TRADE AND HEALTH CARE: AN ANALYSIS OF INDIA'S FOREIGN TRADE IN PHARMACEUTICAL PRODUCTS

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Dissertation submitted in partial fulfillment of the requirements for the degree of Master of Philosophy in Applied Economics of the Jawaharlal Nehru University

Shabeer KP

M.Phil in Applied Economics

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I hereby affirm that the work for the dissertation, ***Trade and Health Care: An Analysis of India's Foreign Trade in Pharmaceutical Products,*** being submitted as part of the requirements of the M Phil Programme in Applied Economics of the Jawaharlal Nehru University, was carried out entirely by myself and has not formed part of any other Programme and not submitted to any other institution/University for the award of any Degree or Programme of Study.

June 19, 2002

Shabeer KP

Certified that this study is the bona fide work of Shabeer KP, carried out under our supervision at the Centre for Development Studies.

D Narayana
Fellow

Achin Chakraborty
Associate Fellow

Chandan Mukherjee
Director
Centre for Development Studies

to my parents

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Shabeer KP

Abstract of the Dissertation

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The establishment of the World Trade Organisation (WTO) as a culmination of the Uruguay Round of multilateral trade negotiations has resulted in an unprecedented liberalisation of global trade. This study seeks to analyse the impact of trade liberalisation on the health care sector by focusing on one of its central elements namely the pharmaceutical products. Scholars like Baris and Mcleod (2000) commenting on trade in pharmaceutical products have expressed the apprehension that increased trade in pharmaceutical products will have negative impacts on developing countries by the way of worsening their balance of trade. We contend that this fear arose due to some broad generalisations about the trade in pharmaceutical products without sufficient empirical support. To argue our case that increased trade in pharmaceutical products do not necessarily result in adverse impacts on developing countries, this study takes an analytical look at the foreign trade in pharmaceutical products of India, a developing country.

Given that India has a pharmaceutical industry that is one of the largest and most advanced among the developing countries, we have tried to seek answers to the following questions: what are the extent and patterns of India's foreign trade in pharmaceutical products in the context of trade liberalisation and what factors contributed to it? Does India possess a comparative advantage in the global pharmaceutical trade? What are the potential impacts of WTO agreement of Trade Related Aspects of Intellectual Property Rights (TRIPS) on the Indian pharmaceutical industry? And what sort of strategies are the Indian pharmaceutical companies adopting to face the challenges of impending product patent regime?

The study has used the official trade data supplied by the Directorate General of Commercial Intelligence and Statistics (DGCI&S) for the analysis of India's foreign trade in pharmaceutical products. Owing to problems in data harmonisation and the specificity of objectives, the study has chosen the period from the year 1987-88 to 1999-2000 as the period of analysis. The results of the data analysis seems to have went against the theoretical argument which, says that increased trade in pharmaceutical products will have a negative impact on the balance of trade of developing countries. Instead, India has a positive balance of trade in pharmaceutical products with exports growing at a healthy 11 per cent. At the same time, the growth of imports has turned out to be statistically insignificant during the period of analysis. These results validates our hypothesis that increased trade in pharmaceutical products need not necessarily result in negative impact on developing countries by way of worsening balance of trade. However, it is also found that the growth rate of export has declined in the post-liberalisation period compared to the pre-liberalisation period and there occurred a trend break in the year 1991. The dissaggragated analysis reveals that India has been exporting more formulations than bulk drugs and it is the sharp increase in the exports of the former that accounts for the healthy growth in exports. The decline in the imports of pharmaceutical products is attributed to the decline in the imports of bulk drugs. The study also examined the direction of India's pharmaceutical trade. India's trading partners are grouped into three categories on the basis of their per capita gross domestic product in the year 1998. Following the method of classification adopted by the UNCTAD, the countries are grouped as high-income, middle-income and low-income countries. As far the destination of India's pharmaceutical export is concerned, the low-income countries have consistently improved their share to occupy the first position. They improved their share in the import also, but still about 85 per cent of pharmaceutical import are contributed by the high-income countries.

To enquire into the question of whether India holds a comparative advantage in the trade of pharmaceutical products, the study has used the method of Revealed Comparative Advantage Index (RCA Index) developed by Bela Balassa. The RCA Index measures the pattern of comparative advantage as revealed by the observed trade flows among a group of countries. The countries chosen are the United Kingdom (UK), Switzerland, China and Brazil. These countries are India's major competitors in the global trade in pharmaceutical products. The computed indices reveal that India, along with the UK and Switzerland, does indeed have a comparative advantage in the trade of pharmaceutical products. At the same time, Brazil and China, India's major competitors from the developing world, do not posess comparative advantage in the trade of pharmaceutical products according to the computed RCA index.

Being a signatory of the Uruguay Round, India is going to introduce product patents for pharmaceutical products in 2005 in order to comply with its TRIPS provisions. The IPA (1970) recognised only process patent for pharmaceutical products that allowed Indian pharmaceutical companies to reverse-engineer the drugs introduced in developed countries and sell them at a fraction of price of the patented drugs. But from 2005 this will not be possible. This is compelling Indian pharmaceutical companies to rethink their age-old strategies. At the same time, the TRIPS regime is also opening up a new opportunity for Indian pharmaceutical companies in the form of rapidly expanding global market for generics (i.e. off-patent drugs) as a number of drugs are coming out after completing their 20 year old patent protection as per TRIPS. With their expertise in cost-effective process technology, Indian Companies stands to gain from this expansion of generics markets. When we analysed the response of Indian pharmaceutical companies to the impending new intellectual property regime, focusing some major players, it is observed that most of them are resorting to the strategy of consolidation (mergers and acquisition) and collaboration (alliances and joint ventures) in the domestic as well as in the overseas market. Companies of all sizes are working hard to find an optimal growth path that will enable them to face future challenges and to take newer opportunities. A mindset to reduce the dependence on the old formula of copying drugs patented by other firms and focus more on R&D were evident among the Indian Companies. It is also noticed that the Companies are adding capacities with an eye on the export market, where they are increasingly focusing on formulations for which margins are higher than bulk drugs.

To sum up, many interesting points have emerged from our study. First of all, it was found that India has had a positive balance of trade in pharmaceutical products that is showing an increasing trend. India is now exporting more value-added formulations than bulk drugs and its dependence on imported bulk drugs are coming down. The country also holds a comparative advantage in the global trade of pharmaceutical products, when its major competitors from the developing world do not have the same as revealed by the computed RCA indices. It is observed that Indian pharmaceutical companies are increasingly resorting to strategies of consolidation and collaboration to face the inevitable challenges posed by the product patent regime and to capture the opportunities emerging out of the expanding global market for generics. Finally, it is encouraging to note that Indian Companies have started paying greater attention towards R&D, especially towards the development of new chemical entities, which have always remained as the major weakness of the Indian pharmaceutical industry.

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Chapter I

INTRODUCTION

1.1 The Context

As is well known, the conclusion of the Uruguay Round of multilateral trade negotiations, marked by the Final Act, transformed the General Agreement on Tariff and Trade (GATT) into a permanent organisation, namely the World Trade Organisation (WTO). The WTO has extended the rules governing commercial relations among trading partners to a number of new areas that were previously excluded from the trade liberalisation process. The Multilateral Agreements constituting WTO are framed as a single treaty, and must be accepted as a single package. This situation differs from previous agreements under GATT, whereby member countries could pick and choose the agreements they wanted to adhere to. For the first time in history, a global trade agreement has been forged that is binding and enforceable at the national level. The main objective of the WTO Agreements is to provide a full competitive opportunity of trade among the member countries. Following which, there are four basic principles. They are (1) Non-discrimination, (2) Reciprocity (3) Market access and (4) Fair competition. Of these four principles, non-discrimination is the basic and fundamental rule. The principle of non-discrimination has two dimensions, namely Most Favoured Nation (MFN) treatment and National treatment. MFN rule requires that, at the border, products made in members' own countries be treated no less favourably than goods originating from any other country. In other words, Member State shall not discriminate as between member countries against a like product originating or destined for any other member country. If the best treatment is offered to a trading partner supplying a specific product, then the same treatment must be applied, immediately and unconditionally, to the imports of this good originating in all WTO members, so that they all remains most favoured. The MFN obligation is complemented by the National treatment rule, which requires that foreign goods are to be treated no less favourably in terms of taxes and other measures with equivalent effect than domestic goods. It implies the 'national treatment' to all like products whether imported or domestically produced. As on October 2000, 138 countries were members of WTO.

Concerns have been raised about the impact of various WTO Agreements on the Developing World. The differential and more favourable treatment to developing countries has suffered a massive dilution in the Uruguay Round. Earlier such treatment meant a lower degree of

obligation for developing countries. Now, with some exceptions, it largely means only a longer time frame for implementation of the commitments.

It is a historical experience that trade flows affect public health and to quite a significant extent at that. Thus, the resultant trade liberalisation as an aftermath of Uruguay Round is expected to have diverse and widespread impacts on health. In fact, it is pointed out that the greatest indirect challenge to health in the present century would be the global liberalisation of trade (Walt 1998). This study seeks to analyse the impact of trade liberalisation on the health care sector by focusing on one of its central elements namely the pharmaceutical products[1].

1.2 International Trade in Pharmaceutical Products: The Issues

The pharmaceutical trade is playing a major role in the field of not only international trade as a whole, but also international health. Trade in pharmaceutical products raises questions about basic human needs, quality of life, health hazards and the associated value judgement. It is argued that increased international trade in pharmaceutical products can have a negative impact on the economy of developing countries through worsening the balance of trade (Baris and Mcleod 2000). They point out certain potential benefits and risks associated with freer trade in pharmaceuticals for developing countries. The reduction of tariff on the import of pharmaceuticals, as a part of trade liberalisation, will increase the inflow of foreign-made drugs in the country. For the countries with little or no capacity for drug research and/or manufacturing, this increase will augment drug availability, which, in theory, will improve health. For the countries with infant pharmaceutical industries, the resultant increase in the import of foreign pharmaceuticals could threaten domestic production.

Since most of the developing countries lack production capabilities in pharmaceutical products, they are an important export market for the production of industrialised countries (Foster 1993). Pharmaceutical products constitute a major import item for the third world countries as a whole (Gish 1975). On the other hand, it is pointed out that there exists a latent trade opportunity in pharmaceutical products for developing countries since, these countries have a comparative advantage in the pharmaceutical research because of lower salaries, lower

[1] The significance of pharmaceutical products in the health care sector is well-examined by World Bank (1993,1994), Lindgren (1984), Santerre et al (2000), Temin (1980), Foster (1993), Chetley (1990), Melrose (1982) etc.

risk of litigation and specific epidemiological profiles, apart from the abundant availability of medicinal plants and potential substances for future drugs (Woolvaardt 1998).

It is also viewed that trade liberalisation can enable developing countries to benefit from the innovations in the world pharmaceutical industry, by way of importing new products and/or technology from developed countries (Kinnon 1998). At the same time, the task of identifying issues involved in pharmaceutical trade is complex because of the multifaceted typology of pharmaceuticals themselves (Gesler 1996).

The analysis of trade in pharmaceuticals will remain incomplete without the discussion of WTO Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) and its implications for the pharmaceutical sector. The scope of TRIPS Agreement is much broader than any previous agreement in this field. The Agreement extends patent protection, both product and process patent, for a minimum term of 20 years from the date of filing. The harmonisation of patent protection policies means that countries that did not previously provide protection for pharmaceutical products will now have to do so. Many studies, Bettcher, Yach and Guidon (2000), Levin (1987), Kinnon (1998), Labonte (2000), Gervais (1998) to name a few, have analysed various issues regarding the protection of intellectual property in pharmaceutical products. It is said that since large industries like pharmaceuticals crucially depend on the protection of intellectual property, the TRIPS Agreement is a crucial foundation for the global trading order (Gervais 1998). It is pointed out that stronger patent protection will stimulate innovation in pharmaceutical products (Wasunna and Wyper 1998, Levin 1987, Nogues 1993). At the same time concerns have been raised by scholars about the possibility of massive escalation of prices of pharmaceutical products as a consequence of TRIPS Agreement (Kealya 1997, Challu 1991). There is also a contention that TRIPS Agreement can lead to perverse transfer of technology and a significant decrease in local pharmaceutical production in developing countries.

Between 1980 and 1994, total world exports of pharmaceutical products grew rapidly to US$ 57 billion up from US$ 14 billion. In 1994, the OECD countries accounted for 92 per cent of the world pharmaceutical exports and 78 per cent of the imports. Developing countries had a share of 17 per cent in the world imports, but contributed only 6 per cent to the exports. (Tarabusi and Vickery.1998).

To summarise the main issues that are emerging, on the one hand, it is argued that increased international trade in pharmaceutical products will have a negative impact on developing countries since they lack sufficient production capabilities in pharmaceutical products. On the other hand, it is also contended that there exist a latent trade opportunity in pharmaceutical products for developing countries and they can be benefited from the global liberalisation of trade.

We doubt that the apprehension showed by Baris and Mcleod that increased trade in pharmaceutical products will have a negative impact on developing countries might have arisen due to some broad generalisations without sufficient empirical support. To support our case that increased international trade in pharmaceutical products will not necessarily result in adverse impacts on developing countries, the present study seeks to analyse the foreign trade in pharmaceutical products of India, a developing country.

1.3 The Pharmaceutical Trade, WTO and India

India is relatively better off than many other developing countries because it has a reasonably well-developed pharmaceutical industry (Agrawal et al 2001). Indian pharmaceutical industry is capable of manufacturing nearly all drugs needed in the country. Infact, the UNIDO put this Indian industry in category 4, i.e. technologically developed to be self-reliant, with research capabilities for the discovery of new chemical entities (WHO 1988). However, the per capita expenditure on pharmaceuticals in the country is amongst the lowest in the world (Panchal 2001). In the year 1990, the per capita expenditure on pharmaceuticals was only $ 3 (World Bank 1993). Though the country had a large pharmaceutical industry, still a major chunk of the population do not have the access to drugs. Further, a majority of population living in rural areas and urban slums had no or very little access to modern drugs (WHO 1988).

The argument that tariff reduction on imported pharmaceuticals will encourage more imports into the country may not be quite straightforward in the context of a country like India. It is plausible that a reduction in tariffs might have been accompanied by a continuous depreciation of the domestic currency, which may have offset the effects of tariff reduction. In fact, it is conceivable that, instead of the expected increase in imports, the domestic producers might have exported more.

The evidence that can be drawn from export-import data of pharmaceutical products is not very conclusive. Absolute figures alone are not very illuminating. It is of vital importance to know which product category of pharmaceuticals that India got a comparative advantage vis-à-vis its competitors. For this purpose, this study is using a measure that has got sound theoretical backing, namely the "Revealed Comparative Advantage Index" or RCA Index developed by Bela Balassa (1965). RCA measures the patterns of comparative advantage as are revealed by the observed trade flows among a group of countries. The countries are chosen from the major competitors of India in the global trade in pharmaceutical products.

The Indian Patent Act, 1970 provides only the process patent for pharmaceutical products. As a signatory of Uruguay Round, it is obligatory on India's part to provide the product patent by 2005, which is the deadline facing the developing countries for the formal introduction of product patent, to comply with the TRIPS Agreement. This means that the Indian pharmaceutical industry scenario will have drastically changed by 2005 AD. It is argued that, because of the new patent regime, the Indian pharmaceutical industry will face "serious disgrowth", as it will no longer have the possibility of manufacturing patented products (Kealya 1997). The driving force that will change the character and shape of the pharmaceutical sector in India will be the impending product patent regime (Panchal 2001). The introduction of product patent in the country is expected to lead to a shakeout in the Industry.

Many studies[2] have shown the apprehension that the Indian pharmaceutical industry would be adversely affected by the introduction of product patent in the country to comply with TRIPS provisions. One major reason that has been sighted for this is the low volume of funds devoted to Research and Development (R&D) by the Indian pharmaceutical companies. The contribution of Indian companies towards R&D as percentage of turnover is about 1.5-2 per cent which is insignificant when compared to resource allocation of the countries like USA and Japan (towards R&D), which is around 12 and 15 per cent respectively[3]. We believe that even though pharmaceutical industry is among the most highly R&D intensive, it is doubtful whether R&D plays the same pivotal role in the case of Indian companies, which primarily focus on the generic version of drugs.

[2] Kealya (1997), Sengupta (1994), Agrawal et al (2001) to mention a few.
[3] Acharya (1999) points out that R&D spending of Indian pharmaceutical companies is higher compared to its counterparts in other developing countries.

Once the patent expires, it opens huge opportunity for the generic pharmaceutical industry. Worldwide generic markets are growing at a faster rate than that of patented products. For instance, it is estimated that in the US market alone drugs worth $ 35 billion are going to loose monopoly provided by the patent by the year 2005. The Indian pharmaceutical industry can very well utilise this opportunity since it can produce and supply generics at cheap prices.

With the product patents come into force in 2005, the Indian companies hope to flourish by grabbing the global market for generic drugs. The process of consolidation (mergers and acquisition [M&A]) and collaboration (joint ventures and strategic alliances) has now become a generalised phenomenon in the global pharmaceutical industry. M&A and alliances are to achieve common aims such as sharing the R&D results, sharing the risks and cost of product development and to expand market. It is anticipated that the process of consolidation and collaboration in the Indian pharmaceutical industry will increase as the Industry restructures in anticipation of the introduction of product patent in 2005. To what extent, does the Indian pharmaceutical companies have resorted to these kinds of strategies to face the future challenges and to capture the newer opportunities is a crucial question that this study seeks to answer.

1.4 Objectives of the Study

The specific objectives of the present study are:

1. To examine the extent, trends and contributory factors of India's foreign trade in pharmaceutical products in the context of trade liberalisation;
2. To analyse India's foreign trade in pharmaceutical products in a comparative frame work; and
3. To examine the possible impact of Trade Related Aspects of Intellectual Property Rights (TRIPS) on the Indian pharmaceutical sector and to trace out the strategies adopted by the Indian pharmaceutical companies to face this challenge.

1.5 Data Source and Period of Analysis

For the analysis of India's foreign trade in pharmaceutical products, the study utilises the data supplied by the Directorate General of Commercial Intelligence and Statistics (DGCI & S), Ministry of Commerce, Government of India. DGCI & S provides most comprehensive and up to date data on India's foreign trade. It has two major publications (1) Monthly Statistics of

the Foreign Trade of India and (2) Statistics of Foreign Trade of India by Countries. Both publications contain two volumes. Volume 1 gives data on exports and reexports, while volume 2 gives data on imports. Monthly Statistics of the Foreign Trade of India contains commodity by country details and Statistics of Foreign Trade of India by Countries contains country by commodity details, with March issues providing data for the corresponding financial year. Both provide data at a highly disaggregate level. While the former gives data at 2, 4, 6 and 8 digit levels of Indian Trade Classification (ITC), the latter gives data at 4, 6 and 8 digit level of ITC. The data contained in the two publications of DGCI & S for the latest three financial years (since 1995) are available in an electronic data base "India Trades" supplied by Centre for Monitoring Indian Economy (CMIE), Mumbai.

DGCI & S, from April 1987, have adopted a new commodity classification system known as Harmonised Commodity and Coding System (Harmonised System, in short). Indian Trade Classification based on Harmonised System (ITC [HS]) is an extended version of the International Classification System evolved by Customs Co-Operation Council, Brussels. More details about the data sources on India's foreign trade are summarised in the Appendix I. The main sources of information for the analysis of the third objective of the study are the reports of the financial media and various issues of the "Monthly Review of the Indian Economy" published by CMIE.

The period of this study for the analysis of India's foreign trade in pharmaceutical products is from the year 1987-88 to 1999-2000. The rationale for choosing this particular period is as follows. It is our objective to analyse India's foreign trade in pharmaceutical products in the context of trade liberalisation. Although policy efforts directed towards trade liberalisation in the country can be traced back to the late 1970s and mid 1980s, it is only during the 1990s that such measures received a momentum as well as a definitive direction. Foreign trade reforms are an important component of economic reforms launched by the government in 1991. We selected year 1987-88 as our starting point due to the change adopted by DGCI & S in its commodity classification system in 1987, as explained above. As a result of this change, foreign trade data before and after 1987 are not strictly comparable.

1.6 Chapter Scheme

The study is organised in five chapters, including this introduction. Chapter II reviews the evolution of the Indian pharmaceutical industry. The chapter focuses on the policy

environment faced by the Industry and its expansion in a historical perspective. This Chapter aims to give a background for the next two chapters. A detailed analysis of India's foreign trade in pharmaceutical products is presented in chapter III. It examines the extent, trend and contributory factors of India's foreign trade in pharmaceutical products. It also analyses the destination of exports and sources of imports of pharmaceutical products of India. In this chapter, India's foreign trade in pharmaceutical products is examined in a comparative framework, using the RCA index. Chapter IV examines the WTO Agreement of TRIPS and its possible impact on Indian pharmaceutical sector. Emphasis is given to the analysis of strategies adopted by the Indian pharmaceutical companies to face this future challenge as well as to capture the newly generated opportunities in the global market for pharmaceutical products, focusing some major Indian players in the pharmaceutical industry. A summary of findings and concluding remarks are presented in the chapter V.

Chapter II

INDIAN PHARMACEUTICAL INDUSTRY- AN OVERVIEW

2.1 Introduction

Pharmaceutical Industry is described as a 'lifeline' industry, which produces goods that are vitally important for human health care and to the long-term improvement of the standard of living of the people. While the needs of the health care can be met by importing all the necessary drugs from the developed countries, the pharmaceutical industry also offers substantial tangible economic benefits to developing countries if local production is undertaken. Even setting up simple formulation and packaging facilities can save developing countries sizable amounts of foreign exchange. Besides this, pharmaceutical industry offers some other important attractions for developing countries. The Industry by its nature is very much amenable to small-scale production that can suit developing countries. Secondly, machinery for formulation and packaging of pharmaceuticals can be designed for a variety of end products, thus giving the Industry a commercial and economic advantage over other forms of modern industry. Finally, the technology for establishing the preliminary stages of pharmaceutical production is well known and fairly well diffused. Thus, the developing countries can purchase it relatively easily.

