**CMDR Monograph Series No. - 42**

# ECONOMIC REFORMS, WTO AND INDIAN DRUGS AND PHARMACEUTICALS INDUSTRY: IMPLICATIONS OF EMERGING TRENDS*

**Nagesh Kumar****
**Jaya Prakash Pradhan****

As part of the Project :
**ECONOMIC REFORMS, AND HEALTH SECTOR IN INDIA**
Under the aegis of
**United Nations Development Programme (UNDP)**
**and Government of India**

**CENTRE FOR MULTI-DISCIPLINARY DEVELOPMENT RESEARCH**
Jubilee Circle, DHARWAD-580001, Karnataka, India
Ph : 091-0836-447639, Fax : 447627
E-mail : cmdr@sancharnet.in

*Commissioned study for the project.
** Deputy Director General and Consultant of Research and Information Sytem for the Non-aligned and othr Developing Countries (RIS), respectively.

# Economic Reforms, WTO and Indian Drugs and Pharmaceuticals Industry: Implications of Emerging Trends

**Nagesh Kumar**
**Jaya Prakash Pradhan**

## 1. Introduction

One of the important successes of economic development in post-Independent period has been ability to ensure availability of life saving drugs at affordable prices. The fact that the life saving and other drugs are available in India at a fraction of prices prevailing internationally has attracted widespread attention from other countries. Competitive prices have also resulted in rising exports of pharmaceuticals from India.This success is a result of a combination of policies consciously followed since late 1960s with the specific objective of providing affordable drugs for the masses. These strategic interventions included incentives for development of indigenous pharmaceutical industry, giving incentives for localization of production right from bulk drugs and intermediates and not just formulations, encouraging generics over branded products, and regulation of prices through the Drug Prices Control Order (DPCO). Finally and more importantly, it included building a national innovation system for developing process innovation capability in the country, through incentives for R&D activity to enterprises and providing an intellectual property protection (IPR) framework designed to facilitate indigenous process development of known compounds. This integrated framework has led to the development of a strong indigenous pharmaceutical industry which presently produces bulk of the country's requirement right from the raw material stage using indigenous and cost effective processes.

Over the past decade, however, there have been a number of changes in the policy framework developed since the late 1960s. Besides import liberalization and removal of restrictions on foreign firms, DPCO has been diluted as a part of economic reforms. The IPR framework is undergoing important changes as per India's obligations under the TRIPs Agreement of WTO covering adoption of product patents by 2005 and provision of pipeline protection

through EMRs (exclusive marketing rights) in the transition period. All these trends of the past decade viz. liberalization of trade, investment and price regulations, and emerging changes in the IPRs are likely to have implications for the availability and prices of pharmaceutical products in India.

In this context this paper briefly reviews different elements of integrated drug policy framework as evolved between 1960s and 1990 and their effectiveness in bringing down drug prices. Then it discusses trends taking place since 1990 that tend to alter the policy framework evolved thus far that are likely to affect the availability of drugs and their prices in the coming years such as liberalization of trade, investment and pricing policies, strengthening IPR regime under TRIPs Agreement, among other policies.

The structure of the paper is as follows: Section 2 summarizes the contours of the integrated policy package evolved by the government of India over the 1950-90 period that led to rapid transformation of the pharmaceutical industry in India. Section 3 overviews the changes brought in the policy frame during the 1990s as a part of the economic reforms and as a part of India's commitments under the WTO Agreements. Section 4 examines the aspects of the Indian pharmaceutical industry development resulting from the policy package followed during the pre-reform period including availability of drugs and relative prices. Section 5 analyzes the implications of the reforms and WTO related changes in the policy frame on the pharmaceutical industry particularly in terms of prices, availability of drugs, technological capability, local production and technology transfer etc. Finally Section 6 concludes the paper with some remarks for policies to minimize the adverse effects.

## 2. Evolution of the Policy Regime

The government has adopted a number of policies over the past four decades to ensure the availability of life saving medicines at affordable prices for the health system of country catering to the needs of the poor masses. The government policy towards pharmaceutical industry can be broadly classified into two categories- (i) industrial policy including policies relating to foreign investment and technology and (ii) pricing policy. The evolution of both these policies is discussed below.

***Industrial policy***

Although foundation of indigenous pharmaceutical industry were laid in 1901 when Prof. P.C. Ray established the Bengal Chemicals and Pharmaceutical Works (BCPW), the country was largely dependent on imports for most of her requirements of drugs and pharmaceuticals at the time of Independence. However, since the Independence, the pharmaceutical industry has received due policy attention given its importance for the health security of the poor. In the first Industrial Policy Resolution 1948 (IPR, 1948) itself, the pharmaceutical industry was included in the list of 'basic industries' and its growth was subjected to plan targets and monitoring. However, the industry had little domestic technological base to start local production of modern drugs at that time. Whatever little growth impetus the industry had during the World War II was over by then. New therapeutic developments in the West with consequent replacement of many older drugs by newer drugs like sulpha, antibiotics, vitamins, hormones, antihistamine, tranquilizers, and psycho pharmacological substances had forced the nascent industry to stop production of many items that it was manufacturing before. The status of the industry was increasingly dependent on imports of bulk drugs and its processing into formulations.

The Industrial Policy Statement, 1956, grouped the pharmaceutical industry in the schedule 'B' where both state and private sector could operate. Although FDI was welcomed and given national treatment in the industry, government was finding it difficult to push MNEs to start domestic manufacture of bulk drugs and reduce the dependence on imports. Given the reluctance of MNEs to start production of important bulk drugs such as antibiotics in the country, the government set up Hindustan Antibiotics Ltd. in 1954 and Indian Drugs and Pharmaceuticals Ltd (IDPL) in 1961. These two enterprises have played an important role in not only starting domestic production of key bulk drugs but have had substantial spillovers in the form of generation of a new breed of entrepreneurs. One survey has shown that founders of one third of the 200 domestic enterprises surveyed had initially worked at IDPL including the founder of immensely successful Dr Reddy's Laboratories Ltd. (DRL) [Felker et al 1997]. The high tariffs also encouraged MNEs to set up local subsidiaries and

indigenize the domestic processing of imported bulk drugs and other raw materials.

The Drugs and Pharmaceutical industry was included the Appendix I of the Industrial Licensing Policy (1973). This priority status meant that under the Foreign Exchange Regulation Act (FERA) 1973, MNEs could retain up to 74 per cent ownership in their affiliates in India against a general limit of 40 per cent on maximum foreign shareholding permissible. However, keeping in mind the critical importance of building a self-reliant pharmaceutical industry, the government appointed a Committee to examine the status of the industry and make recommendations in the early 1970s. The Committee popularly called as the Hathi Committee, after its chairman Mr Jaisukhlal Hathi made extensive investigations into the factors that were preventing achievement of greater extent of self-reliance in the pharmaceutical industry in the country and made a number of recommendations in its Report published in 1975 (Hathi Committee 1975; also see Kumar and Chenoy 1982 for a discussion). A New Drug Policy 1978 was announced to implement some of the recommendations of the Hathi Committee. The Policy had three stated objectives, namely, self-sufficiency in drugs production, self-reliance in drugs technology and accessibility of quality drugs at reasonable prices. In order to achieve these objectives, the pressure was built on MNE affiliates to indigenize the production of bulk drugs from the basic stage. Thus the higher level of 74 per cent foreign equity was made applicable only to those MNE affiliates producing high technology drugs and others producing low technology drugs or processing imported/ domestically purchased bulk drugs were required to reduce their foreign equity holding to 40 per cent. Foreign companies producing finished formulations from imported bulk drugs or from penultimate stage were required to start production from the basic stage within a two year period. Further, licenses to foreign companies were to be given only if the production involves high technology bulk drugs and formulations based thereon. In 1981 the government took the decision of abolishing brand names for five categories of drugs as mentioned under Drug Policy, 1978, which includes analgin, aspirin, chlorpromazine, ferrous sulphate, and piperazine along with its salt. However, the move was blocked by MNEs with a court injunction. Another aspect of the government policies concerning the drugs

and pharmaceutical industry was canalization of imports of bulk drugs. After the detection of a number of cases highlighting the substantial overpricing in imports of bulk drugs by MNEs from their parents or affiliated sources, the government started canalizing the imports of these bulk drugs through IDPL and State Chemicals and Pharmaceuticals Trading Corporation, (a subsidiary of the State Trading Corporation) and MNE affiliates were required to lift their requirements from them. The drug policy has been revised in 1986, however, broad objective of strengthening the indigenous production capability of drugs for ensuring their abundant availability at reasonable prices continued to remain intact.

***Price Controls***

Controls on prices has been an important feature of the Indian pharmaceutical industry right from the 1960s to ensure affordability of drugs to poor masses. The drug price controls have gradually evolved with Drugs (Display of Prices) Order, 1962, Drugs (Control of Prices) Order, 1963 and Drugs (Display and Control) Order, 1966. The attempt to control prices by the government met with resistance from the industry that argued that the controls will hamper the growth of the industry and in the long run limit its ability to meet rising demands for drugs. In view of the above criticisms, the government requested the Tariff Commission to examine the prices of 18 basic drugs and their single ingredient formulations in August 1966. Following the submission of the Tariff Commission report in August 1968, the first Drugs (Prices Control) Order was issued in May 1970. The Order had the prime objective of balancing the welfare of consumer and that of producers i.e. reducing the prices of essential drugs and at the same time ensuring reasonable profits for the growth of the industry by taking account of the prices of materials, conversion cost, packing charges, mark-up, excise duty and sales tax in the calculation of the retail price of a formulation. The government has acquired both the rights to fix the maximum selling prices of essential bulk drugs (those included in the Schedule I of the appendix of the Order) and to change its composition. These 18 essential bulk drugs brought under the purview of DPCO 1970, 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 DPCO 1970 was

revised in 1979 following the promulgation of the Drug Policy of 1978 based on the Hathi Committee recommendations. The revised DPCO categorized drugs into four categories: Life-saving, Essential, Less Essential, and Non-Essential/Simple Remedies. Of these the first three categories came under the ambit of price controls with mark-up (profits allowed) of 40 per cent, 55 Per cent and 100 per cent respectively. In all 347 drugs came under the purview of DPCO accounting for 90 per cent of the industry. Two other measures of the Order that were significant for stimulating indigenous production were: (i) keeping small scale sector out of price control and (ii) the new bulk drugs developed through local R&D in India also exempted from the purview of price control for a period of five years.

The tighter price controls on the first two categories of drugs led MNEs to increase their focus on the production on the less essential and non-essential formulations. Growing resistance of the industry to the DPCO 1979 led the government to issue a modified DPCO in August 1987 that reduced the scope of DPCO to 166 drugs from 347 besides enhancing the stipulated mark-up for the included formulations. As will be seen later that the scope of price controls has been further restricted in the 1990s as a part of the reforms.

### *IPR Regime and Incentives to Domestic R&D Activity*

#### Amendment of the Patent Act

India had inherited The Patents and Designs Act 1911 from the colonial times that provided for protection of all inventions except those relating to atomic energy and a patent term of 16 years from the date of application. However, a few domestic chemical and pharmaceutical enterprises that tried to develop their own technology in the 1960s ran into trouble with foreign patent owners. A number of cases highlighted that foreign patent owners were neither using their patents for domestic manufacture nor allowing them to be used by local firms[1]. That led to a build-up of pressure in the late 1960s for a new patent law. Desai (1980) in a questionnaire survey of 53 firms conducted in 1969 found that by and large foreign firms were against any liberalization of patent laws, Indian firms were not against patents but wanted greater access to patented know-how especially when patent owners not allowing their patents to be used.

The conflict of views was sharper in chemicals and pharmaceuticals where patents had been used to prevent entry of Indian firms. Therefore, a new Patents Act was adopted in 1970 that reduced the scope of patentability in food, chemicals and pharmaceuticals to only processes and not products. Since virtually any chemical compound can be made by a variety of processes, the scope of patent protection was greatly reduced. The term of process patents was reduced to 7 years in food, drugs and chemicals and to 14 years for other products. The compulsory licenses could be issued after three years.

It is by now widely recognized that the abolition of product patents in chemicals and pharmaceuticals has facilitated the development of local technological capability in chemicals and pharmaceutical industry by enabling the domestic firms in their process innovative activity. A number of quantitative studies have shown that the innovative activity of Indian domestic enterprises was facilitated by the softer patent regime under the 1970 Act (see Fikkert 1993, Haksar 1995, Kumar and Saqib 1996).

