Effects of New Patents Regime on Consumers and Producers of Drugs/Medicines in India

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Executive Summary

Indian pharmaceuticals industry grew rapidly in the period 1970 to 1995 in a protective regime marked by process patenting (rather than product patenting) and a strict price regulation on a large number of drugs. This enabled the domestic industry to come up rapidly and achieve considerable technical competence. From a situation where the MNCs dominated the Indian pharmaceuticals market and prices of medicines in India were among the highest in the world, the share of the MNC was reduced to about 20-25 percent by the middle of 2000s and the price of drugs and medicines in India very low compared to the prices prevailing elsewhere.

From 1995 began the process of establishing a new patent regime in India. Also, the price controls were substantially relaxed. How the new regime is going to impact the producers and consumers of drugs/medicines in India is the subject matter of this study. Serious concerns have been raised in the past on the possible serious adverse effect that the new regime may have. At the same time, there is wide recognition that the Indian pharmaceuticals industry has adopted a strategy to meet the challenges of the new patent regime and has been successful at that. India has emerged a major supplier of cheap and quality supplier of generics in the regulated market. The level of R&D activity in the Indian pharmaceutical firms has greatly increased and this has shown up in the application for patents in India. The Indian firms have been acquiring manufacturing facilities abroad. The firms have entered into various types in alliances. There are firms that are engaged in contract manufacturing; there are other involved in contract research and product development and in clinical trials.

The consumers have not also suffered much because of the new patent regime. Although the prices of drugs/medicines have risen in India in the post-1995 period at a rate faster than the general rate of inflation, this is mostly attributable to the relaxation of price control. Even with the price increases that have taken place over the last 15 years or so, the prices of drugs/medicine in India remain low relative to the prices prevailing in other countries, especially in comparison with the prices prevailing in the western countries.

Though being a signatory to TRIPS agreement has resulted in recognition of product patents, the flexibilities in the agreement have given India an opportunity to interpret various clauses keeping the national interest in mind. The denial of patents to frivolous inventions, use of compulsory licensing, pre and post grant opposition, parallel imports, Bolar exception and not allowing extension of patent period beyond twenty years are some of the safeguards against monopoly that India can exercise. Under section 3(d) of the Indian (amended) Patent Act, the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy or a new use of known substance or process is not to be treated as an invention. Similarly keeping the interest of patients, compulsory licences could be given under section 84(1) of the amended act.

The research activities have certainly increased and large firms have started undertaking R&D after 1995 on a much larger scale not only for developing non-infringing processes and new formulations of existing and new drugs engineering but also to develop new molecules. Though the recognition of intellectual property rights have not compelled the MNCs to undertake research at the basic level, big domestic firms have a large number of molecules to treat diabetes, malaria, cancer, inflammation and other metabolic disorders in their research pipeline. The Schumpeterian link between size and innovative activity is observed in the Indian pharmaceutical industry where high R&D is getting translated into increasing filing of patents by large firms. Also, econometric evidence is presented to indicate that the new regime has had a strong favourable effect on R&D activities in pharmaceutical firms, which in turn had shown up in patent applications.

While the large firms are gearing up to face the challenges of the patent regime, the small scale segment of the Indian pharmaceutical industry suffers from various inadequacies including lack of expertise, training and finance for technological up-gradation and adoption of good manufacturing practices (GMP) to meet global quality standards; limited exposure and expertise on IPR issues; limited adoption of information technology (IT) techniques in production and processes; low or negligible R&D expenditure which affects the ability of SMEs to offer innovative solutions; and the inability of SMEs to access finance on easy terms for import of capital goods and undertaking advertising and marketing activities.

To enable the small and medium pharmaceutical companies to face the stiff challenges posed by big pharmaceutical companies, the government has planned several supportive measures including financial assistance. Apart from the government support, the small-scale units have to upgrade their production facilities to the international standards; otherwise they would lose not only the international market but also the generic segment of the domestic market because large firms in the process of meeting the good manufacturing standards would usurp small units' share in the domestic market. Thus, despite their significant share in terms of output and employment in the pharmaceutical industry, the existence of the small-scale units is threatened by increasing competition and need for adherence to good manufacturing practices.

To study the impact of product patent regime on drug prices, an econometric analysis has been carried out for eight therapeutic segments. The analysis brings out that (a) the price elasticity of demand for drugs belonging to the eight segments studied is not high (about -l.1 on average) and (2) the cross-price elasticity of the products of foreign and domestic firms based on the same molecule is low, implying thereby that if a particular molecule based products of domestic firms become costly or unavailable, the consumers may not shift to the products of foreign firms; they may shift instead to other substitute molecules produced by domestic firms. This is attributable in a large measure to the differences in the marketing networks of foreign and domestic firms, and the fact that the marketing reach of foreign firms is less. In this situation, if foreign firms have the exclusive right to supply a particular patented drug, its availability may remain restricted

because of the limited marketing reach of foreign firms. Thus, the problem with product patenting is not only the hike in prices may follow, but also of physical availability of the medicine in the relatively remote areas of the country.

From the analysis undertaken, it appears that as a result of product patenting the prices charged by foreign producers could go up, on average, by about 250 percent, if the foreign firms have full freedom in pricing their product and the government does to resort to compulsory licensing. If this occurs, there will be a loss of consumers' welfare of about Rs 6 billion per segment in respect of the eight segments studied. Projecting for the entire pharmaceutical industry of India, on the basis of a proportion relationship, the overall loss of consumer welfare due to product patenting of pharmaceuticals will be about Rs 220 billion per year. The expected gain to foreign pharmaceutical firms from patent enforcement in all the segments of the Indian pharmaceuticals market comes to about Rs 27 billion (or about $0.6 billion) per year. This is, however, rather small in relation to the profits earned by the global pharmaceutical giants (five among the largest global companies earn a profit about $60 billion per year), and therefore no major redirection of R&D to meet specifically India's health requirements is expected to take place in such firms because of the increase in their earnings from the India market.

Another issue investigated in the study is that despite this major change in the patent regime, the market share of foreign companies has declined during 2004-08 in eight of the eleven segments studied. The analysis reveals that drug price control does have an impact on the market shares. The market share of the drugs under price control tends to get reduced over time, though there are exceptions. However, price control tends to reduce the market shares of both domestic and foreign companies, and this factor by itself should not cause the relative share of foreign companies to decline. At the same time, it needs to be noted that in certain ways, domestic companies are able to offset to some extent the adverse effect of price control on their market share. By increasing the sales of other low cost generic drugs or by introducing new products within the same segment, the domestic companies are able to increase their market share at the aggregate level of segments. The main reason why the new patent regime has not seen an increase in the market share of foreign companies is that the existing foreign companies have mostly been operating in the generic segments only where the domestic companies dominate. Also, even though there has been relaxation of drug price controls and provisions of the Indian product patent Act 2005 has made Indian market favourable to the launching of patented drugs, the foreign companies have not yet launched many of their patented products in India. Most of the MNCs pharma companies have stopped launching latest products in India after 1995 though they have been introducing them in other parts of the world.

An attempt was made for the first time where data on pharmaceutical patents applications was collected, collated, cleaned and classified according to International Patent Classification (IPC) codes, to enable preliminary understanding of the nature and type of the applications. The patent applications which are filed in India are not found to be consistent with the disease burden of the country. Overall, the top five causes of disease, among infectious and parasitic diseases and respiratory infections by estimated

DALYs lost, are lower respiratory infections, diarrhoeal diseases, childhood-cluster diseases, tuberculosis and HIV & AIDS. Clearly, India is dealing with the dual burden of communicable and non-communicable diseases, with vaccine preventable diseases still being an important source of DALYs lost. The patent applications filed in the broad communicable disease segment accounts for 13% of the total patent applications while non-communicable diseases take 86% share of the total patent applications while both these types of diseases comprise approximately 43% each of the total burden of disease. This showed a bias in patent applications for diseases which are more global in nature than those which are tropical in nature afflicting the developing countries.

Overall, it seems there are no immediate danger of price rise due to the new patent system, especially because much of these patented applications/drugs are very similar to the off-patent drugs and offer possibilities of substitution. However, there may be some medium to long run price effects of the new patent system, when far superior patent protected drugs come into the market, whether from Indian or foreign firms. And, this may result in significant loss of consumer welfare. Also, if there is a shift in the type of drugs in terms of the kind of diseases these patented drugs are meant for, there may be a danger that the more needy and vulnerable may be affected. For example, if there is a sudden jump in research into the diseases affecting the developing world like water-borne diseases, vector-borne diseases like malaria & dengue, pneumonia, TB etc, and more efficient drugs under patent come into the global market, this is certainly going to affect prices and the availability of essential medicines. However, given the patterns of R&D, this also does not seem very likely in the immediate future.

Although in the near future, neither the consumer nor the major producers of pharmaceutical products in India may be seriously adversely affected by the new patent regime, there is always merit in being prepared for eventualities, especially because in the longer run the consumers may suffer significant losses due to the new regime. The government must be open and explore all the possibilities of furthering the cause of public health by exercising the many flexibilities of the TRIPS, like compulsory licensing, government use, parallel imports, price control, etc. Also, the deficiencies in the policy and institutional framework which are coming in the way of implementing the TRIPS flexibilities need to be addressed. Further, the government has to guard against the dilution of these flexibilities through the many bilateral and free trade agreements. At the end, no national government can go it alone in the fight to protect public health when numerous global, multilateral and bilateral treaties and agreements are involved. Patents are the other side of R&D, and the best argument for cooperation in R&D – especially in neglected health diseases - is that it is a typical global public good. While India need not immediately fear affordability issues around essential drugs, it will have to ensure that more suitable drugs come into the market for diseases, and that these are available, affordable and accessible for the vast majority of the population. For that, a high level engagement with global players – government, pharmaceutical companies, and international bodies - would be required in a more pro-active manner.

Chapter 1

Introduction

1.1 The Context

The pharmaceuticals industry is one of the world's most research-intensive industries, which is making enormous contributions to healthcare. In order to provide incentives to innovators to undertake research, many countries, especially the developed ones where major innovations take place, have a tradition of strong patent protection. The patent system has become more prevalent after the establishment of the Trade-Related Intellectual Property Rights (TRIPS) Agreement in the World Trade Organisation (WTO) in 1995 which made it compulsory for WTO members to include drugs/medicines in their regime for product and process patents. Facing a trade-off between giving its people abundant access to essential medicines at affordable prices and protecting patents, many developing countries have historically provided little protection for intellectual property rights, while protection of patents has been a crucial policy instrument in industrial economies to ensure adequate returns to innovative efforts in the pharmaceuticals industry. Till 2005, India recognized only process patents under the Indian Patent Act of 1970 whereby domestic firms could manufacture medicines using non-infringing processes. The Indian pharmaceuticals industry developed very rapidly in the absence of a strict patent regime, through reverse engineering with limited focus on innovative research, and provided medicines at much lower prices compared to the prices prevailing in the countries which recognized product patents. The signing of agreement under the TRIPS has changed substantially the conditions and options that are now available to the Indian domestic industry.

This study has been undertaken for the UNCTAD under its Project on "Strategies and Preparedness for Trade and Globalization in India". The main object of the study is

to examine the effects of the new patents regime on consumers and producers of drugs/medicines in India. To understand the implications of the Patent Act (2005) for the consumers of drugs/medicines and for the domestic firms manufacturing those drugs/medicines, it is important to investigate how the competition in the markets of drugs/medicines will be impacted by the introduction of product patents and whether the recognition of product patents would have an impact on the domestic efforts in building technological capabilities and undertaking research efforts, and consequently on bringing new innovations and products to the market. It is important also to go into the effects of patents on prices of drugs/medicines, hence on affordability and on the configuration of the new research and innovation activities in terms of the diseases targeted, all of which have important implications for public health in India.

1.2 Components of the Study

A number of questions relating to the new patent regime are addressed in this study. The major components of the study are as under:

1. A review of the available theoretical and empirical literature on patents, providing alternate perspectives on the relationship between patent regime, drug prices and affordable drug accessibility.

2. A detailed assessment of the overall effect of patents on the prices of one important major molecule and its therapeutic substitutes for nine therapeutic segments belonging to eight important therapeutic categories. This assessment is based on estimated econometric models. The therapeutic categories/segments studied are:

   (i) Cardio Vascular (segments: statins and betablockers),
   (ii) Anti Infective (Anti-Bacterial/ Antibiotic) (segment: Cephalosporins),
   (iii) Anti Inflammation (segment: Muscular relaxant),
   (iv) Anti-Leukemic,
   (v) Anti-Asthmatic,
   (vi) Anti- Helminthic,
   (vii) Anti-Rheumatic, and
   (viii) Anti-Ulcer.

   Using the results of the study on the effect of patents on available consumer choices for drugs/medicines and on the prices, an overall assessment is made of the effects on consumer welfare and profits of pharmaceutical firms in India.

3. Examination of the flexibilities provided in the Indian Patent (Amendment) Act, 2005. Given the adverse effects that enforcement of product patents may have on affordable access to drugs/medicine, an examination of the flexibilities provided in the Act assumes significance.

4. A detailed assessment of the effects of the new patent regime on R&D expenditure of domestic firms and consequently on new innovations.

5. An analysis of the trends in the market shares of domestic and foreign producers in various therapeutic segments in recent years. The purpose is to assess how the new patent regime has impacted the market shares of domestic and foreign firms.

6. A study of the performance of the Indian pharmaceuticals industry since the mid-1990s, particularly an examination of the effect of patent laws on small manufacturers since they are vulnerable and may therefore become insignificant in the Indian market due to their inability to make huge R&D investments.

7. Examination of patent applications for pharmaceutical products in India against the country's disease priorities, and an assessment of the impact of patent regime on public health in India.

8. Examination of the implications of the new patent regime on India's overall development policy space, with particular focus on health.

1.3 Data and methodology in brief

1.3.1 Data

The analyses presented in different chapters of the Report make use of three sets of data: (a) prices, values and units purchased of various brand of drugs/medicine in India, (b) company balance sheet information for pharmaceutical companies in India, and (c) data on patent applications made in India. Of these three, the analysis of patent applications presented here is perhaps the first study of its kind undertaken for India. The three sets of data are briefly discussed below.

(a) Prices, values and units purchased of various brands

For the study on prices and consumer welfare, data on prices, values and units of various brands, both domestic as well as foreign, for various molecules belonging to different therapeutic categories are required. The data on the prices, units and values of various molecules according to various brands producing these molecules are systematically collated only by a private organization, **ORG IMS**. The data are collected from stockists who then sell to retailers. These data have been obtained from ORG IMS for the study, and relate to the period, January 2004 till December 2008.[1]

The monthly sales data in the four geographical zones of India (East, West, North and South), price, dosage form, brand name, generic name of various molecules belonging to various therapeutic categories are provided in the dataset obtained from the ORG IMS. The reliability of this data can be gleaned from the fact that India's Drugs price control authority, **NPPA** relies on their data to decide which drugs should be scheduled (under price control) drugs.

(b) Balance Sheet Data of Pharmaceutical Companies

For the analysis of R&D behaviour and the impact of the new patents regime on R&D intensity of pharmaceutical companies, balance sheet data of companies have been used. These data have been drawn from Capitaline Plus (see www.capitaline.com). Data on a large number of variables contained in the profit and loss account and balance sheet of companies are available in this database.

[1] Data for ten therapeutic categories have been obtained from the ORG-IMS. The analysis of demand structure and price impact of patents has been undertaken for nine segments belonging to eight categories. The analysis of changes in market shares of domestic and foreign firms has been undertaken for one selected segment each of all the ten categories.

(c) Patent data

For studying the impact of patents on R&D and public health, patent data were collected from a database available at a website named 'Big Patent India' which has been compiled by researchers in Columbia University. The basic source of information in this website is the Indian Patent Office, which makes patent related information available to the public in their weekly journals, namely *Official journal of Patent Office*, containing data on patents filed and granted for various therapeutic segments, and in their annual reports.

1.3.2 Methodology

The methodologies adopted for different components of the study are described in the respective chapters; nonetheless, a brief discussion on methodology will be in order here.

(a) Econometric Model to assess the impact of Patents on Prices and Welfare

To estimate the demand function for drugs/medicines, a model involving multi-stage budgeting approach is adopted. Using zone-wise quarterly prices and sales over the five-year period, from 2004 to 2008, for various molecules, price and expenditure elasticities and marginal costs on the supply side are estimated. These estimates have been made for nine therapeutic segment studied. The estimated demand functions are used to carry out counterfactual simulations of what the prices would have been if these drugs were under patent protection. Accordingly, consumer welfare loss due to product patenting as well as associated changes in the profits of domestic and foreign firms operating in the Indian market are assessed.

The estimation of the demand system is done by using the Almost Ideal Demand System (AIDS) specification of Deaton and Muellbauer (1980). After calculating own and cross price elasticities, counterfactual simulations are carried out to examine the impact of withdrawal of domestic products from the market. Costs are unobservable, and

are therefore estimated on the basis of mark up, which is derived in turn from the own price elasticity. The welfare effect is captured through the compensating variation.

(b) Effects of patents on R&D expenditure of domestic firms and innovations

Analysis of determinants of R&D expenditures of pharmaceutical firms has been carried out using company level data taken from Capitaline. The data relate to the period 1995 to 2008. Three years are important during this period with respect to the expected or actual changes in patent regime. TRIPS agreement came into being in 1995. Exclusive Marketing Rights or a regime similar to a product patent regime was introduced with effect from the year 1995. Finally a full-fledged product patent regime was put in place in 2005.

Data for 149 firms belonging to five categories of pharmaceutical firms have been used for the analysis of R&D. A multiple regression analysis has been undertaken. The model is estimated from a panel data set (cross-section multiple period data set), using panel data estimation techniques. To assess the impact of the new patent regime, time-period dummies are used: a dummy variable for observations belonging to the period since 2000, or dummy variables for periods starting slightly earlier than 2000 or slightly later than 2000 to allow for the possibility that the effects of the new regime introduced from 1995 may have been felt with some lag.

A probit model is estimated to explain the decision to undertake R&D and a Tobit model has been estimated to explain inter-firm and inter-temporal variation in R&D intensity. While analyzing the effect of patent regime on R&D, an attempt is made to control for other firm level characteristics and strategies like size, technology purchase, product differentiation and export orientation etc. The analysis of R&D expenditure is supplemented by an analysis of patent applications made by pharmaceutical firms.

(c) Impact of Patent Regime on Public Health

This analysis makes use of the information available on the patents applications received in the mailbox facility till date. Detailed information from the application is used to identify the type of drugs/medicines for which the patent has been requested. Based on these data, the drugs are classified into broad categories of diseases/conditions for which the drug can be potentially used. Further, an analysis of the applications received has been done in the context of the disease priorities of the country, as gleaned from data on disease burden, to see whether the applications are aligned to the existing public health situation in the country.

1.4 Structure of the Report:

The structure of the report is as follows: The next chapter, i.e. Chapter 2, reviews theoretical and empirical literature on the relationship between patent regime, drug prices and affordable drug accessibility. Chapter 3 discussed the new patent system and the legal options/ flexibilities available to India to safeguard its national interests. Chapter 4 discusses the performance of the Indian pharmaceuticals industry in the period since 1995. The focus is on the performance in recent years.

Chapters 5 and 6 present the results of econometric analysis. The former is devoted to the effect of the new patent system on prices and welfare. As mentioned earlier, this analysis is done with the help of estimated demand functions for drugs/medicine belonging to eight therapeutic segments. The latter chapter is devoted to the effect of the new patent regime on R&D efforts and innovation activity among domestic pharmaceutical firms.

Chapter 7 is devoted to the analysis of the inter-temporal changes in the market shares of domestic and foreign firms in various molecules in the therapeutic segments

studied. The aim is to assess the effect of the new patent regime on market shares of domestic and foreign firms.

Chapter 8 presents an analysis of patent applications' relation to drugs/medicine. The object is to assess the public health implications of the patents being sought for. The patent applications are therefore categorized according to the type of disease they are meant for. This is compared with the existing burden of disease to assess the utility of the new patented drugs for betterment of public health.

The final chapter discusses policy issues connected with the impact of new patent regime on public health and the domestic industry. The issues discussed include (a) the distribution of the new patented products across disease categories, and (b) the likely impact of the new patent regime on accessibility and affordability of such drugs by looking at the potential impact on prices.

Chapter 2

Review of Theoretical and Empirical Literature on Patenting[2]

There is a vast and rich literature on the role of patenting on innovation, pricing and consumer welfare. Before taking up an investigation of some of these issues in the context of Indian pharmaceuticals industry in the chapters that follow, it is important to get a basic understanding of the role that patents play, particularly in the pharmaceuticals industry, drawing on the existing theoretical and empirical literature. This is the motivation of this chapter, and it presents a succinct review of the theoretical and empirical literature on patenting, primarily as a background to the analysis presented in later chapters.

2.1 Market Structure, R&D and Innovation

Research and Development (R&D), which is linked to patenting system, is important to study, not only for the analysis of an individual industry, but also from an economy-wide viewpoint. For improvements in welfare, Solow (1957) emphasized an increase in the ratio of capital to labour, leading to technical progress. This progress takes the form of innovation in the industry and its diffusion across all the sectors of the economy. The innovation is of two forms namely product innovation and process innovation. One of the major problems, mentioned by Schumpeter (1943) in this regard, is that innovation has the status of a public good. Any innovation created by one firm provides usable information to the other firms at little and no cost. While all firms in the market stand to gain from the use such information, none is willing to incur the expenses necessary to produce it without compensation. In practice, such compensation often comes through the granting of patent that provides the innovating firm with temporary monopoly and,

[2] This Chapter has been prepared by Dibyendu Maiti.

consequently, allows it to recoup its R&D costs. The dilemma of the patenting system is that, in encouraging R&D, it prevents the diffusion of innovation and consequently creates a noncompetitive situation (Tirole, 1995). As Penrose (1951) notes, "If national patent laws did not exist, it would be difficult to make a conclusive case for introducing them; but the fact that they do exist shifts the burden of proof and it is equally difficult to make a really conclusive case for abolishing them."

Although the effect of patenting on innovation is ambiguous, the significance of patent related policies cannot be denied. One issue here is what should be optimum length of patenting – short term or infinite. With a patent of infinite duration, the problem of appropriating the social surplus arises. Also, aside from any strategic considerations, the monopolist gains less from innovating than does a competitive firm, because monopolist replaces himself when he innovates whereas the competitive firm becomes a monopoly. This is known as *replacement effect*. There is another incentive as well. Since competition reduces profits, the monopolist's incentive to remain a monopolist is greater than the entrant's incentive to become a duopolist, i.e., *efficiency effect*. As Gilbert and Newbery (1982) note, the monopolist has incentive to obtain property rights on an innovation even though he makes no use of it. This occurs, for instance, if the patent relates to a production technology that is not superior to that of the monopolist. This only purpose of patenting then is to prevent the entrant from competing. In order to eliminate the replacement effect, it is sufficient to choose an R&D technology in which the amounts committed per unit of time are considerable, so that the probability of discovery per unit of time is high.

If a firm does not have monopoly power, R&D competition can be equated to a race for a patent. In this situation, each firm may wish to accelerate its research program by incurring additional expenses. The monopolist is much more concerned with the possibility of innovation by the entrant than with the date of his own 'replacement'. Accordingly, in a situation of a race for patent, the monopolist has incentive to commit large R&D investment per unit of time to ensure greater probability of early discovery. Consequently, for a non-drastic innovation, there is a tendency for the monopoly to

persist, because the established firm has a higher probability of obtaining the patent (Fudenberg and Tirole, 1986).

In a recent paper, Ganuza, Llobet and Dominguez (2008) show that competition between innovative firms may end up producing wasteful research expenditure on me-too products. Governments and insurers may then play a gatekeeping role in controlling expenditure and driving it to develop 'drastic innovations' that are less likely to be underpriced as they turn out to be therapeutic breakthroughs

2.2 Risks and Rewards for R&D

Dasgupta and Stigliz (1980), Dasgupta and Maskin (1986), Judd (1985), and Klette and de Meza (1986) have taken up for analysis the issue of risk associated with R&D, and have constructed models of patent races that, under some assumptions, yield a market choice of excessively risky R&D technologies. That is, R&D competitors pick up technologies that involve more 'variance' than is socially optimal. Because the payoff of discovery becomes zero after a given point in time, the firm's objective function is convex in its own discovery date, and this induces firms to choose risky technologies.

If firms choose similar projects, duplication of success (i.e., almost simultaneous discoveries) can be expected to occur more often than if they chose radically different R&D technologies. There has been a lot of research recently on the issue of whether competing firms have an incentive to choose similar technologies. Bhattacharya and Mookherjee (1986) and Maskin (1986) have analyzed the correlation bias when the innovation is patented, and Glazer (1986) has performed a similar analysis for a non-patented but proprietary process innovation by a product-market duopoly. Dasgupta and Maskin (1986) have shown that, under some assumptions, the equilibrium involves socially too much correlation. The intuition for this is that, when a firm moves away from its rival in the space of research projects, the first firm encounters increased probability of being unsuccessful – which is socially desirable. Hence, there may be too much similarly in the choice of project characteristics.

The recent research on innovation has focused more on the positive aspects of R&D than on the normative side of the patent system. It is known that the market may offer too little or too much diversity. The same must undoubtedly hold for product innovations. With infinitely long-lived patents, a firm may have too little or too much incentive to engage in R&D. The appropriability effect, according to which the private surplus from innovation is lower than the social surplus (in the absence of perfect price discrimination), leads to too little innovation. In contrast, the business-stealing effect, according to which a firm that introduces a new product does not internalize the loss of profit suffered by its rivals on the product market, causes too much innovation. Actually, another business-stealing effect arises in patent races: by increasing its R&D effort, a firm reduces the probability of its rivals' obtaining in a patent race, hence over-invest in R&D and thus duplicate too much of research effort (Kamien and Schwartz, 1982). Now, even if one is unsuccessful in determining whether firms engage in too little or too much R&D, the optimal way to encourage or discourage R&D remains to be determined (Nordhaus, 1969). R&D incentives can be altered in a variety of ways. At the input level, R&D expenditures depend on subsidy. At the output level, the payoff for innovation depends on the length of the patent, on the scope of enforcement of patent protection and on the other factors. The other method of encouraging innovation includes the award system and the contractual mechanism. The award system implies competition at the research level. As

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in the case of a patent system, there is no reason why this competition should yield the optimal amount of innovative activity.[3]

A more serious rival to the patent system is a centralized solution known as the contractual mechanism. Although somewhat similar to the award system, the mechanism differs in that the government controls access to the research market. More precisely, the government chooses a certain number of firms and signs a contract with these firms. The contract usually contains more details than are specified when an award is offered. For instance, it often specifies that a certain portion of the research costs will be born by the government. Contracts of this sort may prevent excessive duplication of research costs in areas of interest to governments. However, incentive problems linked to limited yardstick competition are still there. The compromise sought between these two factors depends on the research technology and the ease with which the contracting firms can be controlled. As with the award system, the government must know the value of the innovation.

2.3 Extensive Use of New Technology

As discussed above, an innovating firm secures the exclusive enjoyment of patent. How can there be a wider use of patents? One possibility is through the transfer of technology under licensing. Two types of licensing are discussed in the literature. An independent inventor (or a firm specializing in R&D) may be unable to exploit a patent and therefore may license out the technology to a 'downstream' firm. Second, even if the inventor has production capability, he may still license the technology to a rival. The incentive to license is clear in the first case. The patent would have no value in the absence of licensing. Firestone (1971) notes that most of the patents held by corporations are used exclusively by those corporations and that most patents held by independent inventors are licensed to a single firm. An instance of improved incentives associated with competition is formalized in the incomplete-contract models of Farrell and Gallini (1986) and Shepard (1986), who show that cross-licensing may guarantee ex-post the quality of the licensor's

[3] Scherer (1980) reviews the use of the award system to stimulate inventions related to military uses of atomic energy.

product and increase the incentives for the product's users to invest in relationship-specific capital. . Kamien and Tauman (1983) and Katz and Shapiro (1986) argue that the incentive of a patent holder to license a process innovation exists. Under some circumstances, the licensee's output may not be observable by the licensor. In this case, the fixed-fee contract is a good approximation of reality. One can find a wide variety of licensing agreement in various industries.[4]

Gallini (1984) and Gallini and Winter (1985) make the interesting point that licensing may not only reduce production costs but may also eliminate inefficient R&D expenditures. A licensee has less incentive to invest around the licensor's patent because marginal cost has decreased, which makes innovation less desirable.

2.4 Patent Length and Breadth, and Information Disclosure

In most of the traditional patent-design literature, there has been a focus on the optimal uniform patent length and, more recently, on other dimensions of patent policy such as breadth (Nordhaus, 1969; Klemperer, 1990; Gilbert and Shapiro, 1990; Green and Scotchmer, 1995; Scotchmer, 1996; O'Donoghue, Scotchmer, and Thisse, 1998). There are only two recent articles that study differentiated patent protection in different frameworks. Scotchmer (1999) analyzes a static model with private information on the cost and value of inventions, but no moral hazard (the firm chooses which ideas to develop, but not how much R&D to do). She shows that asymmetry of information is sufficient to justify the use of patents to provide R&D incentives, and that any direct mechanism can be implemented using a renewal mechanism. de Laat (1997) analyzes a patent race in which the imitation delay is private information and studies optimal differentiation of patent length and breadth. Cornelli and Schankerman (1999) argue that most patent systems require payment of a series of renewal fees to maintain patent protection up to the statutory patent life. Typically, more than half of all patents are

[4] Calvert (1964) and Taylor and Silberston (1973) observe that about 50 percent of licensing contracts specify royalties only, 10 percent a fixed fee only, and the remaining 40 percent a two-part tariff or a more complicated arrangement.

voluntarily cancelled by non-payment within ten years of the date of patent application. Thus, even though all countries impose a uniform statutory patent life, there is de facto differentiation in patent lives. Econometric studies have confirmed that renewal fees influence the decision to patent and that more valuable patents are held longer (Pakes, 1986; Schankerman and Pakes, 1986; Schankerman, 1998; Lanjouw, 1998). There is no reason to believe that the existing pattern of de facto patent lives induced by these fees improves welfare. The central idea is that patent fees can be used as an incentive device to implement a policy of optimally differentiated patent lives (and, more generally, differentiated patent protection). The differentiated patent lives can be better, in terms of social welfare, than a uniform patent life. The use of patents as a policy instrument to provide R&D incentives makes sense only if there is private information about the cost or value of inventions (Wright, 1983). In presence of both asymmetric information on cost (R&D productivity) and moral hazard on the R&D effort undertaken by the firm, differentiated patent lives can be welfare improving because of an "incentive effect": allowing firms with high R&D capabilities to choose longer patent lives gives these firms an incentive to invest more R&D resources. Any uniform patent life will provide too much incentive to low R&D-productivity firms and too little incentive to high ones. This generates both a sub-optimal level and distortion in R&D. The optimal scheme involves the government offering firms an incentive-compatible menu of patent lives and associated lump-sum patent fees.

Econometric studies have confirmed that renewal fees influence the decision to patent and that more valuable patents are held longer. Thus, patent fees can be used as an incentive device to implement a policy of optimally differentiated patent lives (and, more generally, differentiated patent protection).