Besides the above-mentioned economic benefits that the development of a pharmaceutical industry can bring, there are quite distinct social benefits that an indigenously based production programme can offer. A relatively independent and self-sufficient pharmaceutical industry can give developing countries more freedom to form the health care policies that are relevant to their peculiar needs than otherwise is the case. A pattern of pharmaceutical production that reproduces the experience of developed countries has certain built-in costs. These costs can be minimised with locally based production facilities governed by a national health policy.

Socio-economic considerations call for a carefully planned strategy for pharmaceutical industry than the free play of market forces. Recognising its crucial role, Indian planners have included the pharmaceutical industry in the 'core sector' when planned economic development of the country was launched in 1951 (Narayana 1984).

This Chapter examines the historical evolution and the policy environment faced by the Indian pharmaceutical industry. The Chapter is organised as follows. Section 2.2 examines the Indian pharmaceutical industry prior to the Indian Patent Act (IPA) 1970. Section 2.3 analyses the IPA 1970 and the role played by it in fostering the Industry. Fourth section reviews the developments in the Industry after IPA 1970. Section 2.5 examines the current scenario of the Indian pharmaceutical industry. The final section provides, in brief, some concluding observations from our analysis.

2.2 Pharmaceutical Industry Prior to IPA 1970

2.2.1 Pre - Independence Period

Allopathic medicines were introduced in India in the late 19th century mainly to provide medical relief to the Britishers. Indigenous production of pharmaceuticals was begun in 1901 with the establishment of Bengal Chemical and Pharmaceutical Works due to the pioneering work of Acharya P C Ray. The unit began with the production of simple galenicals. In 1907, Alembic Chemical Works was established at Baroda jointly by T K Gajjar and Ramitra B D Amin. These units faced several problems like competition from overseas producers, lack of Government support and prejudice against allopathic medicines at that time in the country (Narayana 1984). During the First World War, the Industry received some fillip as the local demand increased several folds and imports were entirely cut off. The production of caffein from teadust and surgical dressings were established during this period in addition to increased manufacture of galenicals. Immediately after World War I, imports of foreign pharmaceutical products, which had stopped completely during the War period resumed again. Since no restrictions were placed on their entry, competition increased and the Industry again received a setback. In spite of this adverse position in 1930, the manufacture of biological products like sera and vaccines, anesthetics like ether and chloroform and coaltar distillation products such as naphthalene, cresol etc was undertaken by the Industry. Indigenous production was sufficient to meet about 13 per cent of the requirement in 1939.

In the history of the Indian pharmaceutical industry, World War II was a significant landmark. It provided a propitious atmosphere for further expansion in production. By 1941, the Industry took up the manufacture of new drugs like Idochlor as well as a number of alkaloids. Besides, the Industry made a beginning in the production of chemotherapeutic drugs like arsenicals,

anti-leprotic drugs and colloidal preparations of calcium, silver manganese and iodine. Self-sufficiency was achieved in the production of sera and vaccines. The production of formulations[1], based on imported bulk drugs, also showed significant expansion during this period. Even though several new formulations were developed in the country, the production activity primarily consisted of processing imported bulk drugs except for few items, which were produced from late intermediaries. The progress achieved in the production of fine chemicals and synthetic drugs were modest. Nevertheless, the Industry which were meeting only 13 per cent of the pharmaceutical requirement of the country in 1939, were in a position to meet up to 70 per cent of the requirement of the country by 1943 (M o C&I 1954).

The post-War development in the West, which witnessed the replacement of many older drugs by antibiotics and new chemotherapeutic agents, placed the Indian pharmaceutical industry at a great disadvantage. As a result, the Indian companies had to stop the production of items that were manufactured during the War years. The Indian pharmaceutical industry could not keep pace with the rapid developments in the global pharmaceutical industry with the result that many of the products made by the Industry became obsolete and surplus and the new drugs whose production had not been developed, had to be almost solely imported. At the time of independence, the small base that existed for the production of the medicines could not make much headway in the absence of consistent Government support to the Industry. The value of production of pharmaceuticals totalled Rs.10 crores in 1947.

2.2.2 Post Independence Era

Immediately after independence, Indian Government addressed itself to the task of achieving high rate of economic growth with special emphasis on speedy industrialisation to raise the living standards of the people. The economic planners of the country felt that without external assistance these goals will remain unfulfilled. The need for foreign capital was more urgently felt in those industries where domestic technological resources were limited or nonexistent. The Industrial Policy Statement of 1948, which made some specific mention in this regard, placed pharmaceutical industry under the category of 'basic industries' requiring considerable investment and high degree of technical skills. Recognising the international character of the pharmaceutical industry and the urgent need to develop a strong production base in the

[1] Formulations are medicines processed out of one or more bulk drugs and are ready for consumption by patients. Bulk drugs are chemicals having therapeutic value and used for the production of formulations.

country, Government permitted the entry of Multinational Corporations (MNCs) to set up units in India to make drugs requiring high quality standards (Narayana 1984).

The structure of the industry during this time is summarised in the following table.

Table 2.1 Structure of Indian Pharmaceutical Industry in 1952

Sector	*Units*	*Investment (Rs Crores)*	*Production (Rs Crores)*
Public Sector	11(0.67)	1.48(6.28)	1.46(3.34)
Foreign Sector	28(1.7)	6.9(29.19)	13.14(37.89)
Large Indian Sector	54(3.29)	9.2(39.17)	13.38(38.58)
Small Indian Sector	1550(94.34)	6(25.38)	7(20.18)
Total	1643	23.64	34.68

Note: The numbers in the parentheses are percentage shares
Source: Ministry of Chemical and Industry (1954)

It may be noticed that the value of output of the Industry has increased from the level of Rs 10 crores in 1947 to Rs 35 crores in 1952, or about 2.5 times. In 1952, the foreign and Indian large sector together accounted for about 68 per cent of the investment and about 76 per cent of production. The public sector accounted about 6 per cent in terms of investment and about 3 per cent in terms of production. The small-scale sector, numerically the largest component of the Industry, accounted 25 per cent of the investment and 20 per cent of production. The total value of imports in 1951-52 was Rs 15.6 crores.

During this period, some structural weaknesses of the Industry were noticed. The most important among them were;

- The Industry was mainly processing and formulating medicines based on imported fine chemicals and bulk drugs; and
- Indigenous productions of several new drugs like antibiotics (penicillin, streptomycin, chloramphenicol and tetracycline), antidiabetics and most vitamins had not commenced. Consequently, India was importing these items.

In the light of these structural imbalances a Pharmaceutical Enquiry Committee was set up to suggest remedial measures with General Bhatia as its chairman. The Committee, after a comprehensive survey, submitted its report in 1954. Its recommendations covered various aspects like licensing, foreign collaboration, production of bulk drugs and selling and distribution. The major recommendations are;

1. Each manufacturing concern should endeavour to produce as many chemicals and drugs starting from basic chemicals in quantities sufficient to meet not only its own requirements but also of other firms which process them.
2. Government should encourage close co-operation between importers and indigenous producers of fine chemicals and intermediates, which was found to be lacking.
3. As regards the foreign concerns, the following guidelines were suggested by the Committee:

(a) Tie-ups with foreign firms, including participation in capital should be preferred to tie-ups with no foreign participation in capital. However foreign capital participation should not generally exceed 49 per cent.

(b) No foreign concerns should be allowed to set up factories unless they undertook to manufacture products which were not manufactured in adequate quantities by other factories, starting from basic chemicals and/or intermediates as near to basic chemicals as possible with in a reasonable time.

Thus, the recommendations emphasised the need for an integrated development of the Indian pharmaceutical industry starting with the production of bulk drugs from basic stages. During this period the MNCs increasingly dominated the Indian pharmaceutical market. These companies earned tremendous profits by over-pricing their products (Sengupta 1994). Antibiotic production finally started indigenously when Hindustan Antibiotics Limited (HAL) was set up in Pimori with help from World Health Organisation (WHO) and United Nation's International Children's Emergency Fund (UNICEF) in 1954. Subsequently, Indian Drugs and Pharmaceutical Limited (IDPL) was set up with the help of Soviet technology in 1961 with two manufacturing units, one at Hyderabad and the other at Rishikesh. The Government of India set up HAL and IDPL with the following objectives,

1. To make the country self-sufficient in pharmaceuticals
2. To free the country from foreign exploitation and
3. To provide cheaper medicines in adequate quantity to the people (M o P&C 1975).

The advent of these public sector undertakings marked an important milestone in the development of Indian pharmaceutical industry. HAL and IDPL together had an investment outlay of about Rs. 56 crores. The field they ventured into was antibiotics and synthetic drugs, which were essential and required in large quantities. With the setting up of these public

sector units, antibiotic prices came crashing down in the country. The MNCs, in order to survive in the Indian market, slashed their prices. It was in this period that they started production of bulk drugs in India for the first time. By the 1960s, the Indian private sector also started growing. Unlike the MNCs, they also set up substantial capacities for the indigenous production of bulk drugs. However, the former, with their superior marketing network managed to keep a stranglehold on the Indian market (Sengupta 1994).

The output of the pharmaceutical industry maintained its increasing trend during the 1960s, from the level of Rs 88 crore in 1960-61 to Rs 250 crore in 1970-71. The average annual output of the Industry during the 1960s was about Rs 146 crores. The investment in the Industry increased from Rs 56 crore in 1962 to Rs 183 crore in 1970-71. The export of pharmaceutical products went up from Rs 1.57 crore in 1960-61 to Rs 8.46 crore in 1970-71 and that of import from Rs 17.78 crore to Rs 24.27 crore during the same period. By 1972, over 100 essential drugs covering a wide spectrum of therapeutic groups and various other pharmaceutical chemicals were produced in India from basic stages. About 60 units were engaged in the manufacture of bulk drugs which are used for the manufacture various formulations.

2.3 The Indian Patent Act (1970) and the Pharmaceutical Industry

The Patent Bill was first introduced in the Parliament in 1967. But Patent Act 1970, came into force only in 1972. One of the stated objectives of the IPA 1970 was the development of an independent-self reliant Indian pharmaceutical industry. It specifically excluded patent coverage for pharmaceutical 'products' and only admitted 'process' patents [2] for a period of seven years (or five years from the date of sealing the patent, whichever is shorter).

With respect to process patents, there are four provisions that substantially limit the scope of protection. First, after three years from date of sealing a pharmaceutical process patent, the 'License of Right' clause applies. Under this clause, the patent owner is obliged to license the patented process to any interested party, with a maximum royalty of 4 per cent payable by the licensee. Second, after three years from the date of sealing, the Government can grant a Compulsory License, if the patented product is not available at reasonable prices or other

[2] In this context, process patent means patenting the process used to make a particular drug formulation. On the other hand, Product Patent means patenting the product (formulation) itself.

public interests are not satisfied. Government sets the terms of Compulsory License, unless the patent owner and the licensee find an agreement between themselves. Third, a patented pharmaceutical process must be worked in India[3] within three years from the date of sealing the patent. Importation of drug produced with the patented process is not considered as working the patent. Fourth, the burden of proof in the case of patent infringement rests with the patent owner.

The Patent Act has been skilfully drafted to protect Indian pharmaceutical industry from foreign competition. It effectively served to legalise 'copying' of drugs that were patentable in the Developed World as newly invented product, but were unprotected in India. The Act allowed Indian companies to reproduce and market newly invented drugs in the Indian market through a different process and at only a small fraction of the cost of the patented drugs in the developed countries. Prior to 1970, when India had product patent for the pharmaceutical products[4], MNCs from the developed countries dominated the domestic market for pharmaceuticals with a share of about 85 per cent. As a result of this policy change, coupled with certain other Government policies, many MNCs slowly opted out of the Indian market due to the disadvantages they faced compared to their local rivals. As a consequence, the pendulum started swinging towards domestic production.

2.4 Pharmaceutical Industry after 1970

A large expansion was envisaged in the production of pharmaceuticals during the Fifth Five-Year Plan (1974-79). With the aim of attaining the rapid growth as envisaged by the Plan and ensuring the availability of drugs, particularly the essential categories, to the consumers at reasonable prices, Government, in February 1974, constituted a fifteen member Committee under the chairmanship of Jaisukhlal Hathi, a former Union minister. The Committee was asked to undertake a thorough investigation on all aspects of the Indian pharmaceutical industry.

2.4.1 Hathi Committee Recommendations

Though Hathi Committee submitted its Report in April 1975, it came into light only in 1977. The Hathi Committee Report is an important landmark in the development of Indian

[3] Working of patent means manufacturing the product in the country where the patent has been granted.
[4] Based on the Patent and Design Act of 1911.

pharmaceutical industry. The committee made some important observations and recommendations. Some of them are;

1. It unequivocally decried the role played by the MNCs in the Industry.
2. It attempted, for the first time, the formulation of an essential drug list.
3. It recommended a gradual shift to generic names from brand names[5].
4. It recommended the introduction of a package of price control measures to make life saving and essential drugs affordable to the people.
5. It recommended production control measures to ensure the production of essential drugs.
6. It recommended immediate dilution of foreign equity in pharmaceutical companies to 40 per cent and progressively to 26 per cent.
7. It recommended a leading role for the public sector and a sectoral reservation in the pharmaceutical industry to encourage the growth of the Indian sectors.

The Hathi Committee was sharply critical of the foreign sector because of its reluctance to produce bulk drugs in the country as well as its non-performance in producing essential drugs. The Committee notes that these firms were more interested in producing inessential drugs or those requiring low technological inputs. Infact, by a majority nine, the Committee has recommended that the MNCs should be taken-over by the Government and managed by the proposed National Drug Authority (Jain 1987).

2.4.2 New Drug Policy (NDP), 1978

Keeping in view the various recommendations made by the Hathi Committee, Government announced the New Drug Policy (NDP) in March 1978. Government had, however, started implementing some of the recommendations of the Hathi Committee even before announcing the NDP, 1978.

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[5] Most drugs have three names, namely, chemical, generic and brand name. The chemical and generic names describe the chemical composition of the active therapeutic ingredients. Chemical names are normally very long, complex and understandable only to scientists. In order to have a more usable name, either the research or medical authorities that are involved in the therapeutic application of the chemical propose a shorter or more concise name to replace the lengthy chemical name. Once the proposed name is accepted by the regulatory agency of the Government, it is thereafter known as generic name. However, most large pharmaceutical companies adopt brand names in order to identify their finished products. Brand names are normally used only in the case of formulations and not in the case of bulk drugs. The brand name differs from manufacturer to manufacturer.

The stated objectives of the NDP were;

- To develop self-reliance in drug technology.
- To provide leadership role to the public sector
- To aim at quick self-sufficiency in the output of drugs
- To foster and encourage growth of the Indian pharmaceutical sector
- To ensure that drugs are available in abundance at reasonable prices to meet the health needs of the people.
- To regulate the Industry as a whole with particular reference to containing and channelising the activities of the foreign companies in accordance with national objectives and priorities.

To realise the above mentioned objectives NDP (1978) laid down the following steps. It divided drugs into three groups for the purpose of reserving items for production by various sectors in the Industry. The first group consists of items that can only be produced by the public sector. The second group of drugs was reserved for the production by the Indian sector. The third group is open for all sectors, including the foreign sector. In considering the industrial license applications, preference will be given to Indian companies over MRTP units and foreign companies. Public sector was assigned a leading role in production and distribution of drugs and pharmaceuticals and adequate outlays are provided for this. Public sector would be encouraged to allocate suitable percentage of their net turnover for R&D activities. NDP also took measures to encourage the consumption of indigenously produced bulk drugs. It, while assigning a commanding role to the public sector and the Indian private sector, placed certain restriction on the growth and expansion of foreign companies. Foreign pharmaceutical companies, which do not manufacture bulk drugs but only process imported or domestically purchased bulk drugs into formulations, are required to bring down their foreign equity holding to 40 per cent. Foreign companies, producing formulations from imported bulk drugs or those manufacturing bulk drugs from penultimate stage, are required to produce such bulk drugs from the basic stage within a period of two years. Foreign companies will only be given license for the production of high technology bulk drugs and formulations based thereon. NDP stipulated that the process of shift to generic names would be started with five drugs namely, Analgin, Ferrous Sulphate, Aspirin, Piperazine and Chlorpromazine (Narayana 1984, Sengupta 1994).

2.4.3 Drug Price Control Order (DPCO), 1979

Statutory controls on the prices of drugs were imposed for the first time in India in 1962 in the wake of Chinese aggression and the declaration of emergency. The Drugs (display of prices) Order 1962 and Drugs (control of prices) Order 1963 was issued mainly to contain inflationary forces expected as a consequence of the War.

The Government announced the Drug Price Control Order on 4th April 1979. The Order empowered the Government to fix the maximum sale prices of selected drugs that are manufactured in the country, after a proper scrutiny of manufacturing costs of the same. It was for the first time that a comprehensive price control was introduced in the pharmaceutical industry[6]. DPCO categorised drugs into four groups.

I - Life saving
II - Essential
III - Less essential
IV - Non essential

Of these, the first three categories were price controlled with mark up[7] of 40, 55 and 100 per cent respectively. The philosophy behind this graded system was to make essential drugs cheaper. On the whole, as many as 347 bulk drugs are put under the price controlled category.

A major lacuna of the Drug Policy 1978 followed by DPCO 1979 was the lack of production control measures. This was contrary to the Hathi Committee recommendations (Sengupta 1994). The 1978 Policy contained no clause to compel manufactures to produce essential drugs. This, when coupled with the graded pricing structure of DPCO proved to be disastrous. Pharmaceutical companies reduced the production of categories I and II, where mark ups allowed were lower. The following table illustrates this point.

[6] In fact, in 1970 the Government has announced a Drug Price Control Order (DPCO 1970) with the objective to build up a rational system of price control. But it was not as comprehensive as DPCO 1979. Only 18 bulk drugs are put under the price control. The Order was aimed more at the control of the profitability of the pharmaceutical companies and thereby it indirectly sought to control the prices of drugs. The Order did not provide a means of checking the drug prices in the economy.

[7] MAPE, that is maximum allowable post manufacturing expense incurred from the stage of manufacturing to retailing and manufacturing margin.

Table 2.2: Drug Production in Response to Pricing Policy (*Per cent*)

Category	*1978*	*1979*	*1980*
I	4.5	4.2	3.6
II	16.7	14.8	13.2
III	67.1	67.8	68.6
IV	11.7	13.2	14.6
	100	100	100

Source: Narayana (1984)

In the mid 1970s, the Indian pharmaceutical industry comprised of 116 units in the organised sector and over 2500 units in the small scale unorganised sector. Out of the 116 units in the organised sector, 25 were foreign units with foreign equity exceeding 50 per cent and 26 units with foreign equity of 50 per cent or less. During the 1970s the output of the Industry expanded with an annual average output worth Rs 593 crore. The following table shows the expansion in the production of bulk drugs and formulations of the Industry during the period 1975-76 to 1980-81.

Table 2.3: Production of Bulk Drugs and Formulations (1975-76 to 1980-81)

Year	*Bulk Drugs (Rs Crore)*	*Growth Rate (%)*	*Formulations (Rs Crore)*	*Growth Rate (%)*
1975-76	130		560	
1976-77	150	15.38	700	25.00
1977-78	164	9.33	900	28.57
1978-79	200	21.95	1050	16.67
1979-80	226	13.00	1150	9.52
1980-81	240	6.19	1200	4.35

Source: Ministry of Chemicals and Fertilisers (1983)

The growth rate averaged nearly 15 per cent per annum for bulk drugs between 1975-76 to 1978-79. The Industry achieved the target of production of Rs 200 crores set by the Task Force (Planning Commission) for the terminal year of the Fifth Five-Year Plan. With respect to formulations, the actual production exceeded the target by 57 per cent due to the high tempo of growth recorded by the Industry between 1975-76 and 1978-79. But after 1978-79,

there has been a considerable deceleration both in the production of formulations and bulk drugs. In other words, the years that followed the announcement of NDP (1978) and DPCO (1979), the production of bulk drugs and formulations increased at a slower rate as compared with growth rate maintained during the 1960s and 1970s. The following table shows the sectoral shares of the pharmaceutical production during the sane period.

Table 2.4: Sectoral Shares of the Pharmaceutical Production (1975-76 to 1980-81)

Year	*Public Sector*	*Indian Sector*	*Foreign Sector*
1975-76	33.08	26.92	40.00
1976-77	34.28	20.71	45.00
1977-78	28.66	31.71	39.63
1978-79	24.50	47.50	28.00
1979-80	26.11	50.44	23.45
1980-81	26.25	51.67	22.08

Source: Narayana (1984)

It may be noticed that the share of the public sector in the pharmaceutical production has come down from about 33 per cent to 26 per cent. At the same time, the Indian sector has increased their share from about 27 per cent to 52 per cent. On the other hand, the Government's policy of regulation of foreign pharmaceutical companies as per the NDP (1978) and the IPA (1970) seems to have affected the share of the foreign sector that have come down from 40 per cent to 22 per cent during the period. Between 1969-79, the number of branches of foreign firms has decreased from 561 to 358 and that of foreign subsidiaries from 223 to 125 in the Indian pharmaceutical industry.

2.4.4 Developments in 1980s and 90s.

The measures that were undertaken following the 1978 Drug Policy and DPCO (1979) led to the rapid growth of the Indian sector, particularly Indian private sector. Infact, UNIDO, in 1980, identified India as one of the countries with capacity to produce all essential drugs indigenously. But during the 1980s, the public sector came to be increasingly marginalised. Due to the bureaucratic and administrative bungling as well as rampant inefficiency and corruption, the public sector units ran up huge losses (Sengupta 1994). This was indeed unfortunate, since it was the public sector, which the Hathi Committee recommended to play a

leading role in the expansion of the Indian pharmaceutical industry. The foreign sector continued to produce principally in low technology areas and it increased production of inessential drugs. They showed little inclination towards increasing bulk drug production while increasing their production of formulations enormously. In essence they continued to play the role of trading centers. Infact, during this period, the small-scale sector produced more bulk drugs than the whole foreign sector put together.