**Incentives to Domestic R&D Activity**

As a part of the national innovation systems, the government in India has spent a considerable effort to develop infrastructure for human resource development, scientific and technological infrastructure and direct involvement in technology development in the public funded national laboratories (see Kumar 2001). Besides creation of S&T infrastructure the government has encouraged industrial enterprises to take up in-house R&D activity through other policy instruments. In 1974 a scheme for recognition of in-house R&D establishments of industrial units was started. The recognised R&D units received facilities for import equipment, raw material, samples, prototypes, etc., for their R&D work under Open General License, without any ceiling. Sometimes foreign collaboration approvals/ extensions were granted with the understanding that importer would undertake R&D activity to absorb the technology. Technology Absorption and Adaptation Scheme (TAAS) of DSIR aims to provide a catalytic support for accelerated absorption and adaptation of imported technologies by the industrial units. It was made mandatory

to highlight efforts taken towards absorption of technology imports in a separate chapter of the annual report of all the importing firms (DSIR, 1986). In addition industry research associations have been set up to take up work on common problems. In 1988 the DSIR launched a scheme of granting recognition to Scientific and Industrial Research Organizations (SIROs).At present there are 159 SIROs recognized by the DSIR. The SIROs have employed qualified scientists and researchers and also established good infrastructural facilities for research.

The New Drugs Policy (1978) obliged the foreign companies with turnover in excess of Rs. 50 million to have R&D facilities within the country with capital investment of at least 20 percent of their net block and to spend at least 4 percent of their turnover on R&D. It also specified one to two percent higher profit ceiling for drug companies engaged in approved R&D work.

Government has evolved from time to time fiscal incentives and support measures to encourage R&D in industry and increased utilization of locally available R&D options for industrial development. Fiscal incentives and support measures presently available include:

- Full Income Tax relief on the in-house R&D expenditure by the company related to the business of the company is permitted. R&D expenditure in government approved in-house R&D centres is allowed a weighted relief of 125 per cent since 1998 for companies engaged in the business of manufacture or production of drugs and pharmaceuticals, besides electronic equipment, computers, telecommunication equipment, computers, telecommunication equipment and chemicals. In the Budget 2000, the weighted relief was raised to 150 per cent.
- R&D units can also avail, weighted tax deductions for sponsored research programme in approved national laboratories, universities and IITs, weighted tax deduction on R&D expenditure in drug, pharmaceuticals, electronic equipment, computers, telecommunication equipment, financial support for R&D project, exemption from price control for bulk drugs produced based on indigenous technology.

- Expenditures made on capital equipment and related to research activities by recognized R&D units are allowed to be written off in the year the expenditures are incurred.
- In 1996-97 government proposed to provide for a five year tax holiday to approved companies whose main objective is scientific and industrial research. It is provided to all new and existing companies, which are accorded approval before April 1, 1998. Besides, the government have introduced a system of allowing accelerated depreciation in respect of blocks of assets and rationalized the rate structure by reducing the number of rates as also by providing for depreciation at higher rates.
- Donations given to scientific research associations, institutions and universities are exempted from income tax provision. Scientific research institutions, associations, Universities and colleges that undertake research in medical, agricultural, natural and applied sciences are exempted from income tax on donations from industry and other sources. The donors are also allowed deductions from their income to the extent of donation.
- All SIROs are eligible for custom duty exemption on the imports of scientific equipment, instruments, spares, accessories as well as consumables for R&D activities.
- 1996-97 budget introduced the provision of custom duty exemption on specific goods imported for use in R&D projects funded partly by any Department of the central government and undertaken by the company in their R&D unit recognized by DSIR. Furthermore, imports of equipment, spares, accessories and consumables for research purposes by public funded research institutions, universities, IIT, IIS Bangalore and Regional Engineering colleges are also exempted from the duty.
- All SIROs are eligible for excise duty exemption on the imports of scientific equipment, instruments, spares, accessories as well as consumables for R&D activities; computer software, CDROM, recorded magnetic tapes, micro films, microfiches and prototypes for R&D.

- Public funded research institutions are also given excise duty waiver on purchase of indigenously manufactured equipment, pare parts and accessories and consumables for scientific research.

In order to encourage in-house R&D and commercialization of indigenous technology, DSIR has instituted National Awards for Outstanding R&D Achievements and Commercialization of Public Funded R&D in 1987 given annually.

Funding of R&D Projects in Industry

Over the years a number of programmes for directly supporting R&D activity in the industry have been started by different scientific agencies of the Indian government. These include:

- DSIR operates a Programme aimed at Technological Self Reliance (PATSER) to support R&D projects in Industry. About 100 R&D and design and engineering projects have been supported by the end of 1998. Some of these projects involve collaboration with public funded R&D institutions.
- DST is funding several industrial R&D programmes such as Home Grown Technology Projects, Drugs and Pharmaceuticals Research Programme, Instrument Development Programme and Advanced Materials development Programme.
- Department of Biotechnology (DBT) has been promoting and financing various aspects of biotechnology R&D activity undertaken by industry and other institutions including applications in drugs and pharmaceuticals.
- Technology Development Fund: This Fund created out of collection of a 5 per cent cess imposed on the technology import payments is used to help the indigenously developed technologies reach the stage of commercial production. A Technology Development Board has been constituted in 1995 to utilize the Fund by providing grants, loans or equity capital for the purpose of promoting indigenous technology development and application.
- In the Budget for the year 2000-2001, a separate fund Rs 150 crores for supporting R&D activity in pharmaceutical industry was announced.

Incentives for Utilization of Indigenous R&D

The government has promoted the National Research Development Corporation (NRDC) with the specific responsibility of transferring technology from R&D laboratories to industry. NRDC commercialises the technologies developed with government support, undertakes further work towards upscaling the laboratory know-how, setting up pilot plant, etc., and even provides risk finance to development projects. In addition, utilization of indigenous R&D is sought to be promoted by various other incentives. All goods manufactured by a wholly Indian owned company are exempted from excise duty provided these are patented in any two countries from amongst India, USA, Japan and any one country of the EU for a period of three years. The drugs and medicines developed indigenously do not fall in purview of the Drugs Price Control Order for the first five years. A higher rate (40 percent) of investment allowance and depreciation is applicable to plant and machinery installed (since 1987) for manufacture of goods based on indigenous technology. The indigenous technology-based products were exempt from provisions of industrial licensing and proposals based on indigenous technology enjoyed a preferential treatment in industrial licensing. Royalties earned by Indian companies abroad through export of indigenous technologies are completely free of tax, and those earned within the country are given a 40 percent rebate.

Furthermore, to inculcate technological entrepreneurship in the country, the public sector financial institutions such as IDBI, ICICI, IFCI have set up venture capital funding companies to assist new generation of techno-entrepreneurs. Private venture capital funds and angel investors have been allowed to operate in India as per the SEBI regulations.

DSIR has set up Technology Business Incubation Centres at the research institutions to facilitate speedier transfer of know-how developed. IITs and other technology institutions are setting up industrial consultancy and extension centres to facilitate utilization of domestic R&D and encourage technology entrepreneurship among their alumni. DST has set up S&T Entrepreneurial Parks. These Parks provide infrastructural facilities to techno-entrepreneurs to start their business activity expeditiously.

## 3. Reforms and Implementation of WTO Commitments

The industrial, trade and technology policy framework evolved over the 1950-90 has considerably changed in the 1990s as a part of the economic reforms undertaken by the government and also the implementation of the commitments undertaken by the country under the WTO Agreements. The important changes have been brought about in the industrial policy and FDI policy, trade policy, regime governing the exchange rates and capital markets, patent protection and price controls. In what follows we summarize the changes that have been brought about particularly those relevant for the pharmaceutical industry.

Industrial Policy

The New Industrial Policy (NIP) announced on 24th July 1991 and subsequent amendments brought far-reaching changes in the policy regime governing the industrial investments. Although the NIP dismantled the industrial licensing (or approval) system by abolishing the requirement of obtaining an industrial license from the government, drugs and pharmaceuticals industry is included among the 14 specified industries that continue to remain under the ambit of licensing given the social well-being consideration. NIP accords a much more liberal attitude to foreign direct investments (FDI) than ever in the post Independence India. The Policy allows automatic approval system for priority industries by the Reserve Bank of India within two weeks subject to their fulfilling specified equity norms. As one of the select priority industries specified in Annexure III-C of NIP, foreign ownership up to 51 per cent was to be allowed on automatic basis for pharmaceutical industry for manufacture of bulk drugs and formulations thereof. Later on, the pharmaceuticals industry was included in the list for automatic approval up to 74 per cent in March 2000 and to 100 per cent in December 2001.

In September 1994, government announced a revision of the Drug Policy 1986 which includes measures like abolishing industrial licensing requirements for majority of drugs barring few; removing restriction on the imported bulk drugs, scraping the linkage requirement (where a stipulated percentage of bulk drug production need to be supply to non-associated formulators), and limiting the scope of price control and

providing for establishment of the National Drug Authority to monitor quality and the National Pharmaceutical Pricing Authority to fix prices of both bulk drugs and formulations. On 15 February 2002, the government unveiled the Pharmaceutical Policy 2002 to take into account the emerging challenges in the wake of WTO Agreements and hence the need for new initiatives 'towards promoting accelerated growth of pharmaceutical industry and towards making it more internationally competitive'. This covered implementation of the recommendations of two committees that the Government had appointed in 1999. These include the Pharmaceutical Research and Development Committee (PRDC) under the Chairmanship of Dr R.A. Mashelkar, DG, CSIR, and the other Drugs Price Control Review Committee (DPCRC) headed by the Secretary, Department of Chemicals and Petrochemicals. The 2002 Policy has abolished the industrial licensing requirements for all bulk drugs cleared by Drugs Controller General (India), all intermediates and formulations except for those produced by recombinant DNA technology, those requiring in-vivo use of nucleic acids as the active principles, and specific cell/ tissue targeted formulations. Automatic approval for foreign ownership up to 100 per cent and foreign technology agreements will also be available for all the cases except those included in the industrial licensing requirements.

Price controls

Another aspect of the reforms has been substantial dilution of the price controls. A new DPCO was notified on 6th January 1995 bringing down the number of drugs under the ambit of price controls to 74 from 166 under the 1987 Order. These 74 drugs covered under DPCO 1995 account for only about 40 percent of the total market thus setting the bulk of the pharmaceuticals market out of price controls. In identifying this list, the Government has followed an exclusion-cum-inclusion criterion, excluding drugs in which there is a sufficient market competition and including those where there is a monopoly situation. Secondly, there is a single list of drugs under the price control with a MAPE (Maximum Allowable Post Manufacturing Expenses) of 100 percent. Thirdly, all formulations under DPCO drugs sold whether under branded or generics cannot escape price fixation. Lastly, exemption period for new drugs produced by indigenous R&D has been increased from

five years to ten years. A National Pharmaceutical Pricing Authority (NPPA) has been set up in 1997 to administer the DPCO. The Pharmaceutical Policy 2002 has proposed further dilution of the price controls following the recommendations of DPCRC 1999. The guiding principle for identification of specific bulk drugs for price controls to be mass consumption nature of the drug and absence of sufficient competition in such drugs. The bulk drugs will be kept under price controls under the new policy if the moving annual total value for any formulator is more that Rs 25 crores and the percentage share of any formulators is 50 per cent or more, or in case of less than Rs 25 crores but more than Rs 10 crores, the share of any formulator is 90 per cent or more. The maximum allowable post-manufacturing expenses (MAPE) will be 100 per cent for indigenously manufactured formulations and 50 per cent of the landed cost in case of imported formulations. The exemption from price controls for drugs developed indigenously has been extended to 15 years or to the term of process patents or indigenous new drug delivery system[2] . With these changes the scope of price controls will be reduced to only 22 per cent of the total market[3] . Therefore, the 1990s have seen a substantial reduction in the scope of price controls in the industry. It is likely to have affected the prices of drugs as will be seen later.

**WTO Commitments: Trade Liberalization and TRIPs**

As a part of the liberalization of trade policy under the reforms and WTO commitments, the tariff rates applicable to drugs and pharmaceuticals have been brought down. A two tiered structure is applicable with a zero per cent tariff and zero per cent countervailing duty for essential items and 30 per cent tariff and a 16 per cent cvd for all others[4] . The new tariff structure therefore, does not differ according to value addition and hence does not give any encouragement to local production.

The TRIPs Agreement of WTO accommodates the demands of the industrialized countries for higher international standards of protection by mandating the extension of patentability to virtually all fields of technology recognized in developed country patent systems, by prolonging the patent protection for a uniform term of twenty years, and by providing legal recognition of the patentee's exclusive rights

to import the patented products. The patent rights are enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced. All the signatories to the trade negotiations are, therefore, obliged to harmonize their IPR regime and to provide product patents for pharmaceuticals and chemicals. The coverage of the patent protection has also been expanded by the provision for patents on micro-organisms and protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof.