There are also numerous studies suggesting that patents typically offer weaker protection than other means of appropriaibility such as lead time, moving rapidly on the learning curve, secrecy and that they stimulate information disclosure rather than

investments in innovation (e.g., Levin et al., 1987; Cohen et al., 2000; Gallini, 2002).[5] Such information dissemination is the essence of the disclosure or contract theory of the patent system, which maintains that society needs to grant property rights to inventors in exchange for public disclosure of their inventions. The disclosure theory has been influential in the history of the patent institution and among legal theorists. Economic analysis has, however, centered around strategic disclosure inherent in the decision to patent (see e.g., Anton and Yao, 2004), without providing a clear conceptual framework for the theory. Denicolb and Franzoni (2003) show that disclosure theory alone suffices to rationalize patents. The same observation is also a part of Kultti et al. (2003), who isolate the circumstances in which patent policy can increase disclosure, the incentive to innovate, or both. Kultti, Takalo and Toikka (2007) argue that if innovation is simultaneous or independent, we can always design a weak patent system where innovators patent their discoveries rather than keep them secret. Such a patent system can stimulate both information dissemination and innovative activity. It can also hinder collusive behaviour, since patents, by definition, afford deviating innovators leverage in the punishment phase. Although some private agreements concerning patents, such as cross-licensing and joint patenting, may be conducive for collusion, it is at most those agreements that should raise antitrust concerns, not the patent system in itself.

Numerous studies suggest that patents typically offer weaker protection than secrecy and that they stimulate information disclosure rather than investments in innovation. Such information dissemination is the essence of the disclosure or contract theory of the patent system, which maintains that society needs to grant property rights to inventors in exchange for public disclosure of their inventions.

Pepell (1995) investigates imitative competition in a two-stage game of strategic product choice in a vertically differentiated market. The innovator chooses its product strategy anticipating the subsequent entry of a rival firm. The rival firm chooses the

[5] At the same time, it should be noted that there are certain sectors where patents have distinct advantage over other means of appropriability. Pharmaceuticals and fine chemicals are such sectors, for which patents are essential.

degree to which it is profitable to differentiate its product from the innovator. It has the second mover advantage that its costs are lower the more closely it copies the innovator's product. But against this advantage is the drawback that the more similar the two products are, the more intense is the price competition between the two firms. The trade-off between imitation and differentiation is affected by the degree of consumer heterogeneity in the market. The relationship between the incentive to imitate and the distribution of income is important, particularly in evaluating the welfare effects of two different policy responses, patent policy and cooperative alliances.

2.5 Technology Transfer, Pricing Issues and Consumer Welfare

In recent years, the issue of patent protection is one of the most contentious issues in the context of technology transfer from the developed North to the developing South. The developed countries feel that the present system provides inadequate protection to intellectual property rights (IPRs) and are interested in strengthening this protection in the world. The poorer countries, on the other hand, are against this protection, as it would increase the profits of the monopolistic Northern firms at the expense of their domestic consumers.

In dynamic contexts, the issue of patent protection and its impact on the innovation rate and welfare are discussed by many authors (see Helpman, 1993; Grossman and Helpman, 1991; Segerstrom *et al*., 1990; Lai, 1998; etc.). They find, in contradiction to the intuition furnished by Schumpeter (1942) and subsequently by Romer (1991), that stronger patent protection should encourage innovation. Deardorff (1991) argued for a case of limiting patent protection geographically rather than extending it universally across the world. Marjit (1994) provides a theoretical discussion on TRIPS and concludes that uniform patent lengths across products and countries can hardly be justified even if one ignores country specific characteristics. Granting patent rights for a significant period can eliminate consumers in poorer nations. The argument that rising prices are going to affect ‘the poor’ severely in a developing country is hard to sustain simply because of tremendous disparity in the initial income distribution. Local

R&D should be positively related to the protection of property rights. Global R&D investments mix disperses towards developing countries given a stronger patent law. It has a particular relevance in Pharmaceuticals, as prices of pharmaceuticals may not have much to do with the sunk cost of R&D.

In similar fashion, Danzon and Towze (2003) argue that patents are generally considered necessary to encourage R&D, particularly in an R&D-intensive industry such as pharmaceuticals to provide access to medicines in developing countries. Acceptance of a 20-year patent term is a condition of membership in the World Trade Organization (WTO), with transitional arrangements for Developing Countries. This has led to widespread concern that the adoption of patents in developing countries will lead to higher prices than are currently paid for generic "copy" products, which would no longer be legal, thereby making drugs even more unaffordable.[6] Danzon and Towze (2003) argue that differential pricing makes it possible to reconcile patents, which are necessary for innovation, with affordability of drugs for developing countries, at least for drugs with an affluent country market. Under well-designed differential pricing, prices in affluent countries (and, to a lesser extent, middle income countries) exceed the marginal cost of production and distribution of drugs in these countries is enough, in aggregate, to cover the joint costs of R&D, while prices in developing countries cover only their marginal

Differential pricing makes it possible to reconcile patents, which are necessary for innovation, with affordability of drugs for developing countries, at least for drugs with an affluent country market. But, some external subsidy is necessary to create incentives to develop treatments for diseases prevalent only or mostly in developing countries. Patents are necessary in such situations, but will not suffice.

[6] It may be pointed out in this context that many of the high demand drugs are not even for diseases that affect the poor disproportionately. One finding of this study is that most of the patent applications are for diseases that disproportionately affect the rich. If one does an analysis of diseases that strike the rich, it would be Non-Communicable Diseases (NCD), and Communicable Diseases (CD) for the poor. At the same time, the poor do suffer from NCD and there is an increasing trend. But their requirements are more for vaccines and other CD drugs. Thus, even if prices are rising for some segments, which is an empirical question, it does not seem as though the poor will be *disproportionately* affected. Of course, they will be affected to the extent that they are also buying the drugs.

cost. For drugs that treat diseases found only in developing countries, there is no high-income market where prices can exceed marginal costs and this excess of price over marginal cost can be used to cover the joint costs of R&D. For most drugs primarily meant for developing countries, the prices that the patients in those countries can afford to pay are insufficient to cover costs and hence not enough to create incentives for innovators to invest in R&D. Thus some external subsidy — either a demand-side subsidy to patients or a supply-side subsidy to innovator firms — is necessary to create incentives to develop treatments for diseases prevalent only or mostly in developing countries. Patents are necessary in such situations, but will not suffice: having the legal authority to charge high prices is of no value if patients or governments cannot pay.

Magazzini, Pammolli and Riccaboni (2004) attempt to set up a model of generic competition and prices, considering the role that some fundamental properties of the markets (e.g., their relative size and growth) have in shaping the dynamics of market structure following patent expiration in four major developed countries (USA, UK, Germany, and France). The history of the national regulatory systems of these countries is characterized by a set of highly differentiated trajectories and patterns that have led to hugely diversified healthcare and pharmaceutical systems, in particular in terms of the extent and regimes of regulation. Evaluation of the efficiency of different forms of government intervention is both theoretically and empirically complex and is further complicated by the fact that regulation takes very different forms across countries and over time. This situation has constantly led to controversies, and sometimes to bitter confrontation. The focal issues in the debate are clearly patent protection and price regulation, two issues that are deeply intertwined. On the one hand, it is widely recognized that patents have an important role as an incentive to innovation in pharmaceuticals. On the other hand, the monopoly power conferred to patent holders should be countervailed by limiting the opportunity to raise prices in a market characterized by informational asymmetries and low-demand price elasticity. However, price regulation is vigorously opposed by the industry and by many economists. First, it is argued that the industry is extremely competitive, even in specific sub-markets. Second, it is maintained that price regulation distorts the price mechanisms, curbs the profits of

companies and hence the incentives to innovation, and in general creates environments where competition is too lenient. Recently, policies have moved toward the use of less invasive regulation and a higher reliance on more market-friendly measures. Prominent among these is the support for the introduction and diffusion of generics after patent expiration.

Chaudhuri, Goldberg and Jia (2006) argue that under the Agreement on Trade-Related Intellectual Property Rights, the World Trade Organization members are required to enforce product patents for pharmaceuticals. They empirically investigate the welfare effects of this requirement on developing countries using data for the fluoroquinolones sub-segment of the systemic anti-bacterials segment of the Indian pharmaceuticals market.[7] The results suggest that concerns about the potential adverse welfare effects of TRIPS may have some basis. They estimate that the withdrawal of all domestic products in this sub-segment is associated with substantial welfare losses to the Indian economy, even in the presence of price regulation. The overwhelming portion of this welfare loss derives from the loss of consumer welfare.

The study by Chaudhuri, Goldberg and Jia (2006) for the fluoroquinolones sub-segment of the systemic anti-bacterials segment of the Indian pharmaceuticals market comes up with econometric results that suggest that concerns about the potential adverse welfare effects of TRIPS may have some basis.

Borrel (2007) uses sales data on HIV/AIDS drugs in a sample of 34 low- and medium-income countries between 1995 and mid-2000 and applies reduced form regression to empirically assess the impact of market exclusivity on pricing of clinically tested ARV drug bundle, i.e. the cocktail therapy. She finds a positive relationship between drug prices and per capita income in both patent and non-patent regimes. This suggests that in non-patent regimes, competition drives the prices to be related to per

[7] There have been other studies on the issue of price rise and welfare loss in the context of India. Two such studies (Fink, 2000; Watel, 2000) are discussed later in Chapter 5.

capita income, and in patent regimes, MNC firms tier the prices of drugs in accordance with the per capita in different countries. Another finding of this study is that drug firms set a very high initial price and then lower it over time. As regards the impact of patents on prices of ARV drugs, Borrell finds that the drug bundles containing at least one original drug in a patent regime are on average prices 70% higher than drug bundles containing only local copies marketed in no-patent regime.

Jonsson (2001) argues that pricing is a crucial part of the success of any product, but is particularly important in the pharmaceutical industry. Price setting for drugs is increasingly dependent on economic factors (cost-effectiveness) and cost containment policies, and drug companies need to address such issues when deciding on a pricing strategy for a product across the globe, throughout various stages of its patent life, and across different formulations, strengths, and pack sizes. Of the two available pricing options for different dose strengths, the offering of a single price, or flat price, has many advantages over the monotonic pricing strategy. Theoretically, the flat price is appealing from a social perspective, since in most case production costs are independent of the strength prescribed. The major role of price is not to ration the scarce availability of "substance" but to recoup fixed cost for discovery and drug development. From a cost-effectiveness perspective, flat pricing also seems rational, since in many cases the physician aims for the lowest dose for a given effect. The dose is increased when the treatment fails to achieve the target. However, there are also benefits to patients. They can receive the dose that they need without incurring a penalty for higher doses. Healthcare providers can feel confident that their patients will be optimally treated; since there are no economic incentives to choose one dose over another for the prescriber. For third- party payers, the additional benefit is that they can easily predict the total expenditures based on epidemiological data about the patient population and defined indications.

Jelovac and Bordoy (2005) investigate the pricing and welfare implications of parallel trade of pharmaceuticals between two countries. Parallel imports are goods produced genuinely under intellectual property right (IPR) protection, placed into

circulation in one market with the consent of the IP right owner, and then imported into a second market where it is legally permitted but does not have the authorization of the right owner. International price discrimination is likely to be caused not only by differences in income across countries, but also differences in other relevant characteristics of the demand. International price discrimination is likely to be caused not only by differences in income across countries, but also differences in other relevant characteristics of the demand. Characteristics of the demand that are especially relevant for pharmaceuticals are connected with insurance and drug needs. Both can be specific to countries. Jelovac and Bordoy also confirm that parallel trade makes the prices converge between countries. As a reaction to the possible entry of parallel traders in the market, the pharmaceutical monopoly producer trades-off the benefits from price discrimination with the losses of facing competition from parallel imports in the high price country. Therefore, the monopolist increases the price in the low-price country, and decreases the price in the high-price country so as to deter some amount of parallel imports. This does not mean that permitting parallel trade results in global uniform pricing but in convergence of the two prices. This contradicts other papers (Malueg and Schwartz, 1994; Richardson, 2002) in which parallel imports are assumed to imply de facto global uniform pricing and it can be reached if consumers value the original drug and the parallel imported drug equally. However, as noted by Maskus (2001), goods that are parallel imported may not be perceived to be of the same quality between markets, even if the manufacturer placed them on the market originally, because of differences in packaging or guarantees. This difference in perception leads in the model to the persistence of some level of price discrimination between countries, even when parallel imports are permitted. Furthermore, the effect of parallel imports on the total welfare is ambiguous. Jelovac and Bordoy identify three cases in which the effect of parallel trade in terms of total welfare can be stated unambiguously. The parallel trade increases the total welfare when it takes

Goods that are parallel imported may not be perceived to be of the same quality between markets because of differences in packaging or guarantees. This difference in perception may lead to the persistence of some level of price discrimination between countries, even when parallel imports are permitted.

place between countries differing in their drug needs only. The rationale behind this positive effect relies on the re-allocation of consumption from individuals with relatively lower needs in the exporting country, towards individuals with relatively higher needs. The opposite reallocation of consumption is the result of parallel trade when countries differ only in their health insurance reimbursement policies. In that case, the total welfare decreases with parallel trade. Allowing parallel imports would also decrease the total welfare if it induces the monopolist to stop selling drugs in the originally low-price country. The rationale for this case follows a result of Hausman and MacKie-Mason (1988): If one market is not served under uniform pricing, then price discrimination yields a Pareto improvement. One specific feature of the Jelovac-Bordoy model is worth mentioning in order to contrast their results with an existing general result over the welfare effect of third-degree price discrimination. In their model, the use of linear demand functions results in the same total quantity of drugs purchased, no matter whether parallel imports are permitted or not. This is analogous to the result of Robinson (1933): If a single price monopoly selling in two markets under constant costs is allowed to discriminate between them, total output is unchanged if both markets have linear demand curves and both markets are served under both regimes (either uniform pricing or third-degree price discrimination). Generalizing and extending Robinson's result, Schmalensee (1981) shows that price discrimination reduces welfare if it does not increase total output. Even though Jelovac and Bordoy do not aim at comparing uniform pricing with price discrimination, they note that their result departs from this classical result: The welfare effect of lowering price discrimination by permitting parallel imports is not necessarily positive, even though the total output remains constant. It is the presence of differentiated co-payments for buying pharmaceuticals in the model that explains this discrepancy: The degree of discrimination in prices does not need to coincide with the degree of discrimination in consumers' prices. However, consumers' prices rather than full prices matter to evaluate the welfare effect of third-degree price discrimination.

An important question raised by Sinha (2001) is whether an increase in patent protection in the South leads to more innovation by the North and whether this increases the level of total welfare. Chin and Grossman (1990) studied the welfare implications of

patent protection in a North-South trading environment. In their model, global patent protection stimulates innovation in the North and thus the North benefits from the patent protection in the South. However, in their model, global welfare goes up or down depending on whether the productivity of Northern R&D is large or small. Diwan and Rodrik (1991) on the other hand, argue that when the North and South have different technological needs and tastes and the R&D resources are limited then the Southern patent protection might have a role in promoting the development of technologies appropriate to the South. They have also shown that increased patent protection in the South might not be good for the North, as more R&D resources would be deployed to suit Southern tastes.

When the North and South have different technological needs and tastes and the R&D resources are limited then the Southern patent protection might have a role in promoting the development of technologies appropriate to the South.

Sinha (2001) argues that when the Northern firm licenses out the first period technology to a Southern firm located in the South, the lower is the degree of patent protection in the South, the higher is the innovation rate in the North and the higher is the welfare in the South. Accordingly, an optimal degree of patent protection is found for the South, which may be zero or some positive degree depending on the parameter configurations.

2.6 Health systems coping with drug firms' market power

One issue of concern, in recent years, has been that how should we tackle the global problem of encouraging research on new drugs for neglected diseases. Theory and evidence have shown that, as a policy instrument, patents do not help to attain such an aim when demand lacks purchasing power. Kremer et al. (2008) have contributed to a new stream of literature that tackles the problem of the development of new medicines as global public goods. They show that firms face the classical hold-up problem: they must first invest in a new drug, but then, once it has been discovered, governments are tempted

to expropriate the innovators by under-pricing it. This makes firms reluctant to invest in drugs that are badly needed by the poor.

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Another area of concern relates to the unique problem of pharmaceuticals. Pharmaceutical markets are unique in one aspect that has not received enough attention. Drug pricing is subject to countervailing forces that lead to corner solutions, namely, towards overpricing or underpricing. It is very common to characterize some countries as markets that support excessively high prices (particularly the US, Germany, and others), and some others as markets with excessively low prices (less developed countries, or even southern countries in the EU). There are some economic fundamentals in drug markets that support the extremes of both overpricing and underpricing. First, as insurance creates inelastic demand and patients are less price sensitive when the insurer is paying the bill (Regan 2007). Demand is also inelastic because access to most medicines requires a doctor's prescription and dispensing pharmacists. In addition, doctors and pharmacists are imperfect agents of their patients. They do not fully internalize the impact of their prescription and dispensing decisions on their patients' after-treatment net utility function. All these drug demand particularities drive prices up. Additionally, patents restrict competition and allow innovators to price medicines above the marginal cost and to obtain quasi-rents that should boost revenues enough to recoup sunk R&D costs. This also encourages price spikes. Second, at the same time, buyer power is brought about by direct government intervention via regulations or public provision of drugs, indirect government intervention in health and pharmaceutical insurance, and even a concentrated private insurance market. Such countervailing power may drive the market to the other corner solution. The industry is prone to suffer the classical hold-up problem. As R&D is a cost that is already sunk at the drug launch stage, government or insurers are tempted to expropriate the industry by setting prices close to the marginal cost, which is well under the average costs

internalized by R&D outlays. This is done, for instance, by circumventing patent rights and avoiding the payment of the fair share of global R&D costs according to the country's income (Duggan et al., 2006 and Kyle, 2007). Both corner solutions have undesirable short- and long-term consequences. Several countries in the world have developed mechanisms to cope with both extremes.

2.7 Alternatives to the patent system

Rising drug prices, an ever larger burden on family budgets and the economy, have led researchers to consider alternative mechanisms for financing drug research. Baker (2004) attempts to provide four alternatives to the patent system. Economic theory predicts that government granted patent monopolies lead not only to deadweight efficiency losses due to the gap between the patent protected price and the competitive market price, but also to a variety of other distortions. Accordingly, the paper proposes the following alternative approaches to the patent system: "1) A proposal by Tim Hubbard and James Love for a mandatory employer-based research fee to be distributed through intermediaries to researchers (Love, 2003); 2) A proposal by Aidan Hollis for zero-cost compulsory licensing patents, in which the patent holder is compensated based on the rated quality of life improvement generated by the drug, and the extent of its use (Hollis, 2004); 3) A proposal by Michael Kremer for an auction system in which the government purchases most drug patents and places them in the public domain (Kremer, 1998); and 4) A proposal by Representative Dennis Kucinich to finance pharmaceutical research through a set of competing publicly supported research centers (Kucinich, 2004)."

Four alternatives to the patents system have been proposed: (A) a mandatory employer-based research fee to be distributed through intermediaries to researchers; (B) zero-cost compulsory licensing patents, in which the patent holder is compensated based on the rated quality of life improvement generated by the drug, and the extent of its use; (C) an auction system in which the government purchases most drug patents and places them in the public domain; and (D) to finance pharmaceutical research through a set of competing publicly supported research centers.

Chapter 3

Flexibilities Provided in the Indian Patent (Amendment) Act 2005[8]

3.1 Evolution of Various Patent Regimes

Patents have been seen as an instrument of economic policy, and countries have changed their patent regimes at different stages of economic development. Till 1836, when the US was in the nascent stages of its industrial capabilities (and before the Paris Convention on Industrial Property was established), it did not provide patent rights to foreigners and even after that, it allowed registration for patents by foreigners on payment of patent fees which were 10 to 15 times higher than what was charged from the US citizens (Scherer, 2004). Until 1891, US copyright protection was restricted to US citizens with biases against copyrights to foreigners (for example, printing had to be on US typesets). The principal rationale for international IP treaties such as the Paris Convention for industrial property and the Berne Convention for copyright was to secure the same treatment for foreigners as given to nationals. The US delayed its entry to the Berne Copyright Convention until as late as 1989, over 100 years after the UK partly due to this requirement. However, both treaties, but more so the Paris Convention (1883), provided considerable flexibilities to member countries to interpret and adopt legal regimes that suited their national interests and level of development. In fact almost half of the 101 signatories to the Paris Convention for the Protection of Intellectual Property did not recognize product patents for pharmaceuticals as late as 1989. Other flexibilities included revocation of patents, compulsory licenses when patented inventions are not worked (produced) with in the patent granting country, limiting the length of patent protection and exclusion of technology from patent protection.

[8] This Chapter has been prepared by Ravinder Jha.

In Switzerland in the 1880s, industrialists did not want a patent law because they wished to continue to use the inventions of foreign competitors. Till 1977, Switzerland did not provide product patents on pharmaceuticals though patents were granted on manufacturing processes. Similarly, many European nations like Italy did not recognize drug patents till they harmonized their patent systems with member European Community nations in 1978. For Spain and Portugal the relevant date was 1992 (Scherer and Watal, 2002).

The best examples in the recent history of development, where patent policy plays a contributory role, are the countries in East Asia, which used weak forms of patent protection to suit their level of technological and manufacturing development. Throughout the critical phase of rapid growth in Taiwan and Korea between 1960 and 1980, during which their economies were transformed, both countries emphasized the importance of imitation and reverse engineering as an important element in developing their indigenous technological and innovative capacity. Even when Korea adopted patent legislation in 1961, the scope of patenting excluded foodstuffs, chemicals and pharmaceuticals and the period of patent protection was much shorter at 12 years as compared to 16-17 years in the US and other developed countries. It was only in the mid-1980s, particularly as a result of action by the US under Section 301 of its 1974 Trade Act that both the countries recognized product patents in pharmaceuticals (Kumar, 2002).

All these changed with the signing of the agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). The Agreement on TRIPS emerged when the Uruguay Round of trade negotiations was completed in 1994. The Final Act of these negotiations created the World Trade Organisation (WTO) and set out rules with which members of the WTO have to comply. The TRIPS Agreement requires all WTO Members to provide minimum standards of protection for a wide range of Intellectual Property Rights (IPRs) including copyright, patents, trademarks, industrial designs, geographical indications, semiconductor topographies and undisclosed information (Correa, 2001). TRIPS took effect on 1 January 1995. WTO Members considered as

developed countries were allowed up to one year to comply while developing economies were allowed a transition period until 1 January 2000, although for developing countries required to extend product patent protection to new areas such as pharmaceuticals, a further period of five years was allowed before such protection had to be introduced. Least Developed Countries (LDCs) were expected to enact TRIPS by 2006 although the Doha Ministerial Declaration on the TRIPS Agreement and Public Health allowed them a further 10 years in respect of pharmaceutical products and in November 2005 the deadline for implementing all other TRIPS provisions was moved to mid-2013.

India signed the TRIPS Agreement in April 1994. Before that, India allowed only process patents under the Patent Act (Act 39 of 1970). The Indian government enacted the Indian Patent Act (IPA**),** 1970 after considerable deliberation and excluded patents on products such as pharmaceuticals and foods. It recognized only process patents for food, medicine and chemical substances. The term of patent protection was 7 years from the date of filing complete specifications or 5 years from the date of sealing (granting) in the case of food, drugs and medicines. Under the Act, pharmaceutical firms were free to devise a non-infringing process to manufacture a drug even if the same was protected by a process patent in India. The soft patent system in pharmaceuticals, combined with a progressive drug policy forcing manufacture from the basic stage, is widely considered to be an important factor in the subsequent rapid growth of Indian pharmaceutical industry, as a producer and exporter of low cost generic medicines and bulk intermediates (discussed later in Chapter 4). The system of granting patents to the manufacturing process and not the end product helped the indigenous pharmaceutical industry develop and succeed in producing molecules that were under patent protection elsewhere, at a cost that was a fraction of the original research cost. Chaudhuri (2005) has analyzed the remarkable growth of the Indian pharmaceutical industry since the early 1970s when product patent protection in pharmaceuticals was abolished in India.

The signing of TRIPS agreement has compelled India to provide product patent protection for pharmaceuticals but given the lack of harmonization in patent laws of different countries and the scope of flexibilities in the agreement, it is up to the individual

country's national laws to reinterpret the scope of patentability, provision of compulsory licensing, parallel imports, data exclusivity and so on.

3.2 Flexibilities in the Indian Patent (Amendment) Act, 2005

As mentioned above, TRIPS set out transitional periods for WTO members to introduce legislation complying with the obligations under TRIPS (UNCTAD, 1996) on Jan 1 1995. For developing countries like India, the deadline for complying with TRIPS was the year 2000. At that time, India's current enactment of the Patent Act of 1970 directly contravened Article 27 of the TRIPS Agreement. According to Article 27 of the TRIPS, patents must be available for any inventions, whether products or processes, in all fields of technology. Until TRIPS, India excluded patents on products such as pharmaceuticals and food. In addition, Article 65.4 of TRIPS provided a special transitional provision for those countries that did not grant product patents. The provision provided an additional five years (until 2005), from the initial TRIPS transitional period, to introduce product patent protection. India took advantage of this extra transition period. However, under TRIPS Article 70.8, India had to provide a means by which patent applications could be filed during the transitional period. The "mailbox provision" which was introduced in the amendment of the Patents Act in 1999 required acceptance of all applications for product patents in the field of pharmaceuticals and agro-chemicals, thereby establishing priority filing dates, while at the same time permitting member countries to postpone granting product patents. In order to compensate this delay in granting product patents, "exclusive marketing rights" (EMRs) were to be provided in accordance with TRIPS Article 70.9 till January 1, 2005. This applied to all patent applications for pharmaceutical or agricultural chemicals filed on or after 1st January 1995 in India provided a patent and marketing approval was applied for and granted for the same product in another WTO member country. EMR was valid for a period of five years or till the date of grant of the patent or the date of rejection of the application for the grant of patent whichever was earlier. In 2002, the second amendment of the Patent Act provided for changes in the scope of patentable inventions, extension of the term of protection, provision for reversal of burden of proof in cases of process patent infringement, and conditions for compulsory licenses. The third amendment in the Patent Act was a requirement to introduce product

patents in the area of chemicals, pharmaceuticals, and agricultural chemicals and food by January 1 2005.

However, concerns about the implications of the WTO TRIPS Agreement on the access of medicines led to the adoption of the Doha Ministerial Declaration on the TRIPS Agreement and Public Health in Nov 2001. The Declaration clarified the scope for flexibilities which individual nations could adopt to protect public health and promote access to medicines for all

Definition of invention and Exceptions to Patentability

Under Article 27 of TRIPS, patents are to be granted to all "inventions". However, the World Health Organisation (WHO) in its report in 2006 concludes that as there is no definition of invention in the TRIPS agreement, developing countries may determine the definition of an invention, the criteria for judging patentability, the rights to be conferred on patent owners and exceptions to patentability in their national laws.

Some of the amendments in the Indian Patent Act have limited the scope of patentability in pharmaceuticals. The requirement of novelty, as in other patent laws, is met for any invention or technology which has not been anticipated by the publication in any document or used in the country or elsewhere in the world before the date of filing of patent application with complete specification, i.e. the subject matter has not fallen in public domain or that it does not form part of the state of the art. However, in the Indian Patent Act, 1970 clause (ja) of section 2 defined "inventive step" as *"a feature that makes the invention not obvious to a person skilled in the art."* which is substituted in the amended Patent Act 2005 by "a feature of an invention that involves technical advance as compared to the existing knowledge or *having economic significance* or both that makes the invention not obvious to a person skilled in the art". Under section 3(d) of the Patents (Amendment) Act 2005, "the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or the mere use of a known process, machine or

apparatus unless such known process results in a new product or employs at least one new reactant" is not to be treated as invention This has replaced the earlier clause of " the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employ at least one new reactant".

In the opinion of Correa (2007), classes that ought not to be classified as patentable are any new salt, ester, ether or polymorph of an existing chemical entity, a new combination of already existing active ingredients, a new dosage form that allows a new route of administration, a new route of administration of an existing dosage form or a change in formulation. However, the European Patent Office often grants patents on derivatives of known active ingredient, in line with the practice of the German Patent Office and the Federal Patent Court. It may be noted further, as mentioned above, that Section 3(d) of the Indian Patent Act provides an amendment whereby salts, esters, ethers, polymorphs, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in their effectiveness. One such derivative, polymorphs, where same active pharmaceutical ingredient may exist in amorphous solid or crystalline form is not patentable in India as they are deemed within the prior art. The patent holder, GSK, of an H_2 - receptor antagonist (to treat ulcers), namely Cimetidine applied for a grant of patent on its polymorph after five years of grant of patent on the its active ingredient but was rejected in the UK and other countries on the ground that the polymorph was obtained through a process which was already claimed in the original patent but another anti-ulcer drug, Ranitidine, was granted patent on its polymorph till 2002 though its main patent expired in 1995 in the United States (Correa, 2007).

Novartis, the Swiss pharmaceutical multinational challenged the constitutionality of Section 3(d) of the Indian Patent Act which according to the company contravenes article 27(1) of TRIPS. The question is whether due to lack of clear criteria for patentability, member countries have the flexibility to interpret the criteria of patentability. Novartis invented Imatinib Mesylate (Gleevec, brand name) in 1992 to treat life-threatening form of cancer, chronic myeloid leukaemia. It patented the drug in the

U.S. and other countries in 1993 and not in India, as India did not recognize patents at that time. However, the 1993 U.S. patent of Imatinib disclosed the salt Imatinib Mesylate. On India becoming a signatory to TRIPS, Novartis filed for a patent for a beta crystalline form of imatinib mesylate in 1998. This was the first case of grant of a patent like right, exclusive marketing right for the drug in the transitional period. It tried to demonstrate an enhanced efficacy and enhanced bioavailabilty of 30% in studies conducted on rats but the Indian Patent office rejected the patent application on the basis that the patent is for a new form of a chemical entity which was patented before WTO came into being in 1995. Also, under section 3(d) of the Indian patent act, it does not show significant enhancement in efficacy. The patented drug sells at Rs.120,000 per patient per month against its generic versions manufactured by NATCO, Cipla and Ranbaxy at Rs. 8000 per patient per month.

In certain cases, rejection of patent application in India has had a wider impact. When GlaxoSmithKline (GSK) put in its application for patent rights over fixed dose combination (FDC) of pre-1995 drugs of anti-HIV/AIDS namely Lamivudine and Zidovudine with the brand name Combivir, it was rejected by the Indian patent office. Following this development, patent offices worldwide started re-examining the patent application on Combivir (where it has been granted and refuse the application, where it has not been granted) on the basis that it does not fulfill the patentability criteria (Third World Network, 2006).[9]

Mailbox Applications

With the signing of the TRIPS agreement in 1995, the patentees were provided 'mailbox' facility where they could file their applications till 31st Dec 2004 according to article 70.8 of the TRIPS agreement, although the opening of the mailbox and examination of patents was to take place after 1.1.2005. Though the act provided privileges and rights to the patent applicant similar to those who are granted patents, many Indian generic drug manufacturers have been manufacturing generic versions of some of the patented drugs which might have been in the mailbox. To protect the

[9] Available at http://www.twnside.org.sg/title2/intellectual_property/info.service/twn.ipr.info.090603.htm

interests of the generic manufacturers, section 11A does not permit the patent applicant to institute any proceedings for infringement until the patent is granted and entitles the patent holder (in case the application in the mailbox is granted patent) to only reasonable royalty payments from those firms that had made significant investment and were marketing the product before January 2005. While the law has stated that the generic manufacturers would have to pay a "reasonable royalty" to the patent holder, it has not defined "reasonable." Besides article 31(h) of the TRIPS agreement gives the patent holder the right to demand adequate remuneration following the decision to grant compulsory license which might be applied even in the case of mailbox applications.