In the early 1980s, the pharmaceutical industry, led by the MNCs, began making belligerent noises for the reversal of the 1978 Policy - for decreased controls. The Industry argued that, due to the controls introduced in the NDP (1978) and DPCO (1979), drug production has become unprofitable in the country. In this campaign, the large companies of the Indian private sector, which has now consolidated their position in the Industry, joined with the MNCs (Sengupta 1994). The Government announced its New Drug Policy (NDP) on 18th December 1986. The main objectives of the NDP was to:

(a) Ensure abundant availability, at reasonable prices, of all essential life saving and prophylactic medicines of good quality.
(b) Strengthen the system of quality control over drug production and promoting the rational use of drugs in the country.
(c) Strengthen the indigenous capability for production of drugs.

The New Policy was framed with the view to achieve one of the main objectives of the Seventh Five-Year Plan, that is "health for all by the year 2000". The attainment of this objective requires an accelerated development of all inputs in the health care system. Drugs alone are not sufficient to provide health care, yet, if rationally used, they do play an important role in protecting and restoring the health of the people.

The New Policy emphasised the need for setting up of a National Drug Authority and for strengthening the infrastructure facilities for carrying out the quality control. The Policy has sought greater degree of control over the Industry by simplifying and rationalising the procedures. Generic names will be progressively adopted in the case of all drugs included in the list of essential drugs. The operations of FERA companies would be closely monitored. They would be eligible for entry only in those areas where the entry is desirable from the objective of better health care. The list of bulk drugs open for all sectors has been revised

accordingly. The Policy proposes a number of measures to revive the public sector, keeping in view its crucial role in achieving the objectives of the national health programme. These include changing management cultures and values, improvement in product strategy, reduction in inventory levels, better and more sensible marketing strategy, higher capacity utilisation, better utilisation of R&D etc. The Policy called for better integration between health policies and industrial policies in the pharmaceutical sector. The above measures proposed under the NDP are directed towards the speedy growth of the Industry in conformity with the planned objectives (Jain 1987).

The DPCO (1987), based on NDP (1986), reduced the span of price control from 347 bulk drugs to 166 drugs. It decreased the number of price controlled categories into two. Category I consists of drugs required for the national health programmes with the mark up of 75 per cent. Category II consists of drugs other than those in Category I, but which are also considered essential for the health needs of the people, with the mark up of 100 per cent. It was decided to have a uniform norm for all bulk drugs falling in these two categories and the manufactures will be given three options (a) 14 per cent post tax return on net worth or (b) 22 per cent return on capital employed or (c) long term marginal costing with 12 per cent internal rate of return in the case of new plants. Prices of drugs in the decontrolled category will be closely monitored. The Government would retain the right to bring with in the ambit of control any drug in the decontrolled category whenever considered necessary. The changes initiated in the DPCO are intended to make the price control system less cumbersome, but more effective and to ensure a reasonable return to the producers of essential drugs.

In the year 1980, the total number of units in the pharmaceutical industry increased to 5156, of which 144 belonged to the organised sector, with 40 being foreign sector units. The remaining 5012 units were small scale enterprises. The Indian sector's share in the investment in the Industry was about 76.7 per cent. Although the foreign sector units accounted for only 0.78 per cent of the total number of units, their share in total investment was about 23.3 per cent. The production of bulk drugs and formulations during the 1980s is summarised in the following table.

Table 2.5: Production of Bulk Drugs and Formulations (1980-81 to 1989-90)

Year	*Bulk Drugs (Rs Crores)*	*Growth Rate (%)*	*Formulations (Rs Crores)*	*Growth Rate (%)*
1980-81	240		1200	
1981-82	289	20.42	1434	19.5
1982-83	345	19.38	1660	15.76
1983-84	355	2.89	1760	6.12
1984-85	377	6.19	1827	3.81
1985-86	416	10.34	1945	6.46
1986-87	458	10.09	2140	10.03
1987-88	480	4.8	2350	9.81
1988-89	550	14.58	3150	34.04
1989-90	640	16.36	3420	8.57

Source: OPPI Annual Report, 1999-2000.

From the table it can be deduced that the production of formulations have grown at a faster rate (average growth rate of 12.67) than that of the production of bulk drugs (average growth rate of 11.67) during the 1980s.

The economic reforms initiated by the Indian Government in July 1991, trickled down to pharmaceutical industry only in 1994 and that too partially. The Government introduced the Drug Policy, in September 1994, which was followed by the DPCO 1995, both tried to reduce the control mechanisms to meet the demands of the Industry. In the New Policy, industrial licensing has been abolished for all bulk drugs. Now there will be no hindrance for capacity expansion. Foreign investment up to 51 per cent will be allowed in the case of all bulk drugs, their intermediaries and formulations. Above 51 per cent will be considered on a case to case basis, especially in the manufacture of drugs from basic stage / using new technology. Approvals have been made automatic for foreign technology agreement. The number of drugs reserved for the public sector was reduced to only five, namely, Vitamin B_1, Vitamin B_2, Folic Acid, Tetracycline and Oxetetracycline. Controls on the use of imported bulk drugs have also been abolished. In the New Policy, the abolition of licensing requirements for all bulk drugs has made it relatively easier for pharmaceutical companies to modify their product portfolio and lessen the impact of price control. As manufacturing facilities in the case of most pharmaceutical companies are usually suited for manufacturing a wide range of bulk drugs or

formulations, manufactures can now curtail production of a price control category of products and switch to more profitable range of bulk drugs or formulations. Thus, the Policy did liberalise the span of control considerably aiming to attract more investment both from within the country and from abroad.

The Drug Price Control Order (1995), based on NDP (1994) reduced the number of bulk drugs under the price control category to 74. The criteria fixed for the inclusion of a bulk drug in the price control category was that, if its annual turn over exceeds Rs.40 million or Rs.10 million with any single formulator having more than 90 per cent plus share. Drug will be excluded if five bulk drug manufactures and ten formulation manufactures exists, none having more than 40 per cent market share. Drugs, which are indigenously developed for the first time, will be excluded from the price control for five years. In the Order, different mark ups were done away and a uniform mark up of 100 per cent introduced in all cases for all drugs that come under the ambit of price control. Earlier, if the formulations of the price controlled drugs were unbranded and sold under the bulk drug name, then they were outside the DPCO purview. But as per the new order, DPCO is applicable to all formulation types notified in the Official Gazette, even if it is sold unbranded. Small-scale sector's products were earlier exempted from the price control, but under the New Order this allowance has been taken away.

The following table shows the production of bulk drugs and formulations from 1990-91 to 1997-98.

Table 2.6:Production of Bulk Drugs and Formulations (1990-91 to 1997-98)

Year	*Bulk Drugs (Rs Crores)*	*Growth Rate (%)*	*Formulations (Rs Crores)*	*Growth Rate (%)*
1990-91	730		3840	
1991-92	900	17.81	4800	25
1992-93	1150	27.78	6000	25
1993-94	1320	14.78	6900	15
1994-95	1518	15	7935	15
1995-96	1922	26.61	9125	14.99
1996-97	2186	13.74	10494	15.6
1997-98	2623	19.99	12068	14.99

Source: Annual Report 1999-2000, Dept. of Chemical and Petrochemicals.

Unlike the pattern observed during the 1980s, in the 1990s, the growth rate of the production of bulk drugs (average growth rate of 19.39) is higher than that of formulations (average growth rate of 17.6). At the same time, the growth rate of both the categories is considerably higher than that in the 1980s. This might have been the result of the liberalised policy incentives given to the Industry during the 1990s.

During the subsequent years, the Government continued the process of liberalising the pharmaceutical industry by enunciating the following steps. In February 1999, the five drugs hitherto exclusively reserved for the public sector has been de-reserved and opened them for the manufacture by the private sector. Manufacturing units in the public sector are allowed to face competition including those from import. Wherever possible these units were privatised. Foreign investment through automatic route was raised from 51 per cent to 74 per cent in March 2000 and further to 100 per cent in December 2001. In the Union Budget 2001-2002, the Government enhanced the facility of weighted deductions of 150 per cent of the expenditure on in-house R&D to cover as eligible expenditure, the expenditure on filing patents, obtaining regulatory approvals and clinical trials besides R&D in biotechnology.

The Government announced the Drug Policy (2002)[8] on February 15 that envisages a shift from the "controlled" to a "monitoring" regime for the pharmaceutical industry. With the pro R&D stand, the new Policy focuses on making the Indian pharmaceutical industry on par with the international standards. The main objectives of the Policy are:

1. Ensuring abundant availability at reasonable prices within the country of good quality essential pharmaceuticals of mass consumption.
2. Strengthening the indigenous capability for cost-effective quality production and exports of pharmaceuticals by reducing barriers to trade in the pharmaceutical sector.
3. Strengthening the system of quality control over drugs and pharmaceutical production and distribution to make quality an essential attribute of the Indian pharmaceutical industry and promoting rational use of pharmaceuticals.
4. Encouraging R&D in the pharmaceutical sector in a manner compatible with the country's needs and with particular focus on diseases endemic or relevant to India by creating an

[8] The Policy is labeled as "Pharmaceutical Policy 2002" as against the conventional label of "Drug Policy" in the official document, without specifying the reasons for the same.

environment conducive to channelising a higher level of investment into R&D in pharmaceuticals in India.

5. Creating an incentive framework for the pharmaceutical industry, which promotes new investment into pharmaceutical industry and encourages introduction of new technologies and new drugs.

The policy have done away with industrial licensing on all bulk drugs, intermediates and formulations cleared by the Drug Controller General of India, except in the cases of (i) bulk drugs produces by the use of recombinant DNA technology (ii) bulk drugs requiring in-vivo use of nucleic acids as the active principles, and (iii) specific cell/tissue targeted formulations. It also allowed 100 per cent foreign direct investment through the automatic route and automatic approvals for foreign technology agreement. To give a fillip to the R&D activities in the pharmaceutical industry, the policy proposes for the setting up of a Pharmaceutical Research and Development Support Fund (PRDSF) with Rs. 150 crores. Ministry of Science and Technology would set up a Committee to decide on how the funds would be operationalised.

The guiding principle for the identification of specific bulk drugs for the price regulation will be mass consumption nature and absence of sufficient competition. Only bulk drugs with a Moving Annual Total (MAT) value exceeding Rs. 10 crores would be deemed as mass consumption drugs. Further, even if a drug has MAT value of more than Rs. 10 crores and less than Rs.25 crores, it would come under price regulation only if the market share of an individual formulator is 90 per cent or more. For bulk drugs with MAT value of above Rs.25 crores the criterion would be the individual formulator holding market share of 50 per cent or more. All formulations containing a bulk drug as identified using this formula either individually or in combination with other bulk drugs will be kept under the price control. It is expected that with the new criteria, the number of bulk drugs under the price control would come down to 38 from the existing number of 74. With respect to essential drugs identified by the Ministry of Health and Family Welfare and are currently under price control but do not fall under the new turnover/market dominance criteria, the Policy states that National Pharmaceutical Pricing Authority (NPPA[9]) would monitor their price movements and will review their decontrol status if required.. The provision of limiting the profitability of

[9] NPPA was established, on 29th August 1997, with the task of enforcing the provisions of DPCO and to perform the functions assigned to it.

pharmaceutical companies under the DPCO (1995) when pricing the formulations was done away. However if required in public interest, the price of any formulation would be fixed or revised by the Government. Drugs whose process has been patented under IPA (1970), drugs developed through indigenous R&D and formulations involving new delivery systems are exempted from the price control. Under the new Policy, while indigenously manufactured formulations would be allowed a mark up of 100 per cent for post manufacturing expenses, imported formulations would be allowed a margin of about 50 per cent of the landed cost as margins to cover selling and distribution expenses including interest and importer's profit. For the scheduled bulk drugs, the rate of return in the case of basic manufacture will now be higher by 4 per cent over the existing 14 per cent on the net worth, or 22 per cent on capital employed. The Government will however retain the overriding power of fixing the maximum sales price of any bulk drugs in public interest.

2.5 Present Status of the Pharmaceutical Industry

The pharmaceutical industry in India today is one of the largest and most advanced among the developing countries. From the meagre Rs 10 crore worth production in 1947, the Industry has expanded its capability to produce formulations worth Rs 12068 crore and bulk drugs worth Rs 2623 crore in 1997-98. It ranks eleventh in Dollar terms of world pharmaceutical production, but its global market share is only 1.2 per cent. The investment in the Industry which was Rs 24 crore in 1952 has reached Rs 2500 crore by the year 1999. With the expansion in production, the Industry has helped the country to improve its share in the global trade in pharmaceutical products, as shown in the following table.

Table 2.7: India's Share in the World Pharmaceutical Trade

Year	*Share*
1979-80	0.26
1989-90	0.86
1998-99	1.01

Source: UNCTAD and Narayana (1984).

At present there are about 250 large units and about 8000 small units in operation[10], which, along with 5 central public sector units form the core of the Industry. These units produce a

[10] Based on the Annual Report, 1999 - 2000, Department of Chemicals and Petrochemicals, Government of India.

complete range of formulations and about 350 bulk drugs. Today, India is in a position to meet 70 per cent of country's requirement of the bulk drugs and almost all the demands for formulations.

Though, the Indian pharmaceutical industry has successfully emerged as a global player in pharmaceutical production, its performance in the new drug discovery has remained disappointing. Lack of sufficient resources devoted for R&D is a major drawback of the Indian pharmaceutical industry. In the area of discovery of novel drugs and engagement in research directed towards the discovery of new molecular entities, the Industry's portrait is least colourful. Most of the Indian companies do not have a research base.

2.6 Concluding Observations

Indian pharmaceutical industry is shown a steady growth, immune to economic recession and commodity cycles. The record of progress achieved by the Industry can be regarded as spectacular as at the dawn of independence India did not have a production base, which would be called an "industry". From such a low base, the Industry grew rapidly not merely in terms of expansion in physical output but also in the matter of product diversification. Without product patents, Indian firms grown their indigenous markets through the creation of different process. However, to maintain its position in the changed global scenario in the future, Indian pharmaceutical industry must undergo a transformation towards becoming an internationally competitive research based industry. The crux is innovation. To conclude, it is encouraging to observe the Government's initiation of various policy measures designed to strengthen the R&D capabilities of the Industry, which will be crucial keeping in mind the post 2005 scenario.

Chapter III

ANALYSIS OF FOREIGN TRADE IN PHARMACEUTICAL PRODUCTS OF INDIA

3.1 Introduction

No nation is completely self sufficient in drugs, although several approach this position. Countries cannot produce many drugs required to meet their peculiar disease pattern. Capacities are unequally distributed. This situation leads to increased international trade in pharmaceutical products (OECD 1985). Intermediaries play a key role in enhancing this, as international firms ship active ingredients for formulations in the final market (Tarabusi and Vickery 1998). In the advanced segment, the technology of the Industry also encourages trade. There are large economies of scale both in innovation and in some key phases of manufacture. New products, a major form of competition, are extremely expensive to develop and must be sold worldwide to recover their cost. International trade is one response to this necessity, even if Foreign Direct Investment (FDI) is the Industry's most characteristic way of achieving worldwide sales (OECD 1985).

In this chapter, we seek to examine the hypothesis that increased trade in pharmaceutical products does not necessarily result in negative impact on developing countries by way of worsening the balance of trade by taking the case of India. The chapter is organised as follows. Next section examines the aggregate dimensions of India's foreign trade in pharmaceutical products. The disaggregate analysis of its export and import is presented in section 3.3. Section 3.4 deals with the direction of pharmaceutical trade. The theoretical framework and quantitative analysis of comparative advantage is explained in the section 3.5. The last section is the concluding observations.

3.2 India's Foreign Trade in Pharmaceutical Products: An Aggregate Analysis

This section analyses India's export and import of pharmaceutical products at the aggregate from the year 1987-88 to 1999-2000[1]. We begin by looking at the share of pharmaceutical products in India's foreign trade.

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[1] The justification for choosing this particular period is explained in the chapter I.

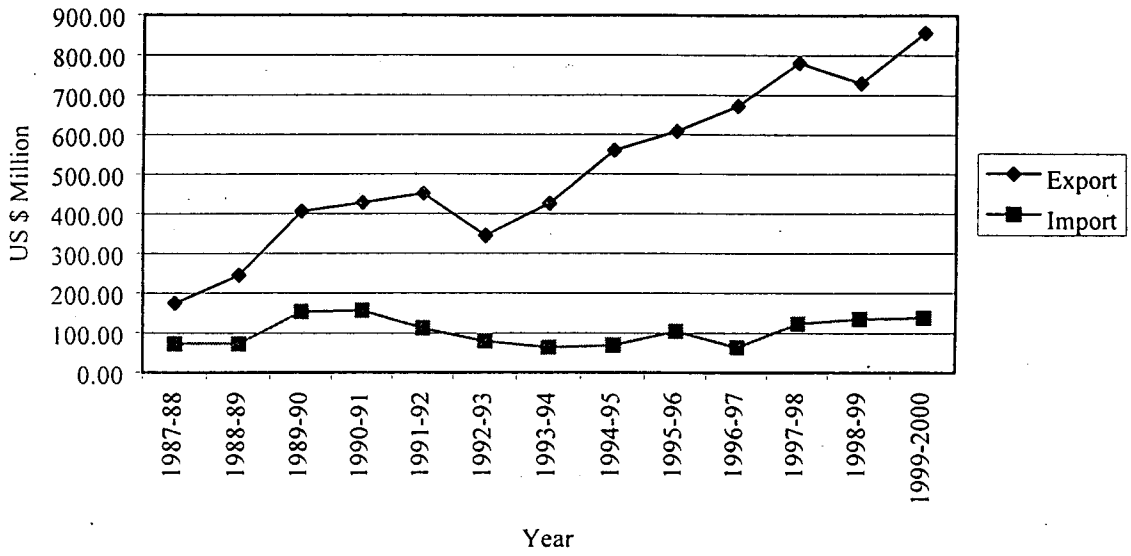
Table 3.1 Share of Pharmaceutical Products in India's Foreign Trade (% of the total).

Year	*Export*	*Import*
1987-88	1.45	0.43
1988-89	1.67	0.37
1989-90	2.45	0.72
1990-91	2.37	0.65
1991-92	2.51	0.57
1992-93	1.86	0.37
1993-94	1.92	0.27
1994-95	1.91	0.24
1995-96	1.91	0.29
1996-97	2.01	0.16
1997-98	2.23	0.30
1998-99	2.20	0.32
1999-2000	2.33	0.28

Source: Various issues of Monthly Statistics of the Foreign Trade of India.

As far as the share of pharmaceutical products in India's export is concerned, it registered a sharp increase from the year 1987-88 to 1991-92 followed by a steep decline in the year 1992-93. Again, the share has marginally increased in the second half of the 1990s. The contribution of pharmaceutical products towards India's import is very meagre with shares of less than 1 per cent in the period of analysis. During the period 1989-90 to 1994-95, the share has consistently fallen, after that it showed no clear trend.

Figure 3.1 Export and Import of Pharmaceutical Products of India



It can be noticed that after the year 1992-93, pharmaceutical export has registered more or less consistent increasing trend. At the same time, import of pharmaceutical products has declined after 1990-91. The study used the popular exponential function[2] for the computation of the growth rates of the variables. The results of the estimated OLS reveals that export have grown at a healthy rate of 11.01 per cent during the period. On the other hand, the growth rate of import turned to be statistically insignificant.

As a next step, we tested change in growth rate (acceleration / deceleration) over the period, using a log quadratic function[3]. It was found that pharmaceutical export is increasing at a declining rate (or decelerating from a positive growth rate). We also computed the sub period growth rates before and after the year 1991 to investigate whether there occurred any considerable variation in the trend after the liberalisation measures. We used the method of kinked exponential[4]. It was found that export has grown at the rate of 17.72 per cent in the first period and its growth rate was 8.47 per cent in the second period. This means that the

[2] Exponential function ($y = ae^{rt}$) is one of the popular methods among the statistical measures for calculating the growth rates. The equation can be estimated by using Ordinary Least Square (OLS) method.

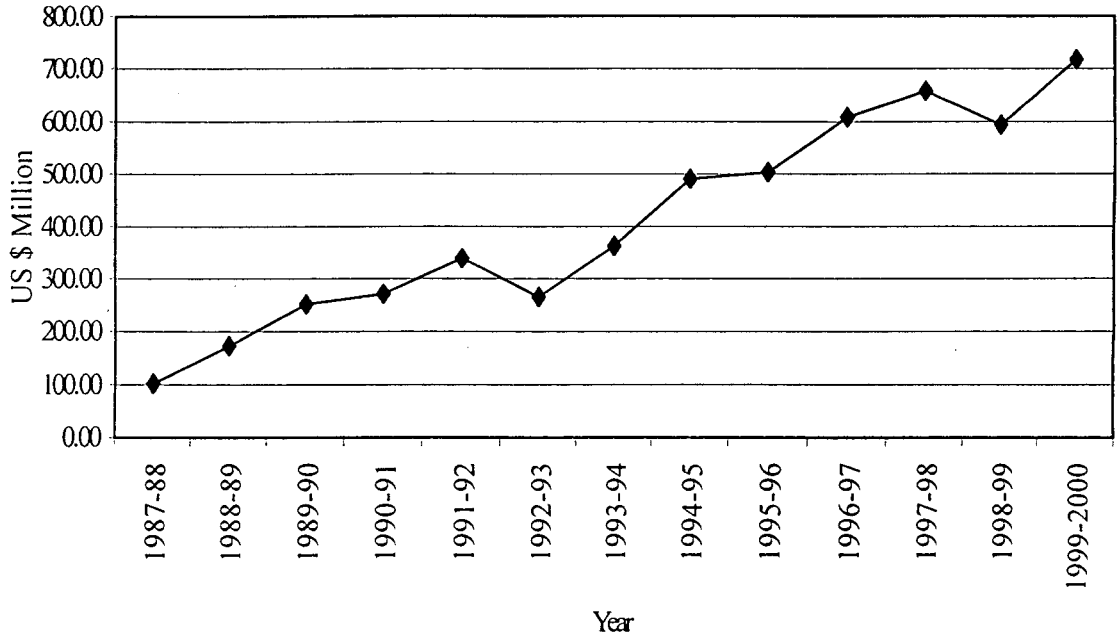
[3] We used the functional form of $\ln Y = a_0 + r_0 t + r_1 t^2 + u_t$. The nature of the growth rate depends up on the sign of both r_o and r_1. The growth rate is (i) accelerating if r_0 and r_1 are positive (ii) decelerating if r_o and r_1 are negative (iii) decelerating from a positive growth rate if $r_0>0$, $r_1<0$ and $t<-r_0/2r_1$ and (iv) accelerating from a negative growth rate if $r_0<0$, $r_1>0$ and $t>-r_o/2r_1$.