The TRIPs Agreement of WTO is likely to have major implications for the drugs and pharmaceutical industry. India will have to extend the scope of patenting to chemical and pharmaceuticals and increase the term of patents to 20 years from the present 7 and 14 years. However, developing countries not providing product patents are given a 10 years transition to evolve product patents. However, in the interim period a mailbox mechanism must be set up to provide exclusive marketing rights (EMR) to applicants for product patents. In order to comply with the India's commitments under the TRIPs Agreement, amendments have been brought in the Indian Patents Act 1970. A 1999 Amendment has been brought to provide for exclusive marketing rights (EMRs) a pipeline mechanism during the transition period to adopt product patents. India has a ten years transition to provide product patents viz. till the end of 2004. A Bill for Second Amendment to the Indian Patents Act 1970 to extend the term of patents to 20 years is in the Parliament. India has also joined the Paris Convention and the Patent Cooperation Treaty in 1998. These changes in the IPR regime are likely to have important implications for the pharmaceutical industry as will be seen later.

Incentives for Domestic Innovative Activity

As a part of preparing the industry to take challenge of TRIPs, the government has taken several initiatives. As observed earlier, a Pharmaceutical Research and Development Committee (PRDC) chaired by Dr RA Mashelkar was set up in 1999. The PRDC has proposed a vision of transforming the country into a knowledge power in the industry. Following the recommendations of PRDC 1999, the Pharmaceutical Policy 2002 has proposed to set up a Drug Development Promotion

Foundation (DDPF) and a Pharmaceutical Research and Development Support Fund (PRDSF) besides incentives for fruits of indigenous development in the form of exemptions from price controls. A new Central Drugs Standard Control Organization has also been proposed to set up to administer safety, efficacy and quality norms of global standards.

## 4. Government Policies and Development of Indigenous Capability in the Indian Pharmaceutical Industry in the Pre-Reform Period

It is by now widely recognized that the integrated policy framework pursued during the 1970s till 1990 covering an industrial policy favouring domestic enterprises, trade policy encouraging domestic production, patents policy and national innovation system facilitating the development of local technology, and price controls have led to a rapid development of Indian pharmaceuticals industry from one dependent on imports for domestic consumption in to a US$ 4 billion industry by 2000 AD, one that is not only self reliant in indigenous manufacture of most of the critical bulk drugs but generates exports surpluses. In 1970 much of the country's pharmaceutical consumption was met by imports and the bulk of domestic production of formulations was dominated by MNE subsidiaries. Of the top ten firms by retail sales in 1970 only two were domestic firms and the others were MNE subsidiaries. In 1996 six of the top ten firms in the industry are Indian firms. By 1991, domestic firms accounted for 70 per cent of the bulk drugs production and 80 per cent of formulations produced in the country (Lanjouw 1998).

Broad-based Production Network

To understand the gradual evolution of the industry, it is useful to look at the changing composition of output of formulations and of bulk drugs in terms of shares of MNEs, public sector, Indian private sector —large and small scale over 1974/5 to 1985/6 period as summarized in Table 1. It is apparent that MNE affiliates dominated the output of formulations in the mid-1970s with over 50 per cent of the market. However, their share had gradually come down to 40 per cent while that of the domestic small-scale companies has gradually increased. A much sharper change in composition is evident in bulk drugs

production where share of MNE affiliates has gradually declined from nearly 40 per cent in the mid-1970s to only 18 per cent. The local public sector and private sector enterprises including small-scale firms have gradually expanded their bulk drug production to achieve self-sufficiency. This would also suggest that MNE affiliates concentrate on production of formulations given their ownership of popular brand names. Public sector enterprises played an important role in starting the indigenous production of bulk drugs in the country in the 1960s and 1970s a trend that was later on picked up by other domestic enterprises. One striking feature of the evolution of Indian drugs industry is faster growth of small-scale sector which has been facilitated by various favorable policies like the exemption from the DPCO, reservation of drugs for exclusive production in small scale sector, process patents permitting them to develop their own process of making a drug at a lower cost, etc. Over the years small scale sector has diversified its production base to produce many important bulk drugs/intermediates like Ampicillin Trihydrate, Amoxycillin, Trimethoprim, Sulphamethoxazole, Analgin, 6-APA, Chloramphenicol, etc. The small-scale firms account for the bulk of the 20,000 companies that exist in the industry now. Therefore, the Indian pharmaceutical industry is broad based and not dominated by a handful of large players.

**Table 1: Growth of Production of Pharmaceuticals in India by Ownership Groups, 1974-75 to 1985-86**

| Year | *Public Sector* | | *MNE Affiliates (Foreign* | | *Organized Indian Sector* | | *Small scale Indian* | | |
|---|---|---|---|---|---|---|---|---|---|
| | *Value* | *% of total production* | *Value* | *% of total production* | *Value* | *% of total production* | *Value* | *% of total production* | *Total* |
| **Formulations** | | | | | | | | | |
| 1974-75 | 25 | 6.25 | 203 | 50.75 | 172* | 43 | | | 400 |
| 1975-76 | 35 | 6.25 | 300 | 53.57 | 225 | 40.18 | | | 560 |
| 1976-77 | 47 | 6.71 | 292 | 41.71 | 241 | 34.43 | 120 | 17.14 | 700 |
| 1978-79 | 60 | 5.71 | | | 800** | 76.19 | 190 | 18.1 | 1050 |
| 1979-80 | 72 | 6.26 | | | 778** | 67.65 | 300 | 26.09 | 1150 |
| 1982-83 | 100 | 6.25 | 640 | 40 | 443 | 27.69 | 417 | 26.06 | 1600 |
| 1983-84 | 110 | 6.25 | 704 | 40 | 487 | 27.67 | 459 | 26.08 | 1760 |
| 1984-85 | 114 | 6.24 | 731 | 40.01 | 505 | 27.64 | 477 | 26.11 | 1827 |
| 1985-86 | 121 | 6.22 | 778 | 40 | 538 | 27.66 | 508 | 26.12 | 1945 |
| **Bulk Drugs** | | | | | | | | | |
| 1974-75 | 33 | 36.7 | 34 | 37.8 | 23* | 25.6 | | | 90 |
| 1975-76 | 43 | 33.1 | 52 | 40 | 25 | 19.2 | 10 | 7.7 | 130 |
| 1976-77 | 48 | 32 | 63 | 42 | 29 | 19.3 | 10 | 6.7 | 150 |
| 1978-79 | 49 | 24.5 | 56 | 28 | 75 | 37.5 | 20 | 10 | 200 |
| 1979-80 | 59 | 26.1 | 53 | 23.5 | 90 | 39.8 | 24 | 10.6 | 226 |
| 1980-81 | 62 | 25.8 | 56 | 23.3 | 95 | 39.6 | 27 | 11.3 | 240 |
| 1981-82 | 67 | 23.1 | 73 | 25.2 | 120 | 41.4 | 30 | 10.3 | 290 |
| 1982-83 | 67 | 20.6 | 72 | 22.2 | 121 | 37.2 | 65 | 20 | 325 |
| 1983-84 | 61 | 17.2 | 65 | 18.3 | 155 | 43.7 | 74 | 20.8 | 355 |
| 1984-85 | 64 | 17 | 68 | 18 | 166 | 44 | 79 | 21 | 377 |
| 1985-86 | 71 | 17.1 | 75 | 18 | 183 | 44 | 87 | 20.9 | 416 |

Note: * includes production in small-scale sector and ** includes production in foreign sector.

Source: (i) Department of Chemicals and Fertilizers, Basic Data on Drugs Industry, 1977-78
(ii) IDMA (1989) Annual Publication
(iii) DSIR (1990)

## Availability and Prices of Drugs

A major achievement of India in the industry has been development of domestic technological capability. Facilitated by the abolition of product patent regime with the Patents Act of 1970, and the availability of S&T infrastructure in the country local enterprises have embarked on a major initiative to develop cost-effective processes for indigenous manufacture of known chemical compounds and other bulk drugs. The development of process innovation capability of Indian enterprises has enabled them to introduce newer medicines within a short time lag. Table 2 shows that most of the drugs could be introduced within 4-5 years of their introduction in the world market. Table 2 also shows that the prices of these drugs in India have been much cheaper compared to rest of the world. For instance, Ranitidine, Famotidine, Astemizole, Ondansetron sell in the US market at about 50 times the Indian prices! The cheaper prices of drugs have made them affordable to the masses of poor in the country and thus have served an important social cause of providing access of modern medicine to poorer people.

**Table 2: Introduction of New Drugs and Relative Prices Patentable Drugs in India**

| Brand & Dosage (pack) | Year | | | | Prices (in Rs in 1994) | | | | Times costlier | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | World Introduction | Indian Marketing Approval | Introduction lag | European Patent Expiry | India | Pakistan | USA | UK | Pakistan | USA | UK |
| *Antibiotic/ Antibacterial* | | | | | | | | | | | |
| Ofloxacin 200mg (4 tab) | | 1990 | | 2001 | 92 | 117.2 | 408.1 | 217.3 | 1.3 | 4.4 | 2.4 |
| Ciprofloxacin 500mg (4 tab) | 1985 | 1989 | 4 | 2001 | 28.4 | 234.6 | 438.2 | 291.5 | 8.3 | 15.4 | 10.3 |
| Norfloxacin 400mg (10 tab) | 1984 | 1988 | 4 | 1998 | 39 | 125.5 | 903.7 | 254.4 | 3.2 | 23.2 | 6.5 |
| Pefloxacin 400mg (4 tab) | | 1991 | | 1998 | 15.6 | 59.4 | | | 3.8 | | |
| *Anti-ulcer* | | | | | | | | | | | |
| Ranitidine 300mg (10 tab) | 1981 | 1985 | 4 | 1997 | 18.5 | 260.4 | 1050.7 | 484.4 | 14.1 | | 26.1 |
| Famotidine 40mg (10 tab) | 1984 | 1989 | 5 | 1999 | 18.6 | 260.4 | 1004.2 | 503.5 | 14 | | 27.1 |
| Omeprazole 20 mg (10 tab) | | 1991 | | 1999 | 29 | | 1270.5 | 671 | | | 23.1 |
| *Cardiac care* | | | | | | | | | | | |
| Lisinopril 5mg (10 tab) | | | | 1999 | 35 | | 264.6 | 181.3 | | | 5.2 |
| Enalapril Maleate 5mg (10 tab) | 1984 | 1989 | 5 | 1999 | 15.9 | 37.2 | 316.9 | 148.8 | 2.3 | | 9.4 |
| Ketoconazole 200mg (10 tab) | 1981 | 1988 | 7 | 1997 | 57.9 | 222 | 1082.9 | 277.2 | 3.8 | | 4.8 |
| *Anti-histamine* | | | | | | | | | | | |
| Astemizole 10mg (10 tab) | 1986 | 1988 | 2 | 1999 | 12 | 120.9 | 647.5 | 142.6 | 10.1 | | 11.9 |
| Others | | | | | | | | | | | |
| Ondansetron HCI 4mg (6 tab) | | | | 2005 | 39.5 | | 2247 | 1287.9 | | | 32.6 |

Source: constructed on the basis of Lanjouw (1998), Watal (2000) with other supplementary information.

**Local Technological Capability and Comparative Advantage**

Indian pharmaceutical industry has emerged in the country as one with a much higher emphasis on technological development and R&D activity. An analysis of about 900 R&D performing companies in the Indian corporate sector summarized in Table 3 shows that R&D to sales ratio for the entire sample for the 1992/3 to 1998/9 was 0.846 per cent, the average ratio for the drugs and pharmaceuticals industry was 1.55 per cent. Furthermore, the data summarized in Table 3 shows that domestic enterprises in the industry are more active in R&D with an R&D intensity of 1.72 per cent compared to 1.1 per cent for their MNE counterparts.

The growing emphasis has led to build up on local technological capability especially in process innovation. The increasing domestic technological capability is reflected in terms of rising exports of drugs and pharmaceuticals. With their cost effective process innovations, Indian companies have emerged as competitive suppliers in the world of a large number of generic drugs. That has resulted in a steady growth of India's exports of drugs and pharmaceuticals. Thus the industry has evolved from being one being highly import-dependent to one that generates increasing export surplus for the country. The faster growth of pharmaceutical exports has resulted in their share in India's exports rising from 0.55 per cent in 1970-71 to over 4 per cent by the 1999/00 (Table 4).