Compulsory Licensing and Government Use

Compulsory Licensing is a procedure whereby a Government can allow any company, agency or designated person the right to make a patented product, or use a patented process under license, without the consent of the original patent holder. Article 31 of the TRIPS agreement allows compulsory licensing on the grounds such as emergency, anti-competitive practices, non-working of a patent, public health or public interest. Under Section 84(1) of the amended Act, an application can be made for compulsory license three years after the grant of a patent: "At any time after the expiration of three years from the date of the grant a patent, any person interested may make application to the Controller for grant of compulsory license" on any of the following grounds:

(i) Reasonable requirements of the public with respect to the patented invention have not been satisfied.

(ii) Patented invention is not available to the public at a reasonable affordable price, or

(iii) Patented invention is not worked in the territory of India on a commercial scale to an adequate extent.

Section 25 allows revocation of patents by the Controller for non-working of a patent, not being offered to public at a reasonable affordable price or not fulfilling reasonable requirements of the public with respect to the patented invention.

The license is primarily granted to supply in the Indian market but it could also be used to export to countries with little or no manufacturing capability. Following the WTO decision of August 2003 allowing export of the entire production under a compulsory licence, the amended Act included an additional section 92A whereby compulsory licence shall be available to manufacture and export to countries with little or no manufacturing capability. With respect to exporting drugs to a country which makes a request for a generic drug, the Act has simplified the compulsory licensing procedure; countries that put in a request for generic drugs do not have to issue a compulsory license.

Thorpe (2002) reviewed this aspect for seventy developing countries and LDCs and found that most of the countries provided compulsory licences in case of failure to exploit the patented drug or exploit it on reasonable terms, while only 13 provided compulsory licences on grounds of public interest and/or national emergency or health emergency. Till now India has not used this facility[10] while Brazil and Thailand have issued compulsory licences. China, Israel, Korea, Mexico, UAE and Singapore have agreed to use the WTO 2003 system only under emergencies and extreme urgent situations. Japan and Germany have agreed to issue compulsory license only for public welfare or for correcting unfair competition. These terms lend themselves to different interpretations across nations.

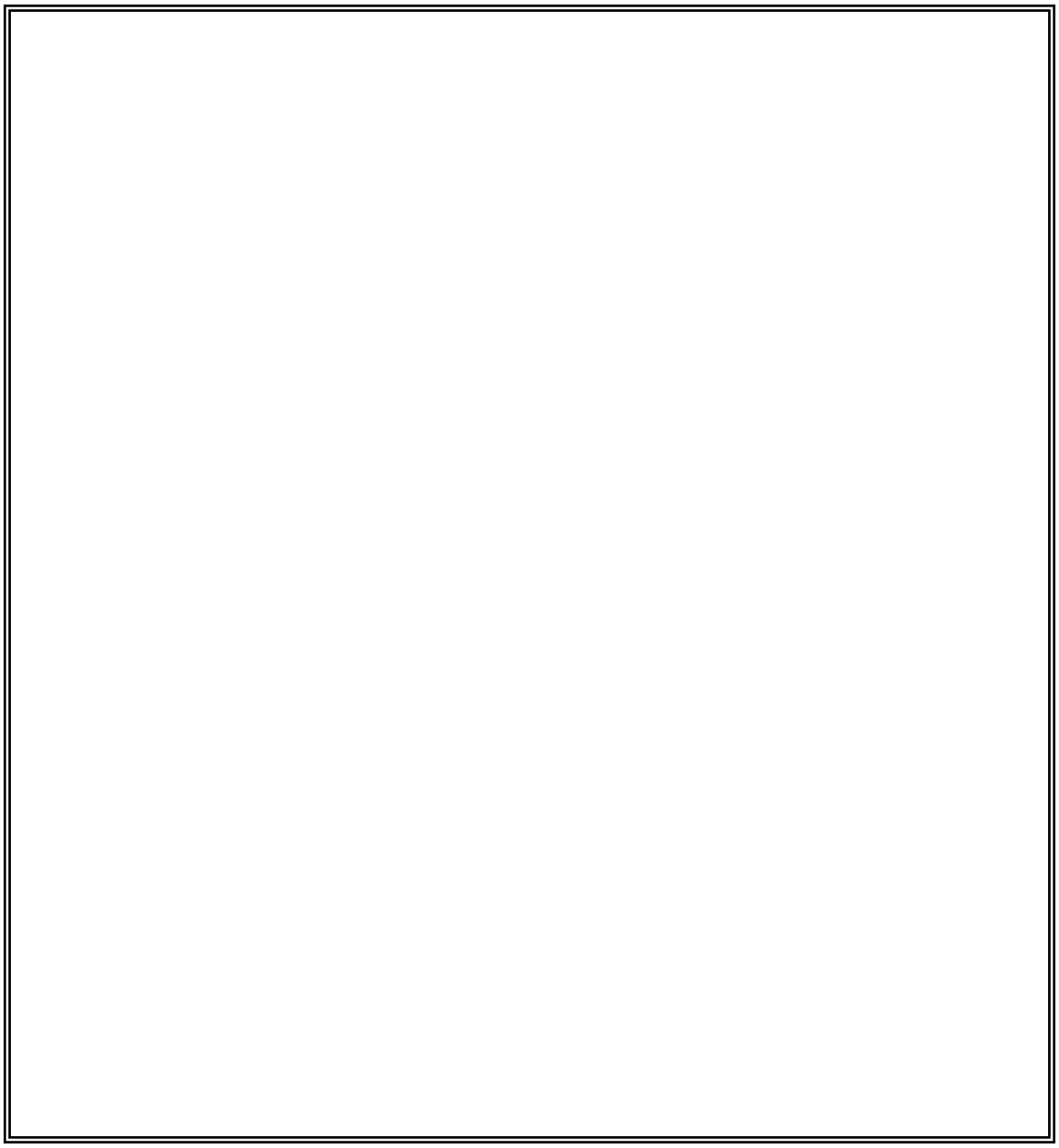
Article 31(b) allows for use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government in cases of public non-commercial use. Under section 47 of the Indian patent act, any process in respect of which a patent is granted or any machine, apparatus or other article in respect of which the patent is granted or in case of a patent in

[10] In the pre-1970 phase only five cases were made for the grant of compulsory licenses out of which only 2 were granted (Chaudhuri, 1984)

respect of any medicine or drug, may be imported for public non-commercial use by the government, like for the purpose of experiment or research including the imparting of instructions to pupils, for government's own use or for distribution in any dispensary, hospital or other medical institutions. Under this "government use" procedure, the prior consent of or negotiations with the patent holder is not required, but adequate compensation has to be paid under section 102. However one TRIPS flexibility that India has not taken advantage of is in Article 44.2 – non-grant of injunction for government use.

Opposition to a Patent

Following article 27(1) of TRIPS, where patents are to be given for new useful and non-obvious inventions, the Indian Patent act in section 25 provides for patent opposition at two levels: pre-grant, upon the publication of the application; and post-grant, upon the grant of a patent (see Box 3.1 on some cases of pre- and post-grant opposition). There are around 458 cases of pre grant opposition filed in various patent offices (Gopakumar, 2010). No patent is to be granted before the expiry of a period of six months from the date of publication of the application. Where an application has been published but a patent has not been granted, any person may oppose the grant of patent or even if patent is granted but before the expiry of a period of one year from the date of publication of grant of a patent, any person can oppose the grant under Section 25 of the Patents Act.



Data Protection

The issue of data protection is one of the most debated aspects of TRIPS. Article 39.3 of the TRIPS agreement mandates protection for the test data submitted by the pharmaceutical and agro-chemical industries for market approval. The pharmaceutical companies have to submit test and clinical data to the national health authorities to obtain marketing approval for a new drug. The marketing approval authorities have to protect such data which is submitted by the originator of new product against unfair commercial use. Data protection is different from patents in that the patents are available to inventions which are novel, involve an inventive step and have industrial application while data protection has to be provided at the time of grant of marketing approval to a new product which may be patented or non-patented. This can result in what is known as "ever greening" (See Box 3.2 on Evergreening). The use of ambiguous terms like "considerable effort", "unfair competition" and "new chemical entities" has led to different interpretations of these terms by different nations according to their national interests. For instance while some countries have introduced trade secret form of protection whereby the regulatory authority can rely on the information on data to grant marketing approval to subsequent applicants for similar products without disclosing the confidential information to them, developed countries like the United States and European Union have adopted data exclusivity as the mode of protection. Under this type of protection the regulatory authority cannot rely on the data submitted by the innovator for approving subsequent applications. This implies non-disclosure as well as non-reliance on the first applicant's data by the regulatory authority. The need for data protection is felt as a means of encouraging innovation and introduction of new products/technology elsewhere in the world without any time lag. Most often, companies use data exclusivity provisions to seek a period of monopoly in a country even if it does not have any patents on the product in the country.

If data exclusivity is introduced, generic companies would have to incur huge costs in data collection for marketing the same drug. The latest recommendations of a

Committee set by the Indian government in 2004 to examine issues relating to data exclusivity, which gave a report in 2007, are that five years data exclusivity be allowed for proprietary herbal drugs and three years for agro-chemicals, and test data for pharmaceutical drugs are to be protected as a trade secret under common law.[11] The drug regulator, who judges the safety and efficacy of the new drug, will continue to refer to the clinical trial data of the original drug to approve generic versions that are chemically the same.

There are safeguards against monopoly by not allowing extension of patent period beyond twenty years on the basis of the provision of data exclusivity. One may make use of the condition that a company will not be eligible for data exclusivity if it does not seek marketing approval within two years of its global launch.

[11] See Reddy and Sandhu (2007).

BOX 3.2: EVERGREENING

Evergreening implies unjustifiably extending the life of patent on any drug or agrochemical beyond the patent life of the original active pharmaceutical/agrochemical ingredient. The data protection policies can extend the life of a patent even when the patent has expired or invalidated and delay the introduction of cheaper generic drugs. Article 39.3 of TRIPS requires protection of data for marketing approval of any pharmaceutical or of agricultural chemical products which utilize new chemical entities, except where necessary to protect the public or unless steps are undertaken to ensure that the data are protected against unfair commercial use. Thus TRIPS provides flexibility to member nations to interpret and determine the form of protection to the test data. One form in which Evergreening is used is Data Exclusivity. Data Exclusivity refers to a practice whereby, for a fixed period of time, drug regulatory authorities do not allow the test data of the innovator company to be used to register an equivalent generic version of that medicine. Data Exclusivity is meant to provide protection for new drugs/ agrochemicals data furnished with the regulatory authorities for regulatory clearances, from "unfair commercial use" by anybody other than the innovator.

Similarly patent claims on any modification to the structure of known molecules can result in Evergreening. Section 3(d) of IPA precludes patent protection for mere discovery of new forms of a known substance, which lacks enhancement of the known efficacy of that substance. The case of Gleevec of Novartis is well known. The company wanted a patent for crystalline form of Gleevec, which is regarded just an incremental innovation of a known molecule. The patent office rejected Novartis application for the product. Similarly the Patent Office also rejected the patent application of SmithKline Beecham PLC, for ethane sulphonate salt of its anti-diabetic drug, rosiglitazone after finding that the company failed to establish that the rosiglitazone derivative has better efficacy than the known patent compound. In yet another case, the Delhi Patent Office rejected the patent application of Gilead Science Inc for its anti-influenza drug, Tamiflu (oseltamivir phosphate), in favour of a pre-grant opposition filed by Cipla Ltd. It was found that the description of the innovation provided by the company is ambiguous amounting to insufficiency and alleged that invention falls under section 3 (d) of the Patent Act. Similarly if an applicant applies for a claim on a combination of two or more medicines for anti AIDS in a single tablet it would be extending the life of patent on these molecules separately and would be termed as evergreening by many jurisdictions. The Patent Office rejected patent application of Pfizer for its drug, Caduet, a therapeutic combination of amlodipine and atorvastatin. The decision against Caduet, a combination Pfizer's Norvasc (amlodipine besylate) and Lipitor (atorvastatin calcium), is in favour of a pre-grant opposition filed by Torrent. (P.A.Francis on www.Pharmabiz.com, accesssed April 29, 2009).

"Bolar" Provision

The rationale for this provision is expediting the introduction of generic version of a patented drug. The "Bolar" provision prevents patentee's exclusive rights under Article

30[12] of the TRIPS which permits member countries to provide limited exceptions to the exclusive rights conferred by a patent. The amended Patent Act under section 107A provides for Bolar exception which would allow a generic drug manufacturer to produce or import patented drugs for the purpose of development and submission of information for regulatory trials before patents expire. In the absence of "Bolar" provision, generic manufacturers would have to wait for the patents to expire before they could initiate regulatory tests for the drug. According to the act, any act of making, constructing, using, selling or importing a patented invention solely for uses reasonably related to the development and submission of information required under any law for the time being in force in India or in a country other than India that regulates the manufacture, construction, use, sale or import of any product will not be considered as infringement.

Parallel Imports

Under Article 28 of TRIPS the patent owner has the exclusive right to stop others from producing, selling or importing the invented product. However, under the legal fiction of the doctrine of exhaustion, IP owners' rights are exhausted upon the first sale of the product. The controversy is about whether these rights are also exhausted internationally so as to permit parallel imports. Parallel imports occur when patented medicines produced or sold abroad with the consent of the patent owner are subsequently imported into the domestic market at cheaper prices without the consent of the owner. Importation of patented products by any person from a person, who is duly authorised under the law to produce and sell or distribute the product, shall not be considered as an infringement of patent rights as per section 107A (b) of the Patents (Amendments) Act, 2002.

[12] Article 30 allows members to provide for limited exceptions to the exclusive rights conferred by a patent, i.e, to define acts that would not be deemed as infringing when made without the authorization of the patent holder (Correa, 2002).

Price Controls

To ensure public access to medicines, price controls may be used as an effective instrument. TRIPS flexibilities do not prevent the control of prices of the patented medicines. India has used price controls even in the process patents era. With the product patents, the need for price controls is even greater. Drug price control is not peculiar to India. In most countries, a majority of drugs is available through public-funded institutions and health insurance mechanisms. Insurance providers serve to depress drug prices as drug firms would be bound to reduce the prices to be part of such schemes. Some monitoring strategies like price negotiations, bulk purchase under National Health Schemes, Health Insurance Schemes etc exist in developed countries like Canada, France, UK, Japan, Germany, etc. These countries have their own monitoring/controlling bodies as per their requirements. For example, Canada's Patented Medicines Prices Review Board through negotiations sets a maximum allowable price that pharmaceutical manufacturers may charge for patented medicines and any attempt to impose higher prices can result in significant fine for the manufacturer. In Australia since 1993, new drugs with no advantage over existing products are offered at the same price. Where clinical trials show superiority, incremental cost effectiveness is assessed to determine whether a product represents value for money at the price sought. In United Kingdom. local healthcare services are provided to the citizens under the National Health Service. Through the Pharmaceutical Price Regulation Scheme (PPRS), the Department of Health and the Association of British Pharmaceutical Industry negotiate profit rates from sale of drugs to the National Health Scheme.

Vernon (2003) provided a comparison indicating various measures of regulating prices in the highly developed countries. The tradeoff between consumers' welfare and the incentive to innovate as a result of price controls is analysed by Sood et al. (2009) for 19 developed countries for the period 1992-2004. Their analysis shows that price regulations have a direct and strong impact on drug firm revenues, but not on drug pricing. Therefore, these mechanisms effectively constrain pharmaceutical expenditure in

markets that have product patent rights. However, t'Hoen (2009) suggests mechanisms which delink the R&D from the pricing issues through award of prizes, establishing patent pools and formation of public-private partnerships. The innovator instead of being rewarded with patent rights could be rewarded prizes. Prize mechanisms can be introduced in areas where the markets are functioning the poorest i.e. diseases that primarily affect poor people living in poor countries. Though the prize system overcomes the problem of limited diffusion of an invention, it is difficult to assess the ex-post value of an invention. The patent system to that extent is more market-based. Also committing to purchase a fixed amount of a product at a specified price in advance could stimulate innovations. On the supply side, push programs such as R&D tax credits, grants, loans etc would work better for domestic industry of any developing country as it faces resource crunch. The pull programs, if could be prevented from problems of moral hazard and uncertainty, work well to simulate investment in neglected diseases by MNCs.
(Kremer, 2006).

As mentioned above, in all developed countries health expenditure is negotiated by either the insurance companies or hospitals to make drugs affordable to the patients and to make it cost-effective for the insurer. Unlike countries where majority of medicines are procured through tenders, India's tender market is restricted only to Tamilnadu. The Rajasthan model of Lifeline fluid stores (hospital pharmacy stores run by Medical societies) for bulk purchase of drugs directly from manufacturers and selling them at reduced prices need to be introduced in other states. This system needs to be strengthened and implemented in other states to narrow down the large variations in prices of different brands of the same medicine. Also the competition to the existing system of medicines can come from alternative traditional system of medicines which could help in keeping prices under check.[13]

[13] It may be mentioned in this context that the Indian government has initiated a move to bring all 354 medicines in the National List of Essential Medicines (NLEM) under price control , thereby enlarging substantially the scope of drug price control in India (as reported by Business Standard, July 15, 2010). National Pharmaceutical Pricing Authority (NPPA) currently controls prices of drugs forming some 20% of the Rs 60,000 crore domestic drug market. In case, all essential medicines in NLEM are brought under price control, NPPA will be controlling about 35% of the domestic drug market.

3.3 Summing Up

The signing of TRIPS agreement has compelled India to provide product patent protection for pharmaceuticals. But, because of lack of harmonization in patent laws of different countries and the scope of flexibilities in the agreement, it is up to the individual country's national laws to reinterpret the scope of patentability, provision of compulsory licensing, parallel imports and data exclusivity.

India made full use of the transitional period of 10 years which was granted to developing countries. Also, various flexibilities have been introduced. The most important flexibility that has been brought in is the use of Section 3(d) to reject the grant of patents to any modification in a patented molecule. This has helped in preventing evergreening to a certain extent. The issue of compulsory license has not been put into use though the guidelines are quite clear. There have been several cases of patent grant opposition, both pre and post-grant. Through its continuous effort to protect public health by not accepting patents on any modifications in the molecules, India has not only reduced the scope of patentability in its own domain but also across other nations (as the example of Combivir of GSK bring out).

Despite the scope for using these flexibilities, there are several loopholes in the legal, political and institutional framework in India, which make the implementation of these flexibilities quite difficult (Gopakumar, 2010). The Patent Office is not technically competent to assess the efficacy and other properties of a claimed patent; the number of competent patent examiners is very less compared to the number of patent applications examined; there are procedural delays in granting compulsory licenses; the Patent Office does not provide complete information on the specification of a patent before grant of a patent which makes pre-grant opposition difficult. The policy to enter into price negotiations with the patent holder rather than price controls also undermines the importance of easy accessibility of drugs; the patent linkage issue and data exclusivity are TRIPS plus obligations which leave less scope for flexibility.

Therefore making full use of TRIPS flexibilities which are incorporated in the Indian Patent Act, as amended in 2005 requires adopting mechanisms by the government, legal experts and patent offices which will balance the issues of affordability and innovation and curb adverse long term effects of the patent reforms.

Chapter 4

Performance of the Indian Pharmaceuticals Industry, 1970-95 and Post-1995[14]

Indian pharmaceuticals industry has evolved from almost non-existent to a world leader in the production of high-quality, low-cost generic drugs (Greene, 2007). It ranks 4th in terms of production volume and 13th in terms of domestic consumption value. It accounts for about 20 percent of global production of generics. Valued at $5.3 billion in 2005, it accounts for less than one percent of the global pharmaceuticals industry.[15]

The domestic pharmaceuticals industry in India meets almost 95 percent of the country's needs (FICCI, 2005). A substantial portion of the production is exported. Cost of production of bulk drugs in India is about 60 percent less than that in the West (Greene, 2007). India has substantial cost advantage also in pharmaceutical research and development, and clinical trials. Implementing the process of a new drug discovery in India will cost only 5 to 10 percent of the cost in the West. For clinical trials, similarly, the cost in India is only a small fraction the costs in the West. The Indian pharmaceuticals industry accounts for the second largest number of Abbreviated New Drug Applications (ANDAs) (Greene, 2007). India is the world leader in Drug Master Files (DMFs) applications with the U.S. Food and Drug Administration (USFDA). There are 75 USFDA approved manufacturing facilities in India, more than in any other countries outside the U.S. All these signify the high level of technical competence achieved by the Indian industry.

This chapter is devoted to an analysis of the performance of the Indian pharmaceuticals industry with a focus on the developments since 1995. The performance

[14] This Chapter has been prepared by Bishwanath Goldar and Ravinder Jha.
[15] According a recent newspaper report, the Indian pharma market including exports and institutional sales is valued at Rs 100, 000 crore or US$ 25 billion.

of the industry during the period 1970 to 1995 is discussed first, following which the developments in the post-1995 period are taken up.

4.1 Development of the Industry during 1970-1995

Prior to 1970, the Indian pharmaceuticals industry was relatively small in terms of production capacity. At the time of Independence in 1947, India's pharmaceuticals market was dominated by MNCs (multinational corporations) that controlled between 80 to 90 percent of the market primarily through imports (Greene, 2007). Foreign companies held the patents for almost all pharmaceutical products in India under patent, and the drug prices in India were among the highest in the world (Greene, 2007; Government of India, 1975). The pharmaceuticals market in India remained import-dependent through the 1960s until the government initiated the policies aimed at self-reliance through local production. At that time, 8 out of the 10 top pharmaceutical firms in India (ordered in terms of sales) were subsidiaries of MNCs. To facilitate independent supply of pharmaceutical products into the Indian market, the government funded five state-owned pharmaceutical companies.

The scene changed radically with the Patent Act of 1970. Product specific patents were disregarded in favour of manufacturing process patents, which allowed Indian companies to reverse engineer or copy foreign patented drugs without paying a licensing fee. This policy initiative created a favorable environment for the domestic industry to grow and acquire technical competence. At the same time, domestic drug prices were set at very low levels under the provision of Drug Price Control Orders of 1970 and 1979. Simultaneously high import tariffs were imposed. In the changed environment, the MNCs could retain up to 74% foreign equity only if substantial part of their production consisted of basic intermediaries and/or high technology bulk drugs. These measures protected the domestic industry, and their share in total production rose while that of MNCs declined gradually. The new patent law together with FERA act (whereby multinationals were directed to bring their equity down from 40% to 26%) and the drug policy of 1978 changed the conditions under which the MNCs could operate

fundamentally. However, as the country depended on MNCs for the supply of bulk drugs and medicines, it had to build up parallel domestic industry, substituting indigenous capacity in order to acquire effective control over the foreign controlled companies. From the early 1960s the investment of foreign controlled rupee companies (FCRC) and foreign branches in medicines and pharmaceuticals increased from 4.1% in 1964 to 7.6% in 1974 to 9.8% in 1978 and further to 11.35% in 1980 of the total foreign investment.[16] This increase in foreign investment despite greater restrictions on the activities of foreign companies can be explained only through the stipulations under Drug Policy of 1978. The government gave production licenses to FERA companies only if they involved high technology bulk drugs and related formulations, provided half of the bulk drug manufacture was sold to other formulators. They were required to produce bulk drugs and formulations in the ratio 1:5 which was further made more restrictive in the Drug Policy of 1986 by changing the ratio requirement to 1:4. Thus foreign investment increased in a period of stringent regulations along with increase in productive capacity. While no new MNCs entered the Indian pharmaceutical sector, many big companies like Ciba-Geigy, Pfizer, Glaxo and Johnson and Johnson continued and increased their manufacturing activities (Jha, 2007).

The domination of MNCs in the market share declined from 68% in 1970 to only 23% in 2004 (Chaudhuri, 2005, p. 18, Table 2.2). The total production of bulk drugs and formulations rose from Rs. 4900 mn in 1974-75 to Rs. 14400 mn in 1980-81 and further to Rs. 354,710 mn in 2003-04 at current prices due to the entry of many domestic firms along with a massive increase in the production by the older firms (Chaudhur, 2005, p. 40).[17] This made the indigenous sector almost self- sufficient and the trade balance as a percentage of exports rose from 8.5% to 78.4% (Chaudhuri, 2005, p. 45)

The growth rates in the value of production of bulk drugs and formulations (at constant prices) in the period 1970-71 to 1979-80 were 14 and 17 percent per annum respectively (Jha, 2007). In the subsequent period 1980-81 to 1994-95, the growth rates

[16] RBI Bulletin –India's International Position July 1975, March 1978 and April 1985.
[17] A detailed analyses of the growth of Indian Pharmaceutical Industry in the changed environment since 1970 is given in Chaudhuri (2005, Chapter 2).

were in the range of 6 to 7 percent per annum. The rapid growth of the domestic industry resulted in a fall in the market share of MNCs. It fell from about 80 percent in the early 1970s to about 33 percent by 1991, and 25 percent by 2007 (Shanmugasundaram, 2008; Nauriyal and Sahoo, 2008).

A major outcome of the changed policy regime that prevailed since 1970 is that the consumers in India could get drugs and medicines at very low prices. Table 4.1 brings this out. The prices reported in the table were those prevailing in the years, 2003 to 2005.[18]

A related issue is the time gap between the introduction of a patented drug in the Western countries and its availability in India. The question is whether the absence of product patenting caused a delay in the availability in the new drugs in India? From a casual examination of this issue, it seems that absence of product patenting did not delay the availability of newly patented drugs, since a copy-version would commonly become available to the Indian consumer in a short period of time. On this question, Sakthivel (2007) observes that relative to other developing countries, the gap between global introduction of new drugs and their entry as generic versions in India has narrowed over the years and the introduction of new drugs in the Indian market has been quite rapid. This is discussed further later in the Chapter.

[18] A comparison of drug prices beween India and the US and between India and Malayasia at the end of the 1980s presented by Subramanian (2008) shows that the prices in the US and Malayasia were substantially higher than those in India, confirming the pattern observed in Table 4.1. Prices of Diclofenac, Atenolol and Ketaconazole in Malayasia were respectively 4.1 times, 8.7 times and 2 times higher than the prices prevailing in India.

Table 4.1: Comparison of Prices of Select Drugs in Different Dosages (Rs.)

Therapeutic segment	Drug Formulation	India	Pakistan	Indonesia	USA	UK
Anti biotic	Ofloxacin 200 mg, 10 tablets	25	216.66	441.67	2377.76	595.84
Anti ulcerant	Ranitidine 150 mg, 10 tablets	5.19	64.39	634.08	2030.16	792.68
Cardiovascular	Atenolol 50 mg, 14 tablets	5.60	62.42	322.56	809.60	NA
Anti cancer	Imatinib Mesylate 100 mg, 10	850	8516.66	9821.96	9329.76	9863.28
Anti biotic	Ciprofloxacin 500 mg, 10 tablets	29	368.36	926.75	2552.44	1079.20
Anti biotic	Norfloxacin 400 mg, 10 tablets	17.59	104.73	130.63	1782.88	277.40
Anti-inflammatory	Diclofenac 50 mg 10 tablets	1.34	36.79	161.12	733.48	191.52
Anti ulcerant	Omaprazole 20 mg, 10 tablets	9.90	358.80	634.08	2030.16	792.68
Cardiovascular	Diltiazem 60 mg, 10 tablets	30	50.23	32.50	410.52	86.64
Cardiovascular	Amlodipine Besylate 5 mg 10 tablets	5.90	87.05	228.78	696.96	353.40
Anti- histamine	Cetrizine 10 mg 10 tablets	7.80	31.03	166.67	928.40	193.04
Anti-Cancer	Carboplatin 150 mg vial	693	1662.78	3702.60	21625.12	4652.72
Cholesterol Reducing	Atorvastatin 10 mg 10 tablets	24	483.85	565.95	1087.68	489.44
Cholesterol Reducing	Lovastatin 20 mg 10 tablets	28.90	159.34	433.33	1180.96	N.A.
Anti-asthmatic	Salmeterol 200	130.25	1407.56	1980	4043.16	7412.28
Urology	Doxazosin 2 mg 10 tablets	25	124.60	341.56	748.88	382.28

Sources: Taken from Jha (2007). Basic sources of information for the table, as mentioned by Jha, are: India Drug Today May/June 2005; Pakistan Pharma guide Jan 2004; USA Redbook 2004; UK MIMS June 2005; Indonesia IMS 2003; Thailand TIMS 2003 (Courtesy: Shri B.K. Keayla)

4.2 Performance Since 1995

In some of the writings on the new patent regime for pharmaceuticals in India, authors have expressed serious concerns about its possible adverse effect on the domestic

industry and the consumers (Chaudhuri, 2004, 2005; Lanjouw, 1998; Watal, 2000). The domestic pharmaceutical industry has, however, been able to meet the challenges of the new regime and exploit it to its advantage with appropriate firm strategies.[19] Leading companies have moved away from a reliance on the domestic market to the development of new drugs, exports to regulated markets, and cooperative agreements with the MNCs (Greene, 2007). Another favourable factor has been that MNCs have been under pressure to turn to contract manufacturing and research services, co-marketing alliances, and outsourcing of research and clinical trials to reduce cost. With such opportunities becoming available, many Indian companies – especially those without the resources for R&D – have embraced custom manufacturing, contact research and market alliances to remain profitable (Greene, 2007).[20] For these reasons, the pharmaceutical firms in India have been able to maintain their growth and financial performance in the new patent regime. Turning to the effect of product patenting on the consumers, it seems they have not so far faced any serious problem of affordability in the new patent regime. These aspects are discussed further below.

4.2.1 Growth

The growth rate of the Indian pharmaceuticals industry has not come down in the post-1995 period in spite of the imposition of a stricter patent regime. During 1980-81 to

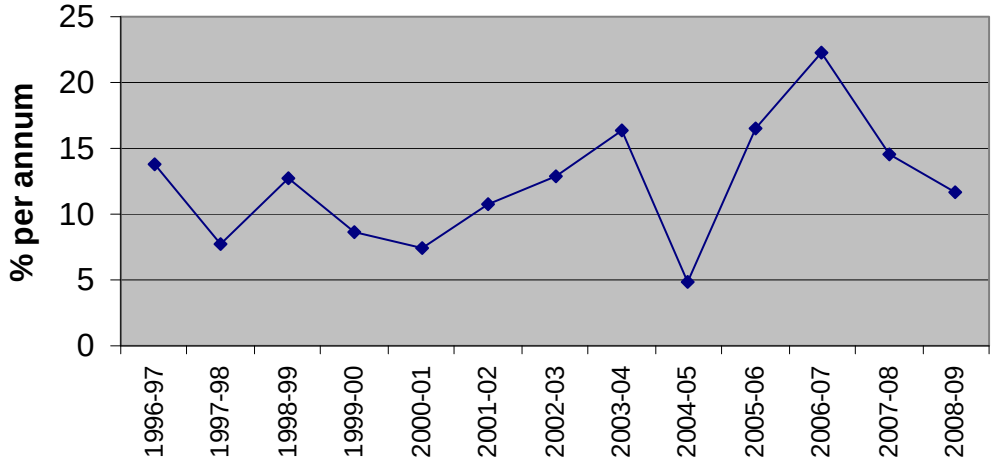
[19] Rai (2008) discusses the strategies Indian pharmaceutical firms have adopted to meet the challenges of the new patent regime. He observes that the industry is adopting a mix of competitive and collaborative business and R&D strategies in the emerging business environment. He concludes that the industry is witnessing a transition phase, and is undergoing consolidation and restructuring. Grace (2004) notes that to meet the product patent challenge, many Indian pharmaceutical firms are adoping a multi-stage strategy of moving up the product value chain and increasing exports to regulated markets. Leveraging their comparative cost advantage, the firms plan to target plain vanilla generics sales to regulated markets in the near-term, and to develop more difficult-to-manufacture generics (e.g. injectables), lower-risk NDAs, and to follow-on biologics in the medium term. Sampath (2008) notes that Indian pharmaceutical firms are persuing a simultaneous collaborator-competitor strategy in local and global markets. They compete with international firms for generic drugs and launch patent disputes to protect their interests. At the same time, they collaborate with international firms on various R&D fronts. Varying business models are emerging depending on what the Indian firms consider to be their intrinsic strengths and how they can capitalize on it.

