratio of bulk drugs to formulations than their local counterparts. Moreover, they also thwarted attempts by indigenous units to produce bulk drugs by means of import-dumping and filing patent suits. On the basis of the report of this committee, the government formulated a comprehensive drug policy. It was introduced in 1978, which was subsequently modified in 1986. It sought to develop a strong pharmaceutical sector, deepen the production base of domestic industry, channelize the activities of foreign companies in accordance with "national objectives'', encourage R&D, and provide drugs at reasonable prices. To achieve these objectives, public sector was assigned a leading role. In contrast, stringent guidelines were issued for control on foreign companies. Foreign companies were directed to bring down their equity first to 40 per cent and then further reduce it to 26 per cent. Higher levels were permissible for firms producing bulk drugs though. Small sector was prohibited for foreign firms. The policy stipulated a 1:10 bulk drugs to formulation ratio for Indian manufacturers with 30 per cent supply to other formulators, and allowed formulations to be produced with a ratio parameter of 2:1 indigenous to imported bulk drugs. However, foreign manufacturers had to follow a 1:5 bulk drug to formulation ratio and had to supply 50 per cent of their production of bulk drug to other formulators. Moreover, foreign companies had to indigenously manufacture bulk drugs and intermediates required for their formulations within a stipulated time frame. It was also compulsory for foreign companies to set up R&D facilities in the country and spend at least four per cent of their turnover annually as recurring expenditure on R&D facilities.

Following the recommendations of the Hathi Committee Report, the DPCO 1970 was also revised in 1979. The government extended the coverage of

DPCO to 347 drugs which accounted for 90 per cent of the industry. All the drugs were clubbed under four categories : life saving, essential, less essential, non essential/simple remedies. Of these, the first three categories were subjected to price controls. In fixing the price, the Government continued to advocate profitability ceiling. In case of bulk drugs, this was through a limit on the company's return on net worth or capital employed. In case of formulations, retail prices of controlled products were decided by applying the concept of MAPE (Maximum Allowable Post manufacturing Expenses) which is akin to a mark-up on ex-factory costs provided to cover all selling and distribution costs including trade margins. The policy allowed the mark up of 40 per cent, 55 per cent and 100 per cent for the life saving, essential and less essential drugs respectively. Non essential drugs were kept out of the purview of price controls. Besides, all drugs manufactured by small scale units were also exempted from price controls. Finally, new bulk drugs developed through local R&D were also kept outside the ambit of price controls. The MNCs were badly hit by these controls. Profitability fell steeply, new investments in the sector dwindled and MNCs discontinued many products The policy however consolidated the growth patterns in the indigenous sector.

Encouragement to R&D*:* This period also witnessed concerted efforts made by the government to encourage R&D activities in industries. Emphasis was placed on the creation of R&D facilities in the private sector. Various policy incentives were provided to firms for setting up in-house R&D units. These included tax incentives, relaxation in import licensing to R&D units and relaxation in industrial licensing for using results of R&D units. The government set up various facilities like Technical Consultancy Organizations (1973), Risk Capital Foundation (1975) and Technology Development Fund (1976) with the objective of providing financial support for modernization or setting up of a unit based on new indigenous technologies. Moreover, various policy measures were adopted to promote linkages between R&D institutions and industry. These were, for instance, gearing up of the National Research and Development Corporation (NRDC) to transfer the R&D results of research institutes to industrial entrepreneurs, relaxation in industrial licensing for manufacturing an item based on the technology developed by national laboratories, and providing financial support through the public sector financial institutions for modernisation or setting up of a unit based on new technology. Promotion of R&D was also a major feature of the Drug policy, 1978, which directed to activate institutes like BCG institute Madras, Heffkins Institute Mumbai and CRI Kasauti to promote R&D in the drug sector.

II.3 Emergence Stage (1985 onwards)

Policy measures announced during !985-1994

Important changes were introduced in the industrial and trade policies in India in the mid 1980s, when emphasis was placed on growth with improving efficiency (VII Plan Document 1985-90, p. 168). Changes in the overall perspective affected government policies for the pharmaceutical industry also. Moreover by the mid 1980s, India had emerged as a major pharmaceutical producer. The indigenous sector had captured a substantial proportion of the market. It was felt that the domestic drugs and pharmaceuticals industry needs reorientation in order to meet the challenges and harness opportunities arising out of the liberalization of the global economy. In that context, the drug policy was revised in 1986. The new policy titled 'Measures for Rationalisation, Quality Control and growth of Drugs and Pharmaceuticals industry in India' emphasised among other things creating an environment conducive to channelising new investment to encourage cost effective production with economic sizes and to introduce new technologies and new drugs. These policies resulted in the dilution of price controls, relaxation of restrictions on the inflows of foreign investment and foreign technology, reduction in trade barriers and relaxed licensing requirements. Following the drug policy 1987, DPCO was also revised in 1987. In the revised version of DPCO, the number of drugs under price control, was reduced significantly from 370 to 143. Moreover, it categorized drugs into two lists with different MAPE: drugs required for National Health Programme (category I) with 75 per cent mark up and others with 100 per cent mark up. Trade polices also underwent significant changes with the pruning of the Negative list for imports.

Post 1994 measures

Major policy initiatives in the direction of liberalization were announced in the Drug policy 1994. The process has since been continuing. Major changes in the policy framework are discussed below.

Relaxation in industrial licensing: The process of liberalization set in motion in 1994, has considerably reduced the scope of industrial licensing and demolished non tariff barriers. Industrial licensing for all bulk drugs cleared by Drug Controller (India) and their intermediaries were abolished except in the cases of (i) 5 identified bulk drugs reserved for the public sector; (ii) bulk drugs produced by the use of genetic engineering; and (iii) bulk drugs that require in-vivo use of nucleic acids. Licensing was also abolished on formulations except

in the cases of specific cell/tissue-targeted formulations. In Feb.1999, reservation of 5 drugs for manufacture by the public sector was abolished, thus opening them up for manufacture by the private sector also. Drugs and pharmaceuticals manufacturing units in the public sector are being allowed to face competition including competition from imports. Wherever possible, these units are being privatized.

Furthermore, conditions stipulating mandatory supply of a percentage of bulk drug production to non-associated formulators are abolished and ratio parameters linking bulk drugs and formulation production and limiting the use of imported bulk drugs also stand abolished.

Encouragement to inward foreign investment: The Government allowed foreign companies to raise their equity stake in their Indian subsidiaries to 51 per cent in 1994. Restrictions on import of drugs were also removed during the same year and several companies raised their stake to 51 per cent. Foreign investment norms have been further liberalized. Foreign investment limit through automatic route was raised from 51 per cent to 74 per cent in March, 2000 and to 100 per cent in December 2001. Automatic approval for Foreign Technology Agreements is being given in the case of all bulk drugs, their intermediates and formulations except those produced by the use of recombinant DNA technology and bulk drugs that require in-vivo use of nucleic acids and specific cell/tissue-targeted formulations. For these products the procedure prescribed by the Government would be followed. Approvals will not now be needed for foreign investment of upto US $50 million compared with a previous level of $15 million.

Facilitating outward FDI: Foreign investment has been made easier by the government's decision to raise the ceiling for automatic approval and to liberalise overseas acquisition regulations. Approvals will not be needed for foreign investment upto US $ 50 million. In addition, the government has extended the facility for allowing pharmaceutical and biotechnology companies to acquire firms upto US $100 million through equity swaps/ADRs/GDRs. Companies can exceed the 100 million limit if their export earning allowed them to do so. The companies can spend as much as 10 times of their export earning to acquire overseas firms through stock swaps.

Relaxation in price controls: In 1995 the DPCO was revised twice. Its basic structure remains same as the prior two orders of 1979 and 1987. But, it did liberalize the span of control considerably. Only 74 out of 500 (down from

163) commonly used bulk drugs are kept under statutory price control. All formulations containing these bulk drugs either in a single or combination form fall under the price control category. The prices of other drugs can be regulated, if warranted in public interest. Moreover, the policy stipulated a single list of drugs under the price control with a MAPE of 100 per cent. Small-scale firms are no longer free of price control. Finally, exemption period for new drugs produced by indigenous R&D has increased from 5 years to 10 years. Under DPCO 1995, the government claims that 40 per cent of market is now covered by price control, down from about 70 per cent under the old order. In addition to controls on drug prices, maximum returns on manufacturing (except basic manufacturing) are fixed at 14 per cent and 22 per cent respectively[1]. No producers come close to these ceilings so this part of the *DPCO is currently not binding*. The National Pharmaceutical Pricing Authority was established on 29th August 1997 as an independent body of experts following the Cabinet Committee's decision in September 1994 while reviewing the Drug Policy. The Authority, inter alia, has been entrusted with the task of fixation/revision of prices of pharmaceutical products (bulk drugs and formulations), enforcement of provisions of the Drugs (Prices Control) Order and monitoring the prices of controlled drugs.

Encouragement to production from basic stage: To encourage manufacturing from the basic stages, the trade mechanism was utilized. Imports of critical intermediates were put in the negative list. Besides, the rate of return in case of basic manufacturing was fixed at a higher level by 4 per cent over the existing 14 per cent on net worth and 22 per cent on capital employed.

Trade Promotion Measures: Till 1986-87, 100 per cent imports were covered under non tariff barriers which included licensing and conditions stipulated therein. In the late 1980s however, the import coverage ratio under non tariff barriers declined steeply (Table 1). Non tariff barriers were replaced by tariffs. As a result, average tariff rate (and ERP) in this industry increased in

Table 1: Trade protection in Drugs : 1980-2000

Year	Import coverage ratio (%)	Average nominal tariff(%)	ERP (%)
1980-87	100	91.3	82.5
87-93	29	107.5	101.2
93-00	2	50.8	51.5

Source: Computed from Das (2001) and Das (2003).

the late 1980s. However 1993-94 witnessed a steep decline in the average tariff rate which continued in the later period. The effective rate of protection, which was as high as 107.84 in 1992-93, declined to 31.6 per cent in 1997-98. It increased marginally to 42 per cent in 1999-00. Apparently, it declined again in the post 2000 period with fall in tariff rates. After the Budget 2003, peak rate of customs duty reduced from 30 per cent to 25 per cent. Customs duty on specified life saving drugs and specified life saving medical equipments reduced to 5 per cent. The countervailing duty (CVD) on these items were also reduced to *Nil* by exempting them from excise duty. CVD on 88 specified life saving drugs and specified life saving medical equipments, presently attracting 5 per cent customs duty has been reduced to *Nil* by exempting them from excise duty. Drugs and materials used for clinical trials were exempted from customs duty. These items have also been exempted from excise duty. The excise duty on the medicines containing alcohol or narcotic substances were reduced from 20 per cent or specific rates to 16 per cent.

Export Promotion Cell in the Pharmaceutical Division: It acts as a nodal agency in the matters related to export of pharmaceuticals. In order to give adequate attention to day-to-day problems faced by the exporters, the Cell interacts with various Ministries/Departments and Indian Missions abroad. The Cell also collects statistical data on export and import of pharmaceuticals in the country and provides commercially useful information on developing and increasing drugs and pharmaceutical exports. The Cell has also been entrusted with organization of seminars and workshops on standards, quality control requirements etc. of important countries so as to prepare domestic companies for exporting their products. Several Indian embassies across the world have also begun preparing reports on issues such as guidelines for licensing of pharmaceutical companies; registration procedures for medicines; local production level; demographic data; and healthcare systems, health indicators and prevalent disease patterns. The government has also proposed to hold a series of educational programmes for domestic exporters with special emphasis on the quality of product.

Amendment in the Patent Law 1970: India has become a member of the Paris Convention and PCT w.e.f. 7.12.1998 and by virtue of this, the Head Office of Patent Office & its Branch offices have become receiving offices for the purpose of international applications filed under PCT. In view of these developments, the Patents Rules, 1972 have been amended w.e.f. 17.11.99 The present Act provides specific provisions for the grant of EMR (Exclusive

Marketing Rights) with a view to fulfill its international obligation under the relevant provisions of the TRIPs agreement. Under the law, new molecules patented for the first time in the world after January 1,1995, will be granted recognition, for which an application needs to be made in India. The developer would be entitled to exclusive marketing rights for five years during the transition period.

Promotion of R&D: Recognising the profound influence of R&D on the prospects and opportunities for the growth of the Indian Drug Industry, Department of Science and Technology (DST), Government of India, initiated a programme on drug development during 1994-95 for promoting collaborative R&D in drugs and pharmaceuticals sector with the specific objectives of synergising the strengths of publicly funded R&D institutions and Indian Pharmaceutical Industry; creating an enabling infrastructure, mechanisms and linkages to facilitate new drug development; and stimulating skill development of human resources in R&D for drugs and pharmaceuticals. The programme supports research in all systems of medicines including setting up of facilities. It supports joint research projects of industry and institution normally on the basis of 50 : 50 sharing of financial requirements between industry and institution. So far 28 industry-institutional alliances have taken place and three product patents and nine process patents have been filed (MST website dst.gov.in)

Fiscal incentives: Finally, several budgetary incentives have been offered on R&D in the industry. Finance Bill 1997 introduced a sub-section (2AB) in Section 35 of the I.T. Act 1961. This sub-section was introduced in order to encourage research & development in drugs, pharmaceuticals, electronic equipment, computers, telecommunication equipment, and chemicals. The sub-section provided for weighted tax deduction of a sum equal to one and one-fourth times of any expenditure incurred on scientific research (not being expenditure in the nature of cost of any land building). The weighted tax deduction was further raised to 150 per cent by the Finance Act, 2000. The sub-section was further amended by the Finance Bill 2001, to include expenditure on in-house R&D by units engaged in the business of biotechnology, as well as cover expenditure on clinical trials, filing of patents under Indian Patent Act (1970) and obtaining regulatory approvals, for weighted tax deduction @ 150 per cent under section 35(2AB) of Income Tax Act. Moreover, a research fund with an initial corpus of Rs. 1500 million has been set up to finance research projects approved by the Department of Science and technology and R&D companies have been granted a tax holiday for 10 years.