[4] It can be estimated by the function $\ln Y = a_1 + b_1 (D_1 t + D_2 k) + b_2 (D_2 t - D_2 k) + u_t$; $D_1=1$ for the first period (pre 1991), = 0 otherwise, and $D_2 = 1$ for the second period (post 1991), =0 other wise. b_1 and b_2 are the growth rates for the two periods with a kink k if the estimated values of the growth rates are different.

growth rate of the export has declined in the post liberalisation period compared to the pre liberalisation period and there exists a trend break in the year 1991.

The balance of trade of India's pharmaceutical products is shown in the Figure 3.2.

Figure 3.2 Balance of Trade in Pharmaceutical Products of India



The balance of trade of pharmaceutical products is showing a steady increasing trend except for the two dips in 1992-93 and in 1998-99. The first dip in the year 1992-93 occurred as a result of fall in both export and import, with the former registering a sharper decline, while the second dip at the 1998-99 occurred as a result of declining export while import registered a modest growth. On the whole, during the period of analysis, the balance of trade was found to be positive. This refutes the argument by Baris and Mcleod (See Chapter I, Section 1.2 for details) that increased trade in pharmaceutical products will have a negative impact on the balance of trade of developing countries.

3.3 Structure and Growth of India's Pharmaceutical Trade: The Disaggregate Analysis

So far we have analysed various dimensions of India's foreign trade in pharmaceutical products at the two-digit level of aggregation. In this section, we are examining the same at the disaggregate level. Pharmaceutical products are classified into six categories at the four-

digit level; there are 30 categories at the six-digit and about 240 categories at the eight-digit level of ITC.

3.3.1 Export

The six categories of pharmaceutical products at the four-digit level are;

Category I - Glands and other organs for organotherapeutic uses.

Category II - Blood fractions, vaccines for human medicine and cultures of micro organisms

Category III - Bulk Drugs

Category IV - Formulations

Category V -Wadding, gauze and similar products

Category VI - Sterile surgical catgut, blood grouping reagents, first aid boxes and kits, dental cements and other dental fillings; etc.

We computed shares of these categories in the export of pharmaceutical products over the period.

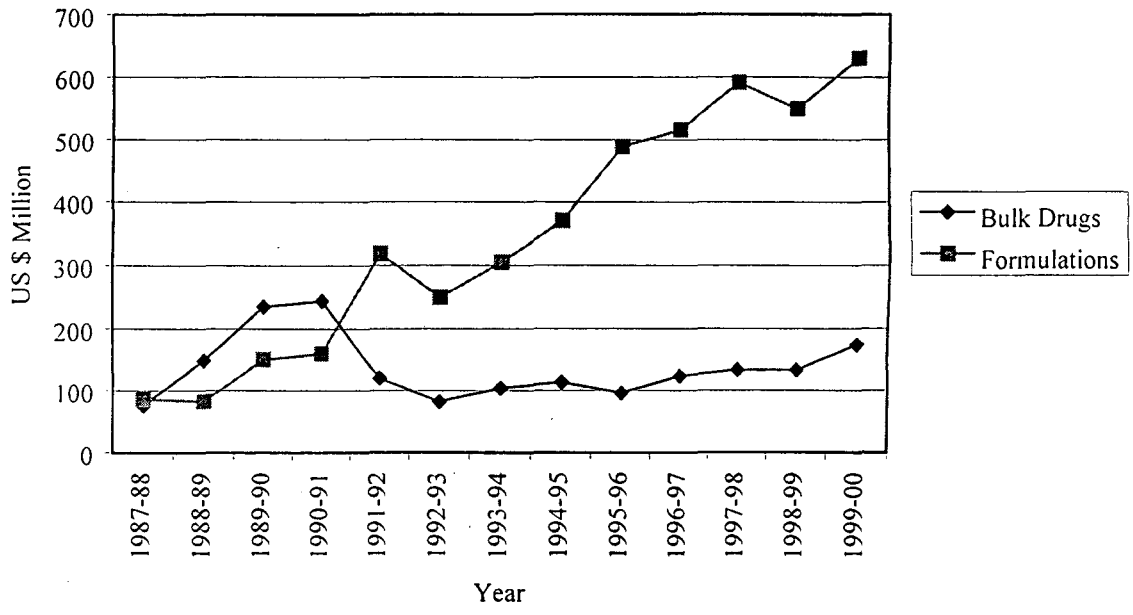
Table 3.2 Composition of Pharmaceutical Exports (4 Digit)

Year	*I*	*II*	*III*	*IV*	*V*	*VI*
1987-88	0.03	4.36	43.46	49.12	0.86	2.17
1988-89	0.06	1.33	60.83	33.80	0.84	3.14
1989-90	0.03	2.49	57.95	37.16	0.32	2.05
1990-91	0.05	2.09	57.14	37.52	0.46	2.74
1991-92	0.04	0.44	26.70	70.71	0.69	1.42
1992-93	0.03	0.35	23.89	72.47	1.34	1.92
1993-94	0.07	9.84	22.26	65.35	1.07	1.41
1994-95	0.08	1.46	22.63	73.61	0.95	1.27
1995-96	0.20	1.83	15.88	80.34	0.97	0.78
1996-97	0.18	2.84	18.58	77.41	0.89	0.09
1997-98	0.32	3.98	17.15	75.67	0.63	2.25
1998-99	0.35	4.27	18.30	75.35	0.74	0.10
1999-2000	0.12	4.24	20.32	73.55	0.73	1.05

Source: Various issues of Monthly Statistics of the Foreign Trade of India

As is evident from Table 3.2 more than 90 per cent of pharmaceutical exports are contributed by the III[rd] and IV[th] categories i.e., bulk drugs and formulations. Among these two, the share of bulk drugs has registered a declining trend with the beginning of 1990. Its share was drastically reduced from 57.14 per cent in 1990-91 to 26.7 in 1991-92. At the same period, the formulations have increased their share from 37.52 per cent to 70.71 per cent. On the whole, what the table reveals is that India's export basket of pharmaceutical products more or less entirely consists of bulk drugs and formulations and that the share of the latter have increased considerably over the period.

Figure 3.3 Export of Bulk Drugs and Formulations



Further, it may be seen that up to the year 1990-91, India exported more bulk drugs than formulations (Figure 3.3). But after 1990-91, export of bulk drugs has declined and remained at a low level. On the other hand, export of formulations has increased more or less consistently, during the period. This was the reason why the shares of bulk drugs declined after 1990-91 and that of formulations increased during this period.

Since more than 90 per cent of pharmaceutical exports are accounted for by the formulations and bulk drugs, we examined these two categories in greater detail to find out the reasons for the observed pattern. At six-digit level, bulk drugs are classified into six categories and formulations into eight categories.

The six categories of bulk drugs at the six-digit level are: I (bulk drug containing penicillin), II (bulk drug containing other antibiotics), III (bulk drug containing insulin), IV (bulk drug containing hormone preparations), V (bulk drug containing alkaloids) and VI (other bulk drugs). We computed shares of these categories in the bulk drug export and is shown in the Table 3.3.

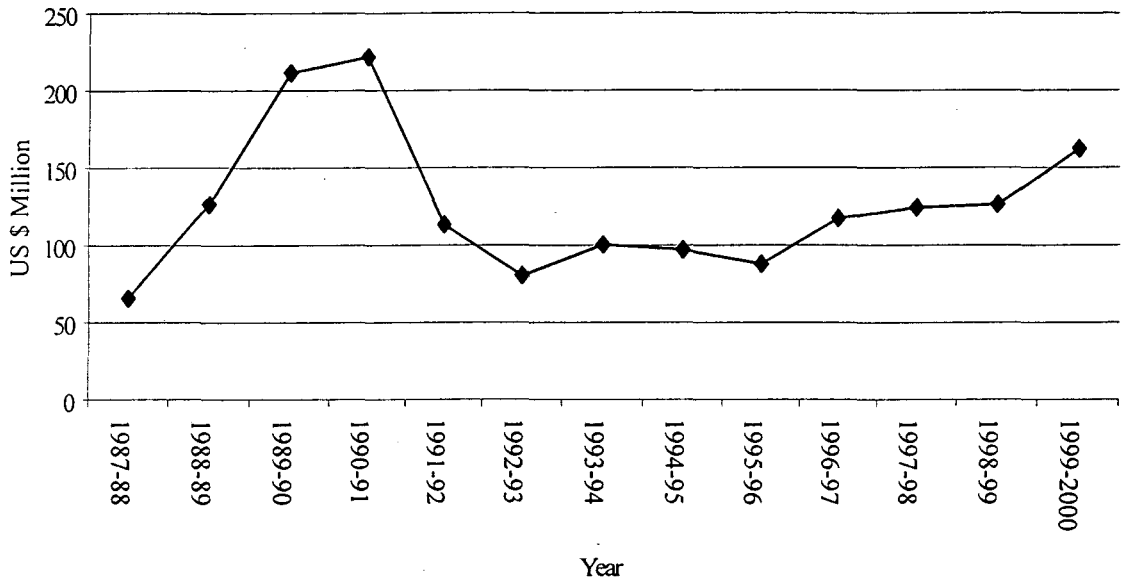
Table 3.3 Composition of Bulk Drug Export

Year	*I*	*II*	*III*	*IV*	*V*	*VI*
1987-88	4.87	4.67	0.97	1.42	1.63	86.40
1988-89	1.49	6.46	5.93	0.30	1.08	84.75
1989-90	1.62	6.62	1.60	0.05	0.64	89.93
1990-91	3.23	4.33	1.29	0.06	0.43	90.64
1991-92	0.52	3.03	0.17	2.05	0.11	94.10
1992-93	1.67	0.28	0.04	0.26	0.04	97.72
1993-94	1.64	0.56	0.48	0.81	0.01	96.49
1994-95	2.85	2.46	0.11	9.31	0.01	85.26
1995-96	1.56	1.39	0.09	5.85	0.05	91.06
1996-97	0.71	1.69	0.44	2.28	0.07	94.81
1997-98	2.69	0.35	0.18	3.93	0.05	92.79
1998-99	0.57	0.25	0.14	4.26	0.08	94.69
1999-00	0.25	0.47	3.78	2.38	0.01	93.11

Source: Various issues of Monthly Statistics of the Foreign Trade of India

It may be noticed that, about 90 per cent of bulk drug exports are contributed by the category of other bulk drugs. In the year 1992-93 and 1993-94, its share was 97 and 96 per cent respectively. The shares of bulk drugs containing other antibiotics and declined especially towards the latter half of the 1990s. On the whole, the export basket of bulk drugs was more or less entirely consisting of other bulk drugs. Its export is depicted below.

Figure 3.4 Export of Other Bulk Drugs



It can be noticed that after the year 1990-91, the export has come down drastically. It was exactly, this decline in the export of other bulk drugs, which contributed to the fall in the export of bulk drugs after 1991.

The eight categories of formulations at the six-digit level are: I (formulation containing penicillin), II (formulation containing other antibiotics), III (formulation containing insulin), IV (formulation containing adrenal cortical hormones), V (formulation containing other hormones), VI (formulation containing alkaloids), VII (formulations containing vitamins) and VIII (other formulations). We computed the shares of these categories in the formulation export and is shown in the following table.

Table 3.4 Composition of Formulation Export

Year	*I*	*II*	*III*	*IV*	*V*	*VI*	*VII*	*VIII*
1987-88	5.95	5.69	0.02	0	0.24	0.53	17.67	69.89
1988-89	5.50	2.85	0.33	0	0.46	0.10	21.24	69.51
1989-90	2.78	3.69	0.01	0	0.47	0.23	19.65	73.15
1990-91	4.50	3.60	0	0	0.01	0.13	31.69	59.59
1991-92	12.56	9.90	1.31	0.02	1.09	0.17	16.42	58.53
1992-93	16.28	10.29	0.07	0	1.98	0.45	9.49	61.55
1993-94	16.44	10.75	0.76	0	2.77	0.72	7.9	60.65
1994-95	17.42	12.94	0.11	0	3.17	0.69	8.32	57.34
1995-96	18.15	15.16	0.03	0	2.39	1.04	7.70	55.52
1996-97	14.77	15.84	0.55	0	3.65	1.14	5.32	58.73
1997-98	13.57	13.47	0	0.01	3.72	1.83	7.11	60.27
1998-99	13.54	14.78	0.51	0	1.69	0.99	8.86	60.05
1999-00	11.61	16.65	0.75	0	1.97	0.62	7.62	60.74

Source: Various issues of Monthly Statistics of the Foreign Trade of India

From the table it can be observed that the categories of formulation containing *penicillin and* formulation containing other antibiotics have increased their shares in India's export of pharmaceutical products. In the case of both the categories, the acceleration in the shares started from the year 1991-92. The share of formulation containing vitamins had declined particularly after the year 1990-91. The category of other formulations has increased its share from the year 1987-88 to 1989-90, but during the 1990s its share has marginally declined. The export of these four categories that together constitutes more than 95 per cent of India's formulation export is depicted in the following successive figures.

Figure 3.5 Export of Formulations Containing Penicillin

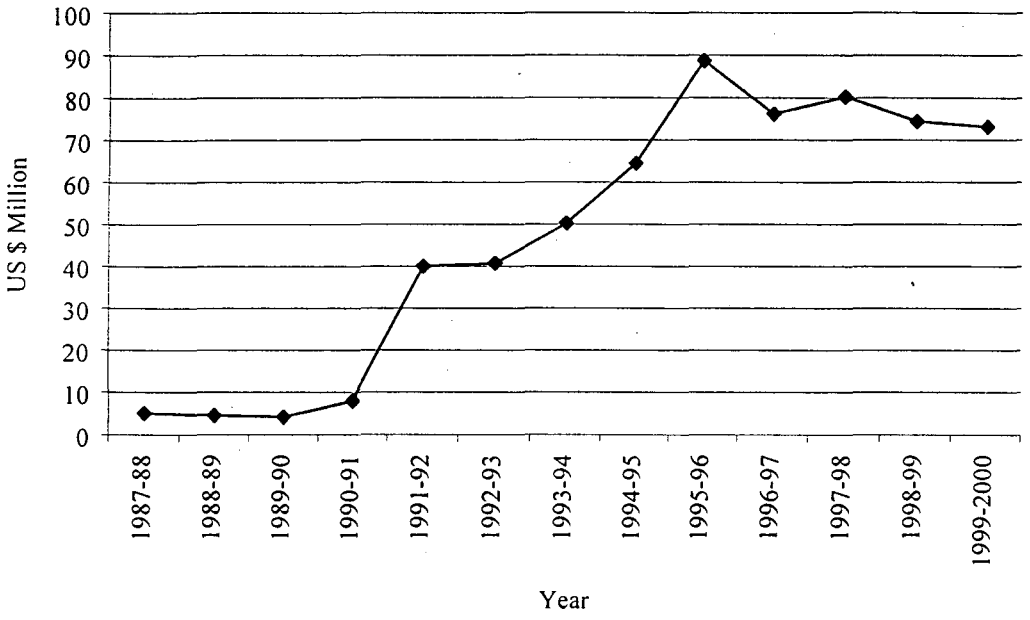


Figure 3.6 Export of Formulations Containing Other Antibiotics

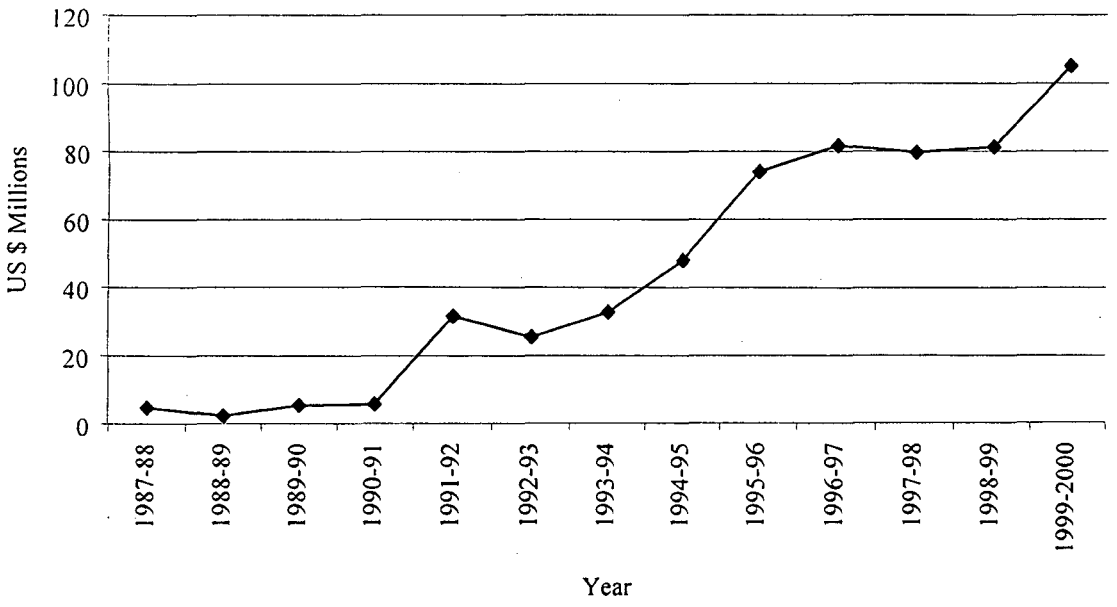


Figure 3.7 Export of Formulations Containing Vitamins

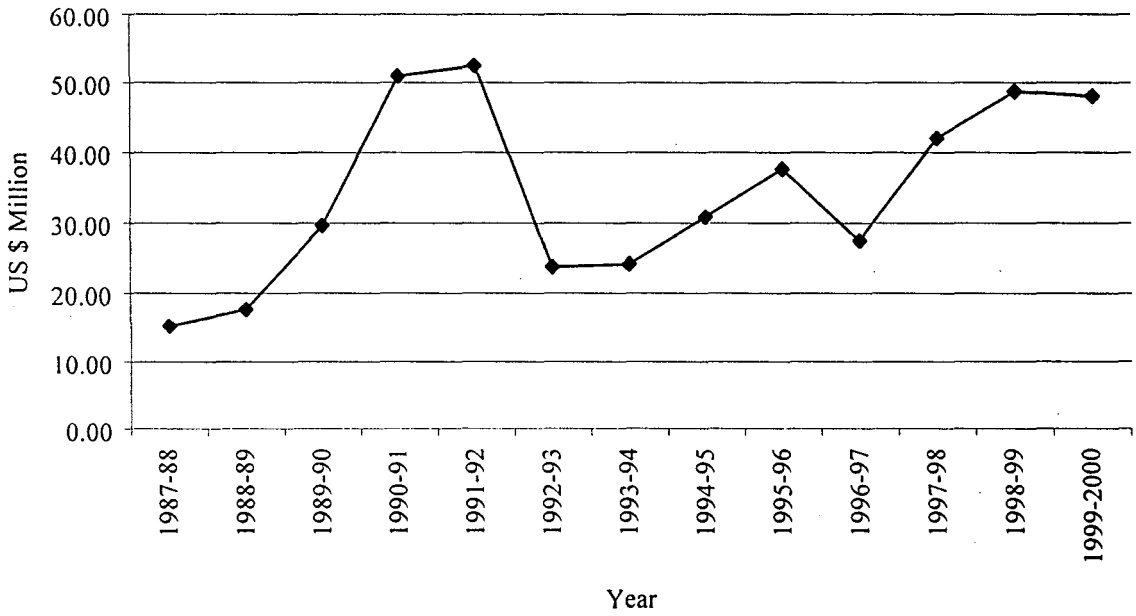
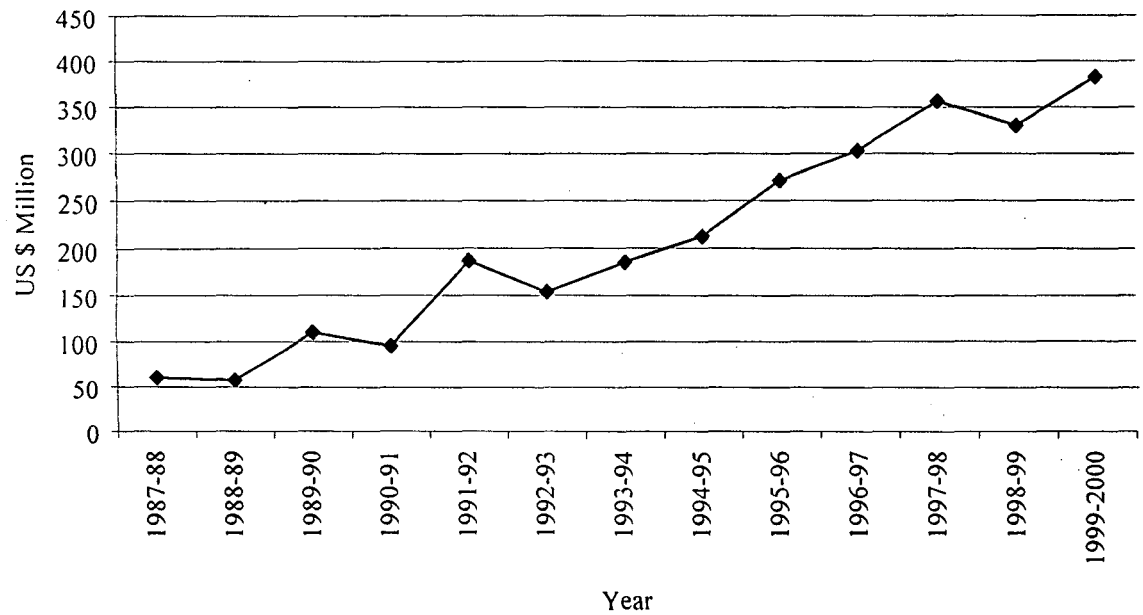