[20] According to Dun and Breadstreet's *Industry Cursor* (October 2008), contract research and manufacturing services (CRAMS) in Indian pharmaceuticals industry has grown from about Rs 2 billion in FY 2002 to about Rs 42 billion in FY 2007 (this is based on industry sources). This is projected to reach Rs 95 billion in FY 2010.

1994-95, the growth rates in the value of production of bulk drugs and formulations in India were 6.1 and 6.6 percent per annum respectively (Jha, 2007). The growth rate of bulk drugs increased to 10.2 percent per annum while that for formulation fell marginally to 5.6 percent per annum during the period 1995-96 to 2004-05. Overall, the growth rate of the pharmaceuticals production during the latter period was not any lower than that achieved during the previous 15 years.

Analysis of growth rate of sales of drugs and pharmaceuticals companies, using CMIE (Center for Monitoring of the Indian Economy) data, reveals that the corporate sector firms have maintained by and large a healthy growth over time. There is no sign of the industry encountering a setback in growth due to the change in the patent regime. This may be seen from Figure 4.1, which shows growth rate in sales of pharmaceutical companies at current prices. During the period, 1996-97 to 2008-09, the average growth rate in sales at current prices was about 12 percent per annum, while the growth rate of sales deflated by the wholesale price index for drugs and medicine was about 5.3 per cent per annum, which is only slightly lower than the growth rate achieved in the period 1980-81 to 1995-96.

Fig. 4.1: Growth rate in sales, drugs and pharamaceuticals companies



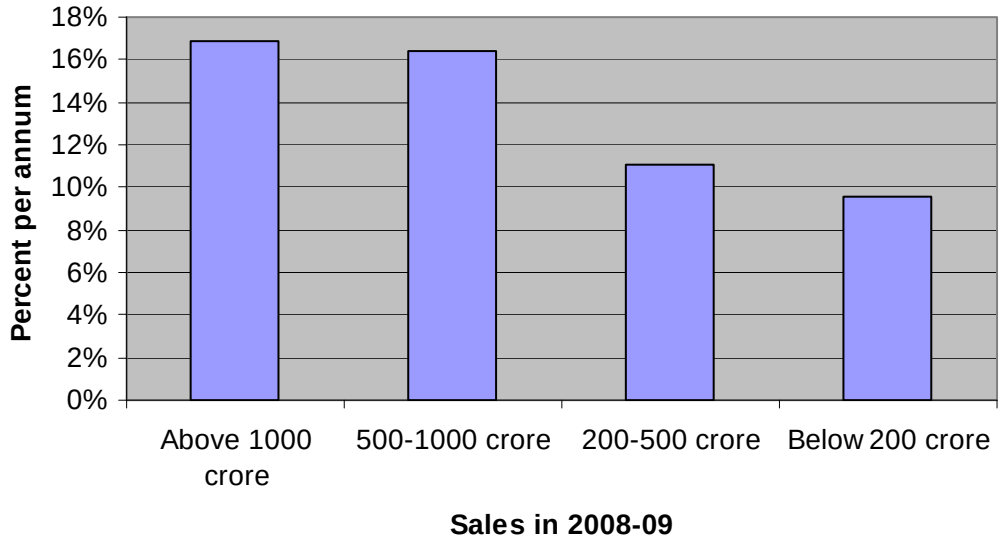
Source: CMIE, *Corporate Sector*, April 2004, February 2009 and January 2010.

Sampath (2008) identifies three factors that are helping Indian pharmaceutical firms maintain a high rate of growth: (a) the expansion of the global generics sector and the increased pressure on 'big pharma' to cut costs, (b) rapid expansion of the local pharmaceutical market and health care within India (traceable to rising personal income, changing disease profie, and increased privatization of health care), and (c) the policy stance of the Indian government in favour of public health and the local industry which provides an assurance to the local firms regarding the legitimacy of their generics production activities. He points out further that all pre-1995 patents do not qualify for protection in India and all products with patent priority dates between 1995 and 2005 can continue to be produced by generic firms despite grant of a patent in India provided the generic manufacturer already had a market approved version of the patented drug in return for payment of "reasonable" royalties to the respective patent holder firms. Sampath argues that this provision and several other provisions mitigate the impact of the TRIPS-compliant patent regime on the local firms.

It may be mentioned here that the growth of MNCs has been slower than the growth rate achieved by the domestic Indian pharmaceutical firms in the period since 1995. A comparison of the growth rate in fixed capital (gross block) between domestic and foreign companies shows that the growth rate for domestic companies was about 20 percent per annum during the period 1995 to 2005 whereas that for MNCs was only about 5 percent per annum (Jha, 2007). The same pattern holds also for the growth rates in production. The implication is a fall in the share of the MNCs in the Indian pharmaceuticals market. In the production of bulk drug by major companies in India, the share of MNCs declined from 10 percent in 1995 to 2 percent in 2005 (Jha, 2007). In the production of formulations, similarly, the share of MNCs fell from 62 percent in 1995 to 28 percent in 2005. Evidently, despite the major changes introduced in the patent regime making it more favourable to the MNCs than to the local firms, the MNCs have experienced a significant fall in their market share. One possible argument could be that the changes had not really come into effect till 2005. However, it should be noted that certain effects of policy change (e.g. effect on R&D) had already started to show, perhaps in anticipation of the policy chage. This issue is analyzed further in Chapter 7.

The growth rate of large companies has in recent years been significantly higher than that of relatively smaller pharmaceutical companies. Figure 4.2 shows growth rates of deflated sales (sales deflated by the wholesale price index for drugs and medicine) in the period 2005-06 to 2008-09 for pharmaceutical firms in India divided into four slabs according to their sales value in 2008-09. It is seen that the largest size firms grew at the rate of 17 percent per annum; the growth rate of the smallest size firms was only about 10 per cent per annum.

Fig. 4.2: Average growth rate in deflated sales, 2005-06 to 2008-09 (firms classified according to size)



4.2.2 Profitability

Not only has the Indian pharmaceuticals industry been able to maintain output/sales growth in the new patent regime, it has also not suffered any major decline in profitability.[21] Table 4.2 shows profitability of pharmaceutical firms at the aggregate

[21] Shanmugasundaram (2008) notes that there has been a fall in the debt-equity ratio in the selected pharmaceutical firms studied by him, which he attributed to the production of high-risk products compared to the low risk products in the process patent regime.

level. Evidiently there is no downward trend in profitiability in the post-1995 period.[22] Table 4.3 shows profitability of large pharmaceutical firms in more recent times. Six monthly results are compared between 2007, 2008 and 2009. Again, there is no indication of a general downward trend in profitability. Rather the average profitability rose between 2007 and 2009.

Table 4.2: Profitability, Drugs and Pharmaceutical Firms

Year	Profits to sales ratio		Ratio of profits to capital employed	
	(1)	(2)	(3)	(4)
1996-97	14.5		22.5	
1997-98	13.4		19.9	
1998-99	13.7		21.5	
1999-00	14.3		21.9	
2000-01	15.4		23.2	
2001-02	17.7		28.2	
2002-03	17.9	16.6	28.9	23.0
2003-04		16.4		25.0
2004-05		15.3		20.0
2005-06		15.3		19.7
2006-07		17.6		22.6
2007-08		16.3		20.0

Notes: The definitions of different series differ. Series (1) is PBDIT(NNRT)/Gross sales; Series (2) is PBDITA net of P&E and OI/Net sales. Similar difference is there between Series (3) and (4).

Source: CMIE, *Corporate Sector*, April 2004 and February 2009

It should be emphasized that the Indian firms could achieve this in spite of the restrictions that the new patents regime imposed on them and the competition they had to face in selling a rising part of their output in the western country markets. It seems that the changed strategy that the Indian pharmaceutical firms adopted in response to the introduction of the new patent regime did work well and helped them maintain their rate

[22] Examination of trends in profitability ratio for 10 major domestic pharmaceutical companies reveals that in most cases there was an increase in the profitability ratio between 1995 and 2005. In some cases, there was a marked increase in profitability between these two years. Profitability ratio in Aurobindo for instance increased from 7% in 1995 to 15.5% in 2005, while that in Cadila increased from 6.2% in 1995 to 11.4% in 2005 (Kiran and Mishra, 2009).

of profit. Another factor that may have contributed positively to financial performance is that the coverage of price control on drugs was reduced substantially in 1995.

Table 4.3: Profitability in Select Large Pharmaceutical Firms, 2007-09

Company	Six months period ending	Profits before interest, depreciation and tax % net sales (six month period)		
		2009	2008	2007
Ranbaxy Labs.	December	45.16	-52.70	18.77
Glaxosmit Pharma	December	35.14	50.37	51.78
Wockhardt	December	-15.12	-52.65	21.40
Aventis Pharma	December	22.22	28.72	25.42
Strides Arcolab	December	18.82	41.46	-46.23
Abbott India	November	18.03	15.09	19.26
Pfizer	November	26.35	29.25	25.29
Cipla	September	27.71	17.80	23.20
Dr Reddy's Labs	September	28.20	23.04	24.78
Lupin	September	20.83	22.71	22.19
Aurobindo Pharma	September	24.41	17.88	16.94
Piramal Health	September	20.87	16.56	18.93
Cadila Health.	September	35.51	26.11	21.67
Sun Pharma.	September	35.59	42.19	28.32
Ipca Labs.	September	23.42	16.07	24.25
Torrent Pharma.	September	31.23	22.63	21.35
Orchid Chemicals	September	23.78	7.77	45.83
Ankur Drugs	September	20.48	18.18	14.97
Alembic	September	10.47	9.04	19.89
Surya Pharma.	September	16.45	18.81	17.84
Glenmark Pharma.	September	16.17	35.44	32.11
Nectar Lifesci.	September	21.48	20.47	18.71
Divi's Lab.	September	32.89	46.98	41.28
Ind-Swift Labs.	September	18.02	18.59	18.18
FDC	September	32.22	26.01	20.03
Unichem Labs.	September	27.58	26.06	21.23
Elder Pharma	September	17.84	19.67	20.09
Ind-Swift	September	14.09	14.83	13.04
Novartis India	September	32.39	32.08	29.93
J B Chem & Pharm	September	22.31	22.73	19.06
Average		23.48	19.37	21.65

Source: Computed from Capitaline data.

4.2.3 R&D

In the new patent regime, there has been a marked rise in the R&D expenditure incurred by the Indian pharmaceutical firms. In the previous regime, the domestic firms used to invest in R&D primarily to reverse engineer the patented drugs in India. The motives for R&D have probably undergone considerable change in the new regime. Now, the R&D efforts seem to be directed at the generic market both at home and abroad where the firms have to invest in R&D to get marketing approvals in the developed countries by conducting bio-equivalence studies or for process development of bulk drugs or product development of formulations.[23]

Table 4.4 presents the R&D intensity of some major pharmaceutical companies in India in the period 1997 to 2005, taken from the study undertaken by Jha (2007). In most cases, there has been a substantial increase in the ratio of R&D expenditure to sales. The largest increases are observed for Ranbaxy, Dr. Reddy's labs, and Sun Pharma. Further, the R&D intensity of foreign companies has not increased as much as the domestic companies. This aspect is studied further in Chapter 6.

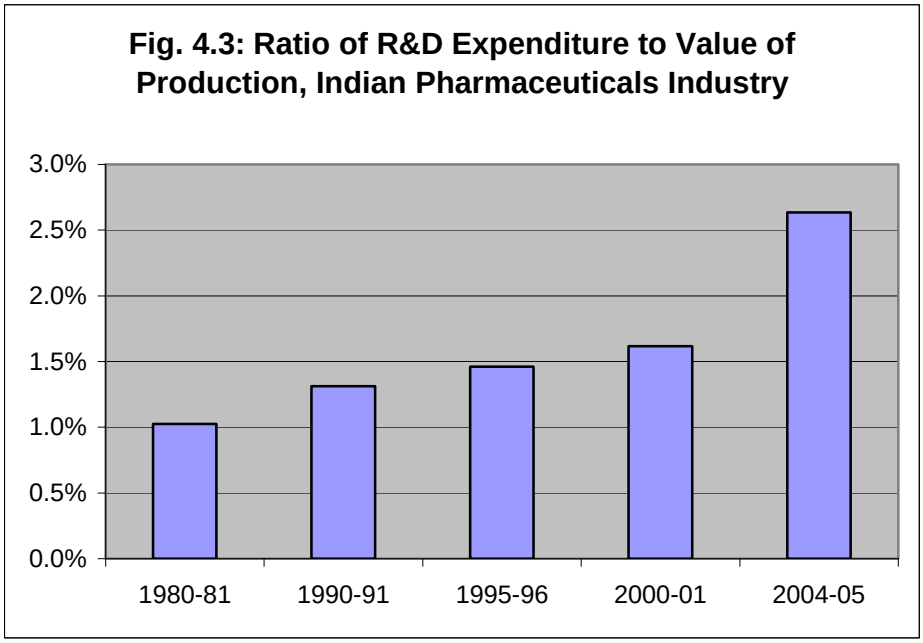
Aggregate R&D spending by the industry has increased from about Rs 1.6 billion in 1995-96 to Rs 10.8 billion in 2005-06 (Nauriyal and Sahoo, 2008). The ratio of R&D expenditure to the value of production in the pharmaceuticals industry has increased from about 1.0 percent in 1980-81 to 2.6 percent in 2004-05 (Figure 4.3). The increase has been relatively more marked after 2000. Between 2000-01 and 2004-05, R&D intensity has increased from 1.6 percent to 2.6 percent.

[23] For a discussion on the increased R&D efforts of Indian pharmaceutical firms in the post-1995 period, see among others Dhar and Gopakumar (2006).

Table 4.4: Research & Development Expenditures a proportion of Net Sales

Company	1997	1998	1999	2000	2001	2002	2003	2004	2005
Ranbaxy	4.3	3.7	3.5	2.9	4.2	3.2	5.5	6.5	18
Dr. Reddy's	3.1	2.1	2.2	2.7	4.2	5.9	9.6	12.9	18
Cipla	3.6	4	3.8	3-8	3.8	3.3		2.7	5
GSK (Foreign)	0.4	0.4	0.49	0.5	0.4	0.3	0.3	0.29	0.2
Pfizer (Foreign)	1.4	2.7	3.1	4.0	3.8	3.1	2.6	3.5	3.7
Sun Pharma	3.9	4.1	2.7	3.9	4.0	4.5	7.6	11.5	11.5
Aurobindo	-	-	-	1.9	0.8	1.2	1.8	3.6	4.6
Nicholas Piramal			5.5	1.8	1.7	2.1	1.6	3.8	8.4
Wockhardt	6.6	8.5	4.8	4.1	7.2	6.2	7.9	7.8	9.6
Cadila Health	1.0	1.4	3.4	4.4	7.9	7.0	3.7	7.9	10.7
Lupin	2.5	1.2	1.1	1.7		5.6*	3.4	3.9	6.7

Source: Jha (2007). The figures report in the table are based on Annual Reports of companies, except for one case marked by asterisk (*) which is based on company data taken from ***Capitaline***.

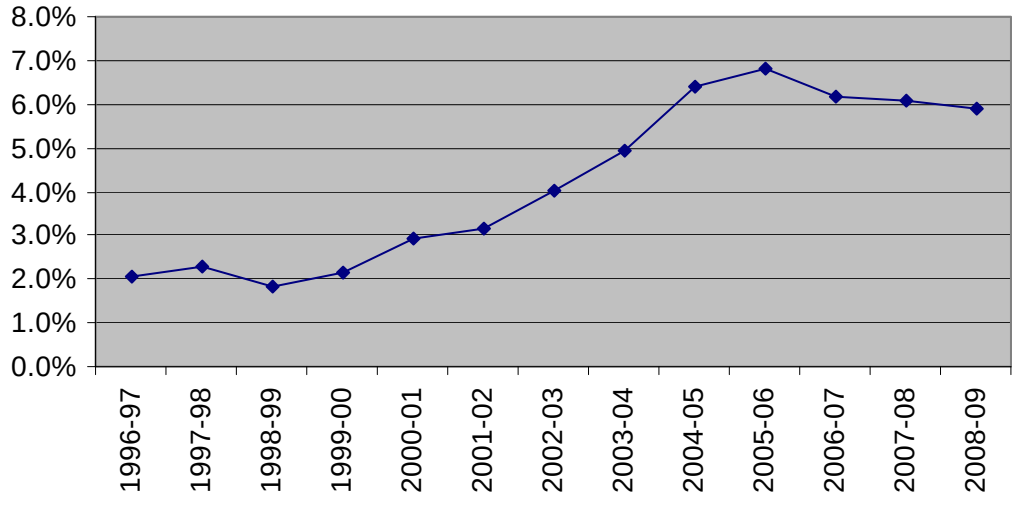


Source: Based on data on production and R&D reported in Nauriyal and Sahoo (2008)

While the aggregate R&D expenditure in pharmaceutical firms has become much bigger than what it was in 1995, it should be noted that the expenditure is highly concentrated. A large part of the R&D expenditure is incurred by some 15 companies (Greene, 2007). Analyzing R&D data for 35 pharmaceutical companies, Nauriyal and Sahoo (2008) find that the top ten firm account for about 78 percent of the total R&D expenditure of the 35 companies. The degree of concentration is still greater in respect of R&D done for new drug discovery and development. Greene (2007) notes that the vast majority of the industry's R&D expenditure on new drug discovery and development is incurred by a limited number of companies, with Dr Reddy's and Ranbaxy at the forefront.

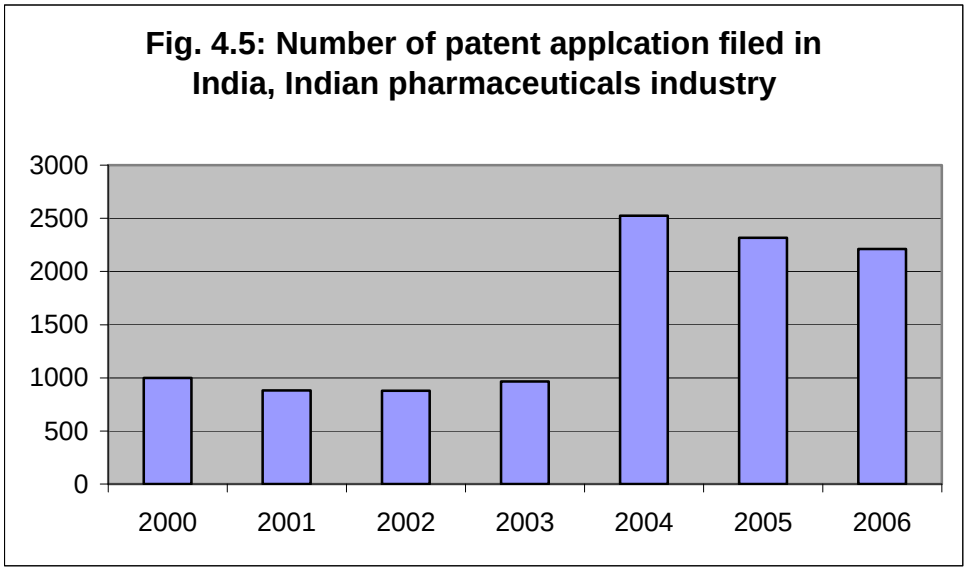
Data on pharmaceutical companies taken from Capital line reveals that the ratio of R&D expenditure to sales of pharamceutical companies increased from about 2% in 1996-97 to about 7% in 2005-06. R&D intensity did not increase further in subsequent years, and in 2008-09 it was about 6%. This is depicted in Figure 4.4.

Fig. 4.4: R&D Intensity, Indian Pharmaceutical Firms



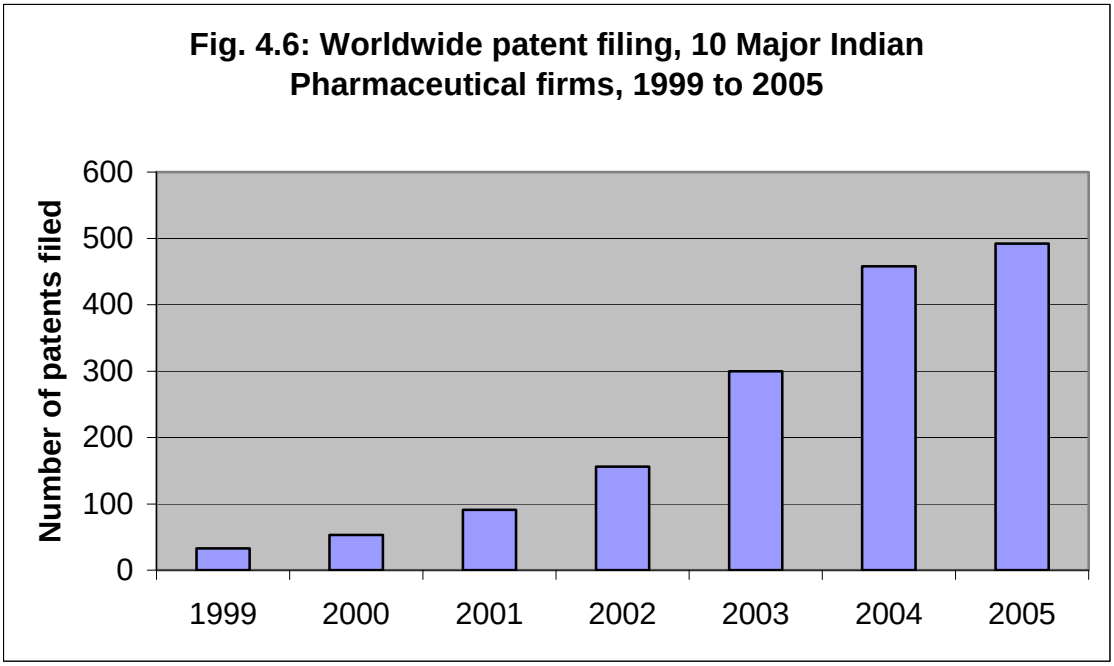
Source: Based on Capitaline data

The R&D efforts of the Indian pharmaceutical firms are reflected in the number of patent applications filed. Figure 4.5 shows the number of patent application files in the years 2000 to 2006. It will be noted that there has been a sharp increase in the number of applications filed from 2004. This is consistent with the increase in R&D intensity noticed in Fig. 4.3 and 4.4. It may be mentioned here that most of the patent applications are for bulk drugs and not for formulations (Nauriyal and Sahoo, 2008).



Source: Data taken from Nauriyal and Sahoo (2008)

Figure 4.6 shows the growth in the number of worldwide patents filed by major pharmaceutical firms in India. A sharp rise in patent application since 2003 is evident from the figure. It may be mentioned in this context that the number of patents granted by the US Patent and Trademark Office (USPTO) and by the European Patent Office (EPO) to Indian pharmaceutical firms has increased sharply from 1999. Till 1998-99, the number of patents granted per year was very small. It increased since then, reaching to over 60 per year in 2004 (Chadha, 2009).

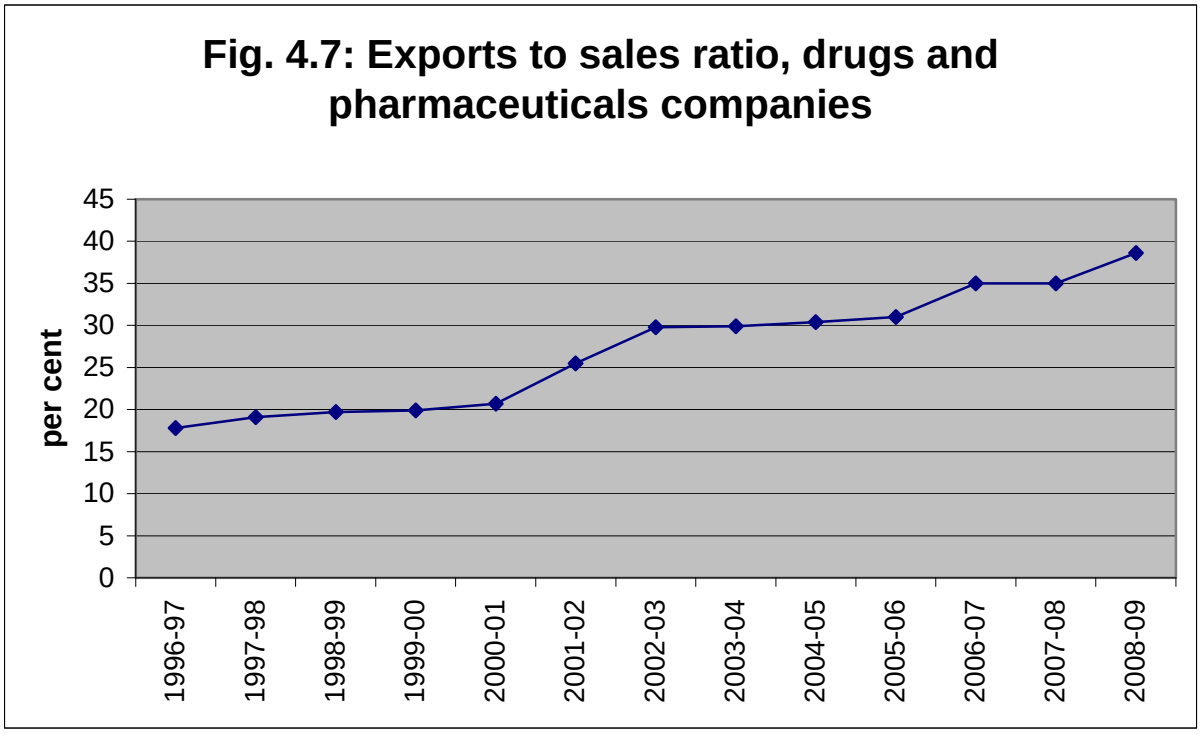


Lall (2002), Smith (2000) and some others have argued that India has now reached a stage in pharmaceutical production where stronger IPRs would induce greater innovation by local firms. Accordingly, one may think that a stronger IPR regime will provide stimulus for domestic investment in R&D for product innovation for local needs. This may not, however, be taking place even though a significant increase in R&D expenditure has taken place. Upadhyay, Ray and Basu (2002) have shown that Indian firms prefer to undertake basic research in therapeutic areas like Cardiovascular, Central Nervous system and other non-communicable diseases, which have a vast international market. In these areas it is also easy for them to enter into an R&D tie-up with leading global players for further development of a lead molecule. Lanjouw and Cockburn's (World Development, 2001) study on India hints at the lack of R&D in tropical diseases due to the limited market size.[24] Firms' interest in finding therapies for some diseases may be hampered by markets which are simply economically or epidemiologically too small in which case the availability of intellectual property rights will never be sufficient incentive to invest (Jha, 2007).

[24] Based on his survey findings, Sampath (2008) reports that only 6% of the firms that participated in the survey conducted all of their research on local disease condition, and a large majority of the firms (75%) devoted less than 25% of their R&D expenditure on local disease conditions.

4.2.4 Exports

Similar to the observed increase in R&D intensity of pharmaceutical firms, there has been a marked increase in export intensity. CMIE's corporate sector data indicate that the ratio of exports to sales in drugs and pharmaceuticals firms in India has increased from about 18 percent in 1996-97 to about 39 percent in 2008-09, as depicted in Figure 4.7.



Source: Based on CMIE publication, Corporate Sector, April 2004, February 2009 and January 2010.

Nauriyal and Sahoo (2008) report that pharmaceutical exports have grown at the rate of 26 percent per annum during the period 1980-81 to 1994-95 and at the rate of about 21 percent per annum during the period 1995-96 to 2005-06. Growth rate of imports of pharmaceutical products has been relatively slower: about 19 percent per annum in the former period and about 12 percent per annum in the latter. The relatively

faster growth in exports than imports implies an increase in net foreign exchange earnings by pharmaceutical companies.

As in the case of R&D, exports of pharmaceutical products are also concentrated among a small number of firms. The top 10-15 exporters account for a sizeable part of total exports. The importance of exports has grown dramatically since the beginning of this decade due to declining profit margins and the extremely price-competitive nature of the domestic Indian pharmaceuticals market (Greene, 2007). Exports have grown to become an important source of revenue for the major pharmaceutical companies in India.

India exports pharmaceutical products to more than 200 countries. The leading destinations are USA, Russia, Germany, UK and China (Greene, 2007). To accelerate their growth, the major pharmaceutical firms in India are looking at the regulated markets of the USA, Japan and Europe, the semi-regulated markets of BRIC countries, and the less regulated markets of Africa, Middle-east and south east Asia. India has become a very important source of generic drugs to the developing world and the leading supplier of AIDS drugs to the world.

Most of India's exports are to the developed countries. The exports to these countries consist primarily of bulk drugs, accounting for about 60 percent of total pharmaceutical exports. The remainder, mostly formulations, is exported to the countries of the former Soviet Union and to developing countries. India is a leading supplier of less expensive antibiotics, cancer therapy and AIDS drugs to the developing world.

In 2005, USA accounted for more than a quarter of India's exports of pharmaceutical products. However, India's share in US pharmaceutical imports is rather small. In 2006, total US pharmaceutical imports was $61.6 billion out of which imports from India was only 0.7 billion (Greene, 2007, Table 23). This may be contrasted with US imports from Ireland, $14.7 billion, UK, $7.0 billion and France, $4.4 billion. Evidently, while India has a major presence in the global markets for generics, her share in overall pharmaceutical imports is small.

The major pharmaceutical firms in India have experienced a significant increase in R&D intensity as well as exports intensity. It is reasonable to assume that these two are related.[25] . Nauriyal and Sahoo (2008) report that when they consider the ten firms that lead in R&D expenditure and another set of ten firms that lead in exports, only four are common. These firms are Ranbaxy, Dr Reddy's, Cipla and Lupin. This does not signify a high correlation between exports and R&D among the leading firms. However, when changes in exports and changes in R&D expenditure are considerd a significant positive correlation is found.