These sops were consolidated further in the year 2003. In the budget 2003, specified pharmaceutical and bio-technology equipment for R&D exempted from customs duty subject only to their being registered with Department of Scientific and Industrial Research. The condition of minimum export turnover of Rs. 200 million, and restriction on the availability of exemption only upto 1 per cent of export value has been removed. Customs Duty exemption has been provided to specified pharmaceutical and bio-technology equipment imported by a manufacturer having a registered R&D laboratory upto 25 per cent of his export turnover. Deduction of 100 per cent of the profits and gains of such business for a period of ten consecutive assessment years under section 80-IB is allowed to companies carrying out scientific R&D (if such company is for the time being approved by the prescribed authority 1 after 31 st March, 2000 but before the 1 st April, 2003). This deduction has been extended to companies in the scientific R&D business, which are approved by the prescribed authority before 1 st April 2004.

The industry could not find any mention and sops in the 2004 budget, which has disappointed the drug makers. However, a ten-year 100 per cent tax exemption is provided to firms doing research in bio-technology.'

Policy changes expected in the future

India had been granted a 10-year transitional period before it is obliged to enforce patent protection for drugs. In the year 2005 India will have to amend its patent law in accordance with the TRIPs Agreement. Under this agreement, patents shall be granted for any inventions whether product or process in all areas including pharmaceuticals and the effective period of protection is for twenty years from the date of filing the application. Major issues have emerged on account of implementation of our obligations under TRIPs. These include, research and development, price control, attracting FDI and increasing exports. It is against this backdrop that the Pharmaceutical Policy 2002 has been enunciated. The policy is likely to introduce major changes in the landscape of the industry. Though the proposals of Drug policy 2002 have been accepted by the government in principle, the notification has been hanging for more than a year.

In order to review the current drug price control mechanism, with the objective of reducing the rigours of price control, a committee, called the Drugs Price Control Review Committee (DPCRC), under the Chairmanship of Secretary, Department of Chemicals & Petrochemicals was set up in 1999, which has given its report. The recommendations of DPCRC have been examined and

taken into account while formulating the "Pharmaceutical Policy - 2002". It has been decided that the span of price control over drugs and pharmaceuticals would be reduced substantially. However, keeping in view the interest of the weaker sections of the society, it is proposed that the Government will retain the power to intervene comprehensively in cases when prices behave abnormally. After the introduction of the Pharmaceutical Policy 2002, out of the 74 drugs currently under price control, 61 are likely to come out and 18 new molecules are likely to enter the ambit. The total span of control is likely to reduce to 25 per cent.

In its report to the government, the Mashelkar committee on pharmaceutical R&D has recommended a series of measures for enhancing pharmaceutical research. These are for instance, increase cross border collaborative research, increase funding for R&D and create necessary infrastructure for development of R&D. The Committee has laid down stringent standard for pharmaceutical industry seeking price decontrol.

Aside from this, the Committee on Pharmaceuticals and Knowledge based Industries set up in November 1999 headed by Murali Manohar Joshi had constituted a number of sub committees to suggest policy modifications to enhance the competitiveness of this industry. The sub committee led by DS Brar Chief of Ranbaxy has already presented a set of recommendations. These include, price decontrol, partnerships between government, academia and industry for research, monitoring of imports of all active pharmaceutical ingredients (API), time bound approval for accelerating the process of developing Investigational New drugs and New Drug Application (NDA).

Finally, the Pharmaceutical Research & Development Committee has recommended in its report, submitted inter-alia, the setting up of a Drug Development Promotion Foundation (DDPF) and a Pharmaceutical Research & Development Support Fund (PRDSF). Necessary action in this regard has been initiated. In sum, several policy initiatives are expected in the near future in the light of the recommendations made by these committees.

III Growth of the industry

Starting with a low base at the time of independence, the drug industry has grown rapidly in India in terms of number of units, output, investment, exports and imports. This Section analyses growth patterns in various structure-conduct and performance indicators in this industry.

III.1 Structure of industry

The number of pharmaceutical companies has gone up by leaps and bounds. Table 2 shows that the number of units increased dramatically during the 1970s and the 1980s. Apparently, the Patent Act 1970 and price control exemptions for small-scale units saw a rapid proliferation of domestic producers during the 1970s and 1980s. Currently, there are over 20,000 firms. But many of them are duplicate/ fake. According to Industry experts, there are 7000-8000 genuine firms[2]. Employment in the pharmaceutical sector is estimated to have reached almost half a million (OPPI, 2000). Distribution of trade and ancilliary industry employ roughly 2.4 million workers. Thus the total employment (direct and indirect) in this industry is nearly 2.9 million people.

Market structure

MNCs Vs. Domestic firms: In the post independence era over 90 per cent of the industry's market share and ownership was dominated by MNCs. In 1970, the government introduced the Patent Act to break the MNC domination and foster a self reliant indigenous industry. The Patents Act 1970 (effective April, 1972) greatly weakened intellectual property protection in India, particularly for pharmaceutical innovations. As a result, the number of patents granted per year fell by three-quarters over the following decade, from 3,923 in 1970-71 (of which 629 were to Indian applicants, 3,294 to foreign applicants) down to 1,019 in 1980-81 (349 Indian, 670 foreign) (OPPI, 1996). Although all inventors were affected by the weakened patent regime, foreigners, in particular, no longer found taking out a patent in India worthwhile. The lack of patent protection meant that while foreign firms had to pay royalties for new drugs their Indian counterparts could use imitations. This Act therefore encouraged local firms to make copies of the drugs by developing own processes, followed by bulk drug production. Besides,

Table 2: Number (growth) of units in the Indian pharmaceutical industry

Years	Units (average annual growth rate %)	
1952-53	**1643**	
1969-70	2257	(2.1)
1979-80	5156	(12.8)
1989-90	16000	(21.0)
1999-00	20053	(2.5)

Source: Gharpure group of Companies Report on Pharmaceutical Industry, OPPI (2000).

the Drugs Price Control Order, while making the production of pharmaceuticals less profitable for all firms selling in the Indian market, made it relatively less interesting for foreign firms with market options elsewhere. Thus even the price control regime probably contributed to the shift towards a greater share of production being met by Indian firms (Economic Times 28.1.1982). Finally, government policies such as FERA (1973) discriminated against foreign firms and severely limited foreign investment. Restrictions on the import of finished formulations, ratio requirements (where imports of bulk drugs had to be matched by purchases from domestic sources at a fixed ratio) and equity ceilings on foreign participation such as price controls served as a further disincentive to invest in the Indian industry. On the other hand high tariffs at 80 per cent encouraged Indian firms to develop a manufacturing base from the basic stages and produce cost efficient bulk drugs and formulations.

Supported by this regulatory environment, by 1991, Indian firms accounted for 70 per cent of the bulk drugs and 80 per cent of formulations produced in the country (Hamied, 1993). Of the top ten firms by 1996 pharmaceutical sales, six were Indian firms rather than the subsidiaries of foreign multinationals. Domestic firms now produce about 350 of the 500 bulk drugs consumed in the country . In 1997 Indian private firms produced 61 per cent of industry sales, with 38 per cent of sales from multinational firms and one percent from the public sector. The share of Indian companies has gone up further over the years to 76 per cent. It is also observed that new products have been the major growth drivers for the Indian companies, whereas price increase contributes significantly to MNC growth (ORG-MARG 2002). Of the 3000 new products launched in 2000 and 2001, MNCs launced only 100 products. New products contribute 2 per cent of the turnover of MNCs as compared with 99 per cent for Indian companies. Nevertheless, in certain markets MNCs rule. These are : hormones, antidiabetics, dermatologicals, vitamins and respiratory.

Table 3: Share of domestic firms and MNCs in selected years (%) : 1970-2001

Year	Share of domestic	Share of MNCs
1970	20	80
1993	61	39
1998	71	29
2000	74	26
2001	76	24

Sources: Redwood (1994), ORG (2002).

Table 4: Share of domestic and foreign forms in bulk drugs and formulations' markets

	Bulk Drug production		Formulations	
	Domestic firms	Foreign firms	Domestic firms	Foreign firms
1974-75	62.22	37.78	50.75	49.25
1984-85	82.76	17.24	60.02	39.98
1998-99	Na	na	62.94	37.06

Source: Kumar and Pradhan (2002); ORG (2002).

MNCs are much more active in the production of formulations (or branded products) as compared to Indian firms which concentrated more in bulk drugs and generic products (Table 4). Evidence suggests that the share of MNCs has been declining even in the formulations' market.

The share of the public sector is negligible. Bengal Chemicals and pharmaceutical limited (BPCL), Bengal Immunity and Smith Stanistreet Pharmaceuticals Ltd were taken over by the government after they were made sick by the private sector. . However proper utilization of their capacity could not be made and they are facing survival problems now. IDPL which is having the biggest pharmaceutical production facilities is closed down from 1996. Penincillin plant in HAL the biggest in the country has been handed over to private hands. Its streptomysin plant has also been leased to a private company for the production of other drugs.

Concentration: The industry is highly fragmented .Though there are 7000-8000 units, only about 300 are in the organized sector (Pacific bridge Inc. 1999) . These firms control around 60 per cent of the total production. In 1991-92, the share of top 10 firms was roughly 16 per cent. By the late 1990s, it rose to around 18 per cent. In the year 2002, it increased further at the top when 6 firms captured around one-fourth of the market (Table 5). Though the industry is fairly competitive, concentration at the top appears to have increased over time.

One reason for increasing market concentration could be mergers and acquisitions. Following the international trends, mergers and acquisitions have become a common phenomenon in the Indian pharmaceutical industry also. The merger of German Remedies and Zydus Cadilla will enable Zydus to emerge as the fourth largest company with a cumulative market share of 3.5 per cent. The merger of Pfizer, Pharmacia and Parke Davis would put the combined revenue at Rs. 6340 million. The most significant merger that took place in the last two

Table 5: Market share of top 10 firms in India in selected years in the 1990s.

Firm	1991-92	1993-94	1996-97	2002
Ranbaxy	3.37	4.45	4.29	4.6
Glaxo	3.38	3.22	2.68	5.92 (GSK)
Lupin	2.24	2.23	2.38	
Cipla	1.43	1.63	1.73	5.2
Hoechst	1,83	1.70	1.47	
Korpan	0.74	0.97	1.23	
Nicholas Piramal	0.50	0.44	1.22	3.4
Wockhardt	0.80	0.97	1.06	
Alembic	1.50	1.52	1.02	
Torrent	0.70	1.36	0.99	
Sun pharma				2.9
Dr. Reddy's				2.8
Total	**16.5**	**18.5**	**18.1**	**24.8**

Source: CMIE based on a sample of 345 firms and ORG-MARG.

years was that of Glaxo and Smithkline. It consolidated Glaxo's position at the top with a combined turnover of above Rs. 10000 millions. Among Indian companies, Dr. Reddy's acquired American Remedies; Sun Pharma took over Gujrat Lyka Organics, Carcass laboratories, and brand and copyrights of Natco pharma. Nicholas Piramal merged Rhone Poulenc with itself and later acquired Chennai based ICI pharmaceutical. Apparently, this spate of mergers and acquisitions increased the domination of foreign and Indian large firms in the industry. Patentable pharmaceutical markets are already highly oligopolistic/ monopolistic. Watal (1994) provides the market share data for 22 patentable drugs for 1994 (Table 6). It shows that the *top four firms in these markets hold over 75 per cent of the market share*. One may therefore argue that the number of pharmaceutical companies in India is likely to get reduced in the long term through a series of consolidation activities and market concentration will increase further (see also, ICRA 1999).

Table 6: Concentration ratios in patented markets

CR4	No. of drugs
1	8
1-.9	2
.8-.9	6
.7-.8	3

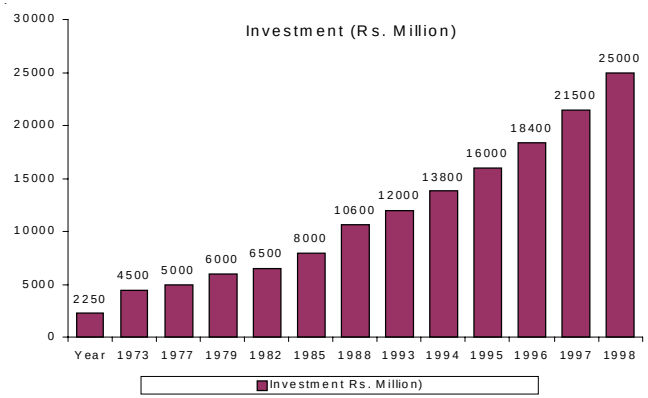
Source: Watal (2000).

III.2 Conduct of the industry

Investment

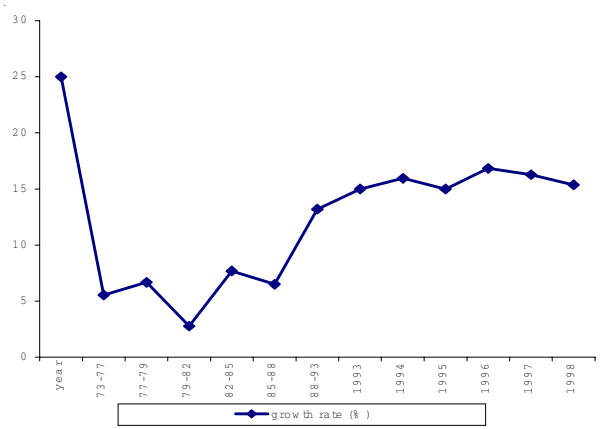
Figure 1 shows that the level of investment increased continuously from Rs. 2.2 billion in 1973 to Rs. 25 billion in 1999. A further analysis of investment patterns however suggests that investment increased sharply in the mid 1970s after the introduction of the Patent Act 1970 (Figure 2). Thereafter the average annual growth rate in investment fell considerably to 5-6 per cent. This was

Figure 1: Investment Patterns in selected years from 1973-1999



Source: OPPI (2000).