Figure 3.8 Export of Other Formulations



Further, a close examination of India's export of pharmaceutical products reveals an important pattern. This may be seen in the Figures 3.9 to 3.11

Figure 3.9 Export of Bulk Drugs and Formulations Containing Penicillin

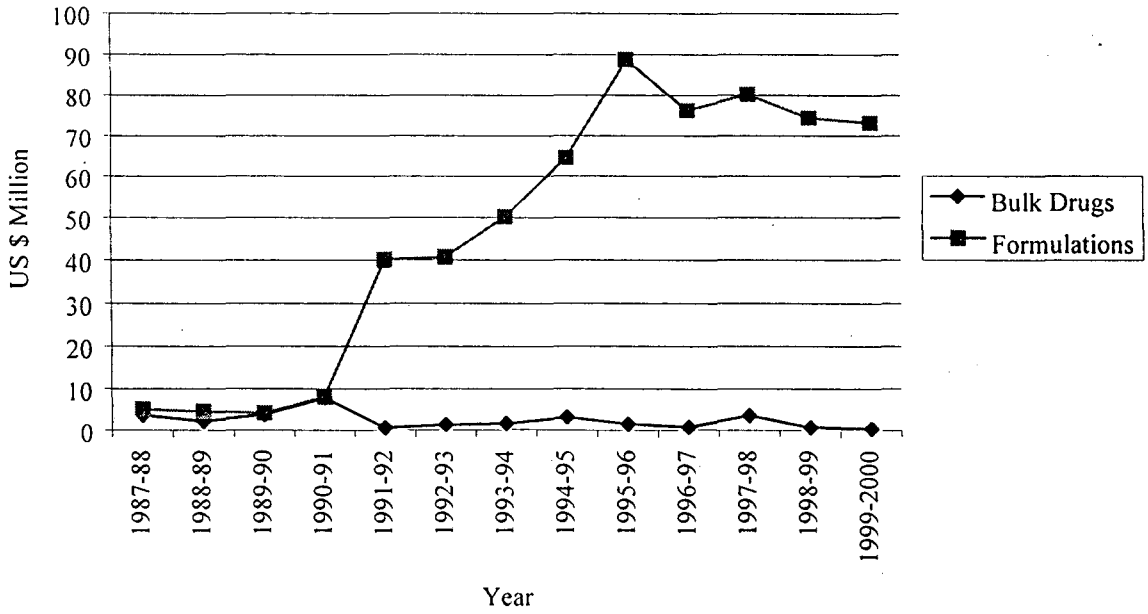


Figure 3.10 Export of Bulk Drugs and Formulations Containing Other Antibiotics

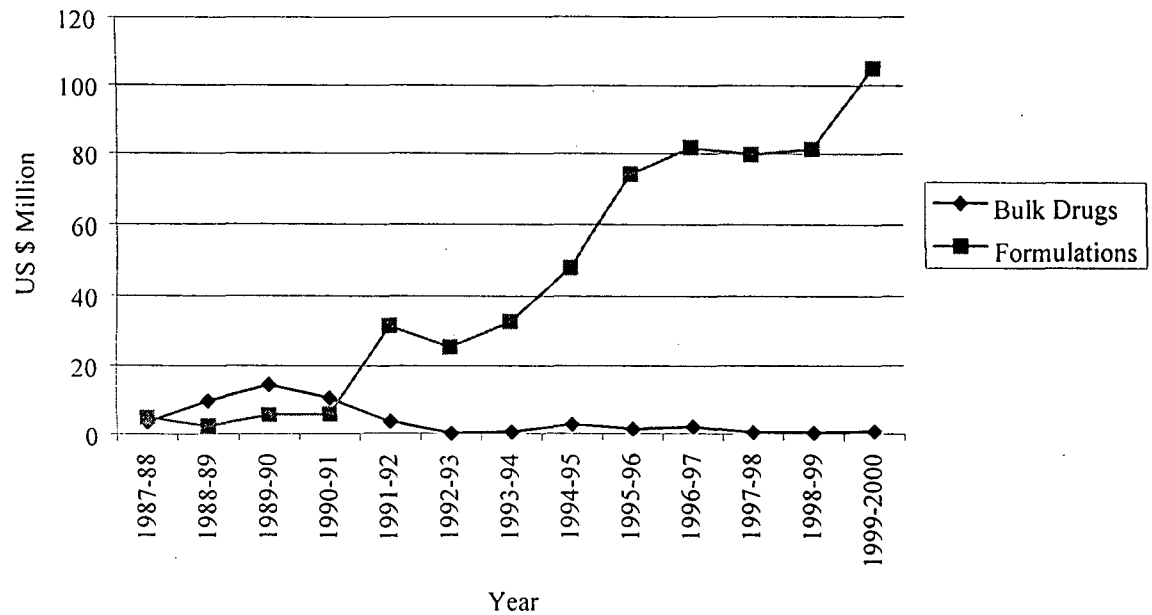


Figure 3.11 Export of other Bulk Drugs and Other Formulations

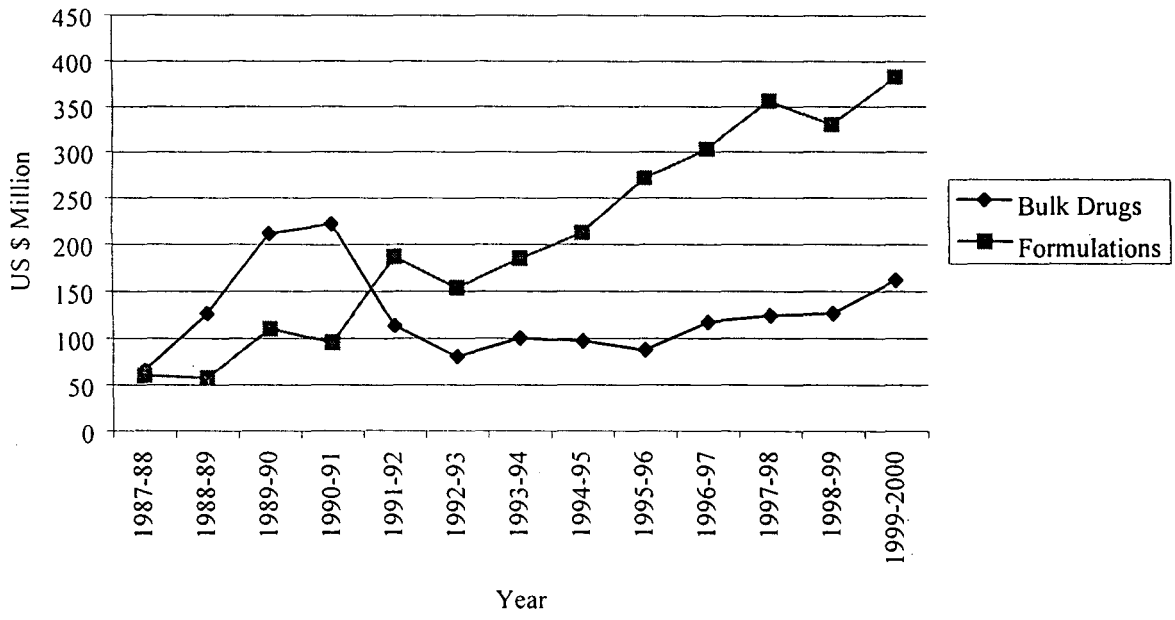


Figure 3.9 shows that while the export of bulk drugs containing penicillin have decreased, the export of formulations containing penicillin have increased. Figure 3.10 shows that, while the export of bulk drugs containing other antibiotics have declined, the export of formulations containing other antibiotics have increased. Similarly, the export of other bulk drugs has decreased and the export of other formulations has increased as shown in the Figure 3.11. These Figures indicate that India that had previously concentrated on the export of bulk drugs now seems to have shifted its focus to the export of more value added formulations categories.

3.3.2 Import

The share of six categories of pharmaceutical products (see Section 3.3.1, page no.33) in the total import are shown in the Table 3.5.

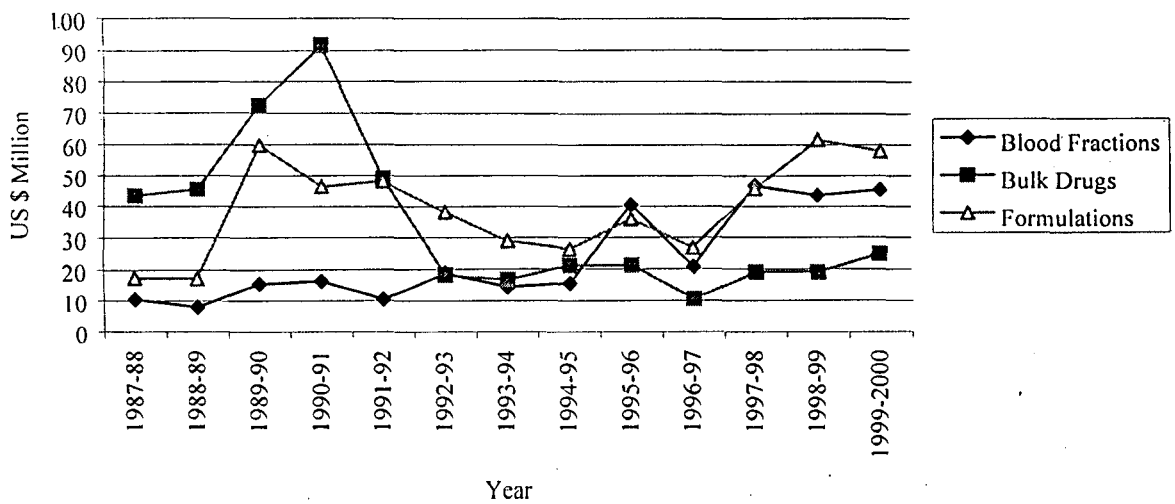
Table 3.5 Composition of Import of Pharmaceutical Products.

Year	*I*	*II*	*III*	*IV*	*V*	*VI*
1987-88	1.79	14.22	59.44	23.65	0.21	0.68
1988-89	1.65	10.87	62.55	23.51	0.57	0.85
1989-90	0.73	10.05	47.16	38.87	1.89	1.36
1990-91	0.32	10.35	58.35	29.65	0.35	0.98
1991-92	0.97	9.33	43.85	43.05	0.75	2.04
1992-93	1.03	23.53	22.68	47.82	0.86	4.07
1993-94	1.23	22.47	26.26	45.28	1.13	3.63
1994-95	1.65	22.37	30.40	38.02	3.55	4.00
1995-96	1.36	38.73	20.26	34.33	1.64	3.78
1996-97	1.42	32.24	16.39	41.78	2.88	5.57
1997-98	1.32	38.03	15.43	37.21	2.37	5.65
1998-99	0.81	32.28	13.97	45.55	1.82	5.57
1999-2000	1.01	32.81	17.88	41.75	1.39	5.17

Source: Various issues of Monthly Statistics of the Foreign Trade of India

It may be seen that the share of blood fractions etc. products have increased its share in India's import of pharmaceutical products. Its share was marked by a sharp increase in the year 1992-93 and in 1995-96. The share of bulk drugs has declined, particularly after the year 1990-91. On the other hand, formulations have enhanced its share especially after 1990-91. Since the major chunk of import of pharmaceutical products is contributed by these three categories, we closely examined them to find out the reason for the declining trend in imports of pharmaceutical products that we observed in the earlier Figure 3.1. Figure 3.12 given below depicts the pattern of import of these three categories.

Figure 3.12 Import of Blood Fractions etc Products, Bulk Drugs and Formulations



The steep decline in the import of bulk drugs may be noticed after the year 1990-91. On the other hand, import of blood fractions etc and formulations registered a rising trend. Import of blood fractions etc. products increased from $ 10 million to $ 45 million, while that of formulations increased from $ 17 million to $ 57 million during the period. Thus from this figure we can assure that it was due to the declined import of bulk drugs that the import of pharmaceutical products showed a declining trend. As a next step, we examined the composition of imported bulk drugs at the four-digit level. As already mentioned earlier, at four-digit level bulk drugs are classified into six categories as I (bulk drug containing penicillin), II (bulk drug containing other antibiotics), III (bulk drug containing insulin), IV (bulk drug containing hormone preparations), V (bulk drug containing alkaloids) and VI (other bulk drugs). We computed shares of these categories in the bulk drug import and shown in the Table 3.6.

Table 3.6 Composition of Bulk Drugs Import

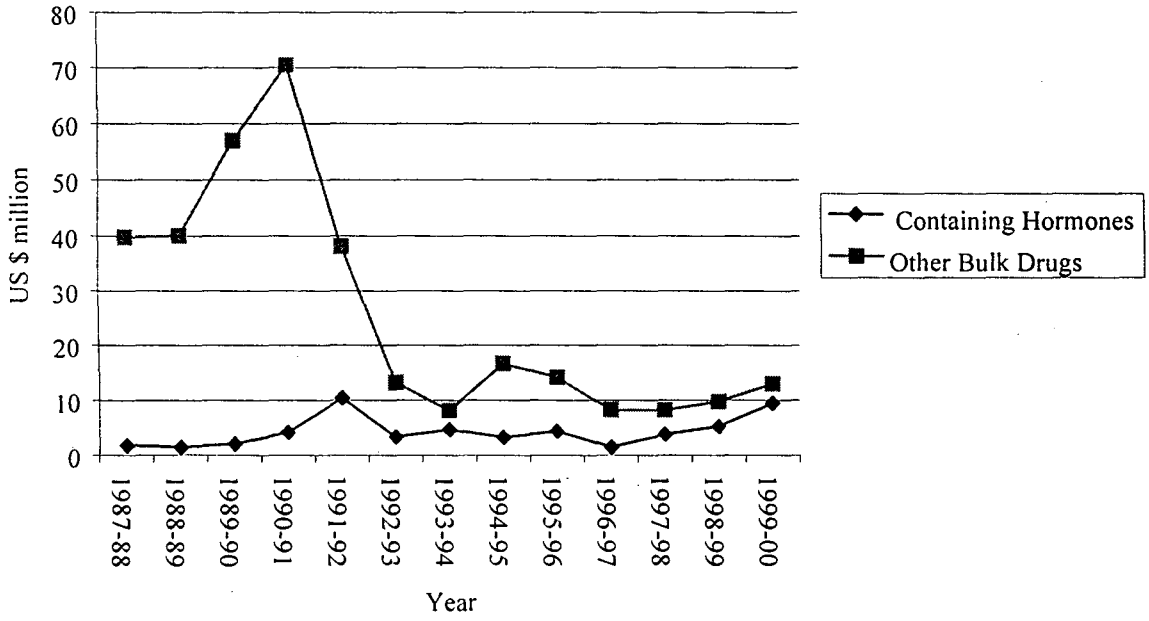
Year	*I*	*II*	*III*	*IV*	*V*	*VI*
1987-88	0.89	1.48	2.04	4.09	0.08	91.44
1988-89	2.83	1.55	4.49	3.25	0.06	87.82
1989-90	11.46	0.82	6.24	2.90	0	78.58
1990-91	1.33	3.37	13.84	4.55	0.06	76.86
1991-92	0.30	1.35	5.64	19.91	0	72.78
1992-93	1.73	1.01	6.31	18.37	0	72.57
1993-94	4.43	1.33	17.45	27.96	0.10	48.74
1994-95	2.61	1.78	1.20	15.62	0.01	78.79
1995-96	2.77	3.40	6.04	20.84	0.27	66.68
1996-97	3.34	2.34	1.67	14.49	0	78.16
1997-98	1.72	3.44	31.49	20.01	0	43.34
1998-99	0.72	8.78	10.99	27.74	0	51.77
1999-00	0.19	0.87	8.20	38.31	0.23	52.21

Source: Various issues of Monthly Statistics of the Foreign Trade of India

It may be seen that major chunk of the import of bulk drugs are accounted for by IVth and VIth category i.e. bulk drugs containing hormones and other bulk drugs. The shares of bulk drugs containing hormones were marked by a sharp increase in the years 1991-92, 1993-94 and 1999-2000. On the other hand, the share of other bulk drugs had shown a consistently declining trend up to the year 1993-94, which was followed by a sharp increase in 1994-95. In the second half of the 1990s there occurred considerable fluctuations in its share.

In order to know the reasons for the decline in bulk drug import, we have to analyse the pattern of import of bulk drugs containing hormones and other bulk drugs. Figure shows the import of these two categories during the period of analysis.

Figure 3.13 Import of Bulk Drugs containing Hormones and Other Bulk Drugs



With the above figure, we can safely conclude that it was due to the sharp decline in the import of other bulk drugs that the import of bulk drugs had declined. Bulk drugs containing hormones did not play any role in the decline in bulk drug import.

3.4 Direction of Indian Pharmaceutical Trade

This section examines the direction of India's foreign trade in pharmaceutical products. For the analysis, India's trading partners are divided into three groups. Countries are grouped on the basis of their per capita gross domestic product in the year 1998. We followed the method of classification adopted by the United Nations Conference on Trade and Development (UNCTAD) in grouping the countries (UNCTAD 2000), as;

Above $ 4000 -- High Income Countries

Between $ 800 and $ 4000 -- Middle Income Countries and

Less than $ 800 -- Low Income Countries.

The results of the analysis are summarised below.

Table 3.7 Destination of India's Pharmaceutical Export (% shares in the total exports)

Year	*High Income Countries*	*Middle Income Countries*	*Low Income Countries*
1987-88	41.27	39.45	19.29
1988-89	41.77	41.19	17.04
1989-90	43.63	46.82	9.55
1990-91	42.77	40.46	16.78
1991-92	46.15	38.46	15.39
1992-93	55.99	18.84	25.17
1993-94	49.59	27.10	23.30
1994-95	46.93	26.35	26.72
1995-96	47.76	23.75	28.48
1996-97	53.35	21.79	24.87
1997-98	39.63	25.03	35.34
1998-99	47.29	17.26	35.44
1999-2000	37.53	24.58	37.89

Source: Various issues of Statistics of Foreign Trade of India by Countries

The above table reveals that, as far as the destination of Indian pharmaceutical exports are concerned, the share of high income countries showed fluctuating, but increasing trend during the period. Nevertheless, its share had received setbacks in the years 1997-98 and 1999-2000. High-income countries, which accounted for about half of the pharmaceutical exports, lost its top position to low income countries. The middle income countries increased their share in the initial years. But its share started showing a declining trend after 1990-91, which has more or less continued in the rest of the period. The countries that improved their share in India's pharmaceutical exports are the low-income countries. Low-income countries that accounted for just 10-20 per cent of India's pharmaceutical exports, now occupies the first position with a share of 37.89 per cent in export in the year 1999-2000.

Table 3.8 Sources of India's Pharmaceutical Import (% shares in the total import)

Year	*High Income Countries*	*Middle Income Countries*	*Low Income Countries*
1987-88	94.87	1.70	3.43
1988-89	94.10	3.08	2.82
1989-90	97.58	2.30	0.12
1990-91	95.69	4.04	0.27
1991-92	96.83	2.89	0.29
1992-93	95.53	3.82	0.64
1993-94	98.29	0.26	1 .45
1994-95	98.76	0.65	0.59
1995-96	95.30	1.07	3.63
1996-97	84.99	1.13	13.88
1997-98	90.95	1.03	8.02
1998-99	92.06	0.80	7.14
1999-2000	87.42	2.32	10.26

Source: Various issues of Statistics of Foreign Trade of India by Countries

As far as India's import of pharmaceutical products are concerned, in the initial years of our analysis up to the mid 1990s, it was almost entirely supplied by the high-income countries. But towards the latter half, the other two country groups have enhanced their shares in the import of pharmaceutical products. Middle income countries have increased their share marginally from 1.70 per cent to 2.32 per cent during the period. At the same time, a creditable performance was noticed in the case of low-income countries. They increased their share from a meager 3.43 per cent to 10.26 per cent. But, still more than 85 per cent of India's pharmaceutical import are coming from the high income countries.

To sum up the analysis of direction of India's pharmaceutical trade, we found that in the case of both export and import, it was the low-income countries that have increased their shares during the period of analysis. While in the case destination of export, they occupy the first position, their share in import is still only around 10 per cent and about 85 per cent of India's import of pharmaceutical products are coming from the high income countries.

3.5 COMPARATIVE ADVANTAGE IN PHARMACEUTICAL PRODUCTS

3.5.1 Theoretical Framework

Comparative advantage is an important concept central to economic theory. A better understanding of how it pertains to the actual world is useful for identifying the consequences of policy shifts and in clarifying economic welfare. Empirical measures of aggregate comparative advantage can identify the overall direction and thrust in which a country's investment and trade should take in order to exploit international differences in product and factor supply and demand. Also, disaggregated measures of comparative advantage may be used to evaluate socially desirable specialisation patterns along narrow product lines (Vollrath 1991).