**Table 3: R&D Intensities in Indian Corporate Sector**

**(percentages)**

| | 1992-93 to 1994-95 | | | 1995-96 to 1998-99 | | | 1992-93 to 1998-99 | | |
|---|---|---|---|---|---|---|---|---|---|
| Industry | Local | MNE Affiliates | Total | Local | MNE Affiliates | Total | Local | MNE Affiliates | Total |
| Drugs and pharma | 1.69 | 1.06 | 1.57 | 1.74 | 1.12 | 1.58 | 1.72 | 1.1 | 1.55 |
| | -0.023 | -0.012 | -0.021 | -0.021 | -0.013 | -0.019 | -0.022 | -0.928 | -0.02 |
| | 128 | 48 | 176 | 220 | 80 | 300 | 348 | 128 | 476 |
| Full Sample | 0.9 | 0.766 | 0.868 | 0.831 | 0.852 | 0.835 | 0.854 | 0.818 | 0.846 |
| | -0.015 | -0.008 | -0.014 | -0.015 | -0.011 | -0.014 | -0.015 | -0.01 | -0.0145 |
| | 1125 | 338 | 1463 | 2169 | 577 | 2746 | 3294 | 915 | 4209 |

*Note* : Parentheses show S.D; the bottom figure represents number of observations.

Source: Kumar and Agarwal 2001

**Table 4: India's Trade in Pharmaceutical Products, 1970-71 to 1999-2000 (Current prices)**

In Rs. Crores (10 millions)

| *Year* | *Trade in medicinal and pharmaceutical products* | | | *Pharmaceutical exports as a % of India's total exports* |
|---|---|---|---|---|
| | *Exports* | *Imports* | *Trade balance* | |
| 1970-71 | 8.5 | 24.3 | -15.8 | 0.55 |
| 1971-72 | 9.6 | 26.6 | -17 | 0.6 |
| 1972-73 | 10.3 | 23.2 | -12.9 | 0.52 |
| 1973-74 | 15.1 | 26.4 | -11.3 | 0.6 |
| 1974-75 | 23 | 34.2 | -11.2 | 0.69 |
| 1975-76 | 22.2 | 36.3 | -14.1 | 0.55 |
| 1976-77 | 24.2 | 42.2 | -18 | 0.47 |
| 1977-78 | 31.2 | 63.6 | -32.4 | 0.58 |
| 1978-79 | 56.5 | 79.2 | -22.7 | 0.99 |
| 1979-80 | 87.5 | 73.9 | 13.6 | 1.36 |
| 1980-81 | 67.4 | 84.6 | -17.2 | 1 |
| 1981-82 | 122 | 84.4 | 37.6 | 1.56 |
| 1982-83 | 112.2 | 88.8 | 23.4 | 1.27 |
| 1983-84 | 155.2 | 146.9 | 8.3 | 1.59 |
| 1984-85 | 234.2 | 137.1 | 97.1 | 1.99 |
| 1985-86 | 157.9 | 177.2 | -19.3 | 1.45 |
| 1986-87 | 161.3 | 213.8 | -52.5 | 1.3 |
| 1987-88 | 326.1 | 167.8 | 158.3 | 2.08 |
| 1988-89 | 473.7 | 236.4 | 237.3 | 2.34 |
| 1989-90 | 849.6 | 399.7 | 449.9 | 3.07 |
| 1990-91 | 1014.1 | 468.4 | 545.7 | 3.11 |
| 1991-92 | 1550.1 | 558.5 | 991.6 | 3.52 |
| 1992-93 | 1533 | 813.2 | 719.8 | 2.86 |
| 1993-94 | 2009.7 | 808.8 | 1200.9 | 2.88 |
| 1994-95 | 2512.3 | 937.2 | 1575.1 | 3.04 |
| 1995-96 | 3408.7 | 1358 | 2050.7 | 3.21 |
| 1996-97 | 4341.8 | 1089.2 | 3252.6 | 3.65 |
| 1997-98 | 5419.3 | 1447.1 | 3972.2 | 4.17 |
| 1998-99 | 6256.07 | 1615.2 | 4640.87 | 4.48 |
| 1999-2000 | 6631.45 | 1502.3 | 5129.15 | 4.07 |

Source: RBI (2000), *Handbook of Statistics on Indian Economy* , Bombay: the Reserve Bank of India

Emerging revealed comparative advantage of India in pharmaceuticals is apparent from Table 5 and Figure 1 which show that India's share in world exports of pharmaceuticals has risen by 2.5 times while her share in all merchandize exports has stagnated at about 0.6 per cent throughout the 1970 to 1998 period.

**Table 5: India's Pharmaceutical exports in World Trade, 1970 to 1998 (Current prices) In US$ million**

| | *Share of India in World Exports* | |
|---|---|---|
| *Year* | *All Merchandize* | *pharmaceuticals* |
| 1970 | 0.6 | 0.4 |
| 1975 | 0.5 | 0.4 |
| 1980 | 0.4 | 0.8 |
| 1985 | 0.5 | 0.8 |
| 1990 | 0.5 | 1.2 |
| 1995 | 0.6 | 1 |
| 1997 | 0.6 | 1.1 |
| 1998 | 0.6 | 1 |

Source: India, *Economic Survey 2000/01* and the UN *International Trade Statistics Yearbook* 1998, United Nations

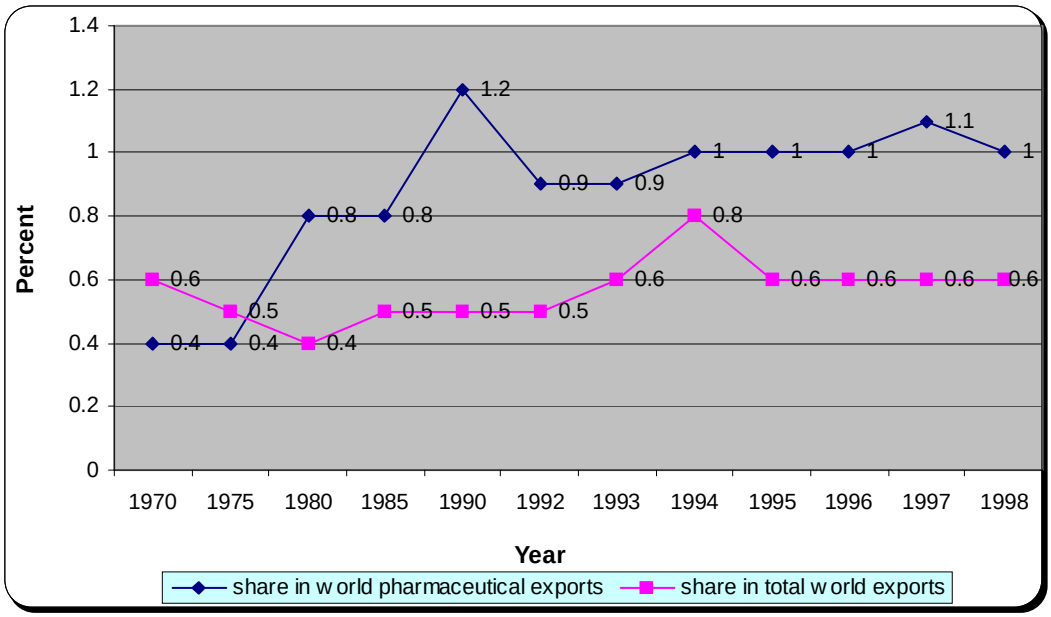


**Table 6: Major Exporters of Medicinal and Pharmaceutical Products in the World**

| **Countries** | **1994** | **1995** | **1996** | **1997** | **1998** |
|---|---|---|---|---|---|
| Germany | 8739.1 | 10268.3 | 10711.8 | 11655 | 14036.7 |
| United Kingdom | 6080 | 7720 | 8320.1 | 8940.2 | 9666.6 |
| Switzerland | 6324.9 | 7589.8 | 8411.2 | 8208.5 | 9854.4 |
| USA | 6184.5 | 6554 | 7330.1 | 8230.5 | 9660.8 |
| France | 5415.4 | 6864.4 | 7244.7 | 7900.8 | 9314.5 |
| Belgium | 3333.1 | 4120.6 | 4301.6 | 4885.5 | 5481.8 |
| Italy | 2759.3 | 3630 | 4299.3 | 4430.3 | 4897.8 |
| Netherlands | 2780.7 | 3973.8 | 3437.9 | 3770.6 | 3519.6 |
| Sweden | 2467.5 | 2546.2 | 2943 | 3057.6 | 3567.5 |
| Ireland | 1847.6 | 2105.8 | 2782.8 | 3356.7 | 4745.4 |
| Denmark | 1615.1 | 2160.8 | 2214.6 | 2272.4 | 2213.3 |
| Japan | 1547.9 | 1843.7 | 1889.4 | 1952.4 | 1915.1 |
| China | 1185.3 | 1582 | 1516.1 | 1536.2 | 1692.3 |
| Spain | 1061.2 | 1164.9 | 1414 | 1516.9 | 1702.6 |
| Austria | 1054 | 1333.7 | 1374.5 | 1324.9 | 1343.1 |
| Hong Kong, SAR | 832.9 | 975.3 | 1020.1 | 967.5 | 882.4 |
| **India** | **585.8** | **724.2** | **814** | **947.2** | **901.1** |
| Canada | 504.7 | 611.1 | 683.4 | 957.7 | 1052.1 |
| Australia | 534.3 | 618.8 | 737.7 | 784.5 | 768.6 |
| Singapore | 494.8 | 601.2 | 616.2 | 616.6 | 592 |
| Mexico | 296.7 | 399.4 | 552.4 | 636.8 | 715.9 |
| Slovenia | 283.1 | 318.8 | 357.7 | 402 | 387.8 |
| Israel | 276.4 | 255.3 | 334.3 | 416.7 | 396.6 |
| Hungary | 249.4 | 276.6 | 281.4 | 357.3 | 311.6 |
| Korea, Republic of | 218.5 | 259.4 | 279.5 | 289.8 | 292.3 |
| Poland | 200.1 | 223.8 | 256 | 294.6 | 196.7 |
| Norway | 190 | 210.1 | 225.4 | 217.9 | 224.2 |
| Finland | 192.1 | 214.4 | 204.9 | 214.5 | 231.4 |
| Argentina | 111.9 | 140.9 | 198.8 | 282.3 | 298 |
| Czech Republic | 150.3 | 185.6 | 218.1 | 213.7 | 210.1 |
| Brazil | 132.8 | 167.6 | 189.1 | 217.3 | 248.1 |
| Portugal | 94.7 | 143.6 | 169.3 | 171.7 | 205.9 |

Source: UN *International Trade Statistics Yearbook* 1998, United Nations

Indian exports of pharmaceuticals received a boost in the late 1980s when a number of drugs went off the patents and Indian companies manufacturing them with cost-effective processes entered the international markets after obtaining FDA approval. Therefore, in the late 1980s, as much as 61 per cent of India's pharmaceutical exports comprised bulk drugs. However, subsequently some of the larger and more dynamic Indian enterprises such as Ranbaxy Laboratories, Dr Reddy's Labs, Cipla and Cadila, have started marketing their own formulations in different countries with the help of a growing network of overseas offices and subsidiaries set up in key international markets. As a result the share of bulk drugs in total exports of pharmaceuticals has come down to around 40 per cent (Table 7).

USA is the biggest market for India's pharmaceutical exports accounting for 10-12 per cent of exports. The export basket of India includes generic drugs like Ibuprufen, Sulphamethoxazole, Metronidazole, Amoxycilline, Ampicilline, Mebendazole, Beta Ionone, Erythromycin, Pappain, Potassium Iodide, Brucine Salts, Cephalexin, Ethambutol Hydrochloride, Trimethoprim etc.