Figure 2: Annual average growth rate in investment (%)



Source: Based on OPPI (2000).

despite the fact that the number of units increased significantly during this period. It could perhaps be due to increasing number of small sector units. It is documented that the share of small sector in total production increased sharply from 18 per cent in 1978-79 to over 26 per cent during the 1980s (Kumar and Pradhan, 2002); the share of the organized indigenous sector and MNCs declined while that of the public sector remained constant. The rate of investment started picking up in the late 1980s perhaps in response to the new drug Policy 1986 that heralded an era of cautious liberalization in this industry.

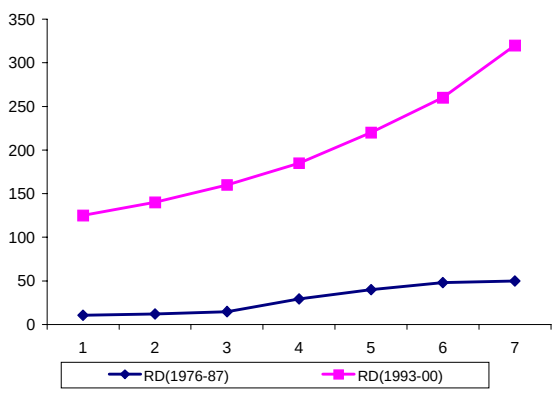
In the 1990s, the rate of investment increased dramatically to 15-17 per cent per annum and maintained the pace in the late 1990s. One may like to note that the liberalization process in the drug industry was initiated in 1994. Apparently tight controls on prices and hence on profit margins affected the incentive to invest in this sector adversely.

R&D

In India R&D is driven by process technology. There is a heavy reliance on foreign technology. R&D expenditures are quite low. Seventy seven firms have in-house R&D departments approved by the Department of Scientific and industrial research. Much of the industry's R&D is done by large firms. R&D expenditures were significantly higher during the 1990s as compared with the 1980s (Figure 3).

Evidence suggests that the pharmaceutical industry in India is the most research intensive industry having the highest R&D-sales ratio. Over the period

Figure 3: R&D expenditures: 1976-87 and 1993-00 (Rs. Million)



Source: Based on OPPI (2000).

Table 7: R&D-production ratio in selected years (%): 1965-66 to 2000

Year	R&D-production ratio (%)
65-66	1.7857
81-82	1.7005
83-84	1.8913
85-86	2.033
86-87	1.9246
93-94	1.5207
94-95	1.481
95-96	1.4616
96-97	1.459
97-98	1.4975
98-99	1.5271
99-00	1.6213

Source: Based on OPPI (2000).

1992-93 to 1999-00 R&D –sales ratio was greater than 1 per cent for only 4 industries- electronics, automobile, drugs and personal care products and drugs industry with the ratio 1.55 per cent emerged as the top R&D spender (Kumar and Aggarwal, 2001 based on CMIE data). Though R&D expenditures in the pharmaceutical industry compare well with other industries in India, they are negligible when compared with the US. R&D sales ratio in the US firms are as high as 17 per cent. Moreover, what is worrying is that R&D expenditures as a proportion of production are have declined in the 1990s (Table 7). In 1965-66, the ratio stood at 1.8 per cent; in 1981-82 it was roughly the same. During the eighties, it increased marginally and reached 2 per cent. However during the 1990s, it declined and reached 1.6 per cent in 1999-2000 again which was less than the 1965-66 level.

III.3 Performance of the Industry

Production

At the time of independence the total drug production in the country was around 100 million (Dubey, 1998). There was no production of bulk drugs. Starting with such a low base, production in this industry grew at a very high rate in the 1950s and 1960s; thereafter, the growth rate slowed down. Between 1970-71 and 1985-86, production increased at the average annual rate of roughly 18 per cent. Since 1985-86 there has again been an exponential growth in the total production in this industry. By 1999-2000, the industry was producing drugs worth Rs. 197 billion.

Table 8: Production of pharmaceuticals (Rs. Million)

Year	Formulation	Bulk	Total
1948	100	-	100
65-66	1500	180	1680 (87.7)
70-71	n.a.	n.a.	3500(21.6)
75-76	5440	1130	6570(17.5)
80-81	12000	2400	14400(23.8)
85-86	19450	4160	23610(12.7)
90-91	38400	7300	45700(18.7)
95-96	91250	18220	109470(27.9)
99-00	159600	37770	197370(20.0)

Sources: Singh (1986), OPPI (2000) ; Parentheses show average annual growth rate.

We fitted a trend line Log (prod) = log a +logb t + dum 90 for the period 1980-81 to 1999-2000.The estimated line,

$$\log(\text{prod}) = 7.225 + .122\,t + .234\,\text{dum90} \qquad R^2 = .99$$
$$(19.05) \quad (3.5)$$

suggests that the total production increased significantly more rapidly during the 1990s as compared with the 1980s .

The industry produces two kinds of products – bulk drugs and formulation. Bulk drugs are active chemical substances in powder form and form main raw material for pharmaceuticals. Formulations are the final preparation such as tablets, capsules, syrups, injectables. These are sold by brand name or are generics. At the time of independence bulk drug production was nil. It grew rapidly in the post independence period and by 1975-76, bulk drugs constituted nearly 17 per cent of the total production in 1975-76. Over the period 1980-00, production of both bulk drugs and formulations increased almost at the same rate. This was despite the introduction of ratio parameters linking bulk drugs and formulation production in the Drug Policy 1978. However, bulk drugs' production increased at a faster rate during the 1990s. As a result, the proportionate share of bulk drugs has increased marginally from roughly 17 per cent during the 1980s to over 19 per cent in the nineties. High growth in bulk drugs was fuelled primarily by the growth in export opportunities in these drugs. In contrast, about 85 per cent of the domestic production of formulations is consumed locally. With the exception of certain life saving, new generation under-patent formulations, India is relatively self sufficient in formulations.

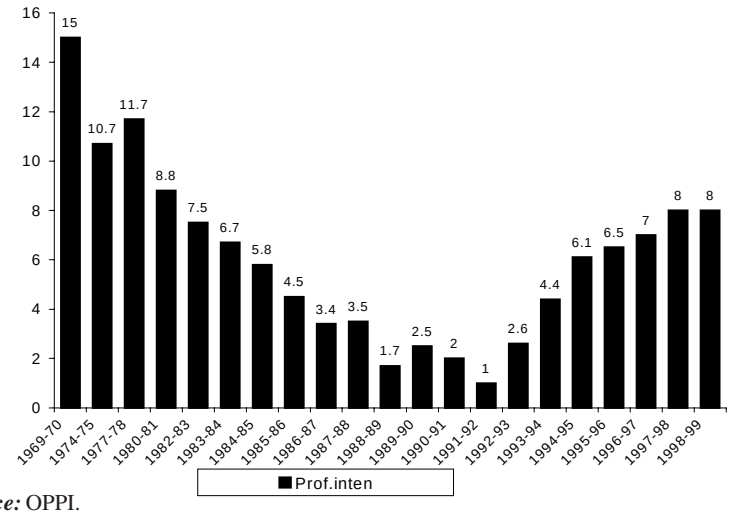
Profitability

The changing economic environment is manifested in the profitability trends. Profitability declined sharply between 1979-1993. However, thereafter it increased continuously (Figure 4).

FDI inflows

There has not been any substantial inflow of foreign investment into India. Neither has there been a substantial inflow of foreign technology in this sector. While during the 1990s, many norms were relaxed with regard to transfer of technology, there was no corresponding increase in the number of technical collaborations in the pharmaceutical sector. The percentage of FDI approved increased sharply in the year 2000. It could in part be due to amendment in the Patent Act 1970. The modified act came into force in 1999. Besides, at the beginning of 2000 the Indian government announced a change in policy regarding the level of investment by foreign multinationals in their Indian subsidiaries and new joint ventures. Foreign companies can now have equity stakes of upto 100 per cent previously it was 51 per cent. In the late 1990s, a number of MNCs had applied to India's Foreign Investment Promotion Board for setting up 100 per cent owned subsidiaries. US company Pfizer and German company Bayer were among the companies that were granted approval. Pfizer will be setting up a wholly owned subsidiary while Bayer has sought to increase

Figure 4: Profits-sales ratio (%) in selected years : 1969-70 to 1998-99



Source: OPPI.

Table 9: FDI inflows: total amount approved, amount approved in the pharmaceutical industry: 1991-2000

Year	Amount Approved	FDI approved in the pharmaceutical industry	% of pharma FDI to total approvals
1991	534	NA	-
1992	3888	NA	-
1993	8859	29.9	0.34
1994	14187	163.0	1.15
1995	32072	185.8	0.58
1996	30147	118.2	0.33
1997	54891	182.9	0.33
1998	30814	91.1	0.30
1999	28367	79.8	0.28
2000	37043	1614.6	4.36
Total	246802	2465.3	1.00

Source: Lalitha (2002).

its stake in its joint venture with the Zydus healthcare group from 51 per cent to 100 per cent. The share of the pharmaceutical industry in total approvals increased sharply in the year 2000 (table 9).

Out ward FDI : Indian subsidiaries world wide

Indian companies are increasingly looking to expand their operations in the West, having built up a substantial presence in Asia and Eastern Europe where companies such as Ranbaxy and Himalaya Drug Company are well known. The domestic industry is aggressively looking at acquisition of not only companies but also brands (Table 10). The industry has acquired over 100 brands in the last two years. Dr. Reddy's acquired Britain based BMS and its subsidiary

Table 10: Subsidiaries of Indian firms abroad

Subsidiary	Country	Owning Indian Company
Glenmark	Canada , Portugal	Glenmark
Dr. Reddy's labs	Netherlands,Hong Kong,Russia	Dr. Reddy's Labs
Himalaya drugs	Russia	Himalaya drugs
Lupin Chemicals	Thailand	Lupin
Ranbaxy	China, Malaysia,Poland,Vietnam Germany, Japan ,France	Ranbaxy
Reddy Cheminor	USA	Dr. Reddy's
Torrent	Russia	Torrent
Wockhardt	Ireland,Saudi Arabia, US, UK, Germany	Wockhardt

Meridian Healthcare for 9.05 million pounds. Ranbaxy acquired one in Germay in 2000, another in Japan in 2001 and RPG Aventis in France in 2003. International business of Wockhardt grew by 87 per cent in the first quarter of 2004. These companies are eyeing new markets and have planned new acquisitions.

Exports

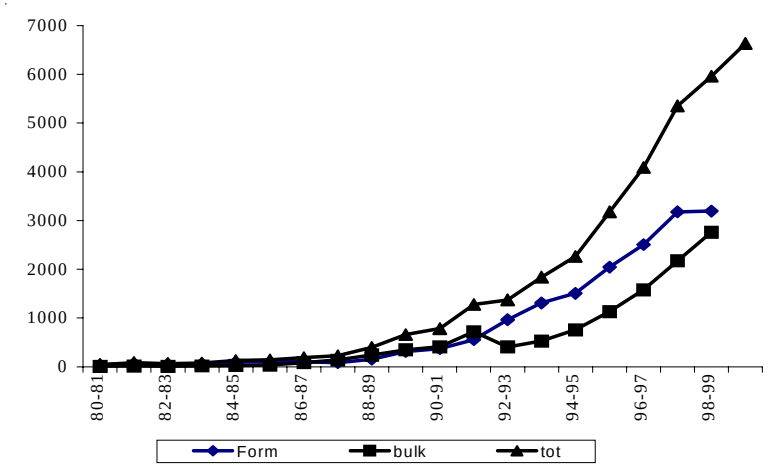
Till the mid 1980s, production of pharmaceuticals in India was mainly for domestic markets.

In the late 1980s, Indian firms started eyeing overseas markets. However, Figure 1 shows that total exports in value terms increased sharply during the 1990s. One may also observe that the exports of both formulations and bulk drugs have increased steadily since 1990-91.

Table 11 shows that exports constituted only 1 per cent to 5 per cent of total production till the mid 1980. In the late 1980s, exports started increasing. During the 1990s more than a quarter of production was directed to the export markets. In fact in the late 1990s, one third of the total production was exported. In 2001-02 exports accounted for around 38 per cent of total production.

Apparently, since 1990 exports have been increasing at an enormous rate. From quality angle the industry meets international standards acceptable to

Figure 5 : Drug exports 1980-81 to 1999-2000



Source: Based on OPPI (2002).

Table 11: Export-production ratio and import-production ratio (%): 1961-2000

Years	Export/production (%)	Import/production (%)
1961-69	1.5	8.6
1969-81	4.3	7.5
1981- 86	4.7	8.8
1986-90	10.1	12.5
1990-95	21.2	14.4
1995-00	33.3	19.6

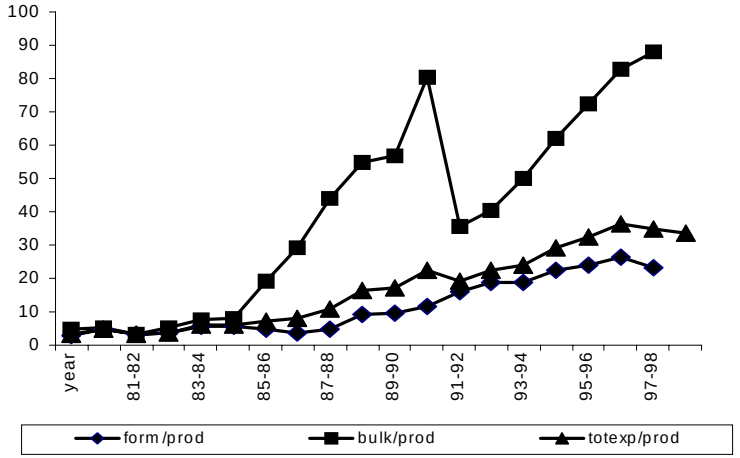
Source: Singh (1986) for 1961-1981; Computed from OPPI (2000) for 1981-2000.

importing countries. Price wise also they are able to offer most competitive prices.