Ideally, any measure of comparative advantage should reflect regional or cross country differences within a hypothetical pre-trade environment, known as autarky[5]. Since in reality all the countries engage in some level of international trade, 'true' comparative advantage in autarky cannot be directly observed. Bela Balassa (1965) introduced the notion of "Revealed Comparative Advantage"(RCA) as a way to approximate comparative advantage in autarky. Quoting him "comparative advantage appears to be the outcome of number of factors, some measurable, others not, some easily pinned down, others less so. One wonders therefore more could not be gained if, instead of enunciating general principles and trying to apply these to explain actual trade flows, one look the observed pattern of trade as a point of departure". Balassa contends that comparative advantage can be revealed through the examination of real world country/commodity trade patterns because actual exchange "reflects relative costs as well as differences in non price factors". Since the actual pattern of trade observed during a period reflects the influence of all types of factors, some index of export performance of the country in respect to different commodities could be derived to indicate the pattern of comparative advantage. Since this pattern in comparative advantage is revealed by the observed pattern of trade flows, it is called "revealed comparative advantage".

The methodology of measuring the RCA is as follows. In the first instance, the country for which RCA needs to be measured and the group of countries among whom the dynamics of comparative advantage needs to be analysed should be selected. Let,

[5] Autarky is a condition where equilibrium prices are unaffected by influences external to an economy.

$X_{ij}w^{(t)}$ = Export of i^{th} product by the j^{th} country to the world in the year t.

$X_{io}w^{(t)}$ = Total export of the i^{th} product, by all countries in the world in the year t.

$X_{oj}w^{(t)}$ = Total export of the country j to the world in the year t.

$X_{oo}w^{(t)}$ = Total export of all products by all countries in the world in the year t.

Revealed comparative advantage indices for i^{th} product of country j in the period t, $RCA_{ij}^{(t)}$ is defined as,

$$RCA_{ij}^{(t)} = \frac{X_{ij}w^{(t)} / X_{io}w^{(t)}}{X_{oj}w^{(t)} / X_{oo}w^{(t)}}$$

This is nothing but the share of exports of the product i by country j in its total exports deflated by the country's share in world exports. RCA_{ij} may take values from zero to infinity with values greater than unity indicating the existence of revealed comparative advantage for the product i for country j.

Stating simply, a country's revealed comparative advantage in the trade of a particular industry has generally been measured by the share of that industry in the country's total exports relative to the country's share in the total world export. If this index is less than unity, it is generally interpreted to mean that the country is at a comparative disadvantage in the trade of the product in question. However if the index exceeds unity (which occurs when industry's share in the country's exports exceeds its share in world trade) this is taken to indicate that the country has a revealed comparative advantage in the sector.

A particular attraction of RCA indices is that it can be easily quantified in the form of an index that can be tested for various types of inter-industry and inter-country comparisons. But the Index is not free from limitations. A number of assumptions of the model have been challenged as being at odds with the existing institutional realities (Yeats 1985). For example, the RCA model requires that existing trade barriers do not discriminate among the alternative suppliers of the same product. However, in reality, there are discriminations among the suppliers of the same product like general v/s most favoured nation tariff on items. Furthermore, the model cannot account for trade distortions associated with national production and export incentives (like subsidies) that are applied to a wide range of agricultural and manufactured products. It has not proved possible to assess empirically the degree to which these factors bias the RCA results. Bowen (1983) specifically critisises RCA

indices by pointing out that RCA treats export and import separately, when comparative advantage is properly a net trade concept. To circumvent this problem, he developed an alternative method of RCA using two indices called net trade index and production intensity index, which are based up on the relationship between a country's production, consumption and trade of a commodity relative to what would occur in a hypothetical neutral comparative advantage world.

3.5.2 Results of the RCA Analysis

Despite its limitations, the method of RCA advocated by Balassa is one of the most frequently used method among the quantitative approaches for the analysis of comparative advantage. We choose four countries, two leading exporters of pharmaceutical products from developed as well as developing world namely, the United Kingdom (UK), Switzerland, Peoples Republic of China and Brazil, whose foreign trade are compared along with India to compute the RCA indices for pharmaceutical products. The year for which these indices are computed is 1995.

Table 3.9 RCA Indices for Pharmaceutical Products

Country	X_{ij}/X_{io}	X_{oj}/X_{oo}	*RCA Index*
U K	15.53	4.74	3.28
Switzerland	13.69	1.59	8.95
China	1.39	2.91	0.48
Brazil	0.25	0.91	0.27
India	1.35	0.6	2.25

Source: India Trades

The computed RCA indices clearly reveals that India has a comparative advantage in the trade of pharmaceutical products. The two countries from the developed world, U K and Switzerland also have comparative advantage in the same. At the same time, China and Brazil, India's competitors in the trade of pharmaceutical products from the developing world, do not have the comparative advantage, since their computed RCA indices are turned to be less than one.

One of the attractions of the RCA method is that it is possible to quantify the comparative advantage at the disaggregated level. So to capture more information about the pattern of comparative advantage in pharmaceutical products, we computed the RCA indices of pharmaceutical products of the four countries along with India at four-digit level of ITC. The results are shown in the Tables 3.10 to 3.14.

Table 3.10 RCA Indices for Pharmaceutical Products of United Kingdom

Product category (Four Digit .ITC)	X_{ij}/X_{io}	X_{oj}/X_{oo}	*RCA Index*
I	13.17	4.74	2.78
II	4.63	4.74	0.98
III	9.8	4.74	2.07
IV	18.05	4.74	3.81
V	10.56	4.74	2.23
VI	15.79	4.74	3.33

Source: India Trades

Table 3.11 RCA Indices for Pharmaceutical Products of Switzerland

Product category (Four Digit .ITC)	X_{ij}/X_{io}	X_{oj}/X_{oo}	*RCA Index*
I	6.66	1.53	4.35
II	14.98	1.53	9.79
III	7.03	1.53	4.59
IV	13.91	1.53	9.09
V	24.43	1.53	15.97
VI	6.82	1.53	4.46

Source: India Trades

Table 3.12 RCA Indices for Pharmaceutical Products of China

Product category (Four Digit .ITC)	X_{ij}/X_{io}	X_{oj}/X_{oo}	*RCA Index*
I	5.45	2.91	1.87
II	0.22	2.91	0.08
III	1.95	2.91	0.67
IV	0.84	2.91	0.29
V	13.06	2.91	4.49
VI	1.16	2.91	0.40

Source: India Trades

Table 3.13 RCA Indices for Pharmaceutical Products of Brazil

Product category (Four Digit .ITC)	X_{ij}/X_{io}	X_{oj}/X_{oo}	*RCA Index*
I	2.09	0.91	2.30
II	0.11	0.91	0.12
III	0.60	0.91	0.66
IV	0.15	0.91	0.16
V	0.20	0.91	0.22
VI	1.33	0.91	1.46

Source: India Trades

Table 3.14 RCA Indices for Pharmaceutical Products of India

Product category (Four Digit .ITC)	X_{ij}/X_{io}	X_{oj}/X_{oo}	*RCA Index*
I	0.24	0.6	0.40
II	0.21	0.6	0.35
III	3.98	0.6	6.60
IV	1.49	0.6	2.48
V	0.33	0.6	0.55
VI	0.24	0.6	0.40

Source: India Trades

The computed RCA indices, that are listed above, shows that the United Kingdom has the comparative advantage in the trade of all except one, product category of pharmaceutical

products. Its comparative advantage is highest in the trade of formulations. Switzerland is the only country in our analysis that has comparative advantage in the trade of all categories of pharmaceutical products at the four-digit disaggragate level. Its comparative advantage is highest in the trade of V^{th} category consisting wadding, gauze and similar products. China has comparative advantage in the trade of category consisting glands and other organs for organotherapeutic uses and category of Wadding, gauze and similar products though at the aggregate level it lacks comparative advantage. Similarly, Brazil has comparative advantage in the trade of category consisting glands and other organs for organotherapeutic uses and category consisting surgical catgut, blood-grouping reagents, first aid boxes and kits etc. As far as India is concerned, unlike the other two developing countries, it possesses comparative advantage in the trade of bulk drugs and formulations and its comparative advantage is higher in the trade of bulk drugs

To sum up, the quantitative analysis of comparative advantage using the Revealed Comparative Advantage indices clearly establishes that India holds a comparative advantage in the trade of pharmaceutical products, while its major competitors from the developing world do not. This calls for proactive policies from the part of government to encourage the export of pharmaceutical products to capture the opportunities.

3.6 Conclusion

In this Chapter we tested the hypothesis that increased trade in pharmaceutical products does not necessarily result in negative impacts on developing countries by way of worsening balance of trade. The computed balance of trade for pharmaceutical products of India reveals that the country had a positive balance of trade in pharmaceutical products, which is showing an increasing trend. This finding validates the hypothesis. We also examined various aspects covering India's foreign trade in pharmaceutical products. We found that the share of pharmaceutical products in India's foreign trade have increased in the case of export, while it declined in the case of import, especially after the year 1991. When we tested the growth pattern of pharmaceutical export, it was found that there occurred a trend break in the year 1991 and the growth rate is higher in the pre-reform period compared to post-reform period. It was found that India's export of pharmaceutical products are almost entirely contributed by the category of bulk drugs and formulations and it was the latter that accounted for the rapid growth of export during the period. Major chunk of the import was contributed by the

category of blood fractions etc products, bulk drugs and formulations and we found that the decline in the import of bulk drugs resulted in the fall of pharmaceutical import. The analysis of direction of pharmaceutical trade reveals that as far the destination of export is concerned, the low-income countries have consistently improved their share to occupy the first position. They improved their share in the import also, but still about 85 per cent of pharmaceutical import are contributed by the high-income countries. We quantified the comparative advantage in the trade of pharmaceutical products using the RCA method advocated by Balassa and found that India possess a comparative advantage in the global trade of pharmaceutical products.

To conclude, some encouraging signs have been observed in the Indian pharmaceutical trade. First of all, India's balance of trade in the pharmaceutical products is positive and is also showing a rising trend. Secondly, we are exporting more value-added formulations than bulk drugs. Thirdly, India's dependence on imported bulk drugs are coming down, which is a good sign since self-sufficiency in the production of bulk drugs is said to be a true indicator of strong domestic pharmaceutical industry. Finally, India holds the comparative advantage in the trade of pharmaceutical products, when its competitors from the developing world do not have the same.

Chapter IV

TRIPS AND INDIAN PHARMACEUTICAL INDUSTRY

4.1 Introduction

The Uruguay Round of multilateral trade negotiations, eighth in the series, was launched in September 1986 at Punte Del Este, Uruguay and concluded in December 1993 at Geneva. The Uruguay Round was perhaps the most complex and controversial, compared to the earlier Rounds of GATT, as its agenda went well beyond the area of merchandise trade. Traditionally GATT has been regarded as a forum for establishing international trade rules in the goods sector. In the Uruguay Round, the multilateral trade negotiations encompassed not only the traditional goods sector, but also extended to three new areas, namely, investment, intellectual property rights and services. Even within the goods sector, the negotiations covered the sensitive areas of agriculture and textiles, which have remained untouched by GATT disciplines for decades. On April 15, 1994, the ministers of member countries signed the Final Act embodying the results of Uruguay Round and establishing the WTO. The WTO came into force on January 1, 1995.

Being a signatory of Uruguay Round, India is going to introduce product patent for pharmaceutical products in 2005 to comply with WTO Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) provisions. The introduction of product patent is expected to lead to a shakeout in the pharmaceutical industry of the country. The present chapter analyses the TRIPS Agreement and its possible impact on Indian pharmaceutical industry. Another issue explored in the chapter is the strategies adopted by the Indian pharmaceutical companies to face the impending product patent regime. The chapter is organised in four sections. Section 4.2 examines the TRIPS Agreement and its impact on Indian pharmaceutical industry. Section 4.3 traces out the strategies adopted by the major Indian pharmaceutical companies as a response to the tightening patent regime. Section 4.4 draws some conclusions.

4.2 TRIPS and Indian Pharmaceutical Industry

4.2.1 The TRIPS Agreement

One of the most significant developments of the Uruguay Round of multilateral trade negotiations was the inclusion of TRIPS issues on the agenda of multilateral trading system. To many outsiders, it was a surprise that something as "esoteric" as intellectual property found its way on to the agenda of an institution that has traditionally been concerned with reduction of trade barriers (Braga and Fink 2001). Intellectual Property Rights (IPRs) became a trade issue for a number of reasons. International trade in goods embodying IPRs increased substantially as the shares of manufacture in total merchandise trade has expanded and with in the manufactures the share of 'high technology' goods increased. Starting from 1980s, a number of industrialised country Governments perceived that inadequate enforcement of IPRs in importing countries is reducing the comparative advantage of their exporting firms. Thus, they strongly argued for the inclusion of IPRs in the agenda of Uruguay Round (Hoekman and Kostechi 2001).

An intellectual property is a creation of mind. It can be defined as information that has economic value when put into use in the market place. It is a generic term used for a set of legal instruments that delineate the exclusive rights granted to creators of knowledge and information. These instruments seek to address certain failures of private markets to provide an efficient allocation of resources. Broadly IPRs can be divided into two groups. The first group consists of patents, industrial designs, copyrights, plant breeder's rights and layout designs for integrated circuits that grant exclusive rights to new innovations and original works of authorship for a limited period. The second group consists of trademarks and geographical indicators that protect the use of words, signs and symbols associated with a particular product or company facilitating the market transactions by assuring consumers that they are purchasing what they intended to purchase (Braga and Fink 2001).

Historically, IPRs are always granted on territorial basis, i.e. each nation protects IPRs only in so far as these rights are exercised in the domestic economy. This obviously led to conflicts among nations on the issues of nondiscrimination and differing standards across nations. Several international conventions were organised that laid down standards for protection of intellectual property. These include Paris Convention (on patents), the Berne Convention (on

copyrights) and Rome Convention (on sound recording and music). These and other conventions were administered by World Intellectual Property Organisation (WIPO), a Geneva based specialised agency of United Nations. Though WIPO conventions achieved some degree of success in nondiscrimination with respect to application of IPRs, they failed to establish a uniform minimum international standard of protection. With growing significance of IPR sensitive goods in the international trade, the producers of intellectual property became increasingly dissatisfied with WIPO's effectiveness. It was their strong advocacy that ultimately led to the inclusion of TRIPS issues in the agenda of Uruguay Round (Braga and Fink 2001).

The negotiations on TRIPS in the Uruguay Round were marked by significant North-South disagreement. Industrialised countries that are the exporters of IPR related products sought an ambitious and comprehensive agreement on standards of protection of IPRs of all kinds. Developing countries, on the other hand, strongly opposed enforcement of IPR standards arguing that it would be detrimental to their welfare and development prospects. They argued that TRIPS are outside the mandate of GATT and thus WIPO is the appropriate forum for the setting and enforcing standards. However, the opposition of developing countries was not universal. Some interest groups within developing countries favoured stronger IPRs (Hoekman and Kostechi 2001, Braga and Fink 2001).

After the lengthy discussion, the TRIPS Agreement was signed at the ministerial conference in Marrakech on April 1994 as a part of the Final Act of the Uruguay Round. TRIPS is one of the three multilateral agreements[1] that form the tripod as the basis for the WTO and hence is binding on all WTO members. TRIPS defines minimum standards of protection and sets out basic procedures that deal with the enforcement of IPRs. TRIPS also require nondiscrimination with regard to the application of IPRs. Moreover, the Agreement makes dispute between member countries with regard to their TRIPS obligations subject to the WTO's dispute settlement system. TRIPS is a complex agreement containing disciplines in seven areas of intellectual property (copyrights, trademarks, geographical indication, industrial designs, patents, layout designs of integrated circuits and undisclosed information) and 73 articles. Its major provisions are summarised in Table 4.1.

[1] The other two are Multilateral Agreement on Trade in Goods and General Agreement on Trade in Services (GATS). All the other WTO Agreements are plurilateral in the sense they are applicable only to those members that accept them.

Table 4.1 Major Provisions of the TRIPS Agreement

Article	*Subject*	*Comments*
3	National Treatment	Applies to persons
4	Most Favoured Nation Treatment	Reciprocity exemptions for copy rights; grandfathering of existing regional and bilateral agreements.
6	Exhaustion	No rule imposed except nondiscrimination.
	Copyright and related rights	
9	Observes Berne Convention	Does not require moral rights.
10	Programs and data compilations protected as literary works	A significant change in global norms.
11	Rental Rights	A significant change in global norms.
12	Neighboring rights protection for phonogram producers and performers	
	Trademark and related marks	
15	Protectable subject matter	Confirms and clarifies Paris Convention.
16	Rights conferred	Deters use of confusing marks and speculative registration; strengthens protection of well-known marks.
19	Requirement of use	Clarifies nonuse. Deters use of collateral restrictions to invalidate marks
21	Licensing and assignment of rights	Prohibits compulsory licensing.
22-4	Geographical indications	Definitions, additional protection for wines and spirits.
	Industrial designs	
26	Protection	Minimum term of protection of 10 years.
	Patents	
27	Subject matter coverage	Patents provided for products and processes in all fields of technology. Biotechnology covered but exception allowed for plants and animals developed by traditional methods.
28	Exclusive right for importation	
31	Other use without the authorisation of the right holder	Severe restriction on compulsory licenses. Domestic production can no longer be required; nonexclusive licenses with adequate compensation.
33	Duration of protection	Minimum 20-year patent length from filing date.
34	Burden of proof in process patents	Defendants must prove process differs from patents.

(Table Continued.....)

	Integrated circuit designs	
36	Scope of protection	Protection extended to articles incorporating infringed design. Significant change in global norms.
38	Term of protection	Minimum 10 years.
	Protection of undisclosed information	
39	Trade secrets protected against unfair methods of disclosure	New in many developing countries.
	Abuse & enforcement of IPRs	
40	Control of anticompetitive practices	Wide latitude for competition policy to control competitive abuses subject to other WTO disciplines.
41-61	Requires civil and criminal enforcement	Costly for developing countries to implement. No nonviolation cases to be brought for first five years.
	Transitional arrangements	
65-66	Transition periods	5 years for developing and transition economies; 11 for LDCs. Only latter can request extension.
70	Pipeline protection for pharmaceuticals	Not required, provisions for maintaining novelty and exclusive marketing rights.
	Institutional arrangements	
71	Review and amendment	TRIPs council to monitor and review agreement on expiration of transitional period.

Source: Hoekman and Kostecki (2001)

Out of the seven areas of intellectual property dealt by the TRIPS, the most controversial and important from the point of view of implementation and operation are the provisions related to patents. WTO members have to comply with provisions of Paris Convention (1967) on patents. At least 20-year patent protection should be provided for almost all inventions, including both processes and products. This lower bound stipulated in the Agreement implies harmonisation towards the standards maintained by the industrialised countries (Hoekman and Kostechi 2001). If a WTO Member feels that the use of an invention will harm (i) public order or public morality or (ii) environment, it can exclude the particular invention from patentability (Das 1998).

In the case of a patent on a product, the owner will have exclusive rights to prevent any body from making, using, selling, offering for sale or importing the product without his consent. But a Member can authorise the use of the patent without the consent of the owner in the following circumstances: (i) national emergency or some other extreme urgency, or for public

non-commercial use and (ii) in other cases, if the proposed user has made efforts to get authorisation from the owner on reasonable commercial terms and conditions, and has not been able to get the authorisation with in a reasonable period of time. This situation emerges when the right holder is not willing to use the patent or let others use it, resulting in the scarcity of the product in the country and thus adversely affecting public interest (Das 1998).

Developed countries have to apply Agreement on TRIPS latest before the expiry of one year from the entry into force of WTO Agreements. Developing countries have to implement it before 1st January 1995. Least developed member countries have the flexibility to introduce TRIPS before 1st January 2006. With respect to developing countries, who presently do not have the system of product patent can further delay the application of the provisions related to product patent by an additional period of 5 years. But during the pendency of implementation they have to take certain measures with respect to pharmaceuticals and agrochemical products. Article 70.8 of TRIPS (Mailbox provision) requires that, from 1st January 1995, these countries have to establish a system that will permit innovators to file patent application for such products. In addition, as per Article 70.9, when the required conditions are met, they have to grant Exclusive Marketing Rights (EMRs) to the patent applications that were registered in the Mailbox. The purpose was to give the inventors of pharmaceuticals and agrochemical products the economic privilege of EMRs for the five-year period preceding 1st January 2005, if their products are denied patentablity even beyond the normal five-year transitional period for developing countries. There is a policy option called Compulsory License (CL) as per Article 31 of TRIPS that can be used by developing countries. A CL allows the use of the invention by a person who has been given the permission by the competent authority, on the grounds of emergency or extreme urgency, anti competitive practices, public non-commercial use, protection of the environment and in public interest. However, as per the Article, as and when the conditions that led to the issue of the CL no longer exist, the license should be revoked.

4.2.2 Impact of TRIPS Agreement on Indian Pharmaceutical Industry

Patents are more important to pharmaceutical industry than any other corporate sector. Since development of a new chemical entity (NCE) takes long period and imposes high risk on investors, patent protection is deemed to be crucial for continuing innovation in the Industry. Patents grant their owners exclusive property rights over the subsequent exploitation of the

new product. This creates a barrier of entry and the firm will continue to receive monopoly rents until the expiry of the patent.

Turning to Indian scenario, under Indian Patent Act (1970), there is no product patent protection for pharmaceutical products. There is only process patent protection (See Chapter 2, Section 2.3). The duration of process patent protection is only seven years from the date of filing or five years from the date of sealing whichever is shorter[2]. Given the lengthy development time required for pharmaceutical products due to the mandatory regulatory requirement for safety, quality and efficacy, and testing of drugs, a seven-year old process term is so short that the patent "protection" would expire even before the relevant product is ready for market launch. This weak patent law allowed Indian pharmaceutical companies to reproduce and market drugs through different processes, typically within one or two years of their invention, at only a fraction of the cost of patented drugs in developed countries.