**Table 7: Composition of India's Pharmaceutical Exports**

**(Current prices) In Rs. Crores**

| *Year* | *Bulk Drugs* | | *Formulations* | | *% share of bulk drugs* | *Total exports* | |
|---|---|---|---|---|---|---|---|
| | *Value* | *As a % of bulk drugs production* | *Value* | *As a % of formulations produced* | | *Value* | *As a % of total production* |
| 1980-81 | 11.28 | 4.7 | 35.1 | 2.93 | 24.32 | 46.38 | 3.22 |
| 1981-82 | 15.45 | 5.35 | 69.34 | 4.84 | 18.22 | 84.79 | 4.92 |
| 1982-83 | 11.34 | 3.29 | 54.6 | 3.29 | 17.2 | 65.94 | 3.29 |
| 1983-84 | 18.46 | 5.2 | 61.46 | 3.49 | 23.1 | 79.92 | 3.78 |
| 1984-85 | 29.25 | 7.76 | 99.5 | 5.45 | 22.72 | 128.75 | 5.84 |
| 1985-86 | 33.36 | 8.02 | 106.59 | 5.48 | 23.84 | 139.95 | 5.93 |
| 1986-87 | 87.16 | 19.03 | 102.12 | 4.77 | 46.05 | 189.28 | 7.29 |
| 1987-88 | 139.71 | 29.11 | 88.25 | 3.76 | 61.29 | 227.96 | 8.06 |
| 1988-89 | 242.87 | 44.16 | 157.29 | 4.99 | 60.69 | 400.16 | 10.82 |
| 1989-90 | 350.5 | 54.77 | 314.2 | 9.19 | 52.73 | 664.7 | 16.37 |
| 1990-91 | 413.4 | 56.63 | 371.4 | 9.67 | 52.68 | 784.8 | 17.17 |
| 1991-92 | 722.6 | 80.29 | 508.7 | 10.6 | 58.69 | 1231.3 | 21.6 |
| 1992-93 | 856.6 | 74.49 | 553.7 | 9.23 | 60.74 | 1410.3 | 19.72 |
| 1993-94 | 1029.6 | 78 | 771.8 | 11.19 | 57.16 | 1801.4 | 21.91 |
| 1994-95 | 1260.7 | 83.05 | 924 | 11.64 | 57.71 | 2184.7 | 23.11 |
| 1995-96 | 1098 | 57.13 | 1239 | 13.58 | 46.98 | 2337 | 21.16 |
| 1996-97 | 1581 | 72.32 | 2509.2 | 23.91 | 38.65 | 4090.2 | 32.26 |
| 1997-98 | 2173 | 82.84 | 2805 | 23.24 | 43.65 | 4978 | 33.88 |

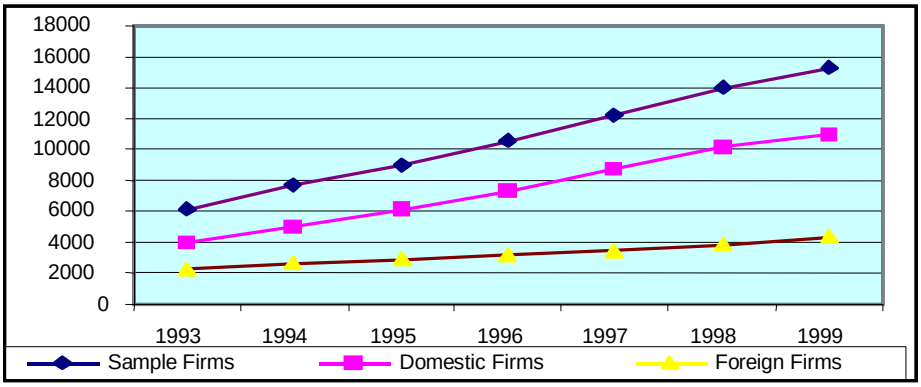
Source: Department of Chemicals and Petrochemicals, various Annual Reports

The technological capabilities of Indian companies have grown to a point when leading MNEs have started to take note of it. For instance, Eli Lilly established a joint venture with Ranbaxy in the mid-1990s for development of a cost effective process for synthesis of Cefaclor, among other products, taking advantage of the latter's process development capabilities. Similarly, Bayer contracted Ranbaxy to develop single doses formulations of its proprietary Ciprofloxacine. A number of leading MNEs have also contracted Indian public funded R&D institutions for synthesis of new molecules and process development. These include Abbot Laboratories, Parke Davis, and Smith Kline and Beecham, among others, that have commissioned Indian Institute for Chemical Technologies, Hyderabad and National Chemical Laboratories, Pune (Kumar,1999, for more details). Astra (now Astra-Zeneca) has set up a full fledged R&D centre in Bangalore to draw upon trained manpower and research infrastructure available in the country, despite the fact that Indian patent regime does not provide product patents.

**Ownership, Firm Size and Technological Dynamism: Recent Trends in Enterprise Performance**

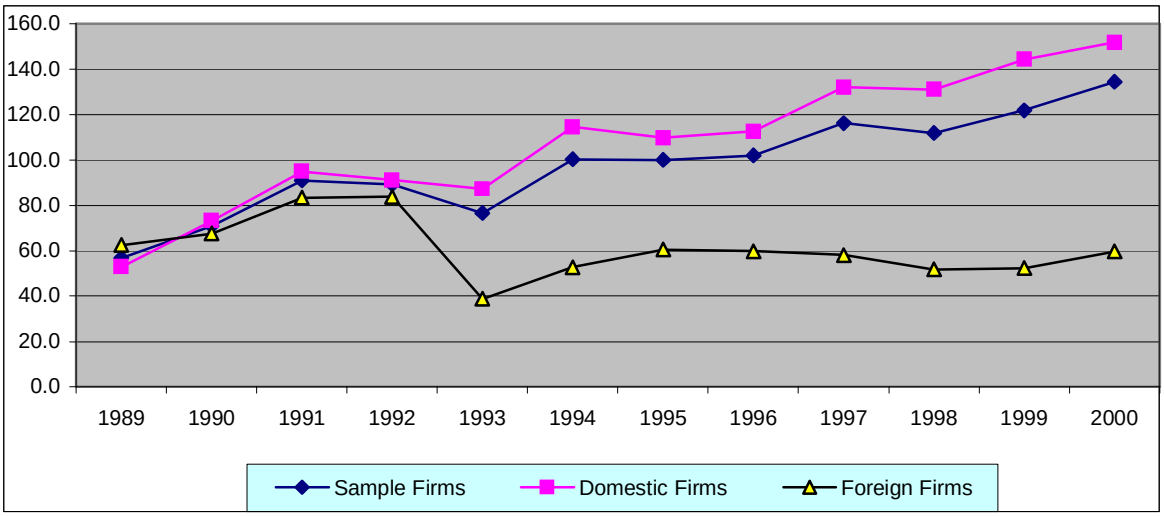
A comparison of the performance of MNE affiliates and domestic enterprises in Indian pharmaceutical industry is made over the 1990s based on a balanced sample of 76 firms (60 domestic and 16 MNE subsidiaries) in terms of different parameters of investment and output, export-orientation, R&D activity, technology purchases from abroad, labour productivity and profitability. The data set has been extracted from the CMIE's Prowess Database. The detailed trends are summarized in the Annex Tables. Here we use graphs to quickly examine the relative performance of the two groups of firms. Figure 2 shows that domestic enterprises have grown faster than foreign firms in the industry in terms of growth of sales.

**Figure 2: Sales of Domestic and Foreign Firms in Indian Pharmaceuticals Industry, 1993-99**




In terms of exports dynamism, whether judged in terms of proportion of sales (Figure 3) or as a ratio of exports to imports (Figure 4), domestic firms reveal a greater dynamism compared to foreign firms. Therefore, the recent export success of the industry is clearly led by domestic enterprises.

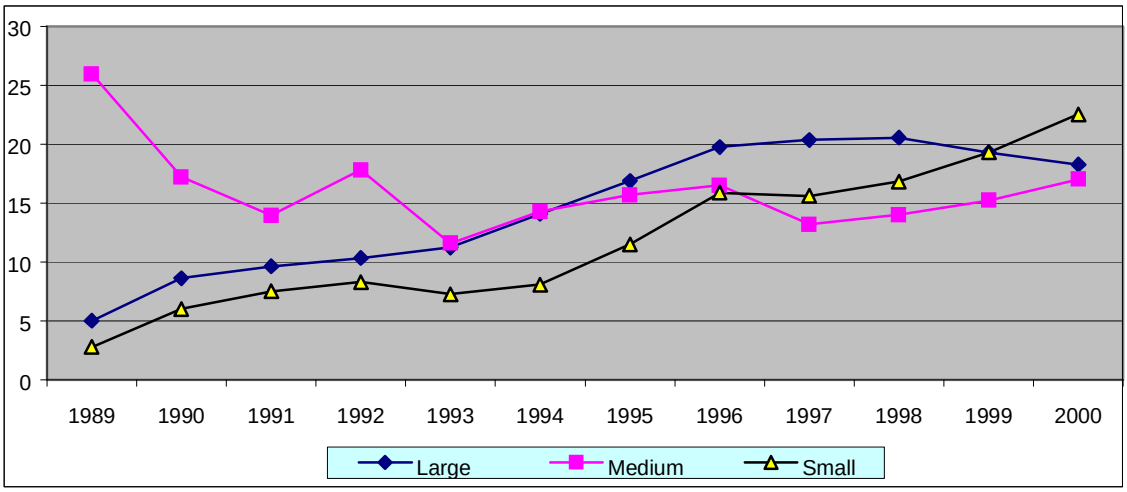
Figure 4: Exports to Imports ratio (%) 1989-2000




Source: based on CMIE sample extracted by the authors

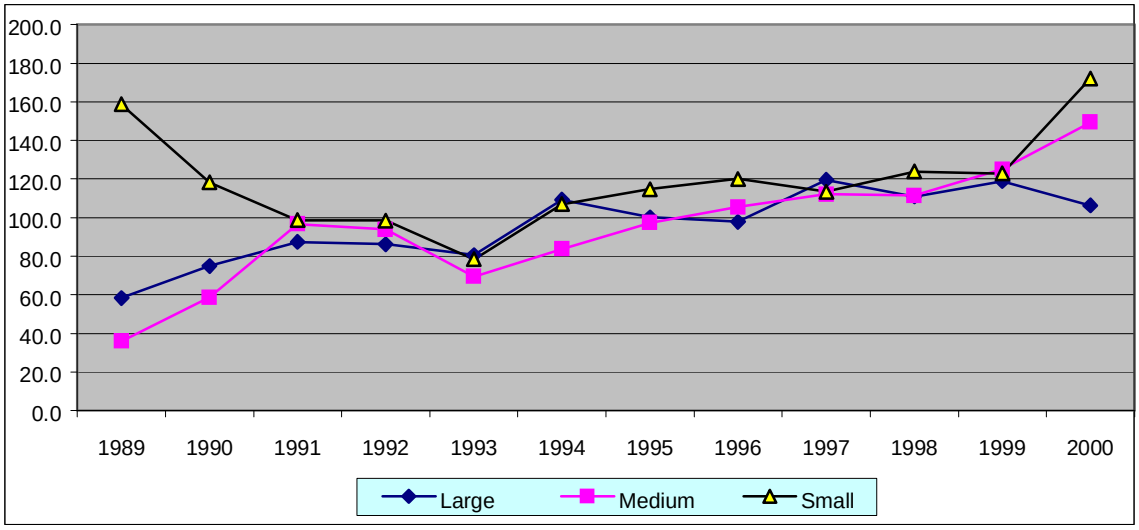
In case the sample firms are reclassified by firm size, one finds that the smaller firms are no less dynamic in terms of exports orientation especially since the mid-1990s. In fact smaller firms have performed better than medium sized firms since the mid-1990s as shown in Figure 5. In terms of export to import ration, the three size groups are quite comparable, as shown in Figure 6.

Figure 5 Firm Size and Export Intensity (%), 1989-2000




Source: based on CMIE sample extracted by the authors

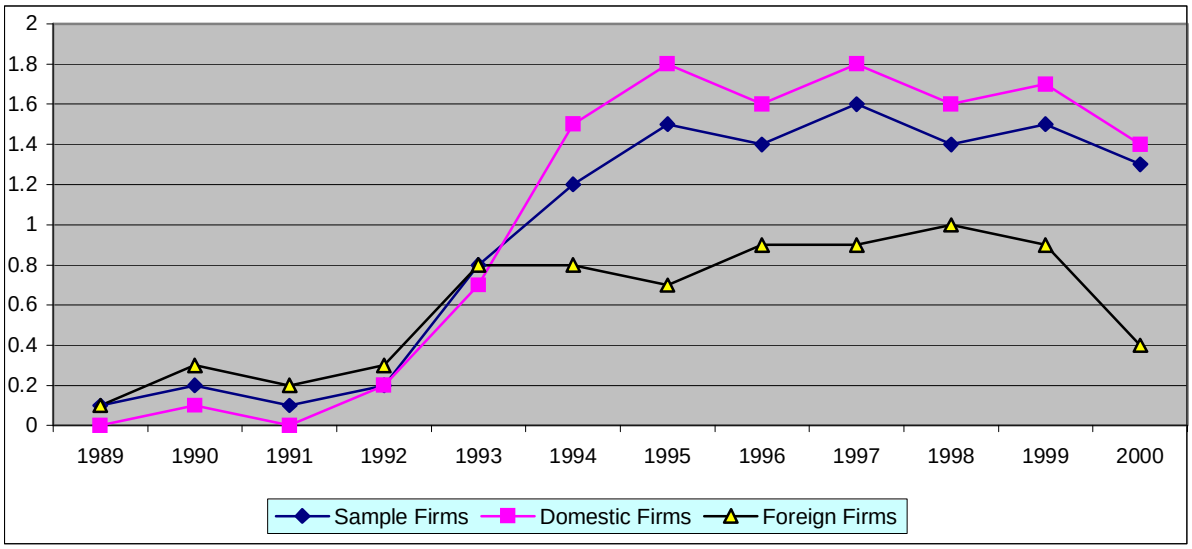
Figure 6 Firm Size and Exports to Imports ratio (%), 1989-2000