The growth in exports of formulations has not been as strong as in the case of bulk drugs. While less than a quarter of production was exported in the formulation sector in 1998-99, over 87 per cent of total bulk was sold overseas (Fig. 6). Marketing of formulations requires an extensive marketing infrastructure which must be complemented with advertising which is essential to establish a brand name. This could in part explain such patterns.

The above analysis is based on the aggregate data provided by the 'Organisation of Pharmaceutical Producers of India' (OPPI). We considered it

Figure 6: Export-production ratio (%): 1980-81 to 1999-00



Source: based on OPPI (2000).

important to use a more disaggregated database to examine the trends and patterns of the export activity of Indian enterprises in this industry over the period of the 1990s. We made use of the on-line Prowess Data Base (2003 version) of the Centre for Monitoring Indian Economy (CMIE), for this purpose. Prowess covers financial data of over 300 pharmaceutical companies incorporated in India. These companies are in both the small scale and the organised sector. The financial data covered by the Data Base includes most of the information that incorporated companies are required to disclose in their annual reports, viz. profit and loss account and a balance sheet along with information contained in the schedules and annex. We used this database to extract export –related information for all the pharmaceutical companies for the period 1990-91 to 2002-2003. That yielded a total of 2290 observations with a varying number of companies in different years. We calculated the export –sales ratio of sample firms in each year of the 1990s. Table 12 presents information on the average export-sales ratio of the sample firms in selected years. It shows that there has been a continuous increase in the export intensity of firms in this industry since 1990 and that exports constituted around one-third of sample firms' sales-turnover in 2003. This supports our conclusions drawn on the basis of the OPPI database.

Evidence also suggests that the export products are now moving towards the direction of developed countries as against India's earlier bias towards Asian and East European region. Table 13 shows that in 1989-90, 44.5 per cent exports were directed to USSR. Germany, USA and UK followed it. By the year 2002, US emerged as the most favoured nation while the share of Russia declined substantially. It also suggests that there has been a tremendous diversification of the export markets during the 1990s. While only 8 markets constituted over 72 per cent of total exports in 1989-90, these markets accounted for only one-fifth of the total exports in 2002-2003.

Table 12: Export-Sales Ratio of pharmaceutical firms in selected years : 1990-2003

Year	Average export-sales ratio	No. of Firms
1990	7.94	51
1995	14.11	194
2000	19.65	220
2001	20.66	220
2002	24.27	173
2003	32.41	45

Source: PROWESS, CMIE.

Table 13: Destination of India's pharmaceuticals' exports in 1989-90 and 2002-03

Year	Share in total 1989-90	Share in total 2002-2003
USSR	44.2	4.0*
FRG	13.2	1.8
USA	3.9	10.8
UK	2.9	2.1
Hong Kong	2.7	0.6
Singapore	2.0	0.6
Poland	1.9	0.3
Japan	1.7	0.2
China	-	3.3
Others	27.5	80.3

Sources : EXIM (1991), DGICS database. * includes Russia only.

To capture the dynamics of the firms' export performance, we examined export-sales ratio of 91 firms for which we had data for all the years after 1995. The distribution of export intensity for these firms is provided in Table 14. It shows two things. One, the share of exporting firms increased in the sample.

Two, the proportion of firms in higher export-sales ratio category increased over the period between 1996-98 and 2001-03. The analysis suggests that the rapid increase in export may be attributed to (1) an increasing number of firms taking to exports and (2) a continuous increase in the proportion of overseas sales of the exporting firms .

Table 14: Distribution of 91 firms by export-sales ratio: 1996-98 and 2001-03

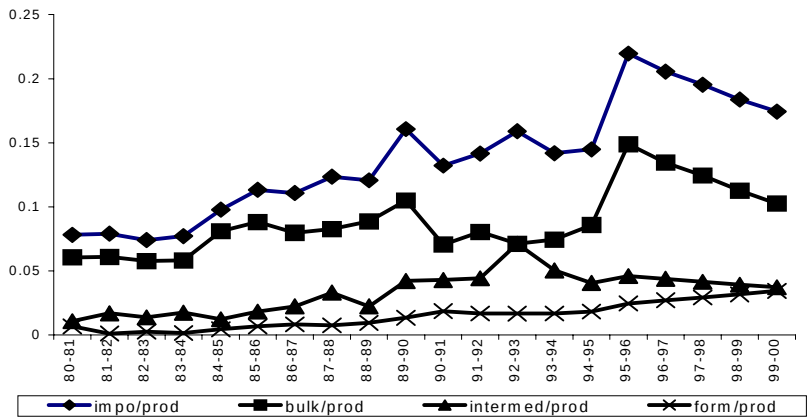
Export intensity	1996-8 (%)	2001-2003 (%)
0	22	19
0-5	35	25
5-10	10	13
10-15	5	7
15-25	8	12
25-50	12	15
>50	8	9
Total	100	100

Source: PROWESS database.

Trade balance

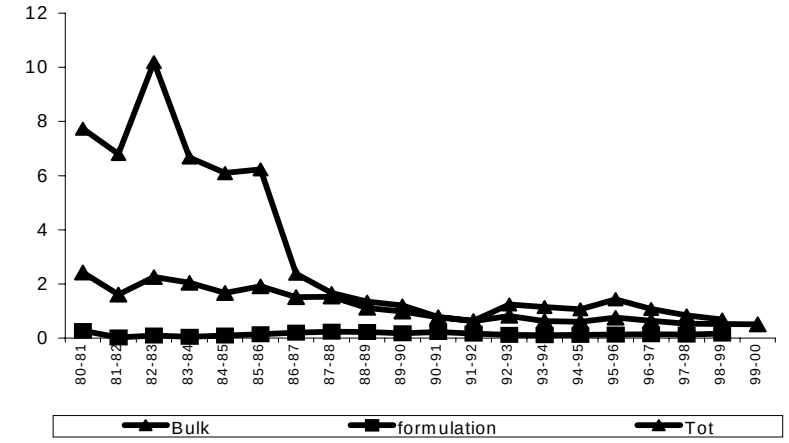
In contrast to exports, imports increased slowly (Fig.7). The import-production ratio increased from 8.6 per cent in the early 1960s to 19.6 per cent in the late 1990s. However, there was a continuous fall in the imports to production ratio between 1995-96 and 1999-00. As a result of slow growth in imports, the

Figure 7: Import-production ration (%) : 1981-82 to 1999-



Source : based on OPPI (2000).

Figure 8: Imports-exports ratio (%) : 1981-82 to 1999-2000



Source : based on OPPI (2000).

industry became a net foreign exchange earner. Figure 8 shows that the ratio of imports to exports fell dramatically for bulk drugs in the late 1980s and the trend continued thereafter. As a result, total imports to export ratio declined from over 2 to 0.5.

In what follows, we use the firm level data to analyse the factors that have contributed to the export competitiveness of the industry.

IV. What factors helped in enhancing the export performance of the industry : Firm level analysis

IV.1 Inter-firm variations in the export performance

Though the export intensity of the industry increased substantially in the 1990s, there were wide inter-firm variations in the export performance. Table 15 provides the distribution of firms by average export-sales ratio between 1999 and 2002. Of the 253 firms for which the information was available, 73 (29 per cent) firms did not export while 74 top exporting firms (29 per cent) exported more than 15 per cent of their sales turnover during this period. The remaining 106 firms (42 per cent) had export-intensity which was varying between greater-than- zero and 15 per cent.

To gain deeper insights on inter-firm variations in the export performance, we analysed the export performance of all the sample firms during the period 1990-2003. Of the 309 firms for which we had data, 173 firms were found to be exporting, the remaining 136 firms were non-exporting. Firms that never exported

Table 15 : Distribution of firms by export intensity : 1999-2002

Export to sales ratio	1999-2002	Share of total
0	73	0.29
0 - 0.025	41	0.16
0.025- .05	21	0.08
0.05 - .075	16	0.06
0.075- 0.10	13	0.05
0.10- 0.125	9	0.04
0.125 - 0.15	6	0.02
0.15 - 0.25	26	0.10
0.25 - 0.50	31	0.12
0.5<	17	0.07
total	253	1

Source : PROWESS database.

or exported in one or two years were considered non-exporting firms. Several firms in this category had missing observations. However in the absence of information these firms were categorised as non exporting firms.

We estimated export trend growth rate of each exporting firm for the period 1990-2003, using the following semi logarithmic function.

$$\text{Log } EXP_t = \log a + \log b\ T$$

Where EXP_t = value of exports in year t, T= time variable

Our analysis revealed that as many as 90 (over 52 per cent) firms had registered a significant trend export growth rate over this period. Of these firms, 75 registered a trend growth rate of over 20 per cent.. These included, Arti drugs, Ajanta Pharma, Ranbaxy, Dr. Reddy's Labs, Lupin, Cadila, Amratanjan, Orchid and Morepen. Of the remaining 83 firms, 40 firms had a negative trend growth rate while 43 firms had positive trend growth rate. The growth rate however was not statistically significantly different from zero in both the cases. One may therefore conclude that though the export performance of the industry has been impressive, there are substantial inter-firm variations. In what follows, we analyse why some firms perform better than the others.

IV.2 Determinants of Exports : Our Hypotheses

Exporting entails costs and risks above those incurred in supplying the domestic market. For example, exporting involves additional transport, distribution and marketing costs international market research and advertising and, depending on the country, additional financial and legal risks. While some of these additional costs vary with the volume exported (eg production and transport costs), others are 'fixed' costs. Some fixed costs can be recovered if the firm does not succeed internationally (eg by selling fixed assets). However, others are 'sunk costs' in the sense that, once incurred, they cannot be recovered if exporting turns out to be unsuccessful (eg the time and money spent on international market research and advertising). The theoretical literature argues that many of these costs are likely to be significant (eg Baldwin 1989, Baldwin and Krugman 1989, Dixit 1989, Krugman 1989). To export successfully, therefore, firms need to possess a competitive advantage to overcome the advantages typically enjoyed by rival firms located in the country into which they export (eg greater familiarity with local laws and customs and lower transport costs, greater familiarity with local tastes). Sometimes the source of

competitive advantage can arise within the firm and is the result of firm's own efforts and vision. At other times, the source of this advantage can arise outside the firm. These could be due to government incentives. These incentives may help in reducing the costs of exporting or offer higher profit margins. The share of exports in total firm's sales (export intensity) therefore depends on two sets of factors : firm specific advantages and government incentives. Algebraically,

$$EXP_i = f \text{ (Firm specific advantages, government incentives)}$$

Where EXP_I is the export intensity of firm i.

Firm Specific Advantages

The competitive advantages of firms, which collectively may be referred to as 'firm-specific factors', are likely to have a pervasive influence on their export performance. The literature on firm-specific determinants of export performance and behaviour is extremely rich (see, for instance, Chetty and Hamilton, 1993, for a thorough review of the literature on the subject) and covers a wide spectrum of issues, such as the relative importance of firms' demographics (Bonaccorsi, 1992; Wagner, 1995), or the relative impact of the beliefs, attitudes and perceptions of the firm's top management (Bijmolt and Zwart, 1994). We will in this paper, focus on technology and cost related factors.

Technological capabilities

Pharmaceutical industry is one of the most research intensive industries. As the quintessential science-based industry, pharmaceuticals depend heavily on high level manpower and substantial R&D for new products and growth. The data collected from the National Science foundation shows that the US pharmaceutical industry spends a greater percentage of sales in research than other American industries including the electronics, communications and aerospace sectors (NSF 2003). Industrial R&D funds as a percent of net sales of R&D performing companies averaged 11 per cent over the period between 1997-2000. Computer and electronics with 8 per cent followed it. According to the PhRMA (2003) annual report, member companies spent roughly 17 per cent of domestic sales on R&D in 2001. Apparently, there is an intense R&D based competition in this industry. Furthermore, there have been mega mergers and acquisitions in the pharmaceutical sector (see for instance Scherer 2000). These are largely motivated by the desire of the companies to pool their R&D portfolios and to position themselves across a wide spectrum of end market products. These mergers and acquisitions have further intensified innovation based competition.

As competition is increasingly technology based, it is expected that technological capabilities would play an important role in determining a firm's propensity to export in this industry. Firm-specific technological capabilities are determined not only by their own R&D efforts but also by the acquisition of technologies from external sources (Jain 1998). In what follows we analyse the importance of the two channels of acquiring technological capabilities for Indian pharmaceutical firms.

Imports of disembodied technologies (MTS): Investment in R&D has shown a dramatic growth in developed countries, in the past 25 years[3] . It may be attributed partly to greater opportunities for innovation because of advances in scientific knowledge[4] and partly to the fact that pharmaceutical R&D processes have become longer, riskier and complex because of more complex scientific tools and an upsurge of new approaches to treat complex diseases. It is documented that only 1 out of 5000 screened compounds is approved as a new medicine. The average cost to develop a new drug has therefore grown from $138 million in 1975 to $802 million in 2000 (phRma 2003). Thus, the research processes in this industry are increasingly becoming time consuming, complicated, risky and costly driving up R&D expenditures in this industry worldwide. Developing countries' firms do not have resources to carry out innovative R&D. Major thrust of R&D in these countries is therefore in improvement in process efficiencies and product quality. Firms get access to newer technologies through imports. Therefore acquisition of newer technologies from external sources (MTS) is expected to be a key factor in the competitiveness of firms.

R&D (RDS): R&D generates not only innovations but also allows firms to better assimilate external technological knowledge. Indian firms are not innovators but they need to perform R&D to absorb foreign technologies. The need to perform R&D for assimilating foreign technologies in this sector is clear from the fact that the pharmaceutical industry in India also is the most research intensive industry having the highest R&D-sales ratio. Over the period 1992-93 to 1999-00, R&D – sales ratio was greater than 1 per cent for only 4 industries- electronics, automobile, drugs and personal care products and the drugs industry with the ratio 1.55 per cent emerged as the top R&D spender (Kumar and Aggarwal, 2001 based on CMIE data).