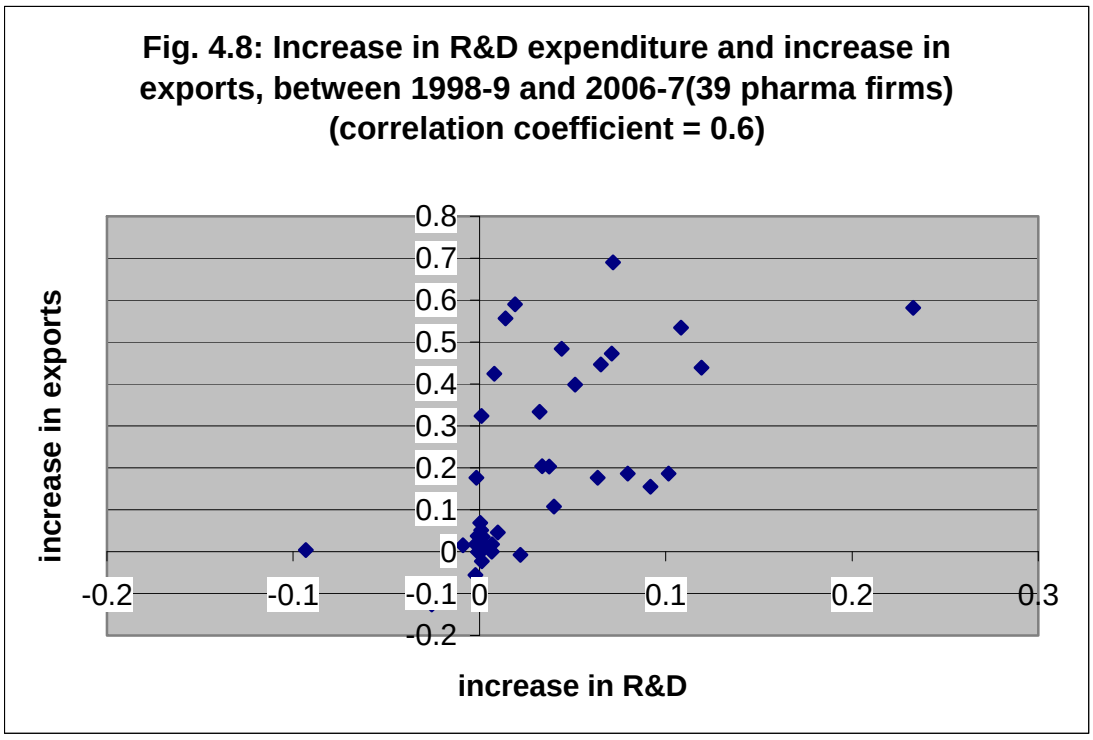
Box 4.1: Product Cycle, Innovation and Exports

Chadha (2009) has studied the product cycle and neo-technology theories of trade in the context of exports of generic pharmaceuticals from India. The study covers 131 pharmaceutical firms for the period 1989-2004. An econometric model is estimated explaining inter-firm and inter-temporal variations in exports. The dynamic panel Generalized Method of Moments esimator is use. The results show that firm size has a significant positive effect on export performance. The results also show that technology proxied by the acqusition of foreign patents has a favourable effect on exports. Chadha concludes that developing countries with innovation skills for process innovations are capable of penetrating international markets in the later stage of product cycle by using patents, which were the barriers to trade in the early stages of the product cycle.

Figure 4.8 shows changes in exports and R&D expenditure between 1998-99 and 2006-07 for 39 pharmaceutical firms. The increases in exports and R&D expenditure have been normalized by the value of net sales in 2006-07.[26] A positive correlation between increases in exports and increases in R&D expenditure is evident from the figure. The correlation coefficient is 0.6.

[25] Aggarwal (2004) find R&D to be a major determinant of exports amoung Indian pharmaceutical firms. Technology imports on the other hand are not found important.

[26] Data have been taken from Capitaline. The firms for which data are available for both 1998-97 and 2006-07 are included. The firms which registered a decline in sales between these two years are excluded.



4.2.5 Takeovers, mergers and alliances

Since the early years of this decade, there has been a significant rise in the number of consolidations, mergers and acquisitions, and other forms of alliance in the Indian pharmaceuticals industry (Greene, 2007). The purpose of such moves was to penetrate overseas markets, especially the regulated markets, diversify and enhance product portfolios, and improve contract manufacturing, packing and R&D facilities.

In 2005-06, 18 Indian companies spent approximately $1.6 billion to acquire generic drug manufacturing firms in Europe, North America and Mexico (Greene, 2007). Some of the important acquisitions made by India firms in the past are Dr. Reddy's purchase of Betapharm Arzneimittel of Germany, Ranbaxy's purchase of Terapia (Romania) and RPG Aventis (France) and Matrix's acquisition of API of Belgium.

Table 4.5 adopted from Greene (2007) provides a selected listing of international acquisitions and foreign tie-ins by Indian pharmaceutical firms (see also, Dhar and Gopakumar, 2006, Annex Table 2). That the level of such activities has been high among major Indian pharmaceutical companies is evident from the table. This seems to be an important factor behind the surge in exports experienced by the firms and their ability to maintain satisfactory financial performance.

Box 4.2: Survival of Pharmaceutical Firms in the New Regime

Chadha and Ying (2008) have studied the survival of Indian pharmaceutical firms in the new patent regime. They have used the Cox proporational hazards model. They use the *Prowess* database for the period 1988-89 to 2005-06. They include 283 pharmaceutical companies in their analysis. They use a dummy variable for the period 1999-00 to 2005-06 to capture the effect of the change in the patent regime. The control variables used in the analysis are: firm size, experience, innovation (captured by a dummy reflecting filing for patent), TRIPs dummy, foreign ownership, and membership of business group. The results show that the probability of exit is higher for smaller firms. The probability of firm exit has gone up in the new patent regime. However, innovative firms have been able to survive the policy change.

A recent major development in the Indian pharmaceuticals industry is the acquision of leading Indian firms by multinational companies. As mentioned earlier, the relative share of the multinational companies was erored after 1970 because of the change in patent policy along with other policy changes introduced. According to recent new paper reports (Economic Times, 24 May 2010), the foreign drugmakers are poised to regain their supremacy in the Indian market. The recent acquision is the acquision of Piramal Healthcare's generic medicine unit by US based Abbott Laboratories. Some other buy-outs that have taken place are: Ranbaxy acquired by Daiichi Sankyo, Santha Biotech acquired by Sanofi Aventis and Dabur Pharma acquired by Fresenuis Kabi. With these aquisions, the market share of multinational has increase to 25%. This tendency is expected to continue in future, and further increases in the market share of multinational companies are quite likely. According to industry analysts, as reported in the Economic Times, the market share of multinationals could soon increase to 50%.

Table 4.5: Selected international acquisitions and foreign tie-ins by the Indian pharmaceutical industry

Company	International acquisition (s)	Foreign alliances, JVS, and other tie-ins
Nicholas Piramal	Pfizer-Morpeth (UK), Avecia Pharma (UK), Dobutrex brand acquisition (US), Rhodia's inhalation business (UK), Biosyntech (NPIL Pharma) (Canada), Torcan Chemical (Canada), 51% of Boots (S. Africa), Bio Syntech	Ethypharm (France), Genzyme (US), Eli Lilly (US), Biogen Idec (US), Chiese Farmaceutici (Italy), Minrad (US), Pierre Fabre (France). Gilead Sciences (US), Allergan (US), Hoffmann-La Roche (Switzerland)
Ranbaxy	Terapia (Romania), Allen -GSK (Spain & Italy), Ethimed (Belgium), Betapharm (Germany), RPG Aventis (France), 40% stake in Nihom Pharmaceuticals (Japan), Brand-Veratide (Germany), Efarmes (Spain), Be-Tabs (S. Africa), Akrikhin (Russia), Basic (Germany), Ohm Labs (US)	GlaxoSmithKline (UK), Janssen-Ortho (Canada), IPCA Labs (US), Zenotech (India), Sonkel (S. Africa), Cephalon (US), Gilead Sciences (US), Schwarz (Germany)
Dr. Reddy's	Betapharm Group (Germany), Trigenesis (US), BMS Laboratories and Meridian Healthcare (UK), Roche's active ingredients business (Mexico), BMS Labs (UK)	Novo Nordisk, Bayer AG (Germany), Par (US), Novartis (Switzerland), Merck (Germany), Clin Tech, Pharmascience (Canada), ICICI (India), Merck (Germany), Schwartz
Aurobindo	Milpharm (UK), Pharmacin (Netherlands)	Gilead Science (US), Citadel (India)
Sun Pharma	Able Lab (US), Caraco (US), Valeant Pharmaceuticals (US & Hungary), ICN (Hungary), Caraco (US), MJ Pharma	Dyax
Wockhardt Pharma	Wallis Labs (UK), CP Pharma (UK), Esparma (Germany), Pinewood Laboratories (Ireland), Dumex (India)	Dynamics (S. Africa)
Cadila	Alpharma (France-formulations), Dabur Pharma Redrock (UK)	Schering (Germany), Boehringer Ingelheim (Germany), Viatris (Germany), Novopharm (Canada), MCPC (Saudi Arabia), Cipharm (Ivory Coast), Geneva (US), GSK (UK), Ranbaxy (India), Mallinckrodt (US), Mayne (Australia), Shinjuki (Japan), Zydus Atlanta
Matrix Labs	22% controlling stake in Docpharma (Belgium), Explora Lab (Switzerland), MCHEM (China), Fine Chemicals (S. Africa), API (Belgium)	Aspen, Emchem, Doc Pharma, Explora Labs
Glenmark	Kinger Lab (Brazil), Uno-Ciclo (Brazil), Srvycal (Argentina), Medicamenta (Czech), Bouwer Bartlett	Forest Labs (US), Lehigh Valley Technologies (US), Shasun (India), KV, Apotex (US)

Source: Greene (2007), Table 5. The basic sources mentioned by Greene are: IBEF, Ernst & Young, The Economic Times, individual company web pages.

4.2.6 Launching of New Patented Drugs in India

Lanjouw (1999) notes that the introduction lag in India for most of the top branded patented drugs ranged from five years to 12 years. Ray and Chakravorty (2007) study the global launch of new drugs over the period 1995-2003 and the launch of these drugs in India in that period. They find that, during 1995-2003, 297 new drugs were launched globally. Of these, 199 (67%) provided no major therapeutic gains, while 98 provided major gains. Also, bulk (80%) of the new drugs had non-tropical therapeutic focus, while only about a fifth had tropical therapeutic focus. Of the 297 new drugs launched globally, only 77 (26%) were subsequently launched in India. Of the 98 innovative new drugs providing major gains, only 30(31%) were subsequently launched in India. Of the 58 new drugs with tropical focus, 21 (36%) were subsequently launched in India. Evidently, a majority of new drugs globally launched during 1995-2003 were not subsequently launched in India (during this period). Analysing the delay in the launch of new drugs in India, Ray and Chakravorty find that only about 15% cases, the delay was small. In the othere 85% cases the delay was moderate or high.

Another intesting observation made by Ray and Chakravorty (2007) is that there has been a downward trend in the number of new drugs launched in India. While 47 new drugs were launched in India during the period 1995 to 1997, only 4 new drugs were launched in India during the period 2001 to 2003 (despite the change in the policy regime). In these three years, 2001 to 2003, 72 new drugs were launched globally, compared to which the launch of new drugs in India is very small.

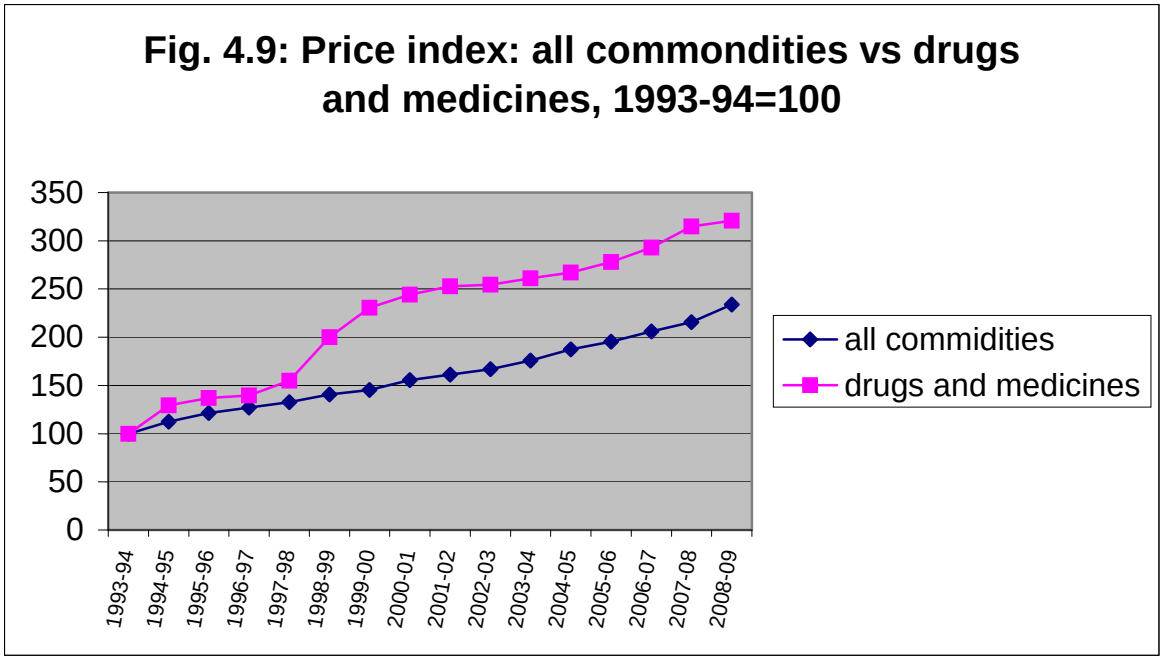
The situation did not improve much immediately after 2005 when the new patent regimes came fully into effect. According to some write-ups available on the internet dating to 2005, the multinational pharmaceutical companies had put on hold plans to introduce their patented drugs in India waiting for clarity in on regularity issues such as data protection, pre-grant opposition and patenting of derivatives.[27] The situation has probably improved more recently especially with the multinationals acquiring some leading pharmaceutical firms in India and thus getting a better control of the market.

[27] Bhuma Shrivastava, 'MNCs freeze patented drug launch in India', September 24, 2005.

4.2.7 Drug Prices

One key side of the pharmaceuticals industry performance is provision of drugs at affordable prices. It has been mentioned above that non-recognition of product patents, thereby permitting the domestic firms to reverse engineer and copy patented drugs without paying a licensing fee, and imposition of price control on a large number of pharmaceutical products from the 1970s resulted in a situation in which the prices of drugs in India were among the lowest in the world (see Table 4.1). How has the situation changed in the new patent regime, which has been accompanied by a drastic pruning of the list of drugs under price control? Concerns have been expressed in a number of earlier studies that product patents may enable the patent holders to charge exorbitant prices for newly introduced drugs making such drugs unaffordable to the general public. Has this been borne out by the experience of the last five years or so?

To assess the price situation, it may be useful to start by looking at the wholesale price index for drugs and medicines. An examination of the trends in the price index reveals that in the post-1995 period the wholesale price index for drugs and medicine has grown faster than that for all commodities. This is depicted in Figure 4.9. Between 1993-94 and 2001-02, the price index for all commodities increased by about 60 percent. The increase in the price index for drugs and pharmaceuticals in this period was about 150 percent. The acceleration in the growth rate of drugs/medicines prices took place between 1997-98 and 2001-02.

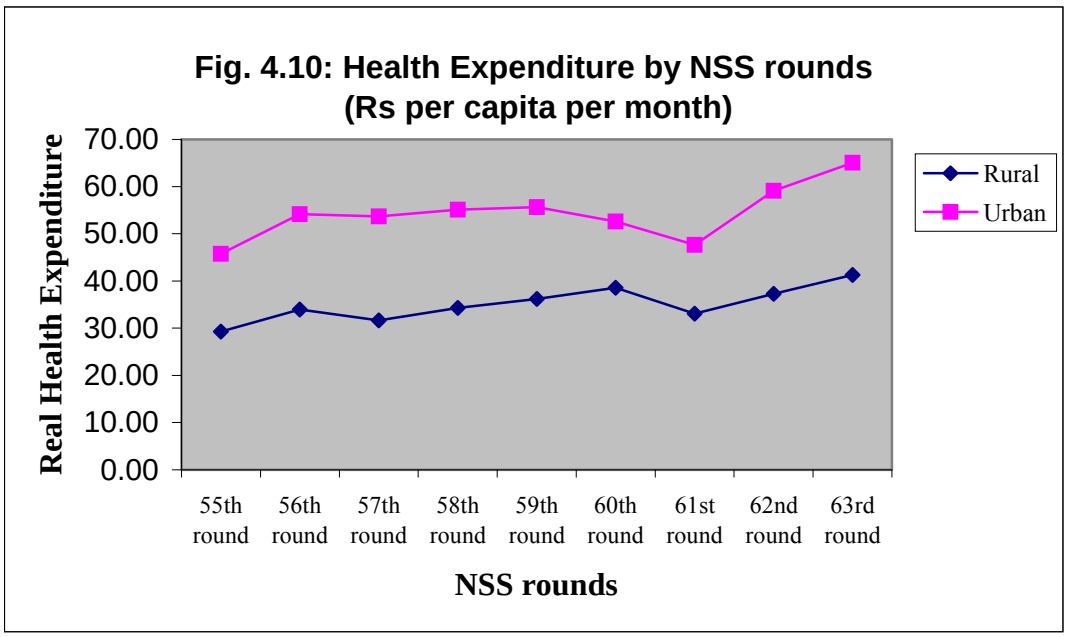


The explanation for the relatively faster increase in the drugs and pharmaceuticals price index seems to lie mostly in the fact that in 1995 many drugs were taken out of price control (see Table 7.1). This is corroborated by the analysis of price trends during 1994 to 2004 undertaken by Sakthivel (2007). He finds that the prices of drugs that were kept under price control remained by and large stagnant or declined over time. On the other hand, the drugs that were taken out of price control in 1995 had in most cases a significant increase in their prices.

It needs to be emphasized in this context that the basket of commodities chosen for the price index and the weights used in the price index are based on the situation in 1993-94. Thus, the index will not capture the effect of new drugs introduced in recent years. Evidently, the prices charged for newly introduced drugs have little to do with the observed increase in the price index.

An alternate approach to the study of drug prices is to consider the increases in household health expenditure (drugs/medicines are the dominant part of the expenditure) using NSS (National Sample Survey) consumption survey results. Figure 4.10 shows deflated per capita health expenditure in rural and urban areas. This analysis reveals that

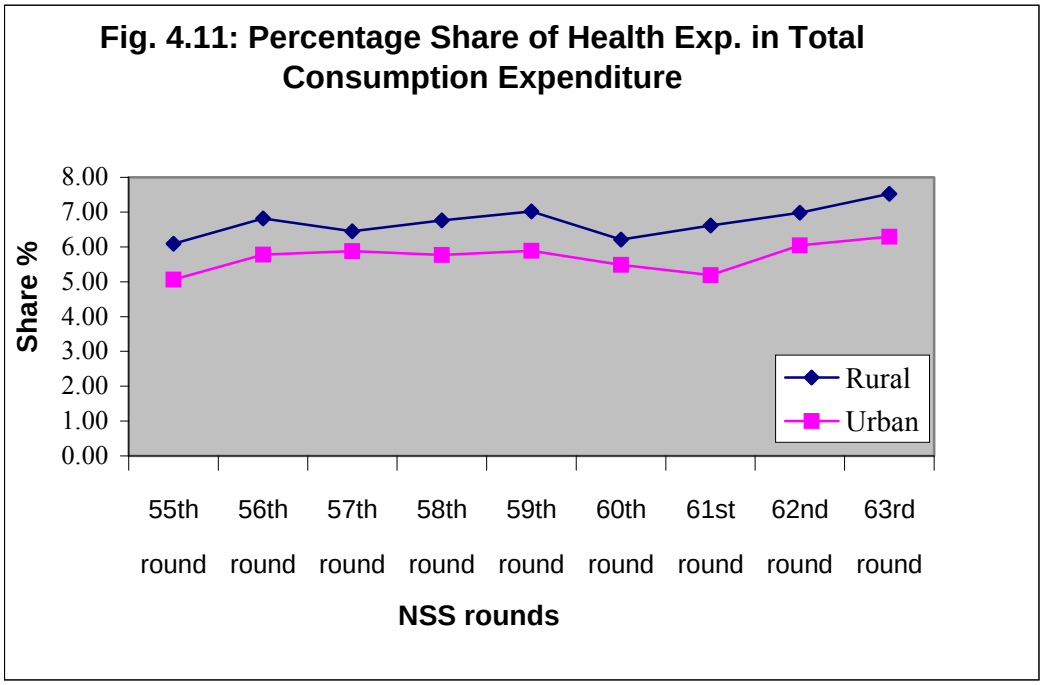
real expenditure has not increased much between 55th round (1999-2000) and 61st round (2004-05). However, from 2004-05, there has been a marked increase. This may in part be a reflection of increasing drug prices as depicted in Figure 4.7, but may also be connected with increases in incomes of households inducing them to spend more on health and with the falling public facilities for health forcing the households to incur more out-of-pocket expenses for health.



Source-National Sample Survey Organization: 55th round (July1999-June 2000), 56th round (July 2000 – June '2001), 57th round (July, 2001-June, 2002), 58th round (July, 2002-Dec, 2002), 59th round (Jan-Dec, 2003), 60th round (Jan'2004-June'2004), 61st round (July'2004 - June'2005), 62nd round (July 2005 - June 2006), 63rd round (July 2006 - June 2007)

It may be mentioned here that the share of health expenditure out of the household consumption expenditure has mostly been in the range of 5 to 6 percent in the NSS rounds from 55th to 63rd, and there has been only a small increase (1 to 1.5 percentage points) over time (see Figure 4.11). This increase can probably be explained largely by the increase in drug prices that followed the removal a number of items from price control. Thus, no major issues of affordability of drugs connected with the new patent regime seems to have appeared so far although this has been a serious concern in the drug patent related literature in the last fifteen years or so. At the same time, there are

possibilities of the new patent regime and certain other developments in the industry resulting in substantial increases in drug prices in India in future. This is discussed further in the next chapter.



Source-National Sample Survey Organization: 55th round (July'1999-June'2000), 56th round (July' 2000 - June'2001), 57th round (July, 2001-June, 2002), 58th round (July, 2002-Dec, 2002), 59th round (Jan-Dec, 2003), 60th round (Jan'2004-June'2004), 61st round (July'2004 - June'2005), 62nd round (July 2005 - June 2006), 63rd round (July 2006 - June 2007)

4.3 Small scale industry

India is a preferred manufacturing destination for pharmaceuticals because of a wide range of capabilities and attractive and cost effective manufacturing opportunities, comparatively low production cost of active pharmaceuticals ingredients (APIs), strong manufacturing capabilities and existence of regulatory approved manufacturing facilities for APIs and formulations and availability of cheap skilled manpower.

The small-scale units in the pharmaceutical industry occupy a very large proportion in India. Their contribution in bulk drugs production as well as formulations is significant. In terms of volumes, it covers almost 65% share of the formulations and 40%

in value terms. (Based on discussions with Mr. Gupta of a small-scale unit Belco Pharmaceuticals who is also the co-chairman of the CIPI[28]). According to the estimates by Pradhan (2008) out of a total of 2872 organized units operating in the Indian pharmaceutical industry, 2673 units were small units in 2000-01 on the basis of ASI unit-level data. The workforce in the pharmaceutical industry is also concentrated in the small-scale segment (approximately 65%), while contribution to the total output stood at 42% compared to 58% by large units[29].

The Indian pharmaceutical industry's expertise in process engineering brought it in the forefront globally and all firms, big as well as small, benefited from non-recognition of product patents. Till 2005, the small scale units had a favorable environment as they were exempted from excise duty, did not have to follow very stringent GMP practices and had government support in the form of captive market for certain drugs apart from being exempted from drug price control orders. They benefited from the loan license facility in the country, due to which there was enough countrywide operations through loan licences along with third party manufacturing where no licence is required.

Since India signed TRIPS agreement in 1995, the pharmaceutical industry has been under pressure to change its research and manufacturing strategies to face the stricter environment from 2005. There are a series of changes in the regulatory area especially amendments in the schedule M to meet the criteria of GMP (good manufacturing practices). This has led to closure of many small units (approximately 3000 units) due to insufficient funds required to set up GMP compatible units or they have shifted to tax-free zones like Himachal Pradesh, Uttranchal, parts of Sikkim to save costs. Although GMP under Schedule M was notified in mid-2005, many SSIs could not adopt these basic manufacturing standards on account of their poor financial status. A good number of SSIs had to subsequently shut down and many more may have to close in

[28] Confederation of Indian Pharmaceutical Industry
[29] The small-scale unit is defined on the basis of the value of investment in plant and machinery which was raised from Rs.1 crore in 1999 to Rs.5 crores in 2001.

future if they fail to upgrade their facilities.[30] An estimate of Rs. 6 crores is often cited as the expenditure required to meet the GMP standard internationally. Out of 26 small-scale units which were exporting from Haryana, only 6 are exporting after the imposition of WHO compliant GMP (information provided by the Co-chairman, CIPI).

To face the challenges of the new patent regime many firms have started upgrading their technological capabilities and started investing in research for developing new molecular entities. If the definition of a new chemical entity includes derivatives, salts, esters and other derivatives of a molecule and thus reserving them under data protection, it would affect various NDDS (Novel Drug Delivery Systems) programmes which several Indian firms, including small scale units undertake. Many SMEs which spend up to Rs. 2 lakhs on R&D will have to discontinue their research activities, as they would be required to do clinical trials for these programmes which their resources will not permit. (www.pharmabiz.com, Dec. 7, 2005)

Other factors which have affected SSI adversely are the changes in policies related to excise duties. The MRP-based excise duty has affected the prices that a manufacturer can charge, including a small-scale manufacturer. Additionally, the attempt to control exports of generic drugs under the new definition of counterfeit drugs by WHO would have seriously affected the SMEs but due to the tremendous pressure exerted by the developing countries including India and Brazil, the World Health Organization (WHO) has dropped the controversial resolution on counterfeit drugs.

On the positive front, Contract Research for major companies is one of the options open to Indian pharmaceutical companies. This option is very important for small and medium enterprises (SMEs) to survive in post TRIPS era in India. Contract research in India is emerging at a rapid pace and many Contract Research Organizations (CROs) are providing services to various companies. Here, companies with good laboratory practices (GLP) and good clinical practices (GCP) can benefit greatly as large firms involved in drug discovery and development would subcontract some research activities

[30] In a field study of pharmaceutical firms undertaken by Kiran and Mishra (2009) covering 68 small-scale firms, about 65% disagreed or strongly disagreed with the amendments in the schedule M.

to them. Loan licensing agreements with major pharmaceutical companies could also be a good survival option for SMEs. Many major pharmaceutical companies have entered into this agreement with some smaller companies that do not have enough financial resources. Small and medium enterprises can take this opportunity of contract manufacturing for their survival post-TRIPS. Many Indian and multinational pharmaceutical companies have agreements with some SMEs for co-promotion and co-marketing of their major brands. To promote pharmaceutical exports from the small and medium enterprises (SMEs), the Pharmaceutical Export Promotion Council (Pharmexcil) is setting up an Intellectual Property Rights (IPR) centre. Over 1,200 SMEs are actively involved in the pharmaceutical exports from the country. Due to the increased focus on IPRs, they are unable to keep up the pace of their exports. A government sponsored IPR centre will educate advice and help them in dealing with patent issues.

There is definitely a need for industry to move up the research value chain in order to compete in the drug development. Given that drug discovery and development comprises of several stages, Indian companies can exploit the areas in which they have comparative advantage like chemistry skills and providing services both in manufacturing as well as research, in intermediate stages of both product and process innovations. The small firms can also provide such services as some domestic CROs have done. With the establishment of the product patent laws in India these SMEs have to consider becoming contract research and manufacturing service (CRAMS) providers to the larger companies as an option. Nicholas Piramal, Shasun Chemicals, Divi's Lab, Dishman Pharma, Cadila Healthcare, Lupin, Matrix Lab and Aurobindo Pharma are some of the companies, which have witnessed impressive growth in revenues from their CRAMs business under various tie-ups with global pharmaceutical majors.

Another potential area for SMEs in India is clinical research. MNCs are discovering that clinical research can be done cost effectively whilst maintaining required standards in order to secure the necessary regulatory approvals. The combined turnover of Indian clinical research organisations is currently estimated at over Rs 500 crores with an annual growth rate of 60 per cent. SMEs can help create and diffuse innovation and challenge existing ways of doing business. The pharmaceutical industry has barriers to

entry in the form of specialised knowledge, international quality standards. Thus SMEs which can generate reasonably innovative processes or products and develop competencies which complement large scale producers and create synergies can survive and create linkages with MNCs.

Chapter 5

Effects of Patents on Prices of Drugs/Medicines[31]

5.1 Backdrop

Under the TRIPS agreement, finalized in 1995, the countries need to recognize and enforce product patents in all fields of technology including pharmaceutical products. There has been much debate and controversy regarding the merits of the new patent regime for pharmaceuticals, particularly from the point of view of developing countries. One view is that unqualified patent protection of pharmaceutical products will lead to substantially higher prices for medicine, which will have adverse effects on health and welfare of the developing countries. An opposite view is that the introduction of product patents is unlikely to raise significantly the prices of drugs because most patented products have many therapeutic substitutes. It has also been claimed that the absence of patent protection has been a disincentive for research-based global pharmaceutical companies to engage in research on diseases that disproportionately afflict the world's poor, implying thereby that patent protection for pharmaceuticals will actually benefit the developing countries by stimulating innovation and transfer of technology.

These claims are, however, based on scanty evidence. Very little is known about the extent to which prices of pharmaceutical products may increase as a result of production patents. Past empirical research on the impact of patents on prices and innovative activities has been conducted almost exclusively for developed countries. Hence, how this is going to impact the research on diseases that disproportionately afflict the developing countries, is difficult to ascertain. At a first step towards filling this important gap in the empirical literature on the effect of product patents, Chaudhuri et al. (2006) have investigated these issues by econometrically analyzing the demand function for Fluoroquinolones (a sub-group with antibiotics) in India, and deriving on that basis

[31] This Chapter has been prepared by Bishwanath Goldar.

the price elasticity of demand for various molecules, supply-side parameters, and the possible effect of product patents on price and welfare.

Chaudhuri et al. (2006) conclude that the concern that about potential adverse welfare effect of TRIPS in developing countries may have some basis. According to their estimates, the enforcement of product patent in the Fluoroquinolones segment in India will result is a significant welfare loss, ranging from $144 million to $450 million annually, depending on the way the policies are implemented, the extent of price regulation, and the degree to which the foreign multinationals respond to the product patent protection by expanding their distribution network or using licensing more extensively. Of this loss, the most part is the loss of consumer surplus, whereas foregone profits form only a small fraction. Thus, the evidence provided by the study does not support the claim that the patent protection will adversely affect the domestic producers of pharmaceutical products. Chaudhuri et al. note that if product patent is enforced for a particular molecule in the Fluoroquinolones segment and the production of that molecule in the domestic firms is stopped, the domestic consumers may not shift to the foreign producer of that molecule, but may shift to other substitute molecules produced by domestic firms. In consequence, patent protection need not reduce the profits of domestic firms, but may increase it in some circumstances.

As regards the subsidiaries of multinationals, Chaudhuri et al. find that the profit gains to such firms from the enforcement of patents will be about $53 million per year provided there is no compulsory licensing or price regulation. The profits could actually be lower. Under certain assumptions about price regulation, the amount of annual profits is found to be $19.6 million. Chaudhuri et al. point out that these figures on profits are very small in relation to the annual sales and profits of big multinational pharmaceutical firms in this segment, and accordingly hint at the possibility that such profits by themselves may not be a strong inducement to undertake research and innovation directed at the needs of developing countries.