Source: based on CMIE sample extracted by the authors

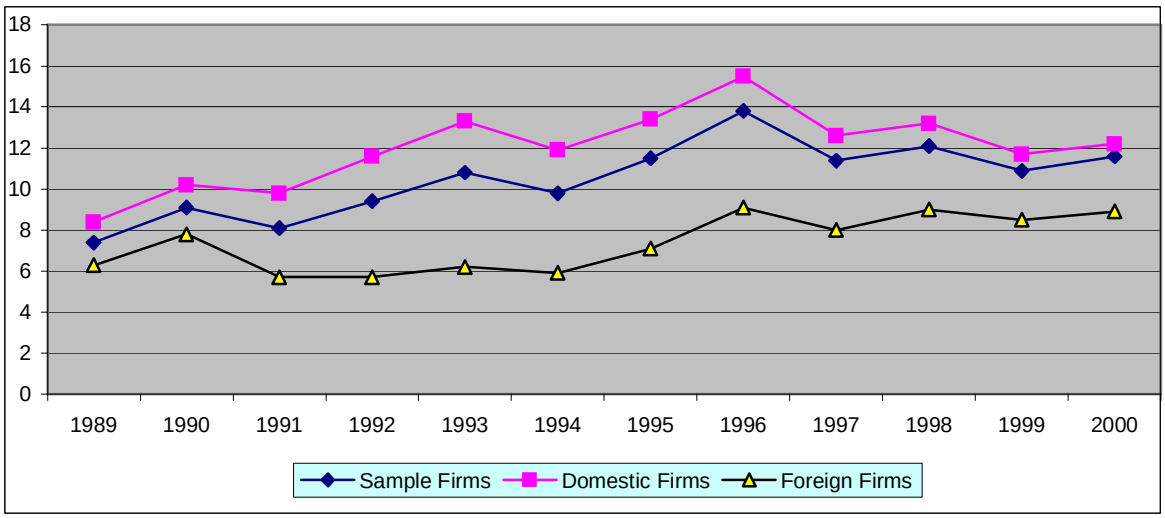
The technological dynamism is examined in terms of R&D intensity (Figure 7) and intensity of technological purchases from abroad (Figure 8). In both these respects again domestic firms appear to be more dynamic compared to their foreign owned counterparts.

Figure 7: R&D intensity
R&D Expenditure to Sales Ratio in %, 1989-2000




Source: based on CMIE sample extracted by the authors

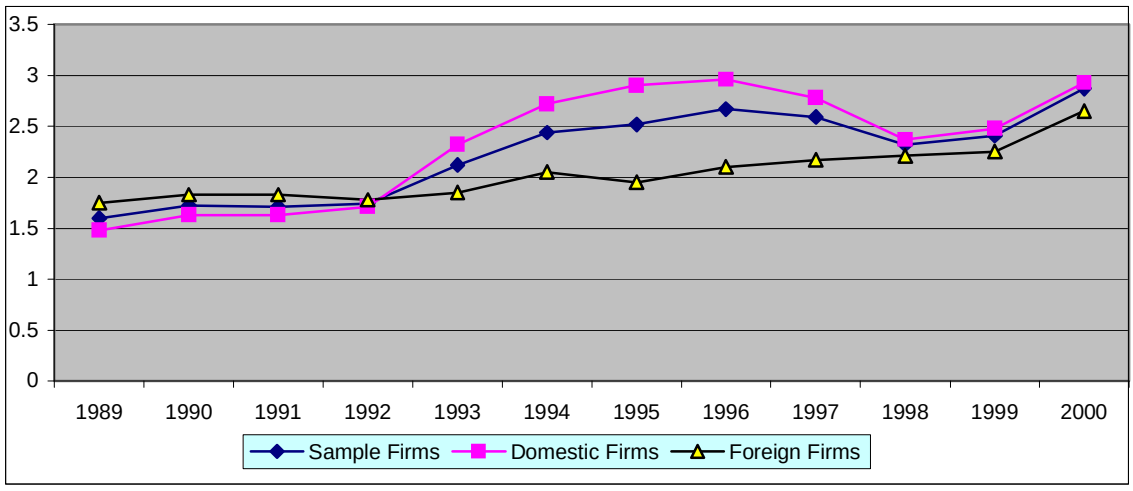
Figure 8: Intensity of Technology Purchases from Abroad
**Royalty Payments to Sales (%), 1989-2000**




Source: based on CMIE sample extracted by the authors

Productivity performance is examined in terms of defined as the net value-added per rupee spent on labor. In terms of labour productivity too, domestic firms do better than their foreign owned counterparts although the gap is narrowing since 1998, as shown in Figure 9.

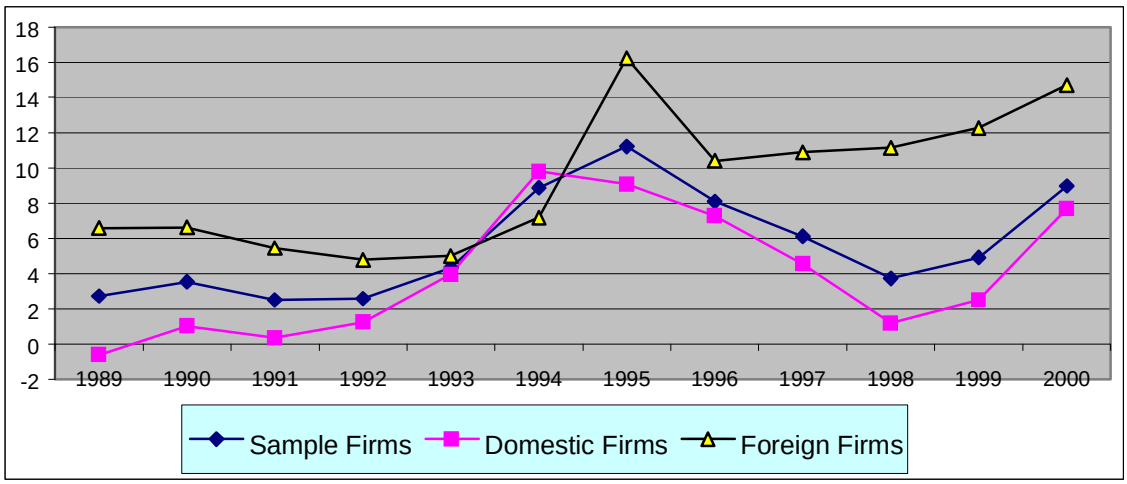
Figure 9: Labour Productivity in Indian Pharmaceutical Industry
**Net Value Added per Rupee Spent on Labour, 1989-2000**




Source: based on CMIE sample extracted by the authors

In terms of profit margins on sales, the pattern observed is reverse. Despite their greater technological and export dynamism and higher levels of productivity, domestic firms report significantly lower levels of profit margins compared to their foreign owned counterparts. MNE affiliates enjoy considerably higher profit margins because of their greater focus on more value adding formulations and their well-established brand names (Figure 10).

Figure 10: Profit Margins in Indian Pharmaceutical Industry
Profit before taxes as a proportion sales, %, 1989-2000




Source: based on CMIE sample extracted by the authors

Thus the Indian pharmaceutical industry has evolved from one dependent upon imports and some formulation activity in the late sixties to one which is able to introduce some of the most sophisticated products indigenously produced within a relatively short lag and at a fraction of the cost, and export a growing proportion of its produce to emerge as a net foreign exchange earner. It is a remarkable achievement especially because it has been accomplished within two decades since the government adopted the new patent regime and other supportive policies.

## 5. Implications of Reforms and TRIPs for Pharmaceuticals Industry

As discussed earlier, the integrated policy framework evolved since the 1970s that facilitated rapid evolution of the local capability building in the Indian pharmaceutical industry has changed considerably in the 1990s with reforms and commitments under WTO agreements. Thus industrial and trade policies have been liberalized while the scope of price controls has been drastically pruned. Important changes in the patent regime are in the offing by 2004 when India will have to provide protection to pharmaceutical products. A pipeline protection has already been provided in the form of EMRs. These changes have significant implications for the prices of drugs as well as for the industry as summarized below.

### *a) Prices of Medicines and Loss of Consumer Welfare*

Prices of medicines are likely to increase on two accounts. First, because of dilution of price controls in the 1990s, and secondly because strengthening of the patent regime as follows.

The considerable dilution of the scope of price controls during the 1990s with DPCO 1995 and subsequently with the Pharmaceutical Policy 2002 is likely to affect the drug prices. The prices of drugs that have gone out of price controls since 1995 DPCO have already increased significantly. Table 8 shows that prices of select drugs unlisted from DPCO 1995 have increased by 77 per cent to 457 per cent between 1995 and 1998. The further dilution of the scope of DPCO with new Pharmaceutical policy is likely to lead to a similar effect.

**Table 8 Price Increase in Some Selected Drugs Unlisted from DPCO, 1995**

| Drug Name | Packing | Price in 1995 | Price in 1998 | Percentage increase in price |
|---|---|---|---|---|
| Diazepam (Anti Depression) | 10 | 3.13 | 9.5 | 204% |
| Ampicillin (Antibiotic) | 4 | 12.85 | 23.15 | 80% |
| Cephalexin (Antibiotic) | 10 | 45.07 | 113.15 | 151% |
| Ethambutol (Anti T.B. drugs) | 10 | 5.92 | 33 | 457% |
| Rifampicin (Anti T.B. drugs) | 10 | 24 | 64 | 167% |
| Pirazinamide (Anti T.B. drugs) | 10 | 17.01 | 46.95 | 176% |
| Lignocaine HCL (Anaesthetic) | 30 ml. | 4.16 | 12.4 | 198% |
| Promethaxine HCL (Anti allergic) | 10 | 1.25 | 3.23 | 158% |
| Antacid liq. (Gastritis) | 200 ml. | 13 | 23 | 77% |
| Oxyfedrine HCL (Angina pectoris) | 10 | 10.44 | 21.41 | 105% |
| Discopyramide Phosphate (Cardiac problems) | 10 | 16.5 | 50.46 | 206% |
| Dipyrideamole (Anti angina) | 10 | 2 | 4.73 | 137% |

Source: D.P. Dubey at http://revolutionary democracy.org/rdv5n1/pharmacy.htm

The introduction of product patents is also likely to affect drug prices in a large number of drugs especially those under the patent protection. A number of studies have examined the effect on prices of medicines after introduction of product patents and have simulated welfare losses for consumers in developing countries. It is widely believed that drug prices will go up upon introduction of product patents as happened in China which introduced them in 1993 [May 2000:99; also see Lanjouw 1998, Scherer and Watal 2001, and Panagariya 1999]. Nogues (1993) finds the welfare losses to 6 developing countries (Argentina, Brazil, India, Mexico, Korea and Taiwan) from introduction of product patents to be between US$ 3.5 billion to $10.8 billion depending upon the assumptions. The gains to the patent owners from such introduction would range between $ 2.9 billion to $ 14.4 billion. The welfare loss to India could be between $ 1.4 billion to $ 4.2 billion in a year. Watal (2000) simulates the likely increase in pharmaceutical prices and decrease in welfare in India with the

introduction of product patents in 22 existing pharmaceutical products and finds that weighted mean drug price in India could increase between 26 per cent (for a linear demand function) to 242 per cent (with a constant elasticity-type demand function). An earlier study by Subramanian (1994) had found the maximum price increase of 67 per cent for India following the introduction of product patents. Fink (2000) finds the range of price increase between 182 to 225 per cent. That suggests that introduction of product patents would affect prices of medicines significantly and unless new drugs are more efficient, there will be a decline in the health levels of population (May 2000). The recent case of huge differences between prices of HIV Aids drugs sold by patent holders in South Africa and their generic substitutes just provides a further evidence to the potential of price increases following the introduction of product patents.

It may be argued that the vast majority of drugs are out of patent protection and hence will not be affected. The criticality of patented product also varies across therapy groups. Figures for the year 1993 as provided by OPPI (1994) based on the audited pharmaceutical market suggests that percentage of sales to on-patent (in UK) drugs in India is significant in three categories namely Antipeptic Ulcerants (84.0%), Quinolones (91.3%) and Hypotensives (89.6%). Other groups accounting for at least 20 percent includes Anthelmintics Ex Schis (30.5%), Opthal Oto Comb (39.4) and Antinauseants (19.7). Therefore, the immediate impact of introducing a product patent regime will have different impact on different therapy groups. The AIDS drugs controversy shows that effective treatment for many of scourges of the day such as cancer, cardiac failures, renal problems, among others, may be affected.