Evidence also suggests that the number of R&D performing firms in this industry has been increasing steadily. The PROWESS database provided by the

CMIE suggests that in 1990, 4 out of 45 firms were R&D performing firms and that they constituted 6.6 per cent of the total number of firms. In 2001, 77 out of 171 (41 per cent) firms were performing R&D. Besides seventy seven firms have in-house R&D departments approved by the Department of Scientific and industrial research. Many firms including lesser known firms such as IPCA , Sunil Pharma Merck, Themis, Ambalal and Arti have multiple R&D Centres.

R&D activity focuses on developing new product development, upgrading manufacturing processes, developing dosage and formulation form of new and existing drugs and improved packaging. These efforts lead to product diversification, better yield, quality improvement, improved productivity, better capacity utilisation and cost containment. Furthermore, many firms are now performing R&D with the focus on export markets. In the technology Notes for the year 2003 (PROWESS 2003), several firms including Korpan, Divi, Dolphin, RPG, Vorin reported that they are focusing on the development of the products that have substantial export potential. Thus a strong R&D bias is expected to augment the international business.

Marketing capabilities

Advertising expenditures (ADS): Pharmaceutical Companies' *Promotional Practices* is another important factor affecting this industry. When a pharmaceutical company develops a new drug it gives the drug two names. The first one is its generic name, which represents the chemical structure or chemical form of the drug. The generic name of the drug never changes. The second name given to the drug is its brand name. The use of brand name confers a considerable scope of product differentiation between a brand name and its generics. Brand-generic differentiation encourages firms to spend heavily on brand promotion. Generic companies also spend some funds on marketing but such expenses for originator (branded) products are much higher than for generic products.

Product differentiation is not always between a brand and its generics, it is between different brands of the same product also. At any time there may be different brands of the same product in the market. Companies may vary an existing molecule through molecular restructuring and introduce their own brands of the similar product. For instance, Glaxo's anti-ulcerant ranitidine is conceptually the same molecule as SmithKline Beecham's cemitidine. Both of them have the same reaction in the human body to prevent ulceric tendencies. However these are two different brands and therefore attract promotional campaign by the firms. The industry is thus characterized by product

differentiation at two different levels : brand-brand differentiation and brand-generic differentiation.

Promotional activities directed at doctors chemists and retailers aim at creating differentiation in their minds by emphasising small differences between competing products and by providing information about side effects. Direct-to-consumer advertising is aimed at influencing the choice of end users. Heavily influenced by advertising, patients become brand conscious and increase brand requests.[5] Advertising reduces the demand elasticity of a brand and has direct bearing on the profit margin. According to data cited by *Government Accounting Office (the USA)* in 2001 companies spent $19.1 billion on all promotional activities. On average, 10.6 per cent of total US sales went for advertising. Brand image and marketing expenses therefore are expected to play an important role in determining a firm's performance.

In India prescription drugs cannot be advertised in the general media. The list of such drugs is quite large and includes all antibiotics and specific painkillers etc. The avenues for advertising are therefore restricted. Companies advertise through trade journals and medical megazines. They also sponsor conferences in India and abroad often at the company costs to establish brand name. At these conferences pamphlets, free samples and other materials are distributed. Average advertisement-sales ratio for 203 companies covered by CMIE in 2001-02 was around 5 per cent which was substantially higher than the R&D intensity. Firms such as Dr. Reddy's, Ranbaxy, Ajanta, cadila, amrutanjan, abbott, Torrent were spending over 8 per cent of their sales turnover on promotional activities. These costs are thus substantial and firms incurring such expenses may be expected to compete in global markets for additional profits.

Industry Structure

High level of concentration is yet another characteristic of this industry. High cost of the R&D, patent protection and advertising expenditures prove to be effective entry barriers for new firms. Owing to these entry deterrents, the industry worldwide is characterized by a high degree of concentration. The leading firms thus enjoy substantial market power in this industry. We therefore expect large sized firms and transnationals to have an edge in the export markets over smaller domestic firms.

Transnationality (FF): Top 10 pharmaceutical companies in the world contributed 50 per cent of global sales while top 20 firms contributed over two-thirds of total sales in 2001. These large companies are of transnational character

and are concentrated in the US and European markets. Apparently, this Industry enjoys a high degree of transnationality. One may therefore expect export intensity of foreign firms to be higher than that of domestic firms.

Size (SIZE): The arguments put forth above suggest that the size barriers in this industry could be formidable barriers to entry for potential new firms and for the survival of independent local firms. Though the industry is fairly competitive, concentration at the top appears to have increased over time. Larger size makes it possible for firms to extend their R&D and the geographical scope of their markets. Thus we expect size to have a positive effect on the export performance of firms.

Another reason why large firms are expected to have higher export intensity is that many of these firms are becoming outward oriented. Outward investment has been made easier by the government's decision to liberalise overseas acquisition regulations[6]. The existing literature (See Kumar and Pradhan 2003) suggests a significantly positive relationship between outward investment and home country exports. Since much of outward investment is undertaken by large firms in this industry, we expect large firms to have significantly higher export intensity.

Cost of production

Variable costs (VCOST): Cost management may also be an important factor affecting the competitiveness of firms. In their Management Discussion and Analysis Reports, many firms indicated that strict measures to control cost of production have made it possible for them to compete in the world markets. Indigenisation of imported raw material, better negotiations, cutting down the consumption of power and steam, reducing wastage, better working capital management and reducing transport costs through improved marketing and logistic team work have given them cost advantages and increasing yield per batch. Firms with lower costs per unit are likely to be more competitive in the overseas markets. We thus expect the variable cost of production to be negatively related with the propensity to export.

Government policy incentives

Left to themselves some firms develop competence and competitiveness due to their global vision. But for the majority, time required to do so would be very long. These firms need export-friendly policies and an enabling trading environment, all of which aim to enhance competitiveness. Governments can therefore play a crucial role in putting into place an export-friendly 'enabling

environment'. The enabling factors in this sector would include comprehensive technology support for all enterprises, access to industrial finance at competitive interest rates, tax relaxation and an efficient and cost-competitive infrastructure , a well developed information structure, outward-oriented trade and industrial rules, and a proactive foreign investment strategy. Like many governments elsewhere, government of India (GOI) too has been giving several export incentives to Indian exporters to promote exports from the country. Such schemes provided both direct and indirect subsidies and included Cash Compensatory Support, Replenishment import licence, tax exemption of export income, subsidised export credit and export credit insurance, bonded warehouses, support for export marketing and so on. Since the effect of all these factors cannot be quantified, we shall try to analyse the effect of some of these government measures on the export performance of firms.

Fiscal incentives

Indirect fiscal incentives on imports of raw materials (IMPR) and capital goods (IMCAP): Export incentives are given by GOI through several institutions/ agencies and under various Acts. Export incentives are primarily given by the Ministry of Commerce through its Directorate General of Foreign Trade (DGFT), and by the Ministry of Finance. Major incentives given by DGFT include Export Promotion Capital Goods (EPCG) Scheme and Duty Exemption/Duty Remission Schemes. The EPCG scheme, first introduced on April 1, 1990 and amended from time to time, allows for the import of capital goods at concessional customs duty. Duty Exemption/Duty Remission Schemes aim at providing imported raw materials at the lower price. While duty exemption scheme exempts import of inputs required for export production from duty, the duty remission scheme enables post export replenishment/ remission of duty on inputs used in the export product (Duty Entitlement passbook Scheme). The Ministry of Finance operates the duty drawback scheme. Under the scheme, excise duty and customs duty paid on inputs is refunded to the exporter of finished products. Thus the objective of this scheme is also to make the imported raw material cheaply available to firms. Aside from this, incentives in the form of Special Import Licence (SIL) were given to exporters for import of goods that are otherwise restricted, by paying normal customs duties. SIL is dead with the removal of all QRs by April 1, 2001.

One expects that the firms importing raw materials and capital goods tend to export more to avail such incentives . These firms may also have advantage over the others as they are able to produce high quality products at lower costs.

There may thus be a positive relationship between intensity of raw material imports and capital goods imports on the one hand and propensity to export on the other.

Income tax exemptions (PCM): The Ministry of Finance tax exempts export profits i.e. profits from exports are exempted from income tax. Profits that a firm in Export Processing Zone makes is exempted from income tax. Similarly, Export Oriented Units are exempted from paying income tax on its profits. Any firm in Domestic Tariff Area (DTA) exporting goods can claim exemption from income tax on the profits it makes from exports . One may expect that the firms with higher profit margins are tempted to export more to avail these exemptions. Thus, we expect a positive relationship between PCM and export intensity.

Liberalization

Liberation measures in the Pharmaceutical industry (LIBDUM): As described above, major policy initiatives in the direction of liberalization in the pharmaceutical industry were announced in 1994 through the 'Drug policy 1994'. Besides, several custom duty and excise duty exemptions were given to the industry and foreign investment norms were liberalised. All these measures are likely to have positive influence on the propensity to export in the post 1994 period. We therefore hypothesise that the average propensity to export increased substantially in the post 1994 period.

Technology support

It is described above that the government has made concerted efforts to encourage R&D activities in this industry. Though the effect of all the measures may not be captured quantitatively, we may analyse the role of the institutional support for R&D promotion given by the government to Indian firms.

Institutional Support (DOMROY): The government has set up various institutions for the promotion of indigenous R&D efforts. In 1978 institutes like BCG institute Madras, Heffkins Institute Mumbai and CRI Kasauli were activated to promote R&D in the drug sector. As described above, the Department of Science and Technology (DST), Government of India has also initiated programmes on drug development for promoting R&D in drugs and pharmaceuticals sector. We expect that the technical fees paid to such institutions is an indicator of the collaboration between a firm and the government research institutions, and hypothesise a positive relationship between such fee and royalty and the propensity to export.

We thus expect the following factors to influence the export performance of firms.

EXP= f (RDS,MTS,ADS,FF,SIZE,VCOST,IMPR,IMCAP, PCM,LIBDUM,DOMROY)

In order to examine the relevance of these factors, we first conducted a primary survey. Primary survey technique was considered important because the survey provides a perspective on the industry from the producer's point of view. In what follows, we shall discuss findings from our primary data analysis.

IV.3 Determinants of Export Competitiveness : Primary Survey Based Analysis

Primary Survey : The Database

A total of 450 questionnaires were sent to analyse how producers evaluate the effectiveness of various factors affecting their export competitiveness. Prospective respondents included the members of OPPI and Indian Domestic Manufacturers Association (IDMA). In Chennai and Delhi questionnaires were filled in by personal interviews. Only a total of 31 responses could be gathered. Of these 31 firms, 5 firms were not exporting. However their responses provided useful insight on the factors that constrained their export performance. Of the 26 firms that were exporting , 10 were in the organised sector while 16 were in the small scale sector. Thirteen firms were producing formulations, 5 produced bulk drugs while 7 firms produced both formulations and bulk drugs. One firms was producing films and foils for the pharmaceutical sector. Respondent included CEO/managing directors, partners and senior managers of export divisions. We examined their responses to draw inferences regarding the factors determining the competitiveness of firms.

The main objective of this part of the research was to assess the effectiveness of specified factors in:

(1) firms' decision to start exporting, and
(2) promoting their export competitiveness.

In what follows, we analyse the responses of the producers to the two questions asked, separately.

Primary Survey : The Analysis

Decision to start exporting: We asked respondents to evaluate the relevance of 6 possible factors that motivated them to export. These factors included technological capabilities related factors and government policy incentive related factors. While specifying the government incentive related factors, we included 'price controls' as one of the factors beside other factors discussed above. This was because, price regulation in this industry is a widely prevalent phenomenon. Government regulates prices either directly or indirectly by regulating monopolies affecting economic conditions in the industry[7]. These controls reduce profitability and increase the incentive to market the products globally. Thus price controls are expected to affect the decision to export positively.

The respondents were asked to mark a four-point scale with values ranging from strongly important (3) to not important (0). Table 7 presents a summary of replies to this question. While summarising the findings, the scale was condensed to 3 levels : the most important, important and not important. A majority of firms revealed that their own R&D efforts and fiscal incentives ,both direct and indirect played a major role in their decision to start export. It is important to note that technology collaborations with the foreign firms were rated rather low. This needs further examination. Price controls were also not assigned an important role in their decision to export. This is in contradiction with the apparent view that price controls motivated firms to export. Price controls were introduced in the 1960s while exports started on a significant scale in the late 1980s. Finally, the response to the 'liberalization' factor was also low. It may be attributed to the fact that many firms started exporting prior to 1991. We expect this to appear significant factor in driving competitiveness.

Firm size-wise patterns suggest that small firms attach rather high importance to government incentives while large firms rate the importance of both R&D capabilities and government incentives highly. Even large firms view government incentives as being more vital than R&D efforts in their decision to start exporting. Technology collaborations seem to have an important impact on the decision to export in the organised sector. This is not so for the small scale sector firms. This is in tune with their response to the relevance of R&D efforts. Small domestic market size also motivated organised sector firms to look outwards; it is not important for the small scale sector firms. This result is self explanatory. A majority of large firms feel that liberalization of trade

policies has positively affected their business. Small firms seem to be divided on this issue.

Our interviews also revealed that vision to be global player and additional profits had been other major forces that attracted Indian firms to foreign markets. The model adopted by Indian firms was first to cater to unregulated markets, then to enter quasi regulated markets and finally to have access to regulated markets. Apparently, firms having R&D capabilities and vision to grow decide to export. Government incentives are crucial motivating factors for them to do so. Relevance of technology-related factors seem to be rather low for small sector firms.

Factors affecting the export performance:To further extend our perception of the export determinants, we asked respondents to evaluate the relevance of 6 groups of factors for their export competitiveness. Table 8 summarises the evidence derived from this question.