While Chaudhuri et al (2006) is undoubtedly a very useful study for understanding the possible effect of patent protection of pharmaceutical products in India, there is obviously a need to carry out such research for other therapeutic segments and find out if a similar pattern holds in other segments as well. This is attempted in this chapter. The basic econometric model and analytical methodology follows by and large Chaudhuri et al. (2006). However, because of the availability of a much bigger dataset for each of the segments considered and for some other reasons, the model used here differs somewhat from the model used by Chaudhuri et al. (2006).

The next section, Section 5.2, discusses the model used for the econometric analysis. The data and the construction of variables are discussed in Section 5.3. The estimates of price elasticity are presented and discussed in Section 5.4. The results of a counterfactual simulation exercise, similar to what Chaudhuri et al. (2006) had done, are presented and discussed in Section 5.5. The findings of the analysis are summarized in Section 5.6, which discusses further the possible effect of patenting on drug prices.

5.2 The Model

As mentioned above, the econometric model used for assessing the demand relationship is by and large the same as that used by Chaudhuri et al. (2006). Consider a therapeutic segment, Q. Let there be n molecules. Let p_i be the price of the i'th molecule and q_i be the quantity sold. Then, the share of the i'th molecule in the total expenditure incurred by consumers on all molecules belonging to the segment Q may be written as:

$$s_i = \frac{p_i q_i}{\sum_j p_j q_j} = \frac{x_i}{X_Q} \qquad \ldots(5.1)$$

In this equation, x_i is the per capita expenditure incurred on i'th molecule and X_Q is the aggregate expenditure on all molecules of the therapeutic segment, per capita.

To specify the demand function, the two-level AIDS (almost ideal demand system) specification is used, as done by Chaudhuri et al. (2006) and a large number of

other studies on consumer demand. The lower level equation gives the shares of different molecules in a therapeutic segment. It may be written as:

$$s_i = \alpha_i + \sum_j \gamma_{ij} \ln p_j + \beta_i \ln\left(\frac{X_Q}{P_Q}\right) \qquad \ldots (5.2)$$

In this equation, s_i is the share of i'th molecule out of the expenditure of all molecules in the specific segment, Q (equation 5.1). X_Q is the overall expenditure on all molecules of the therapeutic segment and P_Q is a price index given by:

$$\ln P_Q = a(p) = \alpha_0 + \sum_i \alpha_i \ln p_i + \frac{1}{2}\sum_i \sum_j \hat{\gamma}_{ij} \ln p_i \ln p_j \qquad \ldots(5.3)$$

For actually implementing the above model, the Stone price index is used instead of the translog price index, as suggested by Deaton and Meulbauer (1980).[32] Thus,

$$\ln P_Q = \sum_i w_i \ln p_i \qquad \ldots(5.4)$$

where w_i are the weights. These are obtained as the expenditure shares averaged over time.

The equation 5.2 above needs to satisfy the following conditions

$$\left.\begin{array}{l} \textit{Adding up}: \sum_k \alpha_k = 1; \sum_k \beta_k = 0; \sum_k \gamma_{kj} = 0 \ \textit{for all } j \\ \textit{Homogeneity}: \sum_k \gamma_{jk} = 0 \ \textit{for all } j \\ \textit{Symmetry}: \gamma_{jk} = \gamma_{kj} \end{array}\right\} \qquad \ldots(5.5)$$

The estimation of equation 5.2 has been done by the SURE method. The adding up, homogeneity and symmetry conditions in 5.5 above have been imposed. This reduces the number of parameters to be estimated.[33]

[32] Chaudhuri et al. (2006) too take this approach.

The Marshallian (uncompensated) price elasticities (at sample mean) may be obtained as

$$\varepsilon_{ii} = \frac{\gamma_{ii}}{w_i} - \beta_i - 1 \qquad \text{own price elasticity} \qquad \ldots(5.6)$$

$$\varepsilon_{ij} = \frac{\gamma_{ij}}{w_i} - \beta_i\left(\frac{w_j}{w_i}\right) \qquad \text{cross-price elasticity} \qquad \ldots(5.7)$$

where w_i are the average expenditure shares. The expenditure elasticities, showing how the demand for different molecules of the segment is impacted by increased expenditure on the segment, may be obtained as:

$$\eta_i = 1 + \frac{\beta_i}{w_i} \qquad \ldots(5.8)$$

The elasticities given above does not take into account the fact that a change in p_i will have an effect on P_Q which will in turn affect the total expenditure on the molecules, X_Q.

To capture this, the value of the following expression needs to be computed:

$$\frac{\partial \ln q_i}{\partial \ln X_Q}\frac{\partial \ln X_Q}{\partial \ln P_Q}\frac{\partial \ln P_Q}{\partial \ln p_j} \qquad \ldots(5.9)$$

The third term is equal to w_i. The first term, at the sample mean, is given by $[1+ \{\beta_i / w_i\}]$. To obtain the second term, the demand function at the top level has to be estimated. A simplified approach is adopted for this purpose, following Hausman and Leonard (2002). The real expenditure on segment Q done by households is taken a function the real income level and the aggregate price index for the segment relative to the price index for all other commodities. Empirical implementation of the model has been done in the following way:

[33] Chaudhuri et al. (2006) imposed additional constraints on the parameters since they had monthly observations for only two years. In this study, the dataset is relatively bigger, for five years, and therefore such constraints on parameters have not been imposed.

Define R, the real expenditure on segment *Q*, as

$$R = \frac{X_Q}{P_Q} \qquad \ldots(5.10)$$

Then, the following model may be estimated

$$\ln R = \phi + \delta \ln\left(P_Q / CPI\right) + \lambda \ln Y \qquad \ldots(5.11)$$

where *CPI* is the consumer price index and *Y* is the real per capita income (per capita real gross domestic product).

After the equation 5.11 is estimated, prices elasticity is computed (following Hausman and Leonard, 2002) as:

$$\varepsilon_{ii} = \frac{\gamma_{ii}}{w_i} - \beta_i - 1 + (1 + \frac{\beta_i}{w_i})(1+\delta)w_i \qquad \text{own elasticity} \qquad \ldots (5.12)$$

$$\varepsilon_{ij} = \frac{\gamma_{ij}}{w_i} - \beta_i\left(\frac{w_j}{w_i}\right) + (1 + \frac{\beta_i}{w_i})(1+\delta)w_j \qquad \text{cross price elasticity} \qquad \ldots(5.13)$$

5.3 Data and Variables

The basic source of data for the analysis presented in this chapter is **ORG IMS,** which is also the source that Chaudhuri et al. (2006) had used. From this source, data on the prices, units and value of sales of various molecules according to various firms/brands producing these molecules have been obtained for several different therapeutic categories. These data have been collected by the ORG IMS from stockists (who then sell to retailers). These data are of high quality and reliable. The data relate to the period January 2004 till December 2008.

The econometric analysis has been carried out for nine therapeutic segments.[34] Some therapeutic categories (for instance, antibiotics) are large, and therefore it is more appropriate to consider a sub-category or segment, as Chaudhuri et al. (2006) had done. The therapeutic segments considered for the study are listed below. For the Cardio Vascular therapeutic category, which is quite large, two segments have been chosen for the study. In other cases, only one segment has been chosen.

Sr no.	**Segment chosen for the study**	**Therapeutic category**
1	Statins	Cardio Vascular
2	Betablockers	Cardio Vascular
3	Cephalosporins	Anti-Infective (Anti-Bacterial/ Antibiotic)
4	Muscular relaxant	Anti-Inflammation
5	Antileukaemics	Antileukaemics
6	Broncho-dilators solid & liquid	Anti-Asthmatic
7	Antihelmintics	Antihelmintics
8	Antirheumatics Nonstr.	Anti-Rheumatic
9	Antipeptic Ulcerants	Anti-Ulcer

The monthly data on various variables for the four geographical zones of India (East, West, North and South) have been aggregated to quarterly observations. For each molecule, there are 80 observations. Separate observations have been formed for domestic firms and foreign firms.[35]

[34] The choice of therapeutic categories for the analysis is guided by the Terms of Reference for the study (as advised by the UNCTAD-India Program). Within the categories, the therapeutic segments were chosen after a prelimary examination of the data (considereing the share in value of sales, presence of foreign firms, etc). In addition to the eight listed therapeutic categories, data were obtained for two more categories, namely Antacid Antiflatulents and Tuberculostatics. Conderable difficulties were, however, faced in constructing the price variable and other variables needed for demand function estimation. Hence, these two therapeutic categories were not included in the econometrtic analysis of price effect. But, these have been included in the market share analysis presented in Chapter 7.

[35] The list of domestic and foreign firms has been taken from ORG IMS. In three cases, firms listed as domestic in the list supplied by the ORG IMS were taken as foreign instead because balance sheet data for these companies drawn from *Capitaline* indicated that the foreign equity share is significant (over 10% foreign equity).

In each of the therapeutic segments considered for the study, there are a number of molecules. Not all molecules belonging to a segment are included in the study. Only the important ones have been included after studying the revenue shares (the selected ones account for 70 percent or more of total revenue of the segment). The molecules of a segment included in the study accounts for a dominant part of the total revenue of the segment.

Estimation of the lower level model (equation 5.2) requires data on total revenue (X_Q), revenue shares (s_i), prices of molecules (domestic and foreign firm groups separately)(p_i) and the aggregate price index (P_Q). The total revenue and revenue shares have been obtained from sales data available in the dataset. For computing the shares, the sales of only the selected molecules are considered, since the shares should add up to one.

For computation of prices, the various brands and stock keeping units (SKU) have been considered. The solids (tablets and capsules) are handled separately from the liquids. The injections and other forms such as inhalers have not been included in the computation of shares, nor in the formation of the price variable, except for one molecule in one of the segments, which was available only in the form of injections.

The construction of the price variable has been done in the following way. First, prices of various SKUs of various brands have been standardized (considering doses, strength and packet sizes). This has been done separately for solids and liquids. The prices of various SKUs and brands have been combined by taking a weighted average using the share in sales as weights. The weights vary over time. This is computed separately for different regions and separate series are formed for foreign firms and domestic firms. The price series so obtained has been regressed on the prices of the five top SKUs and regional dummies. The SKU by brand combinations are considered, and the five most important items in terms of sales are chosen. In the regression equation, per capita expenditure on the segment has been included as an explanatory variable. This exercise is done separately for foreign and domestic firms. The estimated regression equation is then used to provide an estimate of price of the molecule; separately for

foreign and domestic firms, for the four regions.[36] In this manner, separate price series for the four zones are formed for domestic firms and foreign firms engaged in the production of each molecule (selected ones) belonging to the segment. The aggregate price series, P_Q, is formed as a weighted aggregation of the individual prices series for various molecules in a segment, segregated by foreign-domestic dichotomy. The average revenue shares of the different molecules/firm type are used as weights.

The total expenditure on a segment per capita, X_Q, is formed by taking total sales of all molecules belonging to a segment, separated by regions. The region-wise population data are used for computing X_Q. The ratio of X_Q to P_Q enters as an explanatory variable in the lower level AIDS equation estimated. This ratio is taken as the dependent variable for estimating equation 5.11. For estimating this equation, per capita real gross domestic product is used as the measure of Y. The state level estimates of real gross domestic product are aggregated to form region-level estimates.

5.3 Empirical Results

5.3.1 Market Shares and Number of Firms

The shares of domestic and foreign firms[37] producing the selected molecules in the therapeutic segments chosen for the study are shown in Table 5.1. These are averages for the period 2004 to 2008. It will be noticed that the market share of foreign firms is zero or negligible in many cases.[38]

[36] This methodology for working out the price variable follows Chaudhuri et al. (2006).
[37] For definition of domestic and foreign firms, refer to footnote 35.
[38] The shares of different molecules in a segment listed in Table 5.1 do not add up to 100% because the denominator includes all molecules in the segment, i.e. it includes molecules other than those listed in the table.

Table 5.1: Shares of Foreign and Domestic Firms in the Molecules Studied

Segment	Molecules	Share (%) 2004-08		Sales, 2004-08 average (Rs 000)	
		Domestic	Foreign	Domestic	Foreign
Antihelmintics	Albendazole	33.32	31.30	328553	308612
	Ivermectin & comb.	8.10	0.33	79906	3275
	Levamisol	2.59	3.77	25571	37193
	Mebendazole	11.12	0.26	109677	2571
	Pyrental pamoate	4.66	0.01	45996	70
Antileukaemics	Capecitabine	7.06	0.00	27660	0
	Doxorubicin	8.36	2.53	32768	9921
	Gefitinib	12.04	0.81	47175	3160
	Imatinib	11.42	0.00	44746	0
	Methotrexate	20.33	11.02	79651	43169
Antirheumatics Nonstr	Aceclofenac	9.65	0.07	1314820	10040
	Diclofenac	18.91	8.29	2576404	1128552
	Etorecoxib	5.65	0.00	769670	0
	Ibuprofen	7.08	8.09	964855	1102602
	Nimesulide	20.45	0.06	2785311	8531
Betablockers	Atenolol	27.19	0.10	4052711	14423
	Carveditol	14.54	0.00	2167418	0
	Metoprolol	33.49	1.32	4991892	197245
	Nebivolol	6.63	0.00	988896	0
	Propranolol	16.71	0.01	2490858	1770
Bronchodilators solid & liquid	Etophylline comb.	10.76	0.00	339044	0
	Montelukast comb.	14.23	0.04	448190	1299
	Salbutamol comb.	37.31	4.72	1174971	148811
	Terbutaline comb.	1.28	2.67	40297	84217
	Theophylline comb.	11.75	0.00	370061	2
Cephalosporins	Cefadroxil	8.00	0.16	1628349	32027
	Cefixime	22.48	0.28	4577036	57630
	Cefotaxime	7.86	0.00	1600967	118
	Ceftriaxone	12.99	0.23	2644175	46659
	Cefuroxime	5.37	3.11	1093340	633034
	Cephalexin	5.72	3.22	1164351	654823
Muscular relaxant	Baclofen & comb	3.13	3.47	46161	51130
	Chlormezanone & comb.	3.85	0.10	56733	1476
	Chlorzoxa & comb.	40.66	1.38	599357	20297
	Methocarbamol & comb.	4.04	0.00	59561	0
	Tizanidine & comb.	16.16	4.55	238119	67136

(**Table 5.1 continued)**

Segment	**Molecules**	**Share (%) 2004-08**		**Sales, 2004-08 average (Rs 000)**	
		Domestic	Foreign	Domestic	Foreign
Statins	Atorvastatin	82.18	0.86	3426017	36051
	Rosuvastatin	4.47	0.00	186403	0
	Simvastatin	8.66	0.00	361164	0
Antipeptic Ulcerants	Esomeprazole	5.10	0.19	528223	19847
	Omeprazole	18.48	0.04	1915296	4174
	Pantoprazole	22.59	0.30	2341486	31501
	Rabeprazole	20.11	0.52	2084290	54008
	Ranitidine	15.64	6.55	1621153	679207

Out of the 44 molecules belonging to the nine segments considered for the study, the market share of foreign firms exceeds four percent in only seven cases. These are Albendazole, Methotrexate, Diclofenac, Ibuprofen, Salbutamol, Tizanidine and Ranitidine.[39] This aspect is studied further in Chapter 7.

The number of domestic and foreign firms operating in the markets of different molecules is shown in Table 5.2. The ratio of domestic to foreign firms is 10:1 or higher in most cases. Within the group of domestic firms engaged in the production and sale of a molecule (and combinations), there are both large firms and a number of small and medium firms. Usually, 10 or more firms supply a molecule. But, this may not mean that the markets are sufficiently competitive, because the top 3 or 4 firms generally account for a high share of the market (Table 5.3).

Table 5.2: Number of Firms by Molecules and Segments

Segment: Statins						
No of Firms	Atorvastatin	Rosuvastatin	Simvastatin			
Domestic	79	12	21			
Foreign	3	--	--			
Segment: Betablockers						
No of Firms	Atenolol	Carvedilol	Metoprolol	Nebivolol	Propranolol	
Domestic	53	20	22	28	15	
Foreign	2	--	2	--	2	

[39] In another four cases, the market share of foreign firms is between 3 and 4 percent. These molecules are: Levamisol, Cefuroxime, Cephalexin, and Beclofen.

Table 5.2 continued.

Segment: Antihelmintics						
No of Firms	Albendazole	Ivermectin & comb.	Levamisol	Mebendazole	Pyrental Pamoate	
Domestic	107	23	2	14	5	
Foreign	8	1	1	1	1	
Segment: Muscular relaxant						
No of Firms	Baclofen & Comb.	Chlormezanone & Comb.	Chlorzoxa & Comb.	Methocarbamol & Comb.	Tizanidine & Comb.	
Domestic	4	10	127	3	63	
Foreign	1	1	5	--	3	
Segment: Antilucemics						
No of Firms	Capecitabine	Doxorubicin	Gefitinib	Imatinib	Methotrexate	
Domestic	8	12	1	6	10	
Foreign	--	1	1	--	3	
Segment: Cephalosporins						
No of Firms	Cefadroxil	Cefixime	Cefotaxime	Ceftriaxone	Cefuroxime	Cephalexin
Domestic	99	99	57	71	52	76
Foreign	4	6	1	4	3	3
Segment: Broncho dilators, Solids & Liquid						
No of Firms	Etophylline	Montelukast	Salbutamol	Terbutaline	Theophylline	
Domestic	6	13	63	14	27	
Foreign	--	1	6	1	1	
Segment: Antipeptic Ulcerants						
No of Firms	Esomeprazole	Omerprazole	Pantoprazole	Rabeprazole	Ranitidine	
Domestic	24	132	102	85	87	
Foreign	2	6	6	5	4	
Segment: Antirheumatic Nonstr.						
No of Firms	Aceclofenac	Diclofenac	Etorecoxib	Ibuprofen	Nimesulide	
Domestic	115	207	30	142	162	
Foreign	6	10	--	9	6	

Table 5.3: Share of top 4 companies in each Molecule of Different Segments

Company name	Share	Company name	Share	Company name	Share	Company name	Share	Company name	Share
Antilucemics									
Capecitabine		***Doxorubicin***		***Gefitinib***		***Imatinib***		***Methotrexate***	
Nicholas piramal	81.03	Dabur	62.02	Natco pharma	94.83	Natco pharma	95.63	Ipca labs	50.55
Dabur	13.05	Pharmacia	18.00	Astrazeneca	5.17	Sun pharma	3.84	Glaxosmithkline	25.16
Ranbaxy	1.93	Sun pharma	9.22			Cipla	0.44	Sun pharma	9.20
Wockhardt	1.23	Wockhardt	5.00			Hetero healthcare	0.04	Zydus cadila	5.90
Antihelmintics									
Albendazole		***Antihelmintic, Oth. & Comb***		***Levamisol***		***Mebendazole***		***Pyrental Pamoate***	
Glaxosmithkline	48.17	Mankind	48.92	Janssen-cilag	54.90	Cipla	79.80	Ipca labs	55.00
Alkem	7.92	Ochoa lab	15.41	Khandelwal	45.10	Mapra labs	12.06	Merind	41.53
Cipla	7.19	Piramal healthcare	11.98			Cadila pharma	6.19	Euphoric	3.15
Mankind	6.88	Common wealth	6.27			Dabur	0.47	Pfizer	0.20
Antirheumatic Nonstr									
Aceclofenac		***Diclofenac***		***Etorecoxib***		***Ibuprofen***		***Nimesulide***	
Ipca labs	17.39	Novartis	29.75	Zydus cadila	23.44	Sanofi aventis	38.02	Dr Reddy's labs	23.82
Intas	11.78	Piramal healthcare	8.52	Rexcel	14.14	Abbott	13.24	Alkem	13.45
Wockhardt	6.55	Ranbaxy	5.17	Sun pharma	13.32	Aristo pharma	12.42	Panacea biotec	8.73
Aristo pharma	6.47	Emcure	4.17	Dr Reddys labs	8.83	Cipla	7.30	Intas	5.46
Broncholators Solids & Liquid									
Etophylline		***Montelukast***		***Salbutamol***		***Terbutaline***		***Theophylline***	
German remedies	99.41	Cipla	40.15	Cipla	31.76	Cipla	31.76	Modi mundipharma	64.00
Cipla	0.41	Lupin labs	21.63	Franco indian	19.04	Franco indian	19.04	Raptakos brett	8.42
Lincoln pharma	0.17	Ranbaxy	20.34	Aristo pharma	6.90	Aristo pharma	6.90	Sun pharma	6.70
Bio ethicals	0.01	Sun pharma	6.62	Merck limited	6.59	Merck limited	6.59	German remedies	4.97

Cephalosporins											
Cefadroxil		***Cefixime***		***Cefotaxime***		***Ceftriaxone***		***Cefuroxime***		***Cephalexin***	
Lupin labs	17.37	Fdc	18.27	Alkem	63.94	Aristo pharma	32.56	Glaxosmithkline	30.31	Ranbaxy	46.34
Indoco	17.03	Alkem	13.52	Biochem	13.11	Alkem	10.74	Mankind	12.87	Glaxosmithkline	36.52
Aristo pharma	14.06	Macleods pharma	8.12	Lupin labs	6.50	Ranbaxy	7.97	Alkem	10.55	Lupin labs	8.40
Cipla	12.20	Piramal healthcare	7.42	Laborate pharma	3.41	Lupin labs	5.28	Fdc	5.83	RPG life sciences	1.14

Company name	Share	Company name	Share	Company name	Share	Company name	Share	Company name	Share
Muscular									
Baclofen & Comb		***Chlormezanone & Comb.***		***Chlorzoxa & Comb.***		***Methocarbamol & Comb.***		***Tizanidine & Comb.***	
Novartis	51.09	Wockhardt	82.33	Croslands	14.89	Khandelwal	92.29	Dr reddys labs	18.92
Sun pharma	47.20	Navil	6.79	Intas	11.18	Cipla	6.37	Ipca labs	16.37
Intas	0.84	P b labs	5.78	Aristo pharma	10.47	Unimark	1.34	Novartis	11.22
Samarth pharma	0.58	Medico labs	2.08	Wockhardt	8.95			Sun pharma	9.32
Statins									
Atorvastatin		***Rosuvastatin***		***Simvastatin***					
Stancare	15.37	Ranbaxy	59.28	Stancare	47.60				
Lupin labs	9.68	Sun pharma	13.09	U s v	19.71				
Sun pharma	9.34	Glenmark pharma	12.28	Cipla	13.05				
Zydus cadila	9.02	Torrent pharma	5.15	Ipca labs	6.43				
Antipeptic Ulcerants									
Esomeprazole		***Omerprazole***		***Pantoprazole***		***Rabeprazole***		***Ranitidine***	
Torrent pharma	33.81	Dr Reddys labs	41.53	Alkem	18.57	Lupin labs	9.23	Glaxosmithkline	29.09
Ranbaxy	19.19	Zydus cadila	21.14	Sun pharma	18.46	Dr reddys labs	9.13	Cadila pharma	28.79
Unichem	11.44	Mankind	5.70	Aristo pharma	14.64	Wanbury	8.25	Unique pharm	18.09
Sun pharma	10.91	Torrent pharma	5.28	Zydus cadila	12.99	Alembic	6.39	Ranbaxy	10.69
Betablockers									
Atenlol		*Carvedilol*		*Metoprolol*		*Nebivolol*		*Propranolol*	
Ipca labs	14.29	Alkem	30.24	Micro labs	34.36	Glenmark pharma	14.93	Orchid chem. & pharma	35.46
Piramal healthcare	11.19	Stancare	19.08	Torrent pharma	9.40	Piramal healthcare	13.85	Sun pharma	19.13
Zydus cadila	8.32	RPG life scinces	12.51	Dr Reddy’s labs	7.91	Genetica	13.82	Alkem	9.35
Alembic	7.62	Themis medicare	7.56	Astrazeneca	5.55	Ajanta pharma	9.15	Mankind	7.10

5.3.2 Estimate of Price Elasticity

The estimated parameters of the lower level AIDS model and the upper level demand function are presented in Annex 5.1 and 5.2. The estimates of price elasticity based on the estimated parameters are also presented in Annex 5.3. These estimates are presented separately for different regions/zones. A summary of the results obtained is given in Table 5.4 below. It shows both price elasticity and expenditure elasticity. Some summary indicators of inter-molecular substitution and the substitution possibility of the produce of domestic and foreign firms engaged in the production of the same molecule are also presented. The summary results presented in Table 5.4 pertain to the estimates for North zone. Such information for the East zone is provided in Annex 5.4. The results for the West and South zones are similar, and hence not presented in the Report

Table 5.4: Estimates of Own and Cross Price Elasticity, and Expenditure Elasticity, North Zone

Statins

North Zone	Own Price Elasticity		Cross Price Elasticity		Cross Price Elasticity with Other Compound (+ve cases)	d/d	f/f	Expenditure Elasticity	
Molecule	**Domestic**	**Foreign**	**Domestic#**	**Foreign@**				**Domestic**	**Foreign**
Atorvastatin	-1.70	-1.28	(-)	(+)	5/8	4/4	-	1.03	1.71
Rosuvastatin	-0.50	-	-	-	2/6	2/4	-	0.68	-
Simvastatin	-0.51	-	-	-	4/6	2/4	-	0.84	-

Betablockers

North Zone	Own Price Elasticity		Cross Price Elasticity		Cross Price Elasticity with Other Compound (+ve cases)	d/d	f/f	Expenditure Elasticity	
Molecule	**Domestic**	**Foreign**	**Domestic**	**Foreign**				**Domestic**	**Foreign**
Atenolol	-1.41	455.09	(+)	(+)	11/24	5/8	np/4	0.70	-35.29
Carvedilol	-2.64	-	-	-	10/14	4/8	-	1.19	-
Metoprolol	-3.19	-4.50	(+)	(+)	16/24	6/8	np/4	1.47	1.13
Nebivolol	-1.31	-	-	-	8/14	4/8	-	0.74	-
Propranolol	-1.17	218.26	(-)	(-)	9/24	3/8	np/4	1.17	62.41

Antipeptic Ulcerants

North Zone	Own Price Elasticity		Cross Price Elasticity		Cross Price Elasticity with Other Compound (+ve cases)	d/d	f/f	ExpenditureElasticity	
Molecule	**Domestic**	**Foreign**	**Domestic#**	**Foreign@**				**Domestic**	**Foreign**
Esomeprazole	0.27	-5.34	(+)	(+)	15/32	3/8	4/8	1.42	1.06
Omeprazole	-0.34	1.08	(-)	(-)	14/32	2/8	4/8	0.77	-21.60
Pantoprazole	-0.96	5.45	(+)	(+)	18/32	4/8	6/8	0.97	2.40
Rabeprazole	-1.20	-1.93	(+)	(+)	13/32	5/8	6/8	0.82	2.32
Ranitidine	-3.39	1.74	(-)	(-)	18/32	4/8	4/8	1.42	1.12

Antihelmintics

North Zone	Own Price Elasticity		Cross Price Elasticity		Cross Price Elasticity with Other Compound (+ve cases)	d/d	f/f	Expenditure Elasticity	
Molecule	**Domestic**	**Foreign**	**Domestic#**	**Foreign@**				**Domestic**	**Foreign**
Albendazole	-1.19	-0.88	(-)	(-)	14/32	4/8	2/8	0.88	0.93
Ivermectin & comb.	-4.60	-3.95	(-)	(-)	20/32	6/8	4/8	2.06	-2.38
Levamisol	-0.68	-1.07	(+)	(+)	16/32	2/8	6/8	1.35	0.80
Mebendazole	-0.24	42.75	(+)	(+)	14/32	4/8	4/8	1.46	-5.88
Pyrental Pamoate	-7.52	-83.83	(-)	(+)	17/32	4/8	4/8	1.24	NC

Antirheumatic Nonstr.