Is trade liberaliztion and hence increasing competition likely to lead to cheaper prices? That does not appear to be the case . In fact the opposite result may hold good if the findings of recent studies are any guide. In pharmaceutical industry competition does not lead to lower prices because of monopolistic and inelastic nature of demand with consumer unable to consider generic substitutes of the specific brand prescribed. Furthermore, the evidence produced by a study commissioned by the Commission on Macroeconomic and Health (CMH) using data from different countries

finds that tariff reduction on pharmaceutical products and bulk drugs is likely to increase final drug prices rather than reducing them by undermining the low-cost domestic production and hence suggests the need for a careful assessment before further reduction in tariffs (Woodward 2001).

### b) *Local Technological Capability Building*

A number of quantitative studies have shown that the innovative activity of Indian domestic enterprises was facilitated by the softer patent regime under the 1970 Act (see Fikkert 1993, Haksar 1995, Kumar and Saqib 1996). The strengthening and harmonization of IPR regimes worldwide has considerable implications for the process of acquisition of local technological capability in India. The provision of product patents on chemical and pharmaceutical products, for instance, would adversely affect the process of innovative activity of Indian enterprises in the manufacture of chemicals covered by patents. The development of new chemical compounds is generally beyond the capability of most Indian enterprises in view of the huge resources involved. Therefore, they focus attention on process innovations for the known chemicals and bulk drugs. This imitative duplication or reverse engineering activity is an important source of learning in developing countries. Indeed, most industrialized countries of today and newly industrialized countries encouraged local learning through soft patent laws and the absence of product patents in chemicals in the early stages of their development as highlighted earlier (Kumar 2002).

### c) *Industrialization, Technology Transfers and Trade*

*Innovative Activity*

The probability of stronger IPR regime encouraging innovative activity in Indian pharmaceutical industry is very little. A study of the impact of strengthening of pharmaceutical patent protection in Italy since 1978 showed little or no impact on R&D expenditures or on new inventions. Furthermore, R&D activity is found to be significantly determined by absorption of spillovers of others' R&D activity particularly in the case of chemicals and electrical and electronics. The importance of foreign R&D spillovers as a determinant of R&D activity could be even more critical in developing countries where much of the R&D activity is of an adaptive nature. A number of studies

have empirically demonstrated the ability of rather weaker IPRs in stimulating domestic innovative activity in developing countries. Therefore, the evidence on the role of IPRs as a determinant of innovative activity is quite weak. In fact stronger IPRs may actually affect the innovative activity adversely by chocking the absorption of knowledge spillovers that are important determinants of innovative activity (see Kumar 2002, for a review of literature).

***IPRs, Trade and FDI Inflows***

How will stronger patent regime affect India's trade? India's exports of medicines that are patented will not be possible to the signatories of the TRIPs Agreement. Since the least developed countries have ten more years to provide product patents, Indian companies can continue to export to these countries if they do not provide product patents for 10 more years. The introduction of product patents will lead to an international division of labour where developed countries will specialize on newer and patented drugs and developing countries like India will concentrate on more price competitive off-the-patent drugs and generics. It is clear therefore, exports will come down to the extent some of India's exports comprise patented drugs. On the same token, imports of India are likely to go up as the patent owners may like to import the drugs rather than producing them in the country.

Will stronger patent rights help the country attract more FDI or technology transfer? Stronger protection increases the revenue productivity of a firm's intellectual property and should help exporters by making counterfeiting more difficult as has been corroborated empirically by studies. However, the effect of IPR strength on FDI and licensing is not that straight forward. By reducing the transaction cost of transfer of knowledge by MNEs to foreign countries, stronger protection may encourage arm's length licensing of the knowledge and reduce the need for undertaking FDI. On the other hand, it has been argued that poor IPR regime tends to adversely affect the investment climate and hence the probability of MNE investments. Empirical studies have generally shown that the strength of IPP promotes arm's length licensing but they have generally no significant effect on internalized technology transfers viz. FDI. Even the location of R&D investments abroad by MNEs was found to be not significantly

affected by strength of IPP. Thus the contention that stronger norms of IPR protection will facilitate greater inflows of FDI in the country is rather weak in either theoretical or empirical terms (see Kumar 2002 for a survey of literature). Recent trends suggest a reversal of trend of the growing importance of arm's length licensing as a mode of technology transfer as MNEs prefer to internalize the technology transactions (see Kumar 1998). The strengthening of IPRs regime may further limit the access of technology by developing country enterprises. Kim (1997) provides a number of examples of Korean corporations being denied technology licenses by patent holders in the Western world forcing them to reverse engineer the products. A number of local enterprises in developing countries will come under pressure to close down or form alliances with larger firms, resulting in a concentration of the industry [World Bank 2002:137]. Dependence on imports may go up.

### *d) Income Transfers from Developing Countries*

Given the near complete domination of developed countries on technology generation as evident from the 95 per cent ownership of US patents (see Kumar 1998), the strengthening and harmonization of IPRs regime will lead to a substantial increase in flow of royalties and license fees from developing countries to developed countries. McCalman (1999) quantifies the impact of patent harmonization finds that it has the capacity to generate large transfers of income between countries, with US being the major beneficiary. World Bank (2002: Table 5.1) updates the computations of McCalman and suggests that the net patent rents derived by the US (in 2000 US$) could add up to over $ 19 billion, to Germany $ 6.7 billion, and Japan $ 5.7 billion. Among the developing countries, India could see an outflow of patent rents of the order of $ 903 million.

Furthermore, the extension of IPRs to plant varieties could further increase the outgo of royalties for the breeder lines of the seed companies even though the basic raw material for the development of these varieties, viz. genetic diversity which is largely found in developing countries and is supposedly the work of generations of farmers in these countries, is generally available to them free.

***e) Impact on Global Technological Activity and Availability of Drugs***

One of the arguments in favour of a stronger IPR regime is based on the premise that expenditures on R&D were significantly determined by appropriability conditions. Hence, ensuring adequate appropriability with more stringent IPR protection was deemed to be a necessary condition for sustaining the pace of innovation in the global economy. The empirical literature, however, does not support this presumption as patent protection was found to be instrumental for only a small proportion of innovations. On the other hand, studies show that spillover effects of R&D activity of other firms to be a lot more important in inducing firms to undertake R&D compared to appropriability. The R&D outputs of other firms form valuable inputs for the R&D efforts of these firms. Hence, tightening of IPRs is likely to affect innovative activity adversely by stifling these spillovers. Therefore, it is by no means clear that strengthening of IPRs will increase innovative activity even in the developed world especially for solving the problems and diseases faced by developing countries. As World Bank (1999) cautions 'there is now a risk of excessively strict IPRs adversely affecting follow-on innovations and actually slowing down the pace of (technological development)'. Furthermore, the research priorities of MNEs are determined by the purchasing power and very little R&D is currently done on tropical diseases (World Bank 2002). Unless some steps are taken by the international community, such as those discussed by the recent report of WHO's Commission on Macroeconomics and Health (CMH), the pattern is not likely to change significantly in the future (see Kumar 2002).

## 6. Concluding Remarks and Strategic Policy Options

The above discussion has shown that the integrated policy framework that the government evolved over the 1970-90 has been successful in developing a highly vibrant and self-reliant industry that not only meets the local demand of nearly all critical medicines at affordable prices but also generates increasing amount of net exports by exporting pharmaceutical products to over 60 countries. The ability of Indian enterprises to develop cost effective processes has attracted the attention of leading MNEs to the country for entering into strategic alliances with local companies

for process development. This remarkable success was achieved within two decades and was facilitated in large measure by the soft patent regime that the country adopted in 1970.

The liberalization of the industrial, trade and price policies in the 1990s has started to affect the prices of medicines. Even trade liberalization and reduction of tariffs actually lead to higher rather than lower prices of medicines due to peculiar nature of the industry. The adoption of product patents by the end of 2004 as a part of the implementation of the commitments of India under WTO's TRIPs Agreement is likely to have a major impact on the prices of medicines according to a number of simulation exercises available. It is also likely to adversely affect the technological activity of Indian companies, curb exports, lead to income transfers from the country. On the other hand the favourable effects of stronger IPR regime that are claimed namely higher innovative activity and greater inflows of FDI may not materialize.

What strategic policy options exist for minimizing the adverse impact of strengthening of IPRs on the Indian pharmaceutical industry? In what follows we outline a few strategic policy options to keep the Indian pharmaceutical industry.

a) ***Stronger focus on R&D activity and new product development***:
To survive in the post-TRIPs regime the leading Indian pharmaceutical companies will have to launch their own products to stay in the market. Hence an increasing thrust on product development is of critical nature. A few leading companies like Ranbaxy, Dr Reddy's Laboratories, among others have moved in this direction and have a number of new molecules in the pipeline. They are also focusing on the innovation of new drug delivery systems of existing drugs. Some initiatives have already been taken following the recommendations of the PRDC 1999, in the Pharmaceutical Policy 2002, viz. establishment of a Drug Development Promotion Foundation (DDPF) and a Pharmaceutical Research and Development Support Fund (PRDSF). These initiatives are in right direction. However, the Indian

enterprises still spend relatively very small amount on R&D especially on product development. Given the huge resources that are required for product development in the industry, Indian companies and R&D institutions may consider formation of R&D consortia to share costs of development of drugs which they could formulate and market under their own brand names.

***b) Exploiting Market Potential of Indian System of Medicines***

The growing consciousness of the side-effects of modern medicines and increasing interest in alternative medicines especially herbal/ natural remedies in the country as well as internationally offers to Indian companies an opportunity that they could gainfully exploit. India's rich traditional knowledge in Ayurveda, Sidha and Unani and vast variety of medicinal plants, can be effectively tapped. We need to document and standardize the traditional Ayurveda knowledge and provide facilities for testing, clinical trials, and quality control for making these medicines more acceptable within the country and the world. The total market for alternative medicine in the country is estimated at US$ 700 million. It can be increased manifold with standardization of the products. Furthermore, India could exploit opportunities in export of these products with the standardization and quality control. There is already a ready acceptance of several herbal/natural products (e.g. natural laxatives) in the West. With implementation of standardization, building brand names and their getting them known in the Western countries, Indian companies could increase their exports of these products manifold. China is a case in point which has substantial exports of traditional medicine in the form of Chinese balms, medicinal oils etc.

***c) Consolidation of Market Position in the off-the-patent/ Generics Markets***:

Indian companies should consolidate themselves in the markets for off-the-patent drugs and generics by launching their own formulations

under their own trade/ brand names to strengthen their position in the market and also realize higher value addition. Otherwise they risk being substituted by cheaper suppliers of bulk drugs. In strengthening their presence in the western markets, besides establishing their own network of subsidiaries, acquisition of local companies having a foothold in the markets, necessary approvals, and brand recognition would help. Leading Indian companies could form a consortium to acquire a leading pharmaceutical company with good marketing network to push their products abroad. Given largely complementary nature of the product portfolios of Indian companies, it appears to be a feasible option.

***d) Protecting Leading Indian Pharmaceutical Companies from Threat of Foreign Takeovers:***

The technological capability of the country in the pharmaceutical industry is represented by the few leading Indian companies. They need to be protected from threat of hostile acquisitions by their foreign rivals. Although generally these companies are family owned and hence substantial ownership is held by their promoters, the acquisition of Parle Group and its brands by Coca Cola Company some time back suggests that even family owned enterprises are not immune to foreign acquisitions. A number of countries have retained provisions that protect the national champions from foreign takeovers to in national interest. Countries such as France, Malaysia have such provisions. The Exxon-Florio Amendment in the US gives the power to the US President to block any foreign acquisition in the interest of national security. India needs to adopt such provision to guard its strategic interests.

***e) Exploiting the Flexibility in the TRIPs Agreement***

The TRIPs Agreement provides certain flexibilities to include exceptions for research and marketing and compulsory licensing or anti-trust reasons. These should be fully exploited. The Declaration on Medicines and Public Health at the Doha Ministerial Meeting confirmed the right of member

countries to exploit the flexibility available in the TRIPs Agreement. These include adequate provisions for compulsory licensing in the patent legislation in order to safeguard them from possible abuses of monopoly power obtained by patent owners. The compulsory licenses are permitted under Article 31 and Article 8 and 40 of the TRIPs Agreement. The Agreement does not limit the grounds upon which compulsory licenses may be granted and only sets forth the conditions to be applied in the case of granting (see Correa 2000b). This includes specification of grounds of compulsory licensing and the reasonable rates of licensing fees (Scherer and Watal 2001, for a detailed analysis). Recent withdrawal of proceedings by the US against Brazil's compulsory licensing provisions show that intelligently crafted domestic patent laws can meet national objectives and yet be TRIPs compatible (Raizada and Sayed 2001).