The first group of factors was related to the cost of production. The two factors evaluated in this group were the labour costs and other production costs. We asked whether lower costs contributed to their competitiveness in the world market. Our analysis of the responses suggests that cost advantage is an important factor for firms' competitiveness in India. However, this is not the most important factor. While a majority of firms perceives it an important factor, only one-fourth of the firms felt that it was the most important factor. The average response was almost the same for both labour and non labour costs. Interestingly, organised sector firms assign a greater importance to labour costs while for the small firms production costs other than labour appear to be more important. It could be because small firms are more labour intensive and they can effectively bring down their costs by managing non labour costs.

The second group of questions related to the relevance of the technological capabilities of firms in their export performance. More specifically, we asked the respondents to evaluate the importance of their process R&D, introduction of new products and technology purchases from abroad, in their export performance. Two important patterns emerged. One, firms provided a substantially stronger evaluation of the importance of their own R&D efforts than technology purchase. In fact, over 60 per cent respondents did not consider technology purchase an important factor. Two, firms assigned a higher rating to the modification in process technology than to the introduction of new products, reflecting the importance of the pursuit of improvement in processes in the

Table 16: Evaluation by firms of reasons for starting exports

		Most important	Important	not important	Average response	CV
		% of total firms			%	
A. Your R&D capabilities	(av)	23.1	46.1	30.8	1.58	69.8
	(OS)	30.0	50.0	20.0	1.9	52.3
	(SS)	18.8	43.7	37.5	1.3	91.1
B. Equity collaborations with for. companies	(AVE)	3.8	19.2	76.9	0.35	215.2
	(OS)	10.0	30.0	60.0	0.6	161.1
	(SS)	0	12.0	88.0	.19	290.1
C. Technology collaborations with for. Companies	(AVE)	3.8	38.4	57.7	0.69	134.0
	(OS)	0	60.0	40.0	2.2	46.9
	(SS)	6.2	25.0	68.8	0.5	178.9
D. Small domestic markets in your product	(ALL)	11.5	30.8	57.7	0.81	135.7
	(OS)	10.0	50.0	40.0	1.0	105.4
	(SS)	12.5	18.7	68.8	0.69	165.6
E. Tax Incentives	(ALL)	40.0	38.4	21.5	2.08	52.6
	(OS)	42.0	33.0	25.0	2.1	52.4
	(SS)	31.3	37.5	31.3	1.43	87.9
F. Price controls in domestic markets	(ALL)	7.7	42.2	50.0	0.92	110.1
	(OS)	10	50	40.0	0.9	110.5
	(SS)	6.3	43.7	50.0	.93	113.4
F. Concessional imports for exports	(ALL)	34.6	42.3	23.1	1.73	68.4
	(OS)	30.0	60.0	10.0	1.9	52.3
	(SS)	37.5	31.3	31.28	1.62	80.6
H. Trade and FDI Liberalization policies of the 1990s	(ALL)	15.4	38.4	46.2	1.04	110.5
	(OS)	10.0	60.0	30.0	1.00	105.1
	(SS)	18.3	31.3	50.0	1.06	116.3

Note: ALL : All firms; OS organised sector; SS: small scale sector
Source: Primary data

industry's technological trajectory. Size-wise average response patterns suggest that the organised sector firms assign a higher ranking to technological capabilities as compared to the small sector firms. Furthermore, though acquisition of foreign technology was considered important by large firms for starting exports, it was not considered important for driving their export performance. This result we shall explore later.

The third group of factors related to export performance was the brand image and marketing channels. The average responses of 2.04 and 1.65 respectively, suggest that these firm specific characteristics are important factors in driving export performance of firms. Only 15 per cent respondents considered them to be unimportant. Interestingly, firms rated the importance of brand image relatively highly. Around 42 per cent respondents considered it to be the most important factor. On the contrary, only 23 per cent respondents assigned the highest rank to marketing channels. Our sector-wise analysis suggests that small firms have a rather low evaluation of these factors as reasons for driving their exports. This could be because these firms are not capable of spending huge sums to create brand image and marketing channels and many of them are exporting due to contract manufacturing and /or lower costs.

Firm size was not considered important by a majority of firms. Our analysis by size however indicates that the low evaluation of this factor was mainly due to the inclusion of small firms in the analysis. Organised sector firms emerged as highly responsive to this firm specific characteristic.

Our analysis of the responses provides a strong support to the relevance of government incentives in driving export performance of firms in India. Though these incentives are considered relevant by both organised and small sector firms, the former are relatively more responsive to the relevance of their influence.

Finally, the impact of liberalization appears to be favourable on the export performance of firms. Of the 26 exporting firms, 14 firms revealed that liberalization influenced their exporting activity positively (Table 9). Some firms such as Cadila, Sresan, Troikka, Vasu Pharma, Ciron drugs and Sun pharmaceuticals informed that their exports zoomed up while others suggested they were able to diversify destinations. A few firms started exporting activity in the 1990s. Seven firms did not find any change in their export performance. Only one firm reported to have suffered adversely. The remaining 4 firms did not find this question applicable to them because they came into operations in the 1990s.

Table 17: Evaluation by firms of factors that drive their export competitiveness

		Most important	Important	Not important	Average response	C.V.
		% of total firms				%
Low labour cost	ALL	26.9	53.8	19.2	1.62	149.1
	OS	30.0	60.0	10.0	1.91	52.3
	SS	25.0	50.0	25.0	.43	80.2
Low costs other than labour	ALL	23.1	61.5	15.4	1.62	161.0
	OS	20.0	60.0	20.0	1.4	76.7
	SS	25.0	62.5	12.5	1.75	57.1
Regularly introducing new product	ALL	26.9	53.8	19.2	1.73	160.3
	OS	30.0	50.0	20.0	1.80	63.1
	SS	25.0	56.3	18.8	1.68	63.9
Continuous R&D to improve processes	ALL	50.0	34.6	15.4	2.00	171.5
	OS	70.0	20.0	10.0	2.50	38.9
	SS	37.5	43.8	18.8	1.68	70.8
Purchase of new tech.on continuous basis	ALL	19.2	19.2	61.5	0.88	71.1
	OS	20.0	20.0	60.0	0.9	142.9
	SS	18.8	18.8	62.5	.87	143.8
Established image	ALL	42.3	42.3	15.4	2.04	189.3
	OS	60.0	30.0	10.0	2.20	51.6
	SS	31.2	50.0	18.7	1.93	54.8
Marketing channels	ALL	23.1	61.5	15.4	1.65	162.5
	OS	30.0	50.0	20.0	1.60	73.3
	SS	18.7	68.7	12.5	1.68	56.1
Large Firm size	ALL	19.2	19.2	61.5	0.88	71.1
	OS	30.0	30.0	40.0	1.3	102.8
	SS	12.5	12.5	75.0	.62	183.6
Government incentives	ALL	38.5	46.2	15.4	1.77	154.8
	OS	40.0	50.0	10.0	1.90	57.9
	SS	37.5	43.7	18.7	1.68	70.8

Note : ALL : All firms; OS organised sector; SS: small scale sector
Source : Primary data

Table 18: Evaluation by the effect of liberalization on the export performance

Impact	% of total firms
Affected favourably	54.0
Did not find any change	27.0
adversely	4.0
Not applicable	15.0
Total	100.0

Source: primary data

Local firms and Foreign Firms

We interviewed 3 foreign firms. While two were exporting one was a non-exporting firm. The non-exporting firms revealed that the parent company had decided not to export from India. The company has not established manufacturing facility of its own. It hires such facilities for producing formulations using the parents' technology for the domestic markets and competes in domestic markets on the basis of cost advantage.

The exporting firms cited equity collaboration with foreign firms as the major reason for their decision to export. Both of them informed that exports to foreign parent and their foreign operations are among the most important factors driving their competitiveness. Fiscal incentives, established image and lower costs were other actors influencing their competitiveness. They did not assign a very important role to their R&D effort (Table 19).

In sum, the primary data analysis provides a valuable insight on the factors determining export competitiveness of firms in this industry. It not only provides support to our export model but also indicates that there may be differences in the export determinants of small and large firms , and MNE affiliates and local enterprises. In the following section we shall formally test the model using the secondary data and explore how the significance of different factors vary across different groups of firms. The model is,

$$EXPIN = f(RDS, MTS, ADS, FF, SIZE, VCOST, IMPR, IMCAP, PCM, LIBDUM, DOMROY)$$
$$(+, +, +, +, +, -, +, +, +, +, +)$$

where EXPIN represents the export intensity of a firm.

Table 19: Evaluation by firms of factors that drive their export competitiveness : analysis of foreign and domestic firms

Factors	Average Response	
	Foreign firms	Domestic firms
Low labour cost	1.5	1.6
Low costs other than labour	1.5	1.6
Regularly introducing new product	0.5	**1.8**
Continuous R&D to improve processes	1.5	**2.1**
Purchase of new technologies on continuous basis	1.0	0.87
Established image	**2.5**	**2.0**
Marketing channels	**3.0**	**1.7**
Large Firm size	**2.5**	0.75
Government incentives (including tax incentives)	**2.5**	**1.7**
Foreign Operations	**2.5**	0.54
Exports to foreign parents (for foreign firms)	**3.0**	-
Affiliation with foreign firm	**3.0**	-

Source: Primary survey.

IV. 4 Determinants of Export Competitiveness : Secondary Data Based Analysis

Methodology and Data

The secondary data were sourced from the PROWESS data base (2003 release) provided by the Centre for Monitoring Indian Economy. We have already described this database above. It provided data on 308 firms with varying number of annual observations. We had a total of 2290 observations. We dropped firms with missing observations and were left with 2156 observations. Distinction was made between large medium and small firms. For this we examined the size distribution of our sample firms. At the upper end 25 per cent of the total observations were above the sales turn over of Rs. 100 million and at the lower end 25 per cent observations were below the sales of Rs. 45 million. These were identified as two threshold limits. Firms above 100 million of turnover were identified as large firms ; firms below the sales turnover of 45 million were small firms and the remaining firms were middle sized firms. Distinction was also made between domestic and foreign firms. Firms with 10 per cent or more equity holding were identified as foreign firms.

Since some firms did not export at all, tobit model estimates were obtained. In view of the panel structure of the data, we could estimate random effect

models taking account of year-specific variations[8]. However, since we already had a liberalization dummy as one of the variables, the results returned by STATA could not be interpreted. Random effect models were also estimated after dropping the liberalization dummy and the results were found to be remarkably similar. However, these are not presented here to avoid multiplicity of results. We decided to present only tobit model estimates here.

With respect to some of the explanatory variables described above there could be problems of two-way causality. For instance, technology imports by firms are likely to influence their export performance but the intensity of technology imports may itself depend on whether they are exporting or not. Similarly, investment in R&D activities could be high because of outward orientation or vice versa. Finally, the causality between the intensity of exports and cash flow may very well be stated in both directions. To address this problem of causality we have used lagged variables in the analysis. Barring size and variable cost all other variables are lagged. Most lagged variables are created by taking averages of previous three years' values. The objective was to capture the cumulative effects of previous efforts also. For profit margins, we used only a one year lagged variable. The variable definitions are as follows:

EXP_{it}: Exports of goods by *i*th firm as a proportion of its sales in *t* th year.

MTS_{it-1} : Total royalties and technical fee paid abroad by *i*th firm over the past three years , *t-1,t-2 and t-3* as a proportion of its total sales during the same period.

RDS_{it-1}: Total R&D expenditure of *i*th firm in *t-1,t-2 and t-3* years as a proportion of its total sales during these years

ADS : Total advertisement and marketing expenditures by *i*th firm in *t-1,t-2 and t-3* years as a proportion of its total sales during the same period

$SIZE_{it}$: Net sales of *i*th firm in *t* th year (transformed into logarithms).

FF : A dummy variable taking value one for companies with 25 per cent or more foreign ownership by a controlling shareholder.

VCOST : Total variable costs as a proportion of its sales in year t.

$IMCAP_{it-1}$:Total Imports of capital goods by *i*th firm in *t-1 t-2 and t-3* year as a proportion of its total sales during these years.

IMPR: Total imports of raw materials by *i*th firm in *t-1 t-2 and t-3* year as a proportion of its total sales during this period.

PCM_{it-1}: Profit margins before tax of *i*th firm as a proportion of its total sales in *t-1th* year.

DOMROYS : Total royalties and technical fee paid domestically by *i*th firm in *t-1,t-2 and t-3* years as a proportion of its total sales during these years.

LIBDUM: A dummy variable taking value one for years<1996

Empirical results

The results are presented in Table 20. LR chi-square statistics is significant at 1 per cent level indicating that the various determinants of export performance taken together contribute significantly to the explanation of export competitiveness of the pharmaceutical firms.

Firm specific advantages

As expected, R&D efforts appear to confer distinct advantage to Indian firms in foreign markets. These efforts help bring out an improvement in process, product development, packaging and operational efficiencies and are major strength of companies in international markets. Estimations by firm size however indicate that R&D intensity was a significant export determinant only for large firms. For small and medium sized firms RDS emerged insignificant. Small firms do not have required resources to carry out substantial R&D in this industry. In our primary survey also R&D efforts were rated rather low by small sector firms. Their R&D intensity is much lower than that of large firms. Pradhan (2003) found the relationship between firms size and R&D intensity to be inverted U-shaped but the turning point was at the firm size level above which there were only 2-3 firms. He concluded that small size was responsible for keeping R&D performance of the industry at low level. Large firms on the other hand have acquired substantial R&D capabilities. Though most of the research efforts are confined to the process development and quality control and drug delivery system in India, large firms are now increasingly focusing on the basic research. R&D activities of some of them are discussed as under.