North Zone	Own Price Elasticity		Cross Price Elasticity		Cross Price Elasticity with Other Compound (+ve cases)	d/d	f/f	Expenditure Elasticity	
Molecule	**Domestic**	**Foreign**	**Domestic#**	**Foreign@**				**Domestic**	**Foreign**
Aceclofenac	-3.49	11.17	(-)	(-)	16/28	2/8	6/6	1.17	-10.85
Diclofenac	-1.41	-0.58	(+)	(+)	10/28	2/8	2/6	1.21	1.33
Etorecoxib	-0.84	-	-	-	12/16	4/8	-	-0.05	-
Ibuprofen	-1.28	-1.37	(-)	(-)	14/28	4/8	4/6	1.21	1.04
Nimesulide	-1.01	NC	(-)	(-)	16/28	3/8	4/6	0.96	NC

Cephalosporins

North Zone	Own Price Elasticity		Cross Price Elasticity		Cross Price Elasticity with Other Compound (+ve cases)	d/d	f/f	Expenditure Elasticity	
Molecule	**Domestic**	**Foreign**	**Domestic#**	**Foreign@**				**Domestic**	**Foreign**
Cefadroxil	-0.52	14.56	(-)	(-)	16/32	4/10	2/6	0.94	-10.37
Cefixime	-2.70	-2.63	(-)	(-)	22/32	8/10	4/6	0.92	-2.25
Cefotaxime	0.12	-	-	-	10/18	5/10	-	0.99	-
Ceftriaxone	-2.07	-	-	-	10/18	6/10	-	1.08	-
Cefuroxime	-1.98	0.25	(+)	(+)	12/32	4/10	4/6	1.07	0.96
Cephalexin	-0.58	-6.92	(-)	(-)	17/32	4/10	2/6	0.11	4.48

Antileukaemics

North Zone	Own Price Elasticity		Cross Price Elasticity		Cross Price Elasticity with Other Compound (+ve cases)	d/d	f/f	Expenditure Elasticity	
Molecule	**Domestic**	**Foreign**	**Domestic#**	**Foreign@**				**Domestic**	**Foreign**
Capecitabine	21.57	-	-	-	2/12	2/8	-	1.77	-
Doxorubincin	-0.61	0.14	(-)	(-)	6/20	2/8	2/2	1.46	0.91
Gefitinib	3.80	-	-	-	2/12	2/8	-	2.34	-
Imatinib	-3.42	-	-	-	6/12	2/8	-	1.37	-
Methotrexate	-2.68	-7.89	(+)	(+)	4/20	np/8	2/2	0.48	0.12

Muscular Relaxant

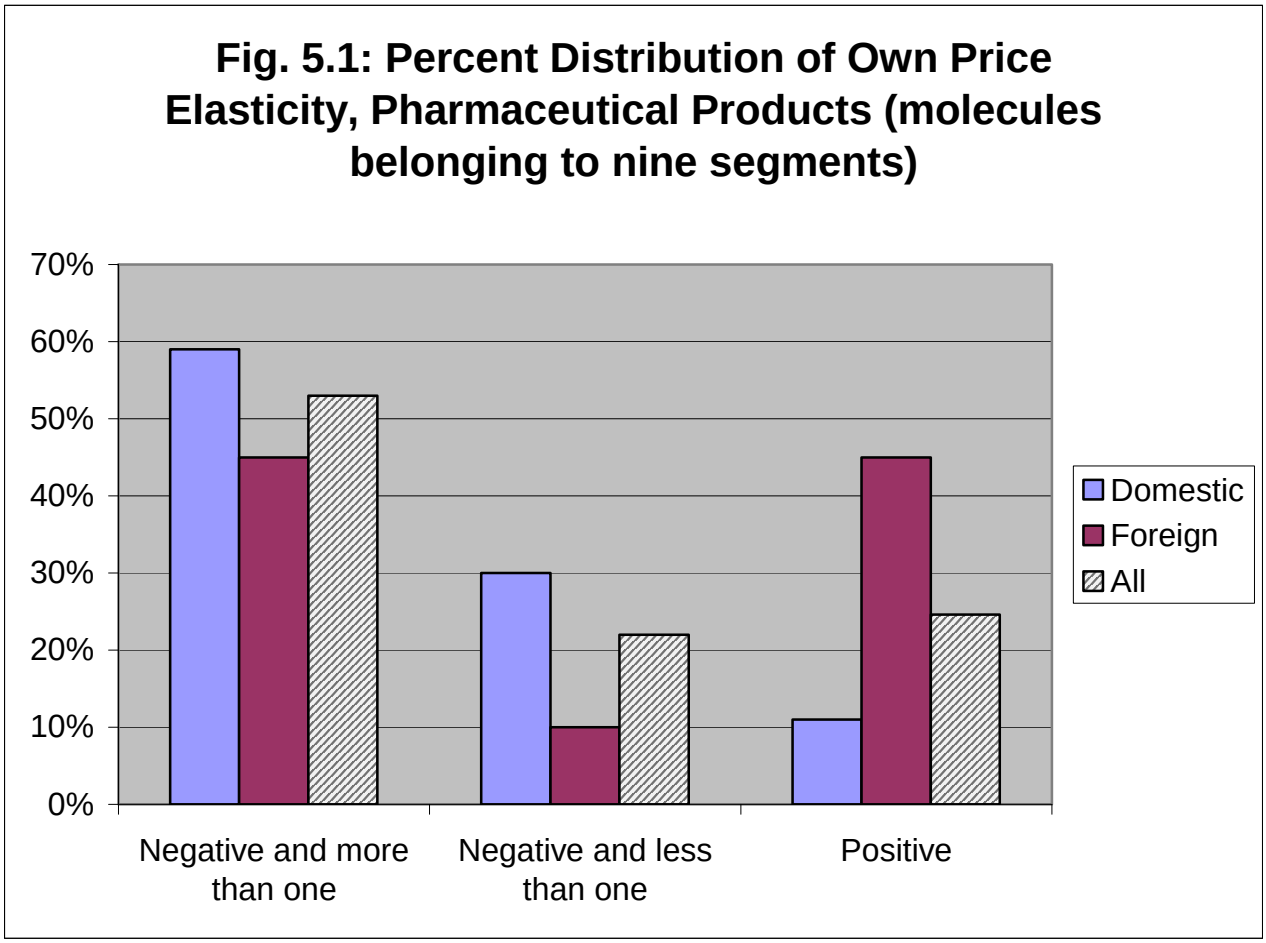
North Zone	Own Price Elasticity		Cross Price Elasticity		Cross Price Elasticity with Other Compound (+ve cases)	d/d	f/f	Expenditure Elasticity	
Molecule	**Domestic**	**Foreign**	**Domestic#**	**Foreign@**				**Domestic**	**Foreign**
Baclofen & comb	-2.84	0.31	(+)	(+)	12/28	6/8	1/6	-0.35	0.43
Chlormezanone & comb	-14.30	7.40	(+)	(+)	15/28	6/8	2/6	-2.92	1.85
Chlorzoxa & comb	-1.37	0.63	(+)	(+)	17/28	7/8	1/6	1.38	-2.04
Methocarbamol & comb	-2.21	-	-	-	10/16	6/8	-	0.69	-
Tizanidine & comb	0.74	-1.00	(+)	(+)	6/28	1/8	2/6	1.05	-0.48

Bronchodilator, Solids & Liquid

North Zone	Own Price Elasticity		Cross Price Elasticity		Cross Price Elasticity with Other Compound (+ve cases)	d/d	f/f	Expenditure Elasticity	
Molecule	**Domestic**	**Foreign**	**Domestic#**	**Foreign@**				**Domestic**	**Foreign**
Etophylline & comb.	-0.81	-	-	-	8/14	4/8	-	1.07	-
Montelukast & comb.	-1.58	NC	(+)	(+)	12/24	2/8	2/4	1.10	-14.08
Salbutamol & comb.	-1.74	-2.23	(-)	(-)	9/24	4/8	np/4	0.90	1.03
Terbutaline & comb.	-0.05	-2.14	(-)	(-)	15/24	4/8	2/4	0.39	1.57
Theophylline & comb.	-0.19	-	-	-	2/14	2/8	-	1.02	-

Note- np=no positive case; NA=not available; NC=elasticity not compute because the share of compound is very low; # change in demand for produce of domestic firm due to change in price of foreign firms; @ change in demand for produce of foreign firms due to change in price of domestic firm. The column with heading d/d shows the number of positive cases of cross price elasticity for the molecules produced by domestic firms. The column with heading f/f shows that for foreign firms.

Of the estimates of own price elasticity for various molecules obtained for domestic firms, about 11 percent of the cases are positive, i.e. wrongly signed, and another 30 percent are negative but less than one (Figure 5.1). Thus, in about 59 percent of the cases, the estimated own price elasticity is found to be negative and more than one. For foreign firms, the proportions are 45, 10 and 45 percent, respectively. Evidently, the price elasticity of demand for foreign firms' products is positive, or negative but less than one, in a majority of cases. The average value of own price elasticity for domestic firms after taking out the top five and bottom five values is –1.38. For foreign firms, the average is computed after leaving out the top seven and bottom seven values (more excluded since there are a high proportion of positive elasticities). The estimated average price elasticity for foreign firms comes to –0.56. The overall average own price elasticity is found to be –1.13.



It may be useful to compare the results obtained in this study with the results reported by Chaudhuri et al. (2006) for their study of Fluoroquinolones. Their estimates of own price elasticity are consistently negative. These range from –1.38 to –5.57, except for one case (foreign norfloxacin) for which the estimate is found to be –0.45. The estimates of Chaudhuri et al. (2006) give the impression of a fairly high price elasticity of demand for Fuoroqunolones (Ciprofloxacin, Norfloxacin, Ofloxacin, etc). By comparison, the elasticity estimates obtained in this study would lead one to conclude that the price elasticity, on average, is not high, and in a section of molecules, the price elasticity is low or very low. This does not seem to be unrealistic conclusion to draw about the price elasticity of demand for pharmaceutical products in India. It is known that the large pharmaceutical firms in India incur huge expenditure on promotion and marketing and the impact such expenditure is to differentiate the product and thus make its demand less sensitive to price changes. There are reasons to believe that the product differentiation created by product promotion and marketing expenses enable large firms to sell their produce at significant premium over the price charged for the same molecule by the medium and small-scale firms. It may be added here that the demand for drugs are to a large extent driven by supply-side factors and this makes demand less responsive to prices. This is further reinforced by the fact that the markets are highly concentrated (as shown by Table 5.3 above). In short, therefore, the finding of a low price elasticity of demand for pharmaceutical products is broadly consistent with other facts known about the industry.

Whether or not the price elasticity of demand is high has important implications for the impact of product patents on drug prices. If the price elasticity is high, elimination of domestic producers may not give much scope to the foreign producers to raise prices. However, if the price elasticity is low, prices may be raised substantially after domestic producers of the molecule quit the market.

A related issue to be discussed here is the cross price elasticity between the produce of domestic and foreign firms based on the same molecule. One would expect the substitution possibilities (in a technical sense) to be very high in such cases (since the products are based on the same molecule), and therefore the cross-price elasticity should be positive. It is interesting

to note that out of the 44 molecules studied, a positive cross-price elasticity between foreign and domestic firms' produce of the same molecule is found only in 15 cases. Some of these are not statistically significant. Thus, there is no strong evidence of strong price responsiveness of demand of produce of foreign and domestic firms based on the same molecule to each other's price. The implication is that even if domestic firms in a particular molecule get eliminated, the consumers in most cases may not shift to the foreign firms producing that molecule.

Chaudhuri et al. (2006) arrive at a similar conclusion about substitutability between products of domestic and foreign firms. In a bid to explain their finding, they point out that anecdotal evidence in various industry studies suggest that the there are marked differences between domestic and foreign firms in the structure and coverage of retail distribution networks. The distribution network in India is such that the market shares enjoyed by a particular pharmaceutical product depend on the number of retail pharmacists who stock the product. The retail reach of domestic firms as a group tends to be much more comprehensive than that of multinational subsidiaries. The implication is that if the domestic firms products based on a molecule become costly or become unavailable, the consumers may not be able to shift to the foreign firms' products based on the same molecule (because of the transport cost or inconvenience of finding the retail store that keeps the products of the foreign firms). Instead, there may be a tendency to shift to another molecule produced by domestic firms in the same therapeutic group.[40]

The sixth column in Table 5.4 shows the proportion of cases in which the cross price elasticity between products (molecules and foreign-domestic dichotomy) is positive. Since, as asserted by Chaudhuri et al. (2006), the substitution among molecules may be greater among domestic firms, the relevant proportions have been shown separately for domestic and foreign firms in the seventh and eighth columns. It is evident from a perusal of the figures reported in the table that there are differences between segments and between different molecules belonging to a segment in regard to the proportion of positive cases. Overall, the proportion of positive cases is about one half. The proportion of positive cases when one considers only the

[40] Lanjouw (1997) notes that it is relatively easy for consumers to switch between drugs in India. The Chemists quite freely substitute alternative, usually lower priced medicine for the prescribed and sell prescription-only medicine without scripts.

products of domestic firms does not differ much from that in the case of products of foreign firms. But, there are differences between segments (though the differences are limited). The proportion of positive cross-price elasticity (reflecting substitution possibilities) is relatively low in Muscle relaxant, Broncho-dilators, and Antilukemics, and it is relatively high in Cephalosporins, Statins and Betablockers.

5.4 Counterfactual Simulation – assessing the effect on prices and welfare

In the counterfactual simulation exercise, a new set of equilibrium prices are obtained for each segment under patent enforcement. Here, two sets of prices have to be worked out. First, a set of virtual prices has to be obtained for the domestic products that will not be available any more once patents are enforced. These prices have to so set that the expenditure share of those products fall to zero. The second set of prices is for the products that remain the market – products of foreign firms and some products of domestic firms. For these products, the new equilibrium prices have to be determined under the assumption of profit maximization. The system of simultaneous equations to be solved to derive the two sets of prices is given below (following Chaudhuri, et al. 2006):

For products i that will be withdrawn from the market

$$0 = \alpha_i + \gamma_{ii} p_i^v + \sum_{j \neq i} \gamma_{ij} \ln p'_j + \beta_i \ln\left(\frac{X_Q^r}{P_Q^r}\right) \qquad \ldots(5.14)$$

For products k that will remain in the market:

$$p'_k = c_k \times \left[1 + \frac{1}{\varepsilon_{kk}(p'_k, .. p'_j, p_i^v)}\right]^{-1} \qquad \ldots(5.15)$$

In the above equation, ε_{kk} is the own price elasticity, which depends on the virtual price of i'th product(s) and the new equilibrium price of the other products that remain in the market. c_k

denotes the marginal cost of product k, which is obtained from the pre-revised price of product k and the own price elasticity of product k. This is done using the following relationship:

$$c_k = p_k \times \left[1 + \frac{1}{\varepsilon_{kk}(p_i, p_j, \ldots . p_k)} \right] \qquad \ldots(5.16)$$

As product prices change, their impact on the aggregate price P_Q is incorporated in the equation system. The effect of P_Q on X_Q is also brought in through equation 5.11. All these together make a system of equations to be solved.[41]

Two points need to be noted in this connection. First, in a number of products, the own price elasticity is positive or negative but less than one. In such cases, equation 5.16 above cannot be used to derive marginal cost. It becomes necessary therefore to make an assumption about the ratio of marginal cost to price for such products; this has been assumed to be 80 percent.[42] In these cases, it also becomes necessary to exogenously set the revised prices of the products after patent enforcement.[43] Chaudhuri et al. (2006) have also faced this difficulty in their analysis. For one of the products (foreign Norfloxacin) considered by them, the own price elasticity was found to be less than one. They assumed that the price of that product will go up by 627% if three or more of the domestic products (out of four) are withdrawn because of patent enforcement. For this study, it has been assumed that the price rise for such products will be by 300% after patent enforcement.[44]

[41] Solution to the system of equations has been obtained by using 'Solver' of MS-Excel. Besides the equations in 5.14 and 5.15, non-negativity constraints have to be imposed on shares of products that remain in the market.
[42] The ratio of profit to sales in pharmaceutical companies is reported to be about 15-17 percent (see Table 4.2). Thus the assumption that marginal cost is about 80% of prices seems reasonable.
[43] In certain cases, withdrawal of domestic products and the resultant change in market shares causes the elasticity to become negative and greater than one in the solution of the system of equations. In these cases, the price given by the solution of the system of equations has been taken rather than fixing the price exogenously.
[44] Such exogenous fixing of prices had to be done in some other cases too, when a problem of convergence of the system of equations was encountered. The choice of the figure of 300% is arbitrary, but seems reasonable. The assumption is based on the estimates of priec increase reported by Chaudhuri et al. (2006). In their counterfactural exercise involving withdrawal of all domestic products, they find that the prices of foreigh Ciprofloxicin will rise by 396% and that of foreign Ofloxicin by 318%. Further support is provided by the estimates of patent induced price rise reported by Fink (2000). One set of his estimates, made under the assumption of relatively low inter-molecular substitution possibilities, suggests that stronger patent protection will raise prices of quinnolones and synthetic hypotensives in India by somewhere in the range of 200 to 400 percent.

The second point is about the price elasticity of demand for an industry and that for individual firms belonging to the industry. It is reasonable to assume that the price elasticity of demand for individual firms will be higher than that for the industry. In other words, if all foreign firms producing a product raise their prices by x%, the percentage fall in aggregate demand for product of firms will be less than what would be the percentage fall in demand of an individual foreign firm, if it alone raises its price by x%. The relationship in equations 5.15 and 5.16 should hold at the firm level, not at the industry level. Chaudhuri et al. (2006) do not take this aspect into account in their analysis, though they recognize the possible bias in the results that may arise.[45] They argue that the estimates will nevertheless be useful as they show how large the maximum profit gains for multinational firms and the maximum profit losses for domestic firms are likely to be under product patent enforcement. Following Chaudhuri et al. (2006), the core analysis presented in this chapter ignores the issue of competition among firms in an industry. However, to incorporate this aspect into the analysis, an alternate set of estimates of price change and changes in welfare has been made for which it has been assumed that the firm level elasticity is two times the industry level elasticity (the price change estimates are shown in Annex 5.5).

Table 5.5 shows the percentage increase in the prices of products of foreign producers that will take place in different molecules of different segments if products of domestic producers are withdrawn as a result of patent enforcement. One column shows the effect of withdrawal of one major domestic product; another column shows the effect of withdrawal of all domestic products. In some segments, the system of equations could not be solved when all domestic products were withdrawn. Hence, in those cases, one or two domestic products were allowed to remain.

[45] Chaudhuri et al. (2006; p. 1501) write: "It is important to note that these estimates do not reflect either the actual marginal cost or the actual markup for these drugs, both because the existence of price regulation implies that the unconstrained first-order conditions are unlikely to hold each period, and because our aggregation across firms of the same domestic/foreign status supplying the same molecule makes the interpretation of these estimates problematic. In particular, the fact that we ignore competition among firms within each product group implies that our estimates will tend to overstate market power."

.

The results of the counterfactual simulation suggest that if all domestic products are withdrawn, the price of foreign products will rise by about 260 percent on average. If only one product (an important one) of domestic producers is withdrawn in each segment, the effect on the price of products of foreign firms will be an increase by about 200 percent on average. The estimate of price increase when one major domestic product is withdrawn obtained in this study is broadly in line with the results of Chaudhuri et al. (2006) for Furoqunolons. According to their estimates, withdrawal of Ciprofloxicin produced by domestic firms will lead to an increase in the product prices of foreign firms by about 200 percent. In the case of Ofloxicin, the corresponding figure is about 120 per cent. However, in regard to the effect of withdrawal of all domestic products, the estimates obtained in this study differ somewhat from the estimates of Chaudhuri et al. (2006). According to the estimates of Chaudhuri et al. for Fluoroquinolones, when all products of domestic firms are withdrawn, the increase in the prices of products of foreign firms is by about 450 percent (excluding the product whose price has been set exogenously, the average is about 350 percent). In comparison to that the estimate obtained here, at about 260%, is lower.

Some discussion on the functional form used for modeling demand for drugs would be in order here. For this study, the AIDS (almost ideal demand system) has been used, as done by Chaudhuri et al. (2006). Alternatively, the random coefficient logit or nested logit models of demand could have been used. Many recent studies on demand have used the logit model. The logit model has the advantage that it avoids inconsistencies and provides more precise demand estimation. It may be shown that, all other assumptions remaining the same, the patent induced price rise with the AIDS model is higher than that with a logit demand model.[46] Also, the random coefficient logit or nested logit model fits the empirical pattern of demand for drugs better than the AIDS model. The implication is that the estimates of patent induced price rise obtained here are probably higher than what these would have been if a random coefficient logit or nested logit model had been used. In a sense, therefore, the estimate of price rise obtained by the AIDS model overstates somewhat the price rise that would be caused by the stricter enforcement of patents.

[46] We thank one of the reviewers for drawing our attention to this point.

Table 5.5: Changes in the Prices of Products of Foreign Firms after Withdrawal of Products of Domestic Firms following Patent Enforcement

Segment	Molecules	Change in Price (%)	
		All domestic products of the segment withdrawn	One domestic product of the segment withdrawn
Antihelmintics	Albendazole	300	92
	Ivermectin & comb.	85	290
	Levamisol	966	114
	Mebendazole	300	300
	Pyrental pamoate	122	66
Antileukaemics	Doxorubicin	300	300
	Methotrexate	78	-2
Antirheumatics Nonstr	Aceclofenac	300	300
	Diclofenac	264	300
	Ibuprofen	68	12
	Nimesulide	273	300
Bronchodilators solid & liquid	Montelukast comb.	300	300
	Salbutamol comb.	86	95
	Terbutaline comb.	120	74
Cephalosporins	Cefadroxil	300	300
	Cefixime	124	125
	Cefuroxime	300	300
	Cephalexin	171	51
Muscular relaxant	Baclofen & comb	300	300
	Chlormezanone &	300	300
	Chlorzoxa & comb.	300	300
	Tizanidine & comb.	272	177
Statins	Atorvastatin	50	113
Beta Blockers	Atenolol	300	300
	Metoprolol	354	-5
	Propranolol	300	300
Antipeptic Ulcerants	Esomeprazole	-33	0
	Omeprazole	300	300
	Pantoprazole	300	300
	Rabeprazole	457	251
	Ranitidine	300	300

Note: For a number of products, the price elasticity of demand is positive, or negative but less than one. The equation system cannot be used to determine their price. For those products, the price rise consequent upon product patent enforcement has been exogenously fixed at 300 percent (based on the results of Chaudhuri at al. (2006) for Fluoroquinolones.

In this context, the simulation exercise done by Fink (2000) for assess the effect of stronger patent rights on Indian pharmaceuticals industry may be mentioned. He considered two groups of drugs, namely quinnolones and synthetic hypotensives, and used brand level data for 1992 for the analysis. In one set of estimates, which are made under the assumption that the elasticity of substitution is 1.1, the patent induced price rise is found to be mostly in the range of 171% to 417% for quinnolones and 142% to 333% for synthetic hypotensives. In another set of estimates, which are made under the assumption that the elasticity of substitution is 2.0, the patent induced price rise is found to be in the range of 21% to 68% for quinnolones and 12% to 49% for synthetic hypotensives. The results indicate that if inter-molecular substitution possibilities are high, the patent induced price rise will be low. Fink accordingly concludes that the availability of close, off-patent therapeutic substitutes can restrain hike in prices following introduction of a stricter patent regime (and thus limit potential welfare losses). The implication is that if future drug discoveries are mainly new varieties of already existing therapeutic treatments, the impact on prices is likely to be relatively small. But, if newly discovered drugs are medicinal breakthroughs, prices may be significantly above competitive levels.

The estimates of inter-molecular cross-price elasticity obtained in this study (see Table 5.4) indicate the substitution possibilities to be low. Thus, it is the first set of estimates of Fink rather than the second set mentioned above that should be compared with estimates of this study. When such comparison is done, the results of this study are found to be broadly in line with the estimates of Fink.

Another study with which comparison could be made is that of Watal (2000). She makes an attempt to estimate the maximum likely increase in pharmaceutical prices (and decrease in welfare) with instantaneous introduction of product patents in existing 22 patentable pharmaceutical markets in India. The estimation is done with the help of data for 1994. According to her estimates, the overall maximum weighted price increase would be a mean of 26 percent with a linear demand function and 242 percent with a constant elasticity demand function. It is more appropriate to compare her estimates based on the constant elasticity demand function with the estimates obtained in this study than her estimates based on

the linear demand function (which are expected to yield a low estimate of price rise). It is encouraging to note that her estimate of average increase in pharmaceutical prices of 242 percent accords well with the estimates of 260 percent and 200 percent obtained in this study under alternate scenarios. Considering the estimates of Fink (2000) and Watel (2000) along with the estimates obtained in this study, it appears that the estimate of price increase (450 percent) made by Chaudhuri et al. (2006) is rather high. This might apply to the specific therapeutic segment (Fluoroquinolones) they had considered, but cannot be treated as an indication of the general expected increase in pharmaceutical prices resulting from the implementation of the product patent regime.

Before proceeding further it should be pointed out that under the TRIPS regime, patents are to be granted only on applications received from 1995 onwards for new, patentable pharmaceutical inventions. Therefore, the pharmaceutical products which had entered the markets before 1995 are not affected. In the analysis presented above, it has been assumed that all domestic producers of the molecules studied have to stop their supplies to the market. This is obviously a hypothetical situation considered for the analysis. This counterfactual simulation nonetheless has utility since it represents the long run situation that may arise if in each therapeutic segment new pharmaceutical products with considerable therapeutic advantage are introduced so that the sales of exiting products become marginal and the new products are under strict product patent regime.

Welfare Impact

To assess the welfare impact of patent enforcement, the loss in consumer surplus and change in profits of domestic and foreign firms has been assessed. The assessment of loss of consumer surplus has been done by applying the methodology used earlier by Hauman and Leonard (2002; equation 11).[47] The estimates of consumer surplus loss are presented in Table 5.6 along with estimates of changes in producers' profits. These estimates have been made under the assumption that all domestic products get withdrawn after product patent enforcement. If

[47] See also, Hausman (1981)

only one domestic product is withdrawn, then the consumer surplus loss will be lower. This has not been separately estimated.

The average consumer welfare loss across the nine segments studied is Rs 5.8 billion. This is lower than the estimate of Chaudhuri et al. (2006) for Fluoro-quinolones at Rs 17.8 billion per year, but significant in absolute value. It seems therefore that the consumers would suffer significant losses from the price rise that would take place as a result of patent enforcement.

Table 5.6: Counterfactual Estimates of Consumer Welfare Losses and Changes in Producers' Profits Due to Patent Enforcement, by Therapeutic Segment

Segment	Consumer welfare loss (Rs billion per year)	Change in Profits (Rs billion per year)		
		All producers	Foreign producers	Domestic producers
Antihelmintics	0.4	-0.1	0.2	-0.3
Antileukaemics	0.3	0.1	0.1	0.0
Antirheumatics Nonstr	8.9	-5.2	-0.6	-4.6
Broncholators solid & liquid	2.3	-0.1	0.8	-0.9
Cephalosporins	12.4	-2.3	1.0	-3.3
Muscular relaxant	4.0	1.0	0.7	0.3
Statins	3.1	-1.0	0.0	-1.0
Betablockers	7.2	0.8	9.2	-8.4
Antipeptic Ulcerants	13.3	1.1	3.3	-2.2
Memo: Chaudhuri et al.				
Fluoroquinolones	17.8		2.4	-2.3

Note: In several cases, the problems with convergence of the equation system make it necessary to give up the assumption that all domestic products are withdrawn. Thus, expenditure on some domestic products is not set equal to zero.

The average loss of profits to the domestic producers of pharmaceutical products across the nine segments studied is about Rs 2.3 billion per year, which coincidentally matches the estimate of Chaudhuri et al. (2006) for Fluoro-quinolones at about Rs 2.3 billion per year. Thus, of the total loss of social welfare, the major part is the loss of consumer surplus; the producer surplus loss of the domestic firms constitutes a relatively smaller part of the total social welfare loss. This conclusion echoes the conclusion that Chaudhuri et al (2006) have drawn in their study.

The average gain to the foreign producers across the nine segments is about Rs 1.6 billion per year. Aggregating across the segments, the total comes to about Rs 15 billion. The total sales of drugs in the nine segments studied in 2008 was about Rs 74 billion. Taking a proportional relationship, the expected gain to foreign pharmaceutical firms from patent enforcement in all the segments of the Indian pharmaceuticals market comes to about Rs 68 billion, or about US$ 1.5 billion. This is under the assumption of complete withdrawal of domestic products and no price regulation or compulsory licensing. With price control or price negotiation and compulsory licensing, the gain in profits of foreign firms may be much lower. How much will be the gain in profits of foreign firms in India under such circumstances is difficult to estimate. But, to hazard a guess, it could be as low as about US$0.5 billion or even lower. This may be contrasted with the profits of global pharmaceutical players. The global sales of some leading multinational pharmaceutical firms in 2005 were as follows: Pfizer ($51.3 bn), Johnson and Johnson ($50.5 bn), GSK ($15.4 bn), Merck ($22.0 bn) and Abbot Labs ($22.3 bn) (source: Greene, 2007, Table 18). The total sales of these five companies was about $150 billion, and assuming a 40% markup, their profits come to about $60 billion. The expected gain of somewhere in the range of US$0.5 billion to US$1.5 billion is rather small compared to the level of profits being earned by these firms, and the MNCs may not therefore have much interest in introducing their patented products in the Indian market early. Also, this may not provide sufficient incentive for the global multinational companies to redirect their research efforts towards diseases that disproportionately afflict the developing countries such as India.

5.6 Summing up the findings and Implications for future

The analysis presented above has brought out that (a) the price elasticity of demand for drugs belonging to the nine segments studied is not high (about l.1 on average) and (2) the cross-price response of the products of foreign and domestic firms based on the same molecule is low, implying thereby that if a particular molecule based products of domestic firms become costly or unavailable, the consumers may not shift to the products of foreign firms, they may shift instead to other substitute molecules produced by domestic firms. This is attributable in part to the differences in the marketing networks of foreign and domestic firms, and the fact that the marketing reach of foreign firms is less. In this situation, if foreign firms have the exclusive right to supply a particular patented drug, its availability may remain restricted because of limited marketing reach. Thus, the problem with product patenting is not only the price rise that may follow, but also of physical availability of the medicine in various remote areas of the country.

The analysis has brought out that as a result of product patenting the prices charged by foreign producers could go up by 260 percent, on average, if they have full freedom in pricing their product and the government does to resort to compulsory licensing. If this occurs, there will be a loss of consumer welfare of about Rs 5.8 billion per segment in respect of the nine segments studied. Projecting for the entire pharmaceutical industry of India, on the basis of a proportion relationship, the overall loss of consumer welfare due to product patenting of pharmaceuticals will be about Rs 237 billion (US$5.3 billion) per year.[48] The expected gain to foreign pharmaceutical firms from patent enforcement in all the segments of the Indian pharmaceuticals market comes to about Rs 68 billion (or $1.5 billion). This is, however, rather small in relation to the profits earned by the global pharmaceutical giants, and therefore no major redirection of R&D to meet specifically India's health requirements is expected to take place in such firms because of their higher earnings from India.

[48] Under the assumption that the own price elasticity of demand for firms is twice that for the industry, the estimated consumer welfare loss (taking all segments into consideration) is about Rs 185 billion per year. The gain in profits to foreign producers is about Rs 58 billion.

The issue of price rise following the enforcement of product patents is an important one. Some inferences based on the econometric analysis have been presented above in this chapter. At the end of the chapter, this issue is revisited, and certain other interesting dimensions are brought in.

Will Drug Prices Rise in Future?

For a vast majority of drugs, the market in India is oligopolistic. The top 3 or 4 firms account for a large share of the market. Commonly, there are a large number of small and medium firms supplying the same drug at a considerably lower price offering some degree of competition to the market leaders. In this environment, the emergence of the Indian firms in the international arena as cheap and quality generic medicine suppliers has its own dynamic of affecting the domestic prices (Sakthivel, 2007). To optimize, the firms will have to equate the marginal revenues from the two markets. In other words, the domestic prices will have to get aligned with the export prices (which are higher than the domestic prices at present), and this is obviously going to affect a large section of the population.[49] "Only companies who see their future as being inextricably linked to the domestic market will retain sensitivity to the affordability issue" (Government of India, 2005).[50] The small and medium scale firms operating the drug markets create a competitive pressure and thus prevent to some extent the large firms from hiking the prices. However, for some reasons, the small-scale pharmaceutical firms in India have lately been facing considerable difficulties (discussed in Chapter 4) and one cannot rule out the possibility that a sizeable part of the small-scale pharmaceutical firms in India may close down in course of time. This development, if it occurs, will obviously strengthen the forces leading to hike in drug prices in India. Needless to say, supportive policy for continuance of small-scale pharmaceutical firms in India is important for ensuring affordability of drugs.

[49] This tendency is strengthened by the fact that of late some large Indian companies have been acquired by the foreign multinationals, and such aquision may increase in future (discussed in Chapter 4).

[50] Will Indian pharmaceutical firms, in the changing environment, move away from serving their traditional low-priced/high-volume markets as they increasingly focus on the more lucrative markets? Grace (2004) argues that this is unlikely to happen. The low-price-high-volume market will remain attractive to Indian pahramaceutical firms because of their low cost structure, their existing expertise in serving this market and the need to balance their more riskey forays into the regulated markets with more advanced products with a stable cash flow from the low-price-high-volume domestic market.

As regards the New Chemical Entities (NCEs), there are grounds to believe that, due to the change in the patent regime, these will be introduced in the Indian market by transnational drug companies at a relatively higher initial price reflecting global reference pricing (Sakthivel, 2007). However, this fact, even if true, may not seriously erode affordability of drugs and medicines in India. This is so for two reasons. First, a large number of drugs are off-patent or will be off-patent soon, and these can adequately take care of the heath needs. Secondly, a portion of the new drugs introduced in the market would probably have only a small advantage over the existing drugs and thus given the low price of off-patent substitutable drugs, the new drugs cannot be priced very high in the Indian markets if the transnational companies wish to make a significant sale. Indeed, one can find several examples where the new patented drugs are only "me-too" molecules and do not have a clear advantage over the old off-patent one (and if such drugs are priced high, the households have the option of using a much lower priced closely substitutable drug). Very rarely is a new-patented drug absolutely irreplaceable in treatment (Ratna, 2004). Even if a new-patented drug is greatly superior for treatment of a particular disease and the patent holder is keen to price it highly, the government can and should use the flexibilities discussed in Chapter 3 above to ensure that it remains affordable to the general public. The patent holder may be permitted to sell the drug in India only at a price negotiated with the government, taking adequate care of affordability. Or, a dual price system could arise: a high price could be charged in the open market with the condition that the drug will have to be made available to the poor households through the public health care system at a vastly reduced price.