On April 15 1994, India became a member of WTO, along with 124 nations. After the membership, it has become obligatory for India to comply with various WTO Agreements, including that of TRIPS. TRIPS Agreement requires both product and process patents in all fields. Thus, India has to change its patent laws. But, Indian Governments have refrained from adopting the various provisions of the TRIPS due to the sharp resistance from various sections of the public. Meantime, the United States and European Union brought out cases against India alleging the absence of effective system for providing EMRs for pharmaceuticals and agrochemical products (a violation of Article 70.9 of TRIPs). WTO panel and appellate body reports issued in 1998 concluded that India had failed to establish a legal basis that adequately preserves novelty and priority with respect to application of product patents for pharmaceuticals and agrochemical product inventions and failed to establish a system for granting of EMRs. India was asked to take necessary steps to amend its patent law to meet the WTO obligations by April 1999. In order to fulfill the obligations, the Government of India promulgated the Patent (Amendment) Ordinance on January 8 1999, changing the IPA 1970 in line with WTO norms. The ordinance provides for (a) filing of applications for product patents in the field of pharmaceuticals and agrochemical products and (b) granting of EMRs for the applicant after a set of legal conditions are fulfilled. It also requires product patents from 1st January 2005 as per WTO obligations.

[2] Compared to 16-20 years from the date of filing in Europe and 17 years from the date of granting in the United States at that time.

There exists a popular concern in the country that changing IPA in accordance with TRIPS provisions will lead to acceleration in the drug prices, making it unaffordable for the common people. But a close examination of the transition mechanism to product patent envisaged in the TRIPS appears to be reducing such apprehensions. The transition mechanism ensures that patents in India will only be granted for totally new discoveries, post January 1 1995. This means that drugs already available in the Indian market, on the date of coming into force of the new law, cannot and will not be patented in India. It takes 8 to 12 years for a new drug to be granted registration by authorities of any country, after which the marketing permission is given. When we deduct this period from the patent life of 20 years as per TRIPs, the inventor enjoys at best only 8-12 years of exclusive marketing for recovering the cost of research. The number of drugs registered worldwide each year is between 25-35. This essentially means that within the transition period (1995-2004) allowed for India, only a handful of new drugs will actually qualify for any form of exclusivity. Even after India starts granting patents, by the time patented products become a significant proportion of those already available locally, it will be another 10-15 years i.e. by 2015-2020. Thus, the impact of TRIPS Agreement on the prices of drugs is likely to be limited, even though the impact might gradually increase over time. At this point, it is difficult to predict how far, if at all, the prices of patented drugs might increase after the introduction of product patent on January 1 2005[3].

In the long run, changes in patent laws in conformity with TRIPS provisions may encourage many firms in India and in other developing countries to undertake more research in inventing drugs for diseases specific to their countries, rather than focusing on cheaply reproducing drugs invented in developed countries.

An emerging area in which lies a big opportunity for Indian pharmaceutical companies is the expanding market for generics (off-patent drugs). Worldwide generic markets are growing at a faster rate than that of patented products. For example it is estimated that in the US market alone drugs worth $ 35 billion are going to loose monopoly provided by the patent by the year 2005. The Indian pharmaceutical industry can very well utilise this opportunity since it can produce and supply generics at cheap prices. Some of the top drugs that are going off-patent are shown in Table 4.2.

[3] We think that the cross country comparison of drug prices can be misleading, since the prices, whether the drugs are covered by patent protection or not, are influenced by many demand side factors,including the existence of health insurance system .

Table 4.2: Major Drugs Going off Patent During 2002-2005

Year of Patent Expiry	*Drug Name*	*Indication*	*Patent Holder*	*Sales in 2000 (US $ Million)*
2002	Purimicort	Asthma	Astra	706
2002	Clarithin	Allergy	Sehering Plough	1250
2002	Buspar	Anti-depressant	Bristol-Myers Squibb	531
2002	Astrovennt	Asthma	Boehringer	800
2003	Letesion	Hypertension	Novartis	600
2003	Cipro	Infections	Bayer	1300
2003	Cardura	Cardiac	Pfizer	900
2003	Blaxin	Infections	Takeda Abbott	950
2003	Wellbutrin	Anti-depressant	Glaxo-Wellcome	900
2004	Taxol	Cancer	Smithkline Pharma	950
2004	Lupron	Fertility	Takeda Abbott	850
2004	Lovenox	Anti-clotting	Rhone Poulenc Rover	600
2004	Diflucon	Cardiasis	Pfizer	910
2005	Zololoft	Anti-depressant	Pfizer	1545
2005	Zofran	Vomiting	Glaxo-Wellcome	650
2005	Zocor	Hyperlipidaemia	Merck	2100
2005	Zithromax	Infectious	Pfizer	1400
2005	Prevacid	Peptic ulcer	Takeda Abbott	2400
2005	Prevacol	Cholesterol	Bristol-Myers Squibb	1100
2005	Paxil	Anti-depressant	Smithkline Pharma	1600
2005	Combivir	AIDS	Glaxo-Wellcome	800

Source: Surendar (2000).

After the Doha Ministerial Declaration[4], the member governments will now be able to circumvent patent laws and ask generic manufactures to produce drugs that are covered by patent, on the grounds of public health. In other words, the governments will be able to invoke CL rules that allow them to ask other drug manufactures to produce patented drugs. Individual countries are now free to determine when and where they should grant a CL and for which disease. For instance, the Indian government can ask the multinational patent holder of a life

[4] WTO Ministerial Conference, Doha, November 9-14, 2001.

saving medicine to lower its price, failing which it can ask Indian pharmaceutical companies to produce the drug. The beneficiary of the CL would be Indian pharmaceutical industry, because it can make generics that are vastly less expensive than patented drugs produced in the developed countries. Doha Declaration even allows member countries to shop around for drugs from markets where their prices are lowest, under the Parallel Import clause. Here also Indian drug manufactures stand to gain because only China, Brazil and India have the ability to produce the cheap generics. India will be the first choice as quality is assured at attractive prices (Subbu 2001, Nair 2001).

4.3 Strategies of Indian Pharmaceutical Companies: An Analysis

The corporate strategies in the world pharmaceutical industry are undergoing a pronounced change. The pharmaceutical companies are resorting to the strategy of consolidation (mergers and acquisitions [M&A]) and collaboration (alliances and joint ventures) to gain a critical size for facing the future challenges.

As far as the Indian pharmaceutical companies are concerned, the strategy of M&A can enable them to utilise the scale and scope economies. Economies of scale will decrease the average cost through technological economies, which affect the minimum size of the plant in the industry, or managerial economies which result in lower production and distribution costs. Economies of scope result from the increase in the number of products offered. Companies will be able to utilise one set of inputs to provide a broader range of products and services. M&A can also facilitate Indian companies to enter into the new geographical and therapeutic markets.

For the Indian pharmaceutical companies to survive in the post product patent era, they will have to develop drugs through original R&D, which is beyond the means of Indian companies, even the large ones. The spate of consolidation activities that are currently taking place in the Indian pharmaceutical industry is mainly attributed to this fact. The bigger size post M&A will allow companies to invest more on R&D. By forging alliances with multinational companies, Indian companies can become a part of overall drug development chain, under which, if they discover an active compound, they can license its drug development to the multinational partner and in turn receive milestone payments as the molecule goes through various trials and approvals.

Another reason for the process of consolidation that are taking place in the Indian pharmaceutical Industry is the rapidly growing global generics market. Increasing consumer pressure on prices and expiry of number of patents are leading to the genericisation of pharmaceutical industry worldwide. With their expertise in cost effective process technology, Indian pharmaceutical companies are looking at the global generics markets as a bright opportunity. Some of the major Indian companies are trying to setup manufacturing facilities abroad and also acquire foreign companies to tap the opportunity. While the strategy of setting up manufacturing facilities abroad and acquiring foreign companies are expensive and limited to a handful of players a large number of companies are entering alliances and tie-ups with foreign firms to capture the overseas generics market.

The comeback of multinational pharmaceutical companies to the Indian market also contributed towards increased consolidation activities in the Indian pharma scenario. MNCs, with an eye on post product patent period, are seeking strategic alliances and co-promotion of their products with deeply entrenched Indian companies that have marketing wherewithal and expertise. Thus, MNCs are trying to occupy the presence in the country though not necessarily with manufacturing or marketing base. Many Indian companies are entering into marketing alliances with MNCs. It appears that this strategy is particularly attractive to mid sized Indian companies who see it as a focused growth path in a future dominated by big manufacturing companies. Some of them are also putting investments to become contract researchers for MNCs. The following section analyses specific strategies adopted by major Indian pharmaceutical companies as a response to the impending product patent regime.

4.3.1 Cipla Limited

With the domestic sale worth Rs 828 crore (total turnover 1086crore) in the year 2000-2001, the Mumbai based Cipla limited is the second largest pharmaceutical company in India[5]. For many years Cipla has been concentrating its efforts on the Indian market. As a result, it has become the largest domestic formulation company with a basket containing about 300 brands. India is Cipla's only manufacturing base. On the domestic front, it has entered into co-marketing arrangement with another pharma major Ranbaxy to market Ranbaxy's once-a-day formulation of Ciprofloxacin. The two companies have also marketed four drugs in the anti-cholesterol, cardiovascular, ant-infectant and ant-depressant segments

[5] Behind the multinational company Glaxo-Smithkline.

For the financial year 2000-01, exports constitute 25 percent of Cipla's turnover. It exports its products to 105 countries. 39 per cent of its exports are to the US. Other export markets include Europe (19%), Africa (16%), the Middle East (15%), Asia (8%) and Australia (3%).

In the overseas market, Cipla follows the strategy of working with partners. Zenith Goldline is Cipla's marketing partner in the US and that of UK is Neolab UK. Cipla has supply-cum-marketing arrangement with US generic manufacturer, Geneva Pharmaceuticals, Novopharma of Canada and Genpharma of Australia. The advantage of this strategy for Cipla is that its overseas partners have an established presence with big portfolio of drugs. While Cipla entirely controls Indian area, its partners in each region look after the business in that region and takes decision regarding pricing, products and registration. Cipla had tie-up with American generic manufacturer, Andrax Corporation, for supplying Omeprazole. This is the generic version of Astra Zeneca's blockbuster anti-ulcerent drug Prilosec, one of the world's largest prescribed drug with global sales of $ 6.3 billion

Cipla worked its way to top in India through its strength in reverse engineering. It had opted to follow the basic research stream and is yet to announce plans for discovery research, while the other major companies have done so. This can lead Cipla into trouble in the post 2005 scenario. Cipla's game plan for the future is to concentrate more on exports. Its main focus is US generics market. Cipla hopes to file eight Abbreviated New Drug Applications (ANDAs) for marketing drugs that go off-patent between the year 2003 and 2006. The Company had already invested Rs. 60 crore in a new facility in Maharashtra to make generic formulations. Cipla hopes to fill the losses in the post 2005 period through its increasing generic business in the overseas, especially in the US.

4.3.2 Ranbaxy Laboratories Limited (RLL)

The Delhi based Ranbaxy laboratories ranks third in the Indian market with domestic sales of Rs.749 crores (global turnover Rs 1745.9 crores) in the fiscal year 2000-01.Unlike Cipla that primarily concentrated on domestic market, Ranbaxy is a global player with roots in number of countries across the globe. In the latter half of the 1990s, when Ranbaxy aggressively followed the global market, it began to affect its domestic business. At that time, the Company resorted to acquisitions in the country. In quick succession, it took over brands like Mox, Suprimox and Zole from Gufic Laboratories, through its 100 per cent subsidiary Rexel

Laboratories. Ranbaxy's bigger catch was Crosslands, Mumbai based profitable Company with significant presence in dermatology and anti inflammatory therapeutic segments. Thus, Ranbaxy strengthened presence in the domestic market. In the domestic market, Ranbaxy is represented by its marketing arms- Pharma (prescription driven business), Stancare(vasculars), Crosslands (dermatology), Rexcel (antiinfectives), Solus (CNS segment) and Generic renamed as Blue R.

Ranbaxy was the earliest among Indian companies to recognise the opportunity lies in the global market for pharmaceuticals and take steps to capitalise on them. In the year 2000-01, overseas revenue accounted for about 60 per cent of Ranbaxy's turnover. It exports to 103 countries and has a presence in 25 countries with 6 manufacturing locations outside India (United States, Ireland, China, Malaysia, Vietnam and Nigeria) . India and US are the two main markets for Ranbaxy. Other important markets are UK, Germany, China and Brazil. The first country that Ranbaxy targeted was China, where it setup its 79 per cent subsidiary Guangzhou China Ltd. The Company began selling formulation in 1995. Ranbaxy is an early entrant into the Russian market. It went there as soon as the country disintegrated and markets opened up. Ranbaxy began its operation in the US through its 100 percent subsidiary, Ranbaxy Pharmaceuticals Inc.. In September 1996, it acquired Ohm Laboratories, the New Jersey based Company. Ranbaxy then entered into a 50:50 joint venture with Schein Pharmaceuticals and had tied up HMS, a highly successful US generic marketing firm. For the expansion of its business in Netherlands, 100 percent subsidiary Ranbaxy BV was set up and Rs 71 crore were invested in it. Ranbaxy had acquired Rima Pharmaceuticals, Ireland and had setup five other subsidiaries namely, Ranbaxy Egypt, Ranbaxy SP (Poland), Bounty Holdings (Thailand), Ranbaxy Mauritius and Basics Gombb (Germany). Now, Ranbaxy has joint ventures or subsidiaries in 14 countries. There is no other company in the world, except Teva, the Israeli Company, that has presence in as many markets as Ranbaxy. In its pipeline the Company have five NCEs .

To face the challenges of the product patent regime, Ranbaxy is equipping itself to become a research based international pharmaceutical company. The Company is allocating increasing amounts of resources towards discovery research. In the year 2000, 20 per cent of the funds went towards discovery research and 80 per cent were spend on generics research. By 2004, the Company hopes to allocate 60 per cent of funds on discovery research and 40 per cent on generics research. The Company also hopes to launch the first molecule from its original

research before the year 2005. In the future, Ranbaxy plans to get into marketing of off-patent drugs in a big way. It expects to make a foray into international market both in terms of export of generics drugs and formulations from India as well as setting up of manufacturing facilities of those drugs in the key markets around the globe. Many overseas generic formulation companies outsource their bulk drug requirements. Ranbaxy, on the other hand, is vertically integrated and can use its low cost bulk drug manufacturing base in India for generic launches overseas. Ranbaxy is therefore likely to derive more value addition than its peers in the global generics market, as it control costs throughout the value chain. The Company also looks for more acquisition of both companies and brands in the future. In the domestic front, Ranbaxy is aiming to tap the Indian rural market with its generic products. It also hopes to enter into licensing arrangements with international drug companies and manufacture their products in India. It already has worked out deals with Dual Nippon and Kowya Hakka of Japan and Eli Lilly of US to manufacture and market their products in India.

4.3.3 Dr.Reddy's Labs

Hyderabad based Dr.Reddy's Labs (DRL) set a new record in Indian pharmaceutical industry by becoming the first Indian Company to license its product to a multinational, Novo Nordisk of Denmark. Over the years, the Company has moved from being just a bulk drug producer to a significant player in the formulation business. Till 1995, DRL's growth and, infact 80 per cent of the turnover came from bulk drug business. At that time, the Company has perfected the act of quickly reproducing drugs launched by foreign firms by slightly different process and releasing it in off-patent countries at even one third the price, utilising India's weak patent law. Later DRL came to realise that sustained growth could only come from strong brands, as it witnessed falling margins as the domestic competition in bulk drug segment hotted up.

DRL resorted to the strategy of brand acquisition for the short-term growth. The first acquisition of the Company was two SOL brands, Riflux and Clamp in 1997. This was followed by the acquisition of Becelac from Pfimex. DRL acquired Styptovik, Styptomet, Styptochrome, Daxt and Trichodoi brands from Culcutta based Dolphin Laboratories. The Company recently acquired the entire range of six dental brands from Mumbai based Group Pharmaceuticals, which helped DRL to emerge as the leader in the dental segment. It also reached a co-marketing agreement with Gland Pharma, a Hyderabad based company, to lauch its intra articular injection Hyaoslosyn.

As far as the overseas markets are concerned, DRL was the first Indian Company that made a dent in the Russian market in 1991. Its joint venture, Reddy Biomed helped its brands Omez, Ciprolet and Enam to emerge as leaders in the CIS region. DRL was the first Indian Company, which successfully challenged a patent and got a 180 day marketing exclusivity in the highly regulated US generics market for Fluexetine 40mg capsules, which is a generic version of anti-depressant drug Prozac. The product was launched in August 2001 in the US market. DRL has also tied up with Genelabs and Biomerieux of France. The Company has ten registered products in the US. To sell generics products in the US, the Company has tied up with the US based pharmaceutical companies Par Pharma, Leiner Healthcare and Warrick. DRL's insulin sensitizer molecule was licensed to Novo Nordisk of Denmark and the Company has received first payment of Rs.15.15 crore for the successful phase 1 research. Novo Nordisk is the world's biggest insulin producer. If clinical trials are successful, then Novo Nordisk will launch the product world-wide and would retain the exclusive marketing rights for all the countries except India where the drug will be co-marketed with DRL, which will make the drug for global sales. In its backyard, the DRL has created an impressive pipeline of nine NCEs-the largest among all Indian companies. They fall into two major desease categories-oncology and diabetes.

It is the research that DRL is banking on for its future success in the product patent era. It hopes that the Company's future will rest on firm foundation of research and will be fuelled by formulation business. Its bulk drugs unit will support this growth and health care division will complement its core business. For the US market DRL will continue its aggressive strategy of challenging the patents and filing ANDAs. It has set a target of getting at least 40 approved ANDAs in its portfolio by 2005 and also attain a size of $ 300 million by 2005. DRL is targeting China and Brazil as its next export market. The Company is also planning acquisitions in the Europe. It is particularly keen on the generic markets of Germany and Canada. The Company will continue to look at high value opportunities in these markets. DRL enjoys the unique advantage of having the wide range of bulk actives and is fully integrated. DRL has six bulk active plants, all of them having US FDA approvals.

4.3.4 Nicholas Piramal India Limited (NPIL)

NPIL has emerged as a strong player in the Indian pharmaceutical industry entirely through its successful acquisition game. The Company has a long history of growth through acquisitions.

The focus strategy of acquisition began in 1988 when the Piramal acquired the Nicholas Laboratories. The next big acquisition was in 1993 when NPIL acquired Roche products, Indian subsidiary of Swiss multinational Hoeffman La Roche. In 1995, it acquired and merged Hyderabad based bulk drug manufacturer Sumitra Pharmaceutical and Chemical with the Company. The Company had also acquired 40 per cent stake in Rhone Poulenc (India) from the multinational Aventis SA and Boehringer Mannheim, Indian affiliate of German health care company Boehringer Mannheim AG. Recently the Company acquired ICI India Ltd., which made NPIL the top player in the cardiovascular segment. The brand buyouts of the Company include brands like Lactocalamine and Burnol.

In the overseas market, NPIL followed the strategy of alliances and takeovers. It had taken over four brands of US pharma major Eli Lilly. The Company had entered into the strategic alliance with Cytron of US and with Swiss multinational Siefried Pharma for export to Europian market. Today, NPIL's alliances and joint ventures are with illustrious international majors like Boots Healthcare International Plc, Allergan Inc and Stryker Cirp.

For the domestic market, the Company has joint venture for distribution of OTC products as Reckitt Piramal (marketing of brands like Dettol, saridon, Burnol, Lacto Calamine etc). There are joint ventures for ayurvedic products namely Solumisk Piramal and Charak Piramal. Other joint ventures are Allergan India and Scholl Piramal.

Acquisition, alliances and joint ventures gave NPIL access to technology and products to keep it going until it could build up its own research base. However, in view of the future challenges and opportunities, the Company's strategies are changing. While the focus on partnership will continue, research and foreign market have also been added into the agenda. NPIL is now looking for international thrust fuelled by research. Already the beginning has been done in export by setting up Laporte Piramal, the 100 per cent export oriented unit in Hyderabad. The worldwide marketing will be handled by a joint venture with Cultor of US. NPIL's strategic alliance with Swiss multinational Seifried Pharma is designed to leverage the latter's skill in the European market. Since the cutting edge in export will come only when the research underpinnings are in place, the Company had acquired the basic research unit of Hoechst Marion Roussel, which has since been renamed as Quest institute of Life Science. Thus, NPIL's focus is now business driven R&D, which means not just patented knowledge but getting a commercial product to the market.

4.3.5 Wockhardt Limited (WL)

Wockhardt is a fast growing Company, which is now beginning to concentrate on reviving up its brands and spending a lot of money on R&D. Wockhardt has several other businesses besides pharmaceuticals, which are going to be the part of demerged life science Company. The impending merger is due to the decision of Wockhardt to create a pure pharma Company and concentrate on Company's pharma competence. The new Company Wockhardt Life Science would have agrisciences, hospitals and IV fluids businesses.

Wockhardt has also resorted to the strategy of acquisition and joint ventures. The Company took over RR Medi Pharma in 1996. Wockhardt had acquired 100 per cent subsidiary in US, Wockhardt Americas Inc. In the same year it formed a joint venture with Rhein Biotech Gmbit of Germany for R&D of biopharmaceuticals. In 1998, Wockhardt acquired Merind from Tatas. Its acquisition of Wallis Labs enables the Company the access to European markets. The Company also had tie-up with Sidmak Labs of US.