- Ranbaxy Laboratories has undertaken drug discovery and development in four therapeutic areas: metabolic disorders (diabetes, dyslipidemia, obesity and associated disorders); cancer; inflammation and anti-infectives. The new initiatives now aim at new molecule research. Ranbaxy spent about Rs.56 crore on R&D (3.6 per cent of turnover) in 1999 and plans to spend six per cent of its turnover on R&D by 2004. The company has received government permission to begin phase 2 clinical trials for its Benign Prostatic Hyperplasia (BPH) molecule and phase 1 clinical trials for its asthma molecule. It is also doing collaborative research with Cipla and

Table 20: Tobit model estimation of export intensity of firms categorized by size and ownership

		Firms categorised by size			Firms categorised by ownership		
	All firm	**Large firms**	**Medium firm**	**Medium firm**	**Small firm**	**Foreign firms**	**Domestic firm**
RDS	0.18055	0.505	0.053		0.103	0.513	0.179
	(2.97)[a]	**(4.20) [a]**	**(0.653)**		**(0.136)**	**(2.62) [a]**	**(2.67) [a]**
MTS	-0.0509	-0.111	3.072		-17.747	0.025	-0.052
	(-0.929)	**(-1.917) [c]**	**(1.557)**		**(-0.909)**	**(0.039)**	**(-0.872)**
RDS*MTS				121.089			
				(3.53) [a]			
ADS	-0.0309	-0.022	-0.279	-0.279	0.069	0.039	-0.105
	(-0.789)	**(-0.19)**	**(-2.93) [a]**	**(-2.99) [a]**	**(0.787)**	**(1.919) [b]**	**(-1.846) [c]**
VCOST	0.000316	-0.034	0.001	0.001	-0.151	-0.182	0.001
	(0.062)	**(-0.987)**	**(0.21)**	**(0.204)**	**(-1.816) [c]**	**(-3.02) [a]**	**(0.134)**
FF	-0.09673						
	(-5.39) [a]						
SIZE	0.036005	0.012	0.034	0.032	0.033	0.023	0.039
	(8.50) [a]	**(1.178)**	**(3.80) [a]**	**(3.69) [a]**	**(2.62) [a]**	**(4.27) [a]**	**(8.05) [a]**
IMPR	0.784856	0.933	1.006	0.985	0.658	0.411	0.805
	(15.04) [a]	**(8.69) [a]**	**(9.11) [a]**	**(9.06) [a]**	**(7.62) [a]**	**(4.40) [a]**	**(13.69) [a]**
IMCAP	0.409859	0.288	0.767	0.743	0.077	-0.042	0.413
	(4.84) [a]	**(3.02) [a]**	**(2.94)[a]**	**(2.89)[a]**	**(0.291)**	**(-0.225)**	**(4.37) [a]**
PCM	-0.03196	0.132	-0.067	-0.068	-0.093	-0.134	-0.033
	(-2.04) [b]	**(3.71) [a]**	**(-3.11) [a]**	**(-3.19) [a]**	**(-1.111)**	**(-1.46)**	**(-1.90) [b]**
DOMROY	-1.50718	-1.083	-3.993	-2.889	-0.211	-1.642	-0.926
	(-2.95) [a]	**(-1.87) [c]**	**(-2.07) [b]**	**(-1.983) [b]**	**(-0.404)**	**(-2.614) [a]**	**(-1.892) [c]**
LIBDUM	0.027691	0.033	0.035	0.033	0.059	-0.011	0.051
	(1.646)	**(0.481)**	**(0.861)**	**(0.815)**	**(1.592)**	**(-0.912)**	**(2.042) [b]**
_cons	-0.11501	0.013	-0.124	-0.114	-0.004	0.072	-0.148
	(-4.516) [a]	**(0.142)**	**(-2.249) [b]**	**(-2.11) [b]**	**(-0.042)**	**(1.107)**	**(-4.637) [b]**
nob	1187	240	497	497	260	190	997
log likelihood	1.828083	55.7851	-84.309	-79.628	-14.319	220.529	-83.703
LR chi2 ( )	440.37	141.96	158.76	168.12	72.31	68.16	367.59

[a] significant at 1 % ; [b] significant at 5%; [c] significant at 10%, parentheses show t-statistics

Bayer. US, EU Japan accounted for 85 per cent of its global sales in the year 2002-2003.

- Dr Reddy's Laboratories has identified drug discovery as one of its long-term strategy. The research focus has been in the therapeutic areas of metabolic disorders, cancer, inflammation and bacterial infection, apart from process research. The company's total expense on R&D as a ratio of sales in 2002-2003 was 9.92 per cent. During 1999-2000, its first anti-diabetic compound, DRF-2593, licensed to Novo Nordisk, entered phase 2 clinical trials and the second lead compound, DRF-2725 entered Phase 1 clinical trials. The company filed for 28 product patents and 13 process patents in India, US and PCT countries. In 2001, the company outlicensed DRF 4158 to Novartis US for $55 million. In the same year it acquired exclusive EMR for its Fllouxetine 40 mg. Capsules. The company is exporting to 60 countries.
- Wockhardt Ltd's R&D spend for the period December 1998 to December, 1999 was Rs.450 million (around eight per cent of total turnover) and it expects its annual R&D expenditure in the coming years to be sustained in this region. The NDDS segment constitutes a major thrust area in R&D for the company. The company is exporting to 61 countries.
- Nicholas Piramal India Ltd's R&D budget in 1998-99 was Rs.246 million (5.7 per cent of turnover) which came down to Rs.92 million in 1999-2000 (two per cent of turnover). The company spent four per cent of its sales turnover to R&D expenditure in 2002-03. Two of its NCEs are: the anti-cancer IM-962 and a joint research initiative with a US company and Aablaquin. Its export markets include US, EU., Japan, South East Asia, Middle East and Latin America.

Several other firms including Alembic, Cadila, Korpan, JB Chemicals, Panacea are also involved in the research on New Chemical Entities. A number of companies such as Torrent, JB Chemicals, Shasun, Orchid, Morepen, Cadila, are filing patents in developed markets of US and EC. These R&D efforts appear to have been critical to their success in international markets.

Contrary to the expectation, RDS emerged as a significant determinant of export performance of foreign firms also. Interestingly R&D intensity of foreign firms is not significantly different from that of domestic firms in this industry (Pradhan 2003). These firms acquire basic technology and technical know how for introduction of new products and processes from their parent companies.

These are adapted to local conditions through R&D and exported to other developing countries. It is found that most MNCs located in India focus mainly on the markets of other developing countries due to parent companies' restrictions (EXIM 1991).

For the overall sample, international technology transfer payments did not turn out to be significant. One may expect that the firms that are continuously updating their technologies have competitive advantages. That does not appear to be the case here. To explain the result it is important to understand the technological characteristics of the industry. In this industry, firms either move forward along one single technological path making successively better products or they adopt various technologies. Firms that choose the former option can also break into the world markets by producing better products and better processes if technology is not protected by patent. The patent Act 1970 in India allowed Indian firms to reverse engineer the technologies which made it possible for firms to improve processes or develop new forms of dosage and formulations. Firms thus diversified the product baskets, contained costs and improved operational efficiency. Therefore it is not important for firms to continuously import new technologies to compete in the world markets. We examined the 'Technology Note' of 86 Firms for the year 2003. Of these 9 firms were MNCs and they reported that they could access technological innovations of their parent companies without making payments. Of the remaining 77 domestic firms, only 23 firms (30 per cent) bought technology at least once in the last 5 years. Around 70 per cent of firms did not import technology during the last 5 years. Dey's chemicals reported that it imported technology in 1968, thereafter its operations have been based on its own R&D.

Our results by firm-size suggest that technology imports are not significant for very large firms. Since these firms have acquired substantial R&D capabilities they are not dependent on imported technologies for exporting. The behaviour of medium firms is however different. Though MTS was insignificant for them also an interactive term between RDS and MTS emerged significant with positive sign. Apparently, their strategy to excel in the world markets has been to continuously update technologies and absorb them using their R&D. These firms perform substantial R&D but their efforts do not appear be substantially large to give them edge in the export markets on the basis of R&D alone. Small Firms do not seem to depend on their technological capabilities for exporting.

Tobit estimates by ownership suggest that this variable is not significant for foreign firms also. The reason is that these firms acquire new technological development from their parent firms without making payments. This is reported by most MNCs in their 'Technical Notes for the year 2002-03'.

ADS did not emerge significant/emerged significant with a wrong sign. This is contrary to our expectations. A debate surrounds the desirability of the high levels of promotional spending in pharmaceutical industry. While the proponents suggest that high promotional spending are informative as they signal high quality opponents argue that the high levels of such spending are wasteful. Our primary survey results suggest that our producers also view brand image and marketing as of high relevance. As discussed above they are also incurring heavy expenditures under these headings. But higher promotional expenditures may not be performance enhancing. Advertising needs to be effective and targeted. Interestingly, ADS emerged significant with positive sign for foreign firms. These firms have already established brand names and marketing channels. Any incremental advertising appears to be resulting in value addition. Our results by firm size suggest that ADS is insignificant for large and small firms. It is significant with negative sign for medium sized firms. It could also be that their advertising is directed more towards domestic markets. This may help them in the export markets in the longer term.

Our results should not be taken to suggest that marketing does not affect export competitiveness of firms. In fact, marketing expenditures are used successfully in building brand image and entering the export markets. Major efforts are made by the firms to receive approval for their manufacturing products which enables them to explore new growth opportunities in these markets. For promoting exports companies are establishing branch offices in several countries (for instance, Cadila, Elder Pharma). Companies are also promoting international business through agents in countries where branch offices are not set up. Some firms are forging marketing JVs. RPG for instance entered into product specific joint ventures with the leading players in European markets. Our results merely indicate that large advertising expenditures incurred by domestic firms may not be justified by the export performance of firms and that small scale firms do not compete on the basis of brand name.

VCOST did not emerge significant for all the firms pooled together. Though it is negative it missed significance. A more disaggregated analysis however

shows that cost containment is a major determinant of the export competitiveness of small firms. This is in line with our findings from the primary survey. Small firms compete primarily on the basis of lower costs and high quality. India has an enormous cost advantage in the production of pharmaceuticals. Manufacturing costs for bulk drugs are one third of those in developed countries (Chaudhuri 1997). Operating costs are half, labour is one-tenth and some important equipment is one-fifth the level of the developed world (as reported in Chaudhuri 1997). Many small scale firms take advantage of the cost factor. They get involved in contract manufacturing which is based on the technology supplied by the customer firms. Their strength lies in producing quality products at low costs. Getting a breakthrough in contract manufacturing helps in increasing global acceptance in terms of quality. Interestingly VCOST emerged significant for the foreign firms also. Apparently these firms are also exporting mainly on the basis of lower cost of production in this country.

FF is significant at 1 per cent with negative sign. Clearly export intensity of foreign firms is significantly smaller than that of domestic firms. This is in contradiction with our expectations. It could however be attributed to the Patents Act 1970. This Act (effective April, 1972) greatly weakened intellectual property protection in India, particularly for pharmaceutical innovations. Although all inventors were affected by the weakened patent regime, it is clear that foreigners, in particular, no longer found taking out a patent in India worthwhile. The lack of patent protection meant that while foreign firms had to pay royalties for new drugs their Indian counterparts could use imitations. This might have affected the R&D and export performance of foreign firms in India.

There is a tremendous literature on the impact of size on the export performance of firms. Given the characteristics of the pharmaceutical industry we expected it to be positive. Our results are quite in line with our hypothesis. SIZE emerged significant in almost all the equations that we estimated. Even in the small firm group it was positive. The only exception is the group of large firms. For this group of firms SIZE is insignificant. This group includes firms with sales turnover of Rs 100 million or more. One does not expect much variation in the size and export intensity in this group.

We attempted to test whether there are non linearity in this relationship but we did not find any. Massive investments R&D and brand promotion may explain the importance of scale economies in this industry.

Government Incentives

Indirect tax incentives provided by the government appear to have had significant impact on the competitiveness of firms. Both IMCAP and IMPR turned significant with positive sign. Apparently, the government incentives allowed cheap imports of raw materials and capital goods which encouraged the firms importing raw materials and capital goods to penetrate into foreign markets to avail such benefits. The use of imported raw materials and capital goods also help them in improving their quality and processes.

Interestingly, IMPR has emerged significant across all groups of firms while IMCAP is insignificant for small and foreign firms. IMCAP also implies transfer of embodied technology. For small firms technological advantages are not important. This may explain the non significance of IMCAP for them. For foreign firms imports of machinery could be a part of their investment and hence it is not relevant.

PCM comes up with a coefficient that is negative.. This result is contrary to our expectation. We hypothesised the relationship between the two to be positive. One may argue that this variable could be significant for large firms only because they are generally earning large profits and exemption from income tax could be an attractive incentive for them. Our results support this argument. This variable is significant with positive sign for large firms. For medium sized firms it is significant with negative sign. It could be that medium sized firms with lower profits might be attempting to break into profitable export markets.

Liberalization seems to have favourably affected the export performance of domestic firms. Foreign firms do not appear to be influenced by these changes in trade and investment policies. There is a simple explanation for this. Though there has been substantial liberalization, the Patent Act has not yet been amended to provide full patent protection. There is an unusual importance of patents in this industry (Norgue 1990). Developing new drugs is costly and risky. Producers invest huge sums in new discoveries with a focus on high profit margins. Patent protection is a significant component of their profit expectation.(Scherer 2000). In the absence of patent protection MNCs do not introduce new products in India. MNCs therefore continue to focus on domestic markets and /or export to developing countries from India as their base

DOMROYS comes up with negative sign in all the equations. It could be that firms have strategic tie ups with domestic research institutes to produce

new products that are directed to domestic markets. Sometimes the objective is to substitute the imported raw material. One of the producers in a personal interview revealed that they involved a CSIR lab to develop technology for producing bulk drug for an anti cancer tablet in India. The aim was to produce the tablet at lower prices for domestic markets. The project however failed and they lost substantial money in the process. Thus these tie ups may not be for improving export competitiveness and may not always result into success.