Box 5.1: Pricing of new patented drugs in India, actual experience

The analysis presented in this chapter, as also similar analysis undertaken in some earlier studies (e.g. Fink, 2000), was based on simulations. Why should the assessment of patent induced price rises be based only on simulations? As five years have passed since the introduction of product patents in India, would it not be useful to examine, how have the newly patented drugs been actually priced in India. Unfortunately, there is not enough information available to answer properly this important question, which is obviously very relevant in the context of the discussion in this chapter. From the scanty information available, it seems that the newly patented drugs are being priced in India much lower than the prices being charged in developed countries or in other developing countries. Pegasys (Pegylated Interferon 2a), Valcyte (Valganciclovir), Tarceva (Erlotinib Hydochloride) have been launced in India in a short period, say a year, since their launch in the US/ EU, and the price are signficantly lower than the prices in developed countries as well as developing countries. Valcyte for instance is sold in India at a price half of the price prevailing in US, Phillipines and Thailand. A signficant gap in price is there also for Mircera (Methoxy Polyethylene Glycol-Erythropoietin Beta) and Januvia (Sitapgliptin Phosphate). Merck launched Januvia, a diabetes drug, in India in 2008 at Rs 43 a pill, roughly a fifth its price in the US. This is a case of differential pricing implemented by Big Pharma in India. From the experience of thses drugs, it seems that the foreign companies have not been able to (or not willing to) price their patented drugs in India at the level of the reference price in other major markets. However, the gap between the price in India and that in Western markets is possibly not as large, as it would have been in case product patents were in not inforce.

Chapter 6

Effect of Patents Regime on Research and Development Expenditure and Innovations[51]

In this chapter, an econometric analysis is presented to gain an understanding of the emerging trends in building innovative capabilities among the pharmaceutical firms in the India, particularly to assess how far these observed trends in the pharmaceutical industry are attributable to the new patent regime. Econometric models are estimated to investigate the factors that determine the level of research and development expenditure incurred by the firms, and how this is connected with innovative activities, particularly the patent applications made by the firms. The analysis is done separately for firms belonging to different groups, formed on the basis of size, type of production and whether it is foreign or domestic.

An overview of the R&D activities in the Indian pharmaceuticals industry is presented first. Then, in Section 6.2, trends in R&D expenditure analyzed, following which the econometric analysis of R&D expenditure and patent applications is presented in Sections 6.3 and 6.4.

6.1 Overview of R&D in Pharmaceuticals Industry

The inventive and innovative activities involve heavy investments in the form of Research and Development (R&D). Inventions are often made as a consequence of research expenditures and result in patents[52](Davies, 1988). Patents are a market instrument which enables the patentee to reap the monopoly rights. R&D intensive industries like the pharmaceutical industry face this dilemma of protecting R&D efforts through intellectual

[51] This Chapter has been prepared by Ravinder Jha.

[52] A Patent is embodied in a legal document, and granted by a government to an inventor, giving him/her the sole right to exploit that invention for a given number of years.

property rights on one hand and making the products of these efforts accessible to the members of the society on the other.

The debate on whether strict patent regimes facilitate innovation in developing countries or whether softer intellectual property rights help spillovers from innovative activity in developed countries for domestic technological effort in developing countries is an old one. Cohen and Levinthal (1989) showed that the positive spillover effects of R&D more than outweigh the appropriability considerations of the innovator for many industries. In the case of chemicals, electricals and electronics, the spillover effect had a positive impact on R&D capabilities. But it is also found by Levin et al. (1987) that product patents on drugs and pharmaceuticals were essential for providing the incentive to innovate whereas very high technology intensive industries like aerospace and industrial machinery did not require patents to innovate because reverse engineering of these products is very costly and difficult (Cohen, 1995). Electronics industry may earn profits on innovations through lead time advantage, sales of complementary products and services (Bessen and Meurer, 2008).[53] But, this will not work for pharmaceuticals. Scherer and Weisburst (1995) studied the patenting effects in Italy and found that the product patents help new drug development provided the domestic industry has the skills or scientific infrastructure needed to leap from imitation to significant drug development. Under liberal patent regimes, economies like Korea, Taiwan and Japan developed technologically like India through reverse engineering. These economies were in their process innovation phase much earlier, in the 1970s and 1980s. On the other hand, countries like India and China entered this phase in late 1980s and 1990s, a period when the United States' pressure on these countries to amend their patent laws was immense. India has certainly reached a stage where it can manufacture sophisticated products without much time lag at a fraction of the cost but that is only true for its capability in generics. The argument that India has now reached a stage in pharmaceutical production where stronger IPRs would induce greater innovation by local firms has been put forward by Lall (2002), Smith (2000) and others who believe that stronger IPRs stimulate domestic investment in R&D for product innovation for local needs. However**,** Kumar (1996, 2001) found an insignificant relationship between patent protection and location of R & D activity.

[53] Available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1103143

The Indian private pharmaceutical sector has been the main spender on R&D with public sector contributing a meager amount. In 2002-03, for instance, the R&D expenditure on Drugs and Pharmaceuticals by the private sector was Rs.881 crore which is more than 99% of the R&D expenditure going into the pharmaceutical sector by industry, while public sector contributed only Rs.4.71 crore. If one compares private sector contribution to total R&D, the share of Drugs and Pharmaceuticals is the largest (Table 6.1).

Table 6.1: Industrial R&D Expenditure, by Leading Industry Group (2002-03)

Industry	Public Sector		Private Sector		Total	
	No. of Units	R&D Exp (Rs. Cr.)	No. of Units	R&D Exp (Rs. Cr.)	No. of Units	R&D Exp (Rs. Cr.)
Drugs and Pharmaceuticals	6	4.71	153	881.11	159	885.85
Transportation	1	0.48	94	652.04	95	652.52
Defence industries	5	338.99	5	7.40	10	322.01
Electrical & Electronic	9	114.86	189	207.15	198	322
Chemicals (other than Fertilizers)	8	9.28	211	232.13	219	241.41
Information Technology	0	0	49	170.93	49	170.93
Fuels	7	178.97	12	54.86	19	233.83
Telecommunications	5	48.91	41	90.81	46	139.72
Metallurgical Industry	10	69.41	60	48.49	70	117.90
Soaps, cosmetics & toilet prep	1	0.10	9	114.29	10	114.39
Others	41	43.24	654	611.72	695	654.96
Total		808.95	1477	3064.93	1570	3873.88

Source: Research and Development Statistics 2004-05, Govt. of India, Department of Science and Technology September 2006

Process of Drug Manufacturing and Various Forms of Research

The process of drug manufacturing basically has two components: (a) Bulk drug production, which involves the production of active ingredients present in the drug, called API (Active Pharmaceutical Ingredient); and (b) Formulation production, which involves the

processing of bulk drugs into finished dosage forms such as tablets, capsules, injections, ointments etc. The formulation technology is simpler and does not involve heavy investment, while the production technology of bulk drugs involving raw material or active ingredient manufacture requires higher investment in plant and machinery.

Currently, the Indian pharmaceutical industry manufactures close to 500 bulk drugs belonging to several therapeutic segments like Anti-infective, Pain Management, Cardiovascular (CVS), Central Nervous System (CNS) and Anti-diabetics. The level of R&D expenditure does not reflect the kind of research undertaken as R&D expenditure is incurred on various forms of research like developing a new molecular entity, new process, new formulation etc. Broadly, the various forms of research that are undertaken in the pharmaceutical industry can be summarized as follows:

(1) Discovery of New Chemical Entities (NCEs) or New Molecular entities (NMEs): New molecular compounds (chemical or biological) are those that have never been used before on humans. They can be of two types:

(a) Innovative drugs: They are compounds that serve unmet medical needs

(b) Follow-on products: These are new compounds that address the same medical need as the innovative drugs and must be tested before market introduction.

(2) Novel Drug Delivery System (NDDS): New mechanisms for delivering therapeutic agents in the desired dosage to the desired site in the body. The NDDS research focuses on maximizing the overall therapeutic and commercial value of commonly prescribed pharmaceutical formulations by enhancing their performance and reducing their adverse event profile. Such innovation also helps to improve the overall quality and efficacy of the drugs and result in superior patient experience

(3) Research on Improved Chemical Entities (Chiral Research): Here, if different isomers in a compound have different therapeutic properties, then efficacy of a drug can be enhanced by separating these isomers and using an isomer with better outcomes.

(4) Discovery of a new therapeutic use of existing compounds: Here, an existing drug is found to be useful in treating new indications. For instance, Aspirin, a pain reliever, is also used for thinning of blood.

(5) R&D in Generics: This simply involves reverse engineering of the original drug using alternative processes which do not infringe on the patented process/processes. For example, to market a generic version in the United States which recognizes patents, a firm has to file an abbreviated new drug application (ANDA) seeking approval to market formulations. To obtain ANDA approval, the firm needs to establish the bio-equivalence of the generic product, which aims to test the similarity between the original drug and the generic.[54]

In India, some of the big firms are shifting their research focus from process innovations to developing new drugs (NCE) or to find alternative methods to deliver a drug (NDDS) (see Table 6.2). Much of the research of new molecular entities takes place in the developed world because enormous amount of investment is required due to novelty and uncertainty associated with developing a new drug. There is also a high attrition rate in the development process. The cost of conducting R&D in the discovery and development of New Chemical entities is considered to be very high compared to incremental improvements in products and process innovations. The discovery stage can last up to 6 years and its average cost is estimated to be US$335 million. The stage after discovery is Development. Once the compound or compounds, have been chosen, they must be transformed into a drug. This process involves several series of trials on animals and humans, all intended to ensure that the drug may be administered to humans with minimum possible risk and that it is superior to, or otherwise complements, existing drugs with the same therapeutic function. The *development* of the drug can take as long as a decade, at an average cost estimated at US$467 million (in year 2000). These trials are subject to the rigorous controls required by the regulatory authorities. Approximately the *discovery and development* of a new drug can take between 7 and 15 years,

[54] The United States Food and Drug Administration (USFDA) requires one of four types of certification with every ANDA to explain the status of the generic company on the patents protecting the branded drug: (1) Para I: The patent information is not filed; (2) Para II: The patent has already expired; (3) Para III: The generic drug would not go to the market until the expiration date of the band name drug has passed; (4) Para IV: The patent on the drug is not infringed upon or is not valid. This involves patent challenge. The generic company that is first to file and wins the litigation gets 180 days marketing exclusivity. For the last 15 years, a few large Indian firms are engaged in this form of research in order to penetrate foreign markets in their generic segment.

and experts estimate the average cost to be $US802 million.[55] Though the US pharmaceutical industry's inflation adjusted R&D expenditure increased over 10 times from $2.5 billion to US$ 27 billion between the early 1960s and early years of this decade, the number of New Chemical Entities (NCEs) has only doubled. In the early 60s, this equated to an average of US$ 179 million per NCE compared to an estimate of US$ 843 million per NCE in 2000 (Brown, 2005). More recently, though the R&D expenditure has doubled between 1995 and 2002, the USFDA approved only 17 NCEs in 2002 as opposed to 56 NCEs in 1996. The approval process of USFDA is taking longer and the costs of new drug discovery and development has resulted in increasing pressure on the global pharmaceutical companies to outsource part of the discovery and development work to developing countries like India and China to reduce costs. The top ten MNCs spend about $50 billion on R&D activity which is roughly 15-20% of their sales. On average, 50 percent of these companies' R&D budget is allocated for the development of in-licensed drugs (from smaller firms) with some companies spending as much as 75-80 percent of their R&D budget on in-licensed drugs.

In India, as mentioned earlier, the majority of the firms are developing non-infringing processes and new formulations of existing and new drugs. Those firms which are involved in the development of new molecules have development partners from developed countries for their research programs. This trend of going into research in new molecules is observed only in the past decade or so. The reasons for this trend can be traced to a combination of the new patent regime in India and outsourcing by the global pharmaceutical firms due to ever-increasing costs. Following are a few research programs of these firms have carried out on new chemical entities. The data are obtained from the annual reports; the latest report available is for the year 2007.

[55] According to DiMasi, Hansen and Grabowski (2003), the cost of developing a new drug has increased from $138 milliono in 1975 to $318 million in 1987 and further to $802 million in 2000. However critics argue that this is an overestimation as it does not account for tax rebates on R&D.

Table 6.2: Research Pipeline of Major Domestic Firms

Company	Therapeutic Segment	No. of Molecules	Research strategy
Dr. Reddy's Labs	Diabetes Cardiovascular, Diabetes Tumours Oncology	7	Tied with Denmark's Rheoscience for development of a diabetes drug, Balaglitazone (which was discontinued by
			Licensing to Perlecan Pharma, its own integrated drug development company.
			Co development with a CRO
			Undertaken by Dr. Reddy's Labs itself.
Ranbaxy	Anti Malaria Anti Asthma BPH	10	Partnership with MMV, trials completed.
Lupin	Anti TB, Anti Psoriasis, Anti Migraine	4	
Nicholas Piramal	Anti cancer agent Inflammation and Antifungal, metabolic disorder	6	Signed drug development agreement with Eli Lilly to develop the molecule for metabolic disorder
Cadila Healthcare	Anti Inflammation, Diabetes, Obesity, Cardiovascular	4	
Glenmark	Asthma	6	Licensed to Forest Labs, UK and Teijin Pharma, Japan
	Diabetes		Licensed to Merck KGaA
	Osteoarthritis		
Torrent	Diabètes, CVS, Obesity	6	Collaboration with AstraZeneca for developing drug for Hypertension.
Dabur	Oncology	1	
Sun	Anti histamine, AntiInflamation for Asthma, Neuropathy (CNS), Muscular Disorder	4	De-merged its research unit to develop molecules and other research programs.
Orchid	Anti diabetes, Oncology, Anti Inflammation	3	

Source: Company's Annual Reports, various issues

6.2 Trends in R&D for different segments in Indian Pharmaceutical Industry:

Basic data for the analysis presented in this section and the next section have been drawn from Capitaline. Using this source, the firms in the Indian pharmaceutical industry have been classified into five categories on the basis of size, type of production and whether it is foreign or domestic. The categories are[56]:

(i) Indian Bulk drugs and Formulations - Large

(ii) Indian Bulk drugs and Formulations - Medium and Small

(iii) Indian Bulk Drugs

(iv) Indian Formulators

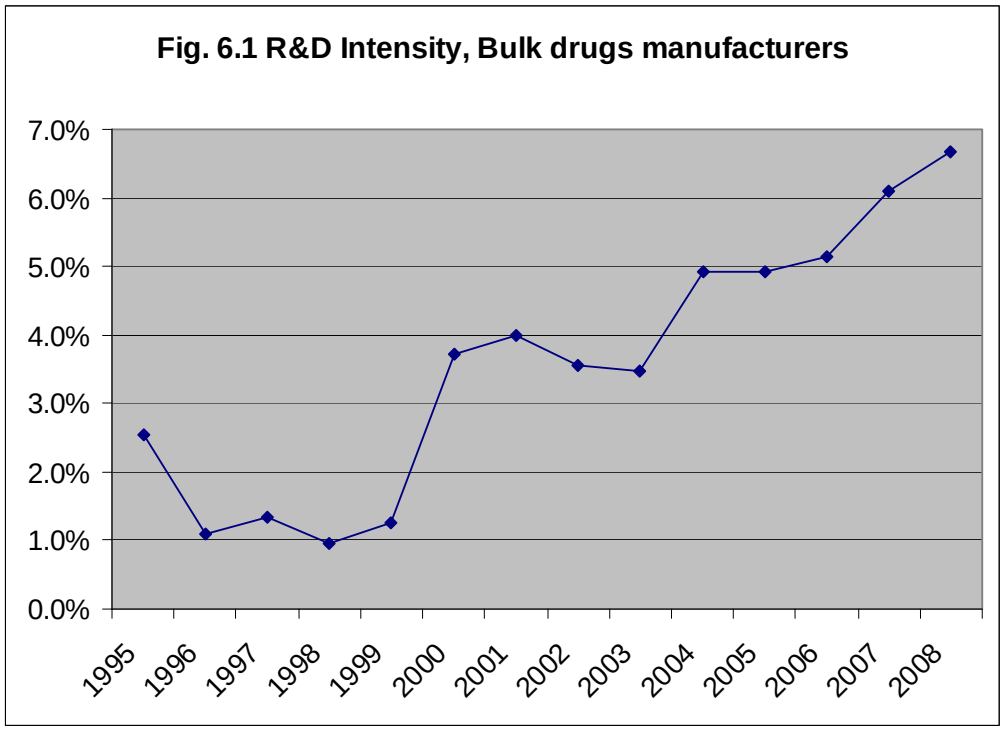
(v) Multinational Corporations

The R&D intensity (ratio of R&D expenditure to net sales) in different years during 1995-96 to 2008-09 is shown for the five categories in Figures 6.1 through 6.5. It is seen from the figures, that in the period since 1995, there was a significant upward trend in R&D intensity among medium/small bulk drugs and formulations manufacturers, large firms engaged in manufacture of bulk drugs and formulations, and bulk drug manufacturers (Fig. 6.1, 6.2 and 6.3). R&D intensity among medium/small bulk drugs and formulations manufacturers, for instance, increased from about 1% in 1999-00 to about 8% in 2008-09. There were similar large increases in the R&D intensity of large bulk drug and formulations manufacturers, and bulk drug manufacturers. The large bulk drug and formulations manufacturers have been investing in R&D from an earlier period as they cater to international markets in a big way and are therefore influenced by the patent systems in those countries in which they are diversifying.

The formulators have not shown any marked upward trend in this regard (Fig. 6.4) as their activity does not require any major technological upgradation. The subsidiaries of multinational firms also do not show any tendency to enhance their investment in R&D (Fig. 6.5); in fact there is a downward trend in their R&D intensity. The product patents are

[56] Capitaline covers only corporate sector pharmaceutical firms. Non-corporate small pharmaceuticals manufacturing units are not covered. The division of pharmaceutical firms into the five categories is provided in the Capitaline data.

welcomed by the MNCs but it seems they prefer to import their patented drugs than undertake research activities in the country. At least at this point, this seems to be the trend in India.



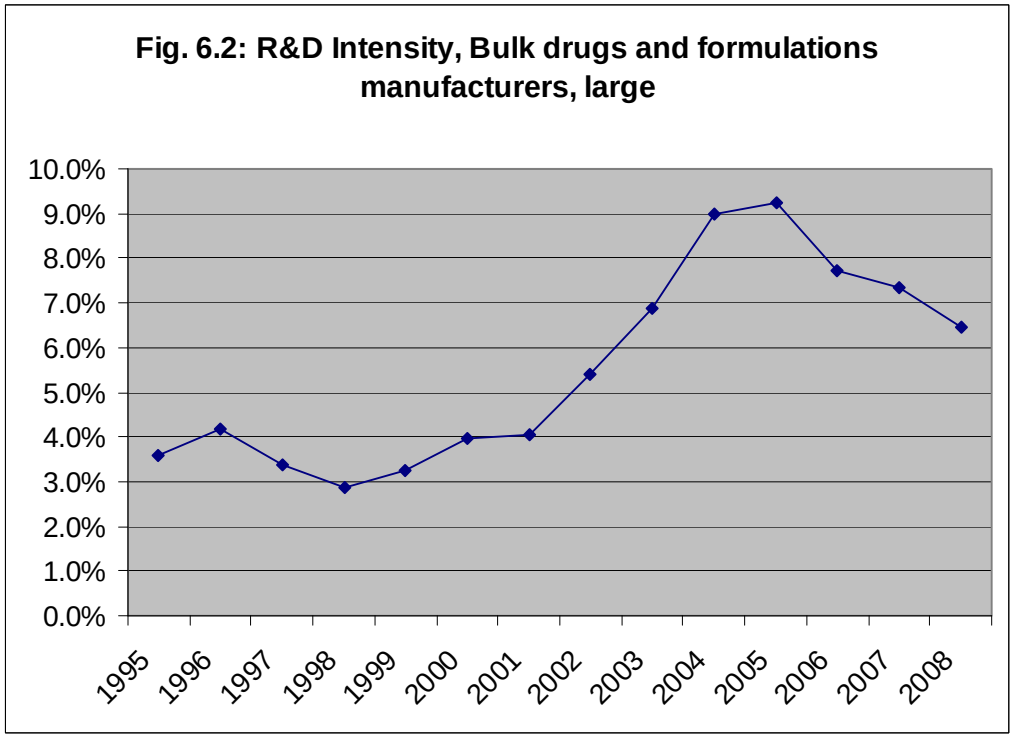


Fig. 6.3: R&D Intensity, Bulk drugs and formulations manufacturers, medium and small

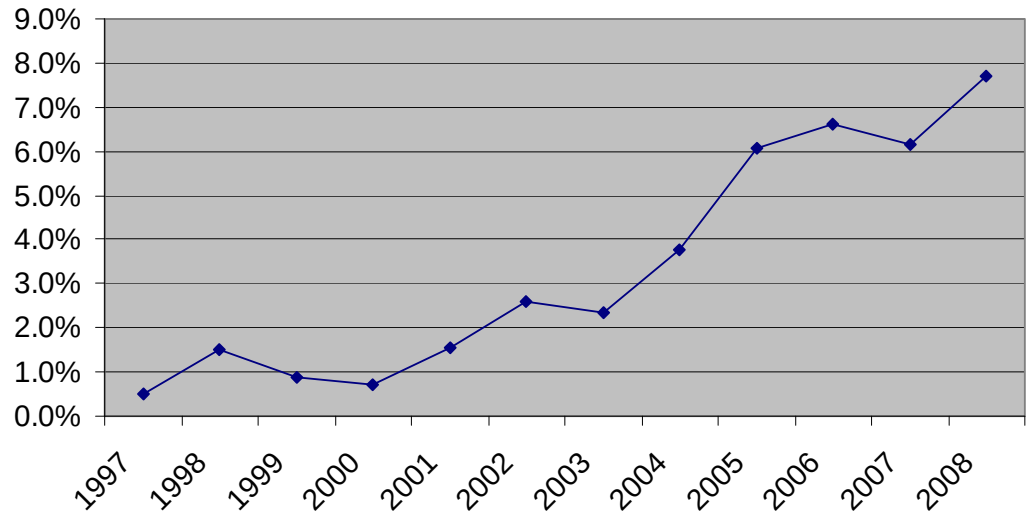
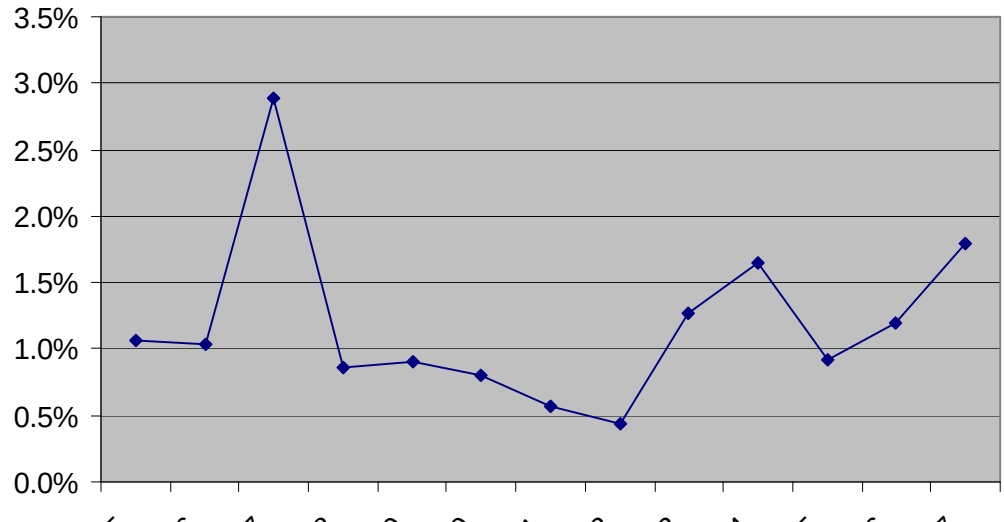
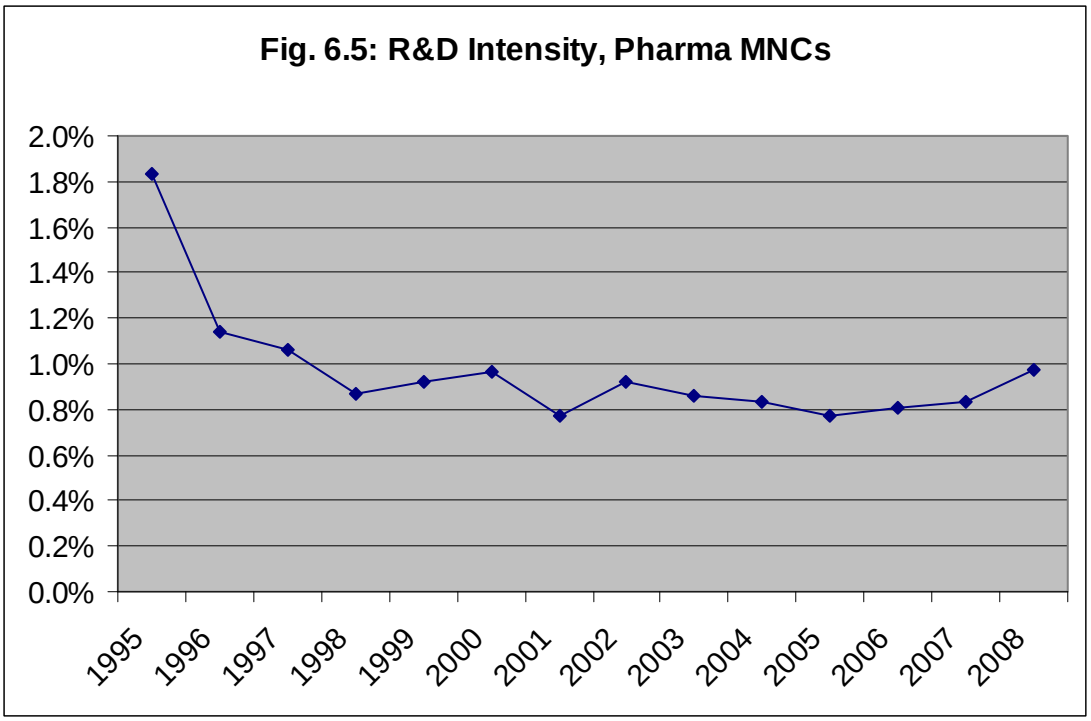


Fig. 6.4: R&D Intensity, formulators





Till now, the domestic firms have invested in R&D either to reverse engineer the patented drugs in India or in the generic market both at home and abroad where they have had to invest in R&D to get marketing approvals in the developed countries by conducting bio-equivalence studies or for process development of bulk drugs or product development of formulations or spent large amounts in litigation in the developed world by challenging patents. Dr. Reddy's Laboratories and Ranbaxy have filed applications on their abbreviated new drug application under Para IV outside US which involves patent challenge. With the changed patent regime in India and large number of drugs going off-patent worldwide by 2009, the large R&D intensive firms in the country are refocusing their research strategies. The relatively smaller (in terms of net sales) firms are still focusing on developing drugs through reverse engineering but the large and some medium sized firms have started undertaking drug development for innovative drugs. The MNCs are barely contributing to total R&D. In fact many of the medium sized domestic companies are spending more on the research activities, like Ind Swift and Indoco, than MNCs.

There is clear evidence of rising research activities among the pharmaceutical firms in the category of bulk drugs manufacturers and large and small/medium scale bulk drugs and formulators. As mentioned earlier, the kinds of research activities that can be undertaken in the pharmaceuticals are quite vast. The large and small/medium bulk drugs and formulations manufacturers in India have the technical expertise to reverse engineer the products patented elsewhere. Thus, they can capture not only the Indian generic market but also the huge and ever growing generic market of the developed world. India's strength lies in manufacturing generics, i.e. off-patented drugs. It is a major supplier of some drugs which are still patented in tighter patent regimes, especially life saving drugs for HIV-AIDS to less developed countries like South Africa at much lower prices. According to a report by IMS Health, in 2006, products with sales in excess of $18 billion lost their patent protection in seven key markets (US, Canada, France, Spain, Italy, Germany and the UK). The U.S. alone represents more than $14 billion of these sales. Generics represented more than half of the volume of pharmaceutical products sold in these seven key markets. With lower-cost therapies replacing branded products in classes such as lipid regulators, antidepressants, platelet aggregation inhibitors and respiratory agents, generics are assuming a more central role and India is slated to be major beneficiary of this change (IMS Health Report, 2007).

6.3 Factors Influencing the Extent of R&D Investment by Firms

Schumpeter linked R&D with market structure and size. Large sized firms, as opposed to small enterprises, normally undertake R&D as it involves a high degree of risk that is difficult to eliminate and big firms are willing to take risks as they are more diversified. Second, the market structure in the form of monopolies provides incentives to undertake R&D since a monopolist does not have competitors ready to imitate his innovation or to circumvent an existing patent on this innovation. From an examination of the R&D intensity (R&D as a proportion of Net Sales) of pharmaceutical firms belonging to different groups, some support is found for the hypothesis that firms of bigger size have higher R&D intensity. It may be added here that Nauriyal and Sahoo (2008) found that out of a sample of sixty Indian drugs and pharmaceutical firms to, only 16 firms account for approximately 90% of R and D expenditure

incurred by the sample firms. This is indicative of a positive relationship between firm size and R&D. Bigger firms also showed much higher rate of patent filings relative to small sized firms. Similarly, Aggarwal (2004) notes that most of the R&D in the Indian pharmaceutical firms is done by large firms, supporting thereby the hypothesis that firm size bears a positive relationship with R&D.

Hypotheses

The determinants of R&D are examined in the framework of Tobit model. The decision of the firms whether or not to undertake R&D is analyzed separately. For this purpose, the probit model is used.

Besides firm size, which has been noted above as an important factor influencing the R&D expenditure in the industrial firms, there are other factors that may influence R&D in firms. The factors that have been considered for the econometric analysis are:

1. Import of technology
2. Exports
3. Advertisement
4. Firm Size
5. Factor Costs, like Employees' cost, imported raw material, excise duty

1. **Import of Technology**: Earlier studies have shown both a positive and a negative influence of imports of technology on the extent of R&D undertaken by firms. Lall (1987) showed that some engineering firms (BHEL and HMT) adapted imported technologies to local conditions and upgraded them overtime while some others like SAIL and ABL (Associated Babcock Ltd) followed a consistent strategy of importing major technologies for new lines but not upgrading existing technologies. Kumar (1987) ascribed the differences on R&D efforts to the mode of technology import. The technologies which are a part of foreign direct investment do not get adapted or modified through indigenous effort while technologies imported under unaffiliated licensing are adapted to suit the local environment since they do not come with the support of the parent companies' research infrastructure (Kumar, 1996). The total amount of technical

fees and royalty payments made as a proportion of net sales of a firm is used to capture the technology imports variable.

2. **Exports:** Scherer (1980) attributes the extension of domestic operations to foreign markets as a source of enhancement in the profitability of R&D and hence increased R&D. Insofar as diversifying the market has an impact on utilizing the innovations, exports will have a positive impact on R&D expenditure. He cites the study by Mansfield et al (1979) where on average 29 to 34 percent of the profits from R&D projects came from overseas exploitation. Kumar (1996) found a positive relationship between export orientation of a firm and both its decision to set up an R&D unit as well as the intensity of R&D expenditure. A positive effect of export intensity on R&D intensity has been reported also by Parameswaran (2008) in his study of Indian industrial firms and Pradhan (2003) in his study of pharmaceutical firms. To measure export intensity, the ratio of exports to net sales has been taken as done in earlier studies.

3. **Advertisement intensity**: Advertisement and other promotional activities to create