Wockhardt has the strategy for post 2005 survival owing to huge investments on R&D. Acquisitions and joint ventures will also remain top most on the Company's agenda for the future. Wockhardt spends about 5 per cent of its turnover on R&D, in which 25 per cent goes to new drug discovery, biotechnology and drug delivery system. The Company hopes to launch its first biotech product, Erithropetin by the year 2005 in the western markets. It had already introduced the product in the Indian market. As far as other strategies are concerned, acquisition would remain as the prime strategy not for size building but for value addition. Similarly alliances and joint ventures would be aimed at market access and technology sourcing to sharpen competitiveness. The Company is also keen on developing its global business, which contribute nearly 33 per cent of the business. Wockhardt had already filed 5 ANDAs in the US.

4.3.6 Sun Pharma

Through a raft of acquisition, takeover, merger of companies and brands, the Mumbai based Sun Pharma reached one among the top Indian pharmaceutical companies. Sun Pharma has acquired the brands Coldact, Roxetomin and Natamox from Tamil Nadu Dadha Pharmaceutical Ltd. (TDPL), Natco and Milmet Laboratories respectively. Tamil Nadu Pharma and Gujart Lyka Organics Ltd. (GLOL) were merged with Sun Pharma. The Company

had also acquired the bulk drug facility of Knoll Pharma and 51.5 per cent stake of the M J Pharma. In the overseas market, it had acquired Caraco Pharma Labs of US. The Company exports its products to 48 countries.

The fundamental and discernible differentiator of Sun Pharma with other Indian pharmaceutical companies is that, its product range is only prescription-driven. Creating and marketing specialty products, by using doctors as facilitator has remained as the prime objective of the Company. Over the years the Company used the viamedia of domestic formulations and export of bulk drugs to take it forward.

To face the future challenges, Sun Pharma wants to pep up its growth with revenues from international markets. With the present level of 20 per cent of revenue coming from export and rest emanating from the domestic market, Sun Pharma is looking for a shift which will involve over the next five years altering the balance to the extent that 40 per cent of total revenue coming from export, so as to broad base the revenue stream. In the post-2005 scenario, the Company hopes that its overseas partners would leverage its network in the US and South Asian markets. Sun Pharma wants to replicate its domestic strategy in the US as well. Focus is on niche therapy, means lower brand concentration risk and fewer block buster drugs necessary to derive the growth. As far as research is concerned, Sun Pharma was a late starter in the discovery R&D, almost three years after Industry leaders Ranbaxy and DRL. The Company is now committed to spend at least 4 per cent of its turn over on R&D. Despite 80 formulations and 60 specialty bulk drugs originating from in house R&D, a question mark persists on the quality of research at the Sun Pharma R&D centers. Despite spending Rs.60 crore on R&D, the Sun Pharma hasn't filed a single patent yet. Thus, the slow progress of the NCE development of the Company can drag its growth in the future.

4.3.7 Aurobindo Pharma

Among the companies that are getting better and better is the low profile, Hyderabad based bulk drug maker Aurobindo Pharma. Aurobindo Pharma is the world's third largest producer of Semi Synthetic Penicillin (SSP). Its portfolio also includes Cepholosporins, Antivirals and Quinolones. By and large Aurobindo Pharma is a bulk drug firm with 90 per cent of its turn over comes from that business and 72 per cent of its turn over exported. Over the years the

strategy of the Company has been the sale of reverse engineered, process patented products in unregulated markets across the world.

Aurobindo Pharma had set up a joint venture with US based Med Pharmex to sell its products in US. Two other joint ventures in the US to manufacture Cepholosporins and Non Cepholosporins with total investment of 12 million will go on stream by 2003. In China the Company is trying for a joint venture in an attempt to broad base its exports.

By 2005, Aurobindo Pharma hopes to reach a turnover of Rs.2000 crore from the level of Rs 950 crore in 2000-01, with an average 25 per cent annual growth in the bulk drugs sold in regulated markets, formulation export to Europe, generic formulations for Latin America and domestic formulation market. Research is the thrust area for the Company in the future, with the recent integration of its R&D Centre. The Company had already invested Rs.25 crore in this facility and plans to put another Rs 35 crore. Development of new molecules will be the Company's long term goal. In the pipeline is a biotechnology and natural product research centre. Aurobindo Pharma also wants to reduce its dependence on bulk drugs from the current 90 per cent to 70 per cent by 2005. That means the Company will have to expand its formulation business drastically.

The spectacular growth of Aurobindo Pharma may slow down after the adoption of product patent in India, since the Company will have to stop producing drugs whose patents extends beyond 2005. The absence of NCE development is a gaping hole in the Company's strategy. The Company is yet to begin its work on R&D for new molecule, as at present that is beyond the Company's resources.

The following table summarises the above case studies.

Table 4.3 Strategies of Indian Pharmaceutical Companies

Company	*Strategies*	*Outcome*
Cipla Limited	Domestic Market -co-marketing arrangements and production of reverse-engineered products. Overseas Market -partnerships and tie-ups with foreign firms. For Future -to concentrate more on exports.	-Became the largest domestic formulation company with export to 105 countries.
Ranbaxy Laboratories Limited	Domestic Market -acquisitions and marketing alliances. Overseas Market -joint ventures and acquisitions. For Future -to become a research based international pharmaceutical company and to concentrate on generics products	-Global player with presence in 25 countries and exports to 103 countries.
Dr.Reddy's Labs	Domestic Market -brand acquisitions and co-marketing agreements Overseas Market -joint ventures and tie-ups. For Future - to increase the research and acquisitions in Europe.	-From a bulk drug producer turned to a significant player in formulation business and exports to 60 countries
Nicholas Piramal India Limited	Domestic Market -acquisitions and joint ventures Overseas Market -alliances and acquisitions. For Future -to increase research and to focus on foreign markets.	-Strong domestic player especially in the cardiovascular segments and have alliances with major international pharmaceutical companies
Wockhardt Limited	Domestic Market -acquisitions and joint ventures Overseas Market -acquisitions joint ventures. For Future - focus on research and acquisitions and joint ventures in Europe.	-Fast developing global business with exports to 94 countries
Sun Pharma	Domestic Market -mergers and acquisitions of companies and brands Overseas Market -acquisitions and alliances. For Future -more focus on export and foreign markets	-Strong domestic player with only prescription drives business and exports to 48 countries
Aurobindo Pharma	Domestic Market -production of reverse engineered products Overseas Market -joint ventures. For Future -focus on production and export of formulations.	-Major bulk drug producer and world's third largest producer of semi-synthetic penicillin.

Source: Reports of the Financial Media.

4.4 Conclusion

This chapter addressed the issues concerning the WTO Agreement of TRIPS and its impact on Indian pharmaceutical industry. Historically, the growth of Indian pharmaceutical industry was marked by the development of indigenous technological capability behind the barrier of weak patent protection, with IPA (1970) recognising only process patents. But as a signatory of Uruguay Round, India had compelled to introduce the product patent by 2005, to comply with the TRIPS Agreement. The foremost concern about TRIPS in India is that drug prices will shoot up once the product patent protection is introduced. But such apprehensions are not well founded when we analyse the transition mechanism of TRIPS, in which patents are granted only to the new discoveries and the Agreement maintains status quo on drugs available in the Indian market up to 2005. On the other hand, the TRIPS agreement is creating a new opportunity to Indian pharmaceutical industry via expanding global market for generics as a number of drugs are coming-out after completing their 20 year old patent protection as per TRIPS. When we analysed the response of Indian pharmaceutical companies to the new IPR regime, it is found that most of them are resorting to the strategy of mergers, acquisition, alliance and joint ventures to strengthen their position in the domestic market and to penetrate into the overseas generics market. It was found that major formulation companies are acquiring domestic bulk drug companies in order to obtain backward integration. Companies of all sizes are working hard to find an optimal growth path for the future. A mindset to reduce the dependence on old formula of copying drugs patented by other firms, and focus on R&D and drug discovery and development were evident among Indian companies. It is also noticed that the companies are adding capacities with an eye on the export market, where they are increasingly focusing on formulations for which margins are higher than on bulk drugs. In our earlier analysis of India's foreign trade in pharmaceutical products, it was seen that the export of some specific categories of bulk drugs are declining, while the export of formulations of the same categories showed an increasing trend (see Chapter 3, section 3.3.1). This particular pattern might have been the result of the above mentioned strategies of pharmaceutical companies to focus on the export of formulations along with attaining backward and forward integration. To conclude, it has been observed that TRIPS Agreement is leading to some far-reaching repercussions in the Indian pharmaceutical industry.

Chapter V

SUMMARY AND CONCLUSIONS

The establishment of World Trade Organisation (WTO) as a culmination of Uruguay round of multilateral trade negotiations (1986-1993) has resulted in an unprecedented liberalisation of global trade. WTO has extended the rules governing the commercial relations among trading partners into a number of new areas that were previously excluded from the trade liberalisation process. For the first time in history, a global trade agreement has been forged that is binding and enforceable at the national level.

The trade liberalisation as an aftermath of the Uruguay Round is expected to have diverse and widespread impacts on health. This study seeks to analyse the impact of trade liberalisation on the health care sector by focusing on one of its central elements namely the pharmaceutical products. Baris and Mcleod (2000), while commenting on trade in pharmaceutical products, have expressed the apprehension that increased trade in pharmaceutical products will have negative impacts on developing countries by the way of worsening their balance of trade. But we contend that this fear arose due to certain broad generalisations about trade in pharmaceutical products without sufficient empirical support. To argue out our case that increased trade in pharmaceutical products does not necessarily result in adverse impacts on developing countries, this study takes an analytical look at the foreign trade in pharmaceutical products of India, a developing country. Given that India has a pharmaceutical industry that is one of the largest and most advanced among the developing countries, we have tried to seek answers to the following questions: what are the extent and patterns of India's foreign trade in pharmaceutical products in the context of trade liberalisation and what factors contributed to it? Does India possess comparative advantage in the global pharmaceutical trade? What are the potential impacts of WTO agreement of Trade Related Aspects of Intellectual Property Rights (TRIPS) on the Indian pharmaceutical industry? And what strategies are the Indian pharmaceutical companies adopting to face the challenge of impending product patent regime?

To set a background for the analysis, the study reviewed the evolution of Indian pharmaceutical industry over the years. Indian pharmaceutical industry has shown a steady growth immune to economic recessions and commodity cycles. The record of progress achieved by the Industry can be regarded as spectacular since at the dawn of independence

India did not have a production base, which could be called an "industry". From such a low base, the Industry has been able to maintain a rapid growth utilising the combination of extensive price regulatory mechanism and weak patent protection, that had compelled the MNCs to pull out from the Indian market. It is pointed out that, still the pharmaceutical industry remains the most highly protected industry in India, whereas most other industries were significantly liberalised in the 1990s.

The study has used the official trade data supplied by the Directorate General of Commercial Intelligence and Statistics (DGCI&S) for the analysis of India's foreign trade in pharmaceutical products. DGCI&S provide the most comprehensive and up to date data on India's foreign trade. Owing to problems in data harmonisation and specificity of the objectives, the study chose the period from 1987-88 to 1999-2000 as the period of analysis. The data analysis seems to have gone against the theoretical argument, which says that increased trade in pharmaceutical products will have a negative impact on developing countries by worsening their balance of trade. Instead, India has a positive balance of trade in pharmaceutical products with exports growing at a healthy 11 per cent. At the same time, the growth of import has turned to be statistically insignificant during the period of analysis. These results validate our hypothesis that increased trade in pharmaceutical products need not necessarily result in negative impact on developing countries by way of worsening balance of trade. However, it is also found that the growth rate of export has declined in the post liberalisation period compared to the pre liberalisation period and there occurred a trend break in the year 1991.

The disaggregated analysis showed that India's export basket of pharmaceutical products more or less entirely consists of bulk drugs and formulations and that the share of the latter has increased considerably during the period. Up to the year 1990-91, India exported more bulk drugs than formulations, after which export of formulations has increased more or less consistently. It was discovered that the fall in the export of bulk drugs after the year 1991 was primarily caused by the decline in the export of other bulk drugs. The increase in the formulation export was attributed by the increase in the export of four formulation categories namely, formulation containing penicillin, formulation containing other antibiotics, formulation containing vitamins and other formulations. The major chunk of India's import of pharmaceutical products consists of blood fractions etc, bulk drugs and formulations. While formulations and blood fractions etc have registered an increase in their shares, the share of

bulk drugs has declined. Thus, it was the declining import of bulk drugs that resulted in the decline in the pharmaceutical imports.

The study also examined the direction of India's pharmaceutical trade. India's trading partners are grouped into three categories on the basis of their per capita gross domestic product in the year 1998. Following the method of classification adopted by the UNCTAD, the countries are grouped as high-income, middle-income and low-income countries. As far as the destination of India's pharmaceutical exports is concerned, the shares of high income countries had showed some marked fluctuations over the years. High-income countries that accounted for about half of the pharmaceutical exports lost its top position to low-income countries. The middle-income countries, though increased their shares in the initial years, started showing a declining trend in their share after 1990-91. The countries that improved their share in India's pharmaceutical exports are the low-income countries and they occupied the first position in the year 1999-2000. As far as sources of India's import of pharmaceutical products are concerned, from the initial years up to the mid 1990s, it was almost entirely supplied by the high-income countries. But after that, the other two country groups have enhanced their shares. While middle-income countries have marginally increased their shares, a creditable performance was noticed in the case of low-income countries. Yet, more than 85 per cent of India's pharmaceutical imports are still coming from high-income countries.

To enquire into the question of whether India holds a comparative advantage in the trade of pharmaceutical products, the study has used the method of Revealed Comparative Advantage Index (RCA Index) developed by Bela Balassa. The RCA Index measures the pattern of comparative advantage as revealed by the observed trade flows among a group of countries. The countries chosen are: the United Kingdom (UK), Switzerland, China and Brazil. These countries are India's major competitors in the global trade in pharmaceutical products. The computed indices revealed that India, along with the UK and Switzerland, does indeed have a comparative advantage in the trade of pharmaceutical products. At the same time, Brazil and China, India's major competitors from the developing world do not possess comparative advantage in the trade of pharmaceutical products according to RCA index.

Since it is possible to quantify the comparative advantage at the disaggregated level using the RCA index, the study also computed the RCA indices for pharmaceutical products at the four-digit level of Indian trade classification (ITC) for all the five countries under the examination. The computed RCA indices showed that Switzerland has comparative advantage in the trade

of all the six categories of pharmaceutical products at the four-digit level. The UK has comparative advantage in the trade of all except one product category of pharmaceutical products. India possesses comparative advantage in the trade of two product categories and similar is the case with other two developing countries, Brazil and China.

Being a signatory of Uruguay Round, India is going to introduce product patents for pharmaceutical products in 2005 in order to comply with its TRIPS provisions. The Indian Patent Act (1970) recognised only process patents for pharmaceutical products that allowed Indian pharmaceutical companies to reverse engineer the drugs introduced in the developed countries and sell them at a fraction of costs of the patented drugs. But from 2005, this will not be possible. The popular concern that introduction of product patent will result in the escalation of drug prices in the country is not well founded when we analysed the transition mechanism of TRIPS, in which patents are granted only to new discoveries and the Agreement maintains status quo on drugs available in the Indian market up to the year 2005. On the other hand, the TRIPS Agreement is creating a new opportunity for Indian pharmaceutical industry via expanding global markets for generics as a number of drugs are coming out after completing their 20 year old patent protection as per TRIPS. With their expertise in the cost effective process technology, Indian companies stand to gain from the expanding global generics market. When we analysed the response of Indian pharmaceutical companies to the impending new intellectual property regime, focusing some major players, it is observed that most of them are resorting to the strategy of consolidation (mergers and acquisition) and collaboration (alliances and joint ventures) in the domestic as well as overseas market. Companies of all sizes are working hard to find an optimal growth path that will enable them to face future challenges and to take newer opportunities. A mindset to reduce the dependence on the old formula of copying drugs patented by other firms and focus more on R&D were evident among the Indian companies. It is also noticed that the companies are adding capacities with an eye on the export market, where they are increasingly focusing on formulations for which margins are higher than bulk drugs.

To sum up, many interesting points have emerged from our study. First of all, it was found that India has had a positive balance of trade in pharmaceutical products that is showing an increasing trend. India is now exporting more value-added formulations than bulk drugs and its dependence on imported bulk drugs is coming down. The country also holds comparative advantage in the global trade of pharmaceutical products, when its major competitors from the developing world do not have the same as revealed by the computed RCA indices. It is

observed that Indian pharmaceutical companies are increasingly resorting to strategies of consolidation and collaboration to face the inevitable challenges posed by the product patent regime and to capture the opportunities emerging from the expanding global market for generics. Finally, it is encouraging to note that Indian companies have started paying greater attention towards R&D, especially towards the development of new chemical entities, which had always remained a major weakness of the Indian pharmaceutical industry.

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Appendix

DATA SOURCES ON INDIA'S FOREIGN TRADE

Statistics holds the pride of place in the international trade especially in the wake of increasing liberalisation of the global economy. In order to formulate national trade policies, various trade agreements, export targets, concessionary benefits etc and to study the interdependence of nations, the foreign trade data are needed (Shastry 1998). Foreign trade data are required to analyse the impact of trade sector reforms on the growth performance of the economy as well as on balance of payments. Reliable and relevant data on foreign trade are important to make any forecast about the future course of exports and to make suitable policy changes in the domestic as well as external sector (Jacob 1999).

The three major sources of data on India's foreign trade are the publications of (i) United Nations (UN) (ii) Reserve Bank of India (RBI) and (iii) Directorate General of Commercial Intelligence and Statistics (DGCI & S). The UN data on trade flows are available from the two different volumes of its publication titled "International Trade Statistics Year Book"[1]. The quantity and value in US Dollars of imports and exports of commodities by countries are given in Volume 2. The data, for majority of countries from the year 1962, are also available in machine-readable form. The major limitation of the UN data are (i) it does not report export or import for those commodities whose share in the total is less than 0.3 per cent and (ii) considerable time lag is involved in making the data available (Veeramani 2001). The usefulness of the UN data on foreign trade is limited due to its lengthy time lag. In the rest of the section we will focus exclusively on the other two sources, especially on DGCI & S data, which is used by this study.

The DGCI & S data are based on customs clearance of merchandise transactions at major ports in the country, where exports are recorded on the basis of shipment of goods and imports on the basis of arrival of goods and their clearance by the customs. RBI brings out trade data based on merchandise trade transactions taking place in the economy which are valued at actual price paid through the banking channel, where exports figures are on the basis of declarations and imports are on the basis of realisation than landed merchandise. The RBI data are available only at the aggregate level in value terms. On the other hand, the DGCI & S data on quantity and value of trade are available at disaggregated 8-digit level. But there is a

[1] Volume 1 is subtitled as "Trade by Country" and volume 2 as "Trade by Commodity".

discrepancy in the data supplied by these two sources. Roy (2001) showed that the trade data from RBI source is higher than those provided by the DGCI & S[2]. He pointed out that the difference between the two sets of data at the aggregate are mainly due the differences in timing of recording, nature of coverage and valuation of transactions. RBI data has a better coverage than that of DGCI & S[3]. As far as valuation of trade is concerned, the difference between the two stems from the conversion factor used for the foreign currency invoice. While RBI converts foreign currencies at average exchange rate for the respective month, DGCI & S data are converted at rates notified by the Ministry of Commerce which are revised as and when there occurs a change of 5 per cent or more in the exchange rate of the rupee. Apart from these sources of discrepancy, there are differences that are specific to imports such as lead in payment, import of mobile equipment such as ships and aircraft and imports under external assistance and commercial borrowing. In addition, there are certain imported items, which are not covered by the DGCI & S as they do not require customs clearance but are compiled in the RBI data.

The DGCI & S data on foreign trade are available at highly disaggregated level for both quantity and value, and thus have definite advantages compared to other sources. It is the most comprehensive and up-to-date official statistics on India's trade flows. DGCI & S has adopted a new commodity classification system known as the Harmonised System (HS) from April 1987 and thus bringing it at par with the one used by the GATT. A salient feature of the HS is to classify products with respect to a basic raw material. Therefore products classified under a particular HS chapter are in increasing degree of value addition of the basic input. The classification consist of 99 chapters represented by two digit codes, 1253 HS subheadings represented by four digit codes and 5062 HS subheadings represented by six digit codes. The eight digit codes of HS, nearly 11035 in number, have been derived by further subdivision of 5062 HS subheadings to capture data on commodities of national importance.

Though the DGCI & S data is the preferred one compared to other available sources, some deficiencies and data gaps of it also have been pointed out. In spite of 8 digit level disaggregation, one often confronts with the non-availability of data on volume of trade in the DGCI & S data[4]. It has also been pointed out that the 8 digit level of disaggregation are not sufficient to arrive at product specific inference. DGCI & S data at the aggregate level are

[2] His analysis reveals that the difference in the magnitude is much higher in the case of imports.
[3] Defense related transactions are covered by RBI and DGCI & S do not cover them for security reasons.
[4] Roy (2001) illustrates the examples of petroleum and related products and drugs and pharmaceuticals for which volumes of trade are not available.

inconsistent in the sense that the sum total of all two digit level data does not add up to the grand total. Another problem is that existing trade data of DGCI & S often do not match with the data on production. In a liberalised economic regime, the need for synchronisation of trade and production data is paramount. This is because, in such a system, international trade plays a key role in influencing the level of output of various sectors of the economy[5]. It has been pointed out that the data on import of defence goods should be included in the DGCI & S data without giving the nature of it, which can obviate avoidable guesswork of value by various international agencies (Asthana 1998). Since no official statistics on country's export according to state of origin are available, it is suggested that the DGCI & S should explore the possibility of its inclusion in their publications. Another problem with the DGCI & S data is that it does not cover data on trade in services. India being a signatory of GATS and with ever expanding global trade in services, it is imperative for the country to evolve a suitable methodology for generating data on international trade in services (Shastry 1998, Venkeswaran 1998).

To conclude this section on data on India's foreign trade, it is clear that there is a need for modifications in the existing database such that it becomes more comprehensive and more importantly relevant and reliable.

[5] See Jacob (1999), Veeramani (2001) and Roy (2001) for details.