Another exception that is permissible is for research that allows researchers to use a patented invention for research, in order to understand the invention more fully. Experimentation on a patented invention is clearly admissible as an exception to exclusive rights under Article 30 (Correa 2000b).

Yet another exception is called the Early Working Exception or 'Bolar' Provision which allows manufacturers of generic drugs to use the patented invention to obtain marketing approval without patent owner's permission and before the expiration of patent. This facilitates the generic manufacturers to market their products as soon as the patent expires. This provision is sometimes called the regulatory exception or Bolar provision under Article 8 (WTO 2001). The US, Canada, Australia, Israel and Argentina have adopted Bolar exception in their patent legislation (see Correa 2000b).

All these exceptions could be fully incorporated in the amended Indian Patents Act.

***f) Resisting the Attempts to Evolve TRIPs Plus Regime and Ever-***

***greening of Patents***

Developed countries are constantly putting pressure on developing countries to implement stricter patent legislation than required under TRIPs, exclude compulsory licensing, parallel imports provisions and include provisions that would result in increasing the life of the patent (ever-greening), as well as grant data exclusivity to them. The TRIPs Agreement however, is clear that a new use for an old formulation does not constitute an inventive step (Art. 27(1)). Therefore, member countries are within their rights not to permit the practice of ever-greening of patents.

g***) Price Controls for Essential Drugs***

Price controls continue to be relevant in the pharmaceutical industry to protect the poor masses from the price increases following the introduction of product patents. The evidence suggests that competition does not lead to lower prices of medicines. Therefore, there is continued relevance of price controls in the industry.

***h) Mobilizing Support for Review of TRIPs at WTO***

Most of the adverse effects concerning TRIPs on poor countries arise not because of IPR regimes but from the attempt to harmonize them across the countries at different levels of development (Panagariaya 1999). There is also a discussion whether TRIPs should fundamentally belong to WTO (Mashelkar 2001). However, the least that could be done is allowing flexibility to developing countries to implement the provisions of the Agreement as and when their level of development has reached a certain stage. This could be achieved if a consensus among the developed countries is built on the differential need of developing countries for IPR regime[1]. A possible revision of TRIPs could incorporate a provision that grants to developing countries a flexibility to implement the TRIPs obligations until they reach a certain per capita income[2]. This way the Agreement would have incorporated development dimension.

These steps may help in moderating the effect of liberalization and TRIPs on the Indian pharmaceutical industry.

## References


Agrawal, Pradeep and P Saibaba (2001) 'TRIPS and India's Pharmaceuticals Industry', *Economic and Political Weekly*, pp. 3787-3790, September 29.

*Business India* (1994) 'Coming of Age', December 5-18, pp. 54-59.

*Business India (1994)* 'Facing the Challenge', June 20-July 3, pp. 141.

*Business India (1994)* 'Leaders in Technology', *July 4-17, pp. 52-60.*

*Business India (2001)* 'The Doctor in Search of Parents', *March 19-April 1, pp.83-102*.

*Business Week* (2001) 'Coming at You, Merck: Can Dr. Reddy's Labs Crack the Global Drug Market', pp. 23-24, April 9.

Correa, Carlos (2000a) '*Intellectual Property Rights, the WTO and Developing Countries, The TRIPS Agreement and Policy Options*, Zed Books: London and New York.

Correa, Carlos (2000b) 'Reforming the Intellectual Property Rights System in Latin America', *The World Economy*, Vol. 23(6), June 2000, pp. 851-872.

Cullet, Philippe (2001) 'Patents Bill, TRIPs and Right to Health', *Economic and Political Weekly*, pp. 4049-4051, October 27, 2001.

Desai, A.V. (1980) 'The Origin and Direction of Industrial R&D in India', *Research Policy 9*(Jan. 1980), pp. 74-96.

DSIR (1990) *Technology Export Potential in Basic Drugs and Pharmecutical Formulations*, A Report prepared under TATT Scheme, Department of Scientific and Industrial Research, New Delhi.

Felker, Greg, Shekhar Chaudhuri, Katalin Gyorgy with Melvin Goldman (1997) *The Pharmaceutical Industry in India and Hungary: Policies, Institutions, and Technological Development*, The World Bank, Washington, D.C. USA.

Fikkert, Brian (1993) *An Open or Closed Technology Policy? The Effects of Technology Licensing, Foreign Direct Investment, and Technology Spillovers on R&D in Indian Industrial Sector Firms*, Ph.D. Dissertation, Yale University.

Fink, Carsten (2000) *How Stronger Patent Protection in India Might Affect the Behaviour of Transnational Pharmaceutical Industries*, Development Research Group, Washington DC., The World Bank.

Haksar, Vikram (1995) 'Externalities, Growth and Technology Transfer: Application to the Indian Manufacturing Sector, 1975-90', Washington, DC: International Monetary Fund, mimeo.

Kim, Linsu (1997) *Imitation to Innovation: The Dynamics of Korea's Technological Learning*, Harvard Business School Press, Boston, Massachusetts.

Kumar, Nagesh (2002) 'Intellectual Property Rights, Technology and Economic Development: Experiences of Asian Countries', *RIS Discussion Paper #25/2002*, RIS: New Delhi.

Kumar, Nagesh (2001) *National Innovation Systems and the Indian Software Industry Development*, A background paper for the *World Industrial Development Report 2002*, Vienna: UNIDO.

Kumar, Nagesh and Aradhana Agarwal (2000) 'Liberalization, Outward Orientation, and In-house R&D Activity of Multinational and Local Firms: A Quantitative Exploration for Indian Manufacturing' *RIS Discussion Paper #7-2000*, RIS: New Delhi.

Kumar, Nagesh and Kamal Mitra Chenoy (1983) 'Multinationals in Less Developed Countries: A Case Study of Drug Multinationals in India', *Internationales Asienforum,* Vol. 14, No. 2/3, p. 175-194.

Kumar, Nagesh and Mohammed Saqib (1996) 'Firm Size, Opportunities for Adaptation, and In-house R&D Activity in Developing Countries: The Case of Indian Manufacturing', *Research Policy*, 25(5): 712-22.

Kumar, Nagesh, Kamal Mitra Chenoy (1982) 'Multinationals and Self-Reliance: A Case Study of the Drugs and Pharmaceutical Industry', *Social Scientist* 107:13-35.

Lanjouw, Jean O. (1998) 'The Introduction of Pharmaceutical Product Patents in India: Heartless Exploitation of the Poor and Suffering'? *NBER Working Paper Series No. 6366*, National Bureau of Economic Research, January 1998.

Mashelkar, R.A. (2001) 'Revisiting TRIPS: A Developing World Perspective', *RIS Digest*, Vol. 18(1-3), September 2001, New Delhi: RIS

May, Christopher (2000) *A Global Political Economy of Intellectual Property Rights: The new enclosures?* London and New York: Routledge.

Nogues, Julio J. (1993) 'Social Costs and Benefits of Introducing Patent Protection for Pharmaceutical Drugs in Developing Countries', *The Developing Economies,* XXXI-1 (March 1993), The Institute of Developing Economies, Tokyo, pp. 24-53.

Nogues, Julio (1990) 'Patents and Pharmaceuticals Drugs: Understanding the Pressures on Developing Countries', *Journal of World Trade 24(6)*: World Bank Washington, USA, pp. 81-104.

Panagariya, Arvind (1999) *TRIPs and the WTO: An Uneasy Marriage*, Seminar presentation made at the WTO on July 20, 1999.

Parthasarathi, Ashok (2001) *The Pharmaceutical Industry: The Phase*, Centre for Studies in Science Policy, Hyderabad.

Phadke, Anant (2002) 'Pharmaceutical Policy, 2001', *Economic and Political Weekly*, pp. 528-529, Vol. XXXVII No. 6, February 9-15.

Prasad, H. Ashok Chandra and Shripad Bhat (1993) 'Strengthening India's Patent System: Implications for Pharmaceutical Sector', *Economic and Political Weekly,* pp. 1037-1058, May 22.

Raizada, B.K. and Javed Sayed (2002) 'IPR and Drugs and the Pharmaceutical Industry-Concerns for Developing Countries', in Dasgupta, Amit and Bibek Devroy (eds.), *Salvaging the WTO's Future: Doha and beyond*, New delhi: Konark, pp. 275-289.

Raizada, Bimal K. (2002) *Trade, IPR and Regulatory Issues*.

Sahai, Suman (2001) ' TRIPS Review: Basic Rights Must Be Restored', *Economic and Political Weekly*, pp. 2918-2919, August 4.

Scherer, F.M. and Jayashree Watal (2001) 'Post-Trips Options for Access to Patented Medicines in Developing Countries', *CMH Working Paper Series Paper No. WG4: 1*

Sengupta, Amit (1994) 'New Drug Policy: Prescription for Mortgaging Drug Industry', *Economic and Political Weekly*, pp. 2526-2531, September 24.

Srinivasan, S. (2001) 'Drug Price Control: Who Is in Charge? *Economic and Political Weekly*, pp. 997-998, March 24.

Subramanian, A. (1994), 'Putting Some Numbers on the TRIPs Pharmaceutical Debate', *International Journal of Technology Management*.

Subramanian, Arvind (1999) *India as User and Creator of Intellectual Property: The Challenges Post-Seattle*. Paper presented at the Workshop on South Asia and the WTO New Delhi.

*The Economist (2000)* 'Sachs on Development: Helping the World's Poorest', pp. 17-20, August 14.

*The Economist* (2001) 'A War Over Drugs and Patents', pp. 47-48, March 10.

*The Financial Times* (1999) 'Winning the Drugs War', pp. 15, 13 April.

Watal, Jayashree (1997) 'Implementing the TRIPS Agreement: Policy Options Open to India', *Economic and Political Weekly*, pp. 2461-2467, September 27.

Watal, Jayashree (2000) 'Pharmaceutical Patents, Prices and Welfare Losses: Policy Options for India Under the WTO TRIPS Agreement', *The World Economy*, Vol. 23, No. 5, pp.733-753.

Watal, Jayashree (2001) *Intellectual Property Rights in the WTO and Developing Countries*, Oxford University Press, New York.

WHO (2001) Commission on Macroeconomics and Health: Report, Geneva: The World Health Organization, 20 December 2001.

WHO/WTO (2001) Report of the Workshop on Differential Pricing and Financing of Essential Drugs, Hosbjor, Norway, 8-11 April.

Woodward, David (2001) 'Trade Barriers and Prices of Essential Health-Sector Inputs', *Working Paper No. 73*, June 2001.

World Bank (1999) *World Development Report 1998/9*, Washington DC: the World Bank.

World Bank (2002) *Global Economic Prospects and Developing Countries 2002*, Washington DC: The World Bank.

WTO (2001) *TRIPs and Pharmaceutical Patents*, World Trade Organization, April 2001.

## End Notes

[1] Desai (1980) documents two of such cases. In one case Hoeshst prevented Unichem Laboratories from producing tolbutamide using a technology licensed from Haffkine Institute of Bombay which had patented the process. In a case that became famous, Unichem Laboratories produced tolbutamide on licence from Haffkine Institute of Bombay which had patented the process. The major difference between the patents was that the Hoechst patent specified at a certain point that sulphur was to be eliminated from a thiouria 'in a conventional manner', and at another point that the elimination was to be done by 'a heavy metal oxide or a salt thereof'. The Haffkine Institute patent specified elimination by hydrogen peroxide. The judge disallowed the defendants' plea that the Hoechst patent was so general as to cover millions of products of which only 220 had been synthesized by Hoechst and still fewer pharmacologically tested, and ruled that the two patents referred to the same invention and that Unichem had infringed Hoechst's patent. In another instance aluminium phosphite, a concentrated fumigant, was patented and imported by a foreign firm. In the payments crisis on 1966 the Directorate-General of Technical Development asked the firm to produce it, but the firm said the process was too difficult to be tried in India. Thereupon Excel Industries produced the fumigant in 2.5 months and marketed it at half the cost of imports. The foreign firm then sent Excel a notice to cease infringement of its patent. After the Unichem judgment the Patents Office began to reject a larger proportion of applications on the grounds of vagueness or incompleteness. The proportion of examined applications so rejected went up from 5 per cent in 1968 to 11 and 16 per cent in the next two years.

[2] [http://www.nic.in/cpc/pharma4.htm].

[3] Ramachandran 2002.

[4] CVD at 16 per cent is applied as the excise duty on domestic production is applicable at the same rate.

[5] Barton 1999 and Sachs 1999 (as cited by Correa 1999) have acknowledged the need for a differential standard for developing countries. Mashelkar (2001) calls for 'TRIPS Plus Equity and Ethics'.

[6] Kumar 2002 has suggested a threshold of US$ 1000 per capita income.