Constraints on firms' export performance

To further extend our perception of the firms' export competitiveness we asked the firms to evaluate the relevance of six factors that might have affected their exports adversely. Table 21 summarises the evidence derived from this question. It suggests that high transaction cost remained the most important factor constraining their export performance. Transaction costs were stated to be high not only due to poor logistics, government bureaucracy and outdated banking laws but also due to strict registration procedures for exporters in importing countries. For exporting, firms have to acquire WHO GMP (Good Manufacturing Practices) certificate which is valid for 3 years now and is product specific. It involves time and cost. One of the firms stated "Normally for export now a days we have to obtain WHO GMP which is valid only for 3 years & it is product specific. Earlier we had WHO GMP certificate issued in 1990 without expiry so we were able to export to countries like Singapore & Malaysia till date. Now schedule M has come so we are all busy in compliance to make state of Art factory. Many new products are required by our foreign counter parts but as we have to obtain Certificate of Pharmaceutical Products it becomes difficult to call & obtain WHO GMP CERTIFICATE PRODUCTS . If we call at this moment for inspection of our products we will not get WHO GMP certificate."

Besides, many firms observed that regulatory restrictions imposed by importing countries are a major constraint in their exporting. They have to acquire a license from the importing countries' authorities, which is granted upon assurance that the manufacturers comply with production and safety standards. Exporters have to submit a number of documents including drug samples. These are tested in the importing countries and upon clearance the exporters are allowed to export. These rules vary from country to country increasing the cost of exporting substantially. Moreover, rules on documentation are not clear. Complete information on documentation is not available. Sometimes there are language problems. In some countries (for instance, the EU), the registration procedure is highly complicated and includes physical inspection. It is observed that firms are unable to get registration even after 3-4

years. Sometimes, importing countries before granting registration to foreign firms seek advice from international experts. These experts may give negative recommendations in order to promote their own countries' firms. Cipla, an Indian firm, which offered an anti-AID drug at a very low price, was not granted license to export the drug to South Africa. Price quoted by the Indian firm was used to compel MNCs to reduce price.[9] The regulatory requirements thus increase transaction costs substantially and appear to be a major export constraint for the majority of firms in this industry.

Aside from transaction costs, high production costs also affect the export performance of firms. According to industry experts[10], poor infrastructure, high cost of power, high interest costs and rigid labour laws are some of the factors that affect the production costs in the industry.

Inadequate marketing infrastructure and lack of information are other important constraints for the firms. To further investigate the role of these factors we asked the non exporter firms to evaluate specified factors that are motivating them to be inward oriented. They also cited the lack of information and absence of marketing infrastructure as a relevant factor for their not looking outwards. A firm stated that it is located in such an isolated place where it has poor accessibility to information on export opportunities.

Some firms also suggested that the problem of duplicate companies and spurious drugs is also a serious constraint for Indian exports. There are instances where duplicate firms in connivance with the local traders and authorities manage

Table 21: Constraints on export performance

Constraining factor	Most i mportant % of firms	Important	Not important %	Average response	C.V.
High Transaction cost	56.0	32.0	12.0	2.1	53.29702
Inadequate infrastructure	32.0	36.0	32.0	1.7	74.34521
Lack of information	12.0	60.0	28.0	1.2	83.33333
Large domestic markets	16.0	32.0	52.0	0.9	128.3974
Antidumping measures	4.0	36.0	60.0	0.7	138.9946
Restrictions placed by technology suppliers/ foreign suppliers	8.0	36.0	56.0	0.8	127.1081

Source: Primary survey.

to export spurious drugs. This affects the reputation of Indian firms abroad. In the year 2002, 52 Indian companies were blacklisted in various foreign countries. These included 4-5 organised sector companies which never exported to the countries where they were blacklisted[11].

Thus high transaction costs both, internal and external, high production cost, absence of information and marketing infrastructure and widespread prevalence of duplicate firms are some of the major export constraints.

V. Policy Implications

India's drug exports have increased dramatically during the 1990s. Since 1990 India has been enjoying positive trade balance. This paper attempted to identify the factors that determine the export competitiveness of firms in the Indian pharmaceutical industry. Our findings suggest that the competitiveness of firms depends not only on firm specific advantages but also on government fiscal incentives. Among the firm specific factors, own R&D efforts emerged as one of the prime factors influencing export competitiveness. Furthermore, it was found that R&D efforts involved in the modification in process technology were more relevant than the introduction of new products, reflecting the importance of the pursuit of improvement in processes in the industry's technological trajectory. Technology imports was not found to have played a significant export-enhancing role. Furthermore, it was observed that the export behaviour differed across different size-groups. While large firms were competing on the basis of their own R&D efforts, medium firms followed a different strategy. Due to lack in the depth of their R&D they imported newer technologies and absorbed them using their R&D efforts to acquire competitiveness. Small firms were competing on the basis of lower costs. Brand promotion and marketing expenditures were not found to be related with the export performance of firms but that could be because these expenditures might not capture the effects of these factors. Primary survey based analysis indicates that marketing and established brand names are highly relevant in the export performance of firms. However such efforts need to be more effective and targeted. The study also shows that firm size is an important firm specific advantage. Large sized firms are more export oriented. Finally, the paper suggests that the technology support given by the government institutions is not affecting the competitiveness of firms favourably. Our primary survey indicates that complex multiple regulatory rules, poor logistics, outdated banking laws, strict regulatory rules followed by importing countries, high production costs and lack of marketing infrastructure

and information are the major constraints in the export constraints of Indian firms.

The paper argues that the government should focus on ruthless export promotion in the TRIPs driven environment. If multinationals aggressively market patented drugs in India, Indian companies can enjoy strong sales in the opposite direction by exporting generics. For this, research and development is an important area that needs attention. R&D spending among most Indian drug firms still averages less than 2 per cent of the total turnover, compared to 17 per cent in the US. Many believe that strengthened patent protection is expected to encourage foreign firms to locate their R&D in India due to sizeable pool of low cost and technically skilled labour. This will set in motion a range of other dynamics such as licensing, co-marketing and joint ventures, generating multiplier effects that benefit local drug manufacturers. Lanjouw (1998) however argued that costs are not the prime concern and there is no reason to expect that the introduction of patent protection would encourage MNCs to locate their R&D here. It is therefore, important to announce new policy initiatives, particularly relating to the research and development and pricing regime. Whilst India may currently lack the resources for conceptual research, it can generate some research and development through molecular restructuring, which involves varying an existing molecule and clinical trials. Moreover, the profits derived from patent protection may in turn be invested in research and development by local Indian firms, thereby stimulating indigenous innovation and competitiveness. Heavy R&D investment is thus the key factor in improving the competitiveness of firms. Industry experts suggest that the firms investing in R&D below some threshold level should be penalized[12]. This could be an indirect inducement for the R&D performers. Evidence indicates that technology transfers through public institutions have not effectively influenced the export performance of firms. It is therefore important to strengthen them and make them effective. In our survey, 37.5 per cent of the firms suggested that strengthening the technology support from DSIR could be one of the most important policy measure affecting their competitiveness. On the other hand, 33 per cent suggested that it was not important. This divided opinion implies highly varied experiences of firms (Table 22). This needs to be looked into.

Another important area that needs attention is marketing and Indian brand promotions in foreign markets. Companies are spending heavy amounts under these headings but these are not proved to be export enhancing. Government can play a proactive role here by providing direct assistance to the industry in

Table 22: Evaluation of government policy measures for export promotion

Policy Measure	% of firms		
	Important	Non important	Average response
Trade facilitation	83.3	16.7	1.63
Coordination with Indian embassies in information dissemination	91.7	8.3	1.88
More liberal fiscal incentives	87.5	12.5	2.08
R&D support from the Department of Science and Technology	66.7	33.3	1.63

marketing. It may help in establishing export networks that allow firms to target foreign markets. Such programmes are quite successful in British Columbia, New Zealand, and Australia. Indian embassies across the world may collect information on issues such as guidelines for licensing of pharmaceutical companies; registration procedures for medicines; local production level; demographic data; and healthcare systems, health indicators and prevalent disease patterns. This information should be made readily accessible through internet. Many firms (92 per cent firms) believed that Indian embassies abroad can play a very important role in information dissemination. Besides, the government may hold a series of educational programmes for domestic exporters with special emphasis on the quality of product and organise trade shows abroad that may provide platform to firms to exhibit their products. Financial assistance may also be offered to firms for participating in international trade shows and foreign travels. Firms seek support mechanism for concessional airfare for export promotion trips (including Trade fair participation) and concessional rate of interest . Though the government has schemes of concessional airfare, many firms are not quite aware of them. One of the respondents who tried to utilize the Marketing Development Assistance scheme in the case of two exhibitions cum conferences that he attended in last financial year, shared his experience with us. He stated that he is yet to receive the grant amount (even after 6 months of submission) and he has now been informed that it may take some 3-4 months further after completion of all the paper work and the decision of the MDA authorities.

Costs are found to be a major factor driving export competitiveness of small firms. However, high costs of basic facilities such as power, poor

infrastructure and high transaction costs offset these advantages. Regulatory requirements, international rules, complex trade procedures, outdated banking laws and government bureaucracy result in high exporting costs. Control measure from DGFT/ customs/ central excises need to be minimized to the extent that they should be only helping the exporters rather than harassing them. Over 83 per cent firms that were interviewed felt that these regulations should be further relaxed and trade facilitation should be initiated. Some of the measures suggested by firms to achieve this are as follows.

- Simplify export procedures
- E-connectivity to avoid delay, paper work and discretion
- State- of –the –art cargo-handling facilities at ports
- Number of nodal agencies monitoring exports should be reduced
- Better infrastructure facilities at lower costs
- Concessional finance
- More freedom should be given to exporters who are earning foreign exchange to the country.
- The government may extend technical and financial assistance in the registration procedures, which involve considerable resources and time.

The country also needs to develop world class standards. This in turn requires stringent quality standards in the domestic markets. For this, in –house regulatory expertise needs to be developed. Until the last two years, there was no registration requirement for a drug in India. Firms could import/ manufacture the product on the basis of the approval from the Drug Controller. In case the drug was already approved in foreign markets, approval could be given on the basis of Phase III test (Confirmatory Clinical test). The Controller could dispense with this requirement also if it was in the public interest. However, two years ago, registration requirements have been introduced in India. This may help in achieving in high quality standards. Patent system should also be strengthened. There are instances where companies have acquired the US patent but they are waiting for the Indian patent. This could be due to lack of patent culture in the country. Industry sources[13] also suggest that modern medicine system in alternative medicines needs to be introduced. Chine has developed a huge export market by introducing modern systems in the alternative medicines. India also has a vast potential here, which needs to be tapped.

Finally, our analysis calls for strengthening and extending the financial incentive packages offered by the government. Following are some suggestions made by the firms we interviewed.

- Revision of DEPB rates
- Simplifying procedures for DEPB
- Extend validity for DEPB by 6 months
- Add more products in custom duty concessions
- Greater tax benefits
- Incentives on R&D

One must however note that while these incentives are WTO compatible, these are countervailable. Moreover, with decline in tariff rates, some of the existing incentives may become redundant. It is therefore important for the government to play a more proactive role by supporting R&D efforts and marketing efforts, facilitating cost reduction by providing basic facilities at lower costs, streamlining trade procedures and providing technical and financial assistance in registration processes. With a more focused approach, the industry will be able to compete fiercely in the world markets.

Endnotes

[1] On basic manufacturing the rates are 18 per cent on net worth or 26 per cent on capital employed.

[2] Our thanks to Mr. Vimal Raizada and Mr. Wakankar for making this point at the National Workshop on International competitiveness in Knowledge based Indian Industries in the RIS-DSIR seminar organized on August 13, 2004).

[3] The ratio of R&D to total sales that was 9.3 per cent in 1970 increased continuously and in 2001, these companies spent roughly 17 per cent of domestic sales on R&D (PhRMA 2003).

[4] With massive expenditure incurred on basic research, scientific knowledge has shown tremendous advancement in this industry. Among the 24 US industry groups on which detailed statistics are published, pharmaceuticals devoted the highest fraction (16.6 per cent) of its total R&D to basic research, for all other firms the comparable figure was 5.3 per cent (NSF, 1996, p.44). Evidence suggests that the new products are becoming available in a short period of 5-7 years making existing products obsolete

[5] A 1998 survey found that 53 per cent of physicians reported an increase in brand name requests up from 30 per cent from mid 1997 before the relation of FDA guidelines for T.V. advertising). Another study found that patient requests were honoured 73 per cent of the time (NIHCM, 1999).

[6] Approvals will not be needed for foreign investment upto US $ 50 million. In addition, the government has extended the facility for allowing pharmaceutical and biotechnology companies to acquire firms upto US $100 million through equity swaps/ADRs/ GDRs. Companies can exceed the 100 million limit if their export earning allowed them to do so. The companies can spend as much as 10 times of their export earning to acquire overseas firms through stock swaps.

[7] In the US, there is very little direct price intervention. However, price competition has recently been influenced by the rapid expansion of health care maintenance organisations (HMOs). Virtually all HMOs use limited lists, or so-called formularies, and by 1995, such organisations accounted for 75 per cent of US drug purchases. In the EU and Japan, on the other hand, where the government is the main purchaser, there is substantial price intervention of one form or another..

[8] Fixed effect tobit models are not yet available.

[9] Our thanks to Mr. Wakankar for making these points in the RIS-DSIR seminar, 13 August, 2004.

[10] Both, Mr. Raizada and Mr. Wakankar emphasized this point in the RIS-DSIR seminar, 13 August, 2004

[11] Mr. Wakankar made this point and was supported by Mr. Raizada in the RIS-DSIR seminar, 13 Aug. 2004.

[12] Mr. Vimal Raizada made this point in the RIS-DSOR seminar, 13th August, 2004.

[13] Mr. Vimal Raizada made this point in his presentation at the RIS-DSIR seminar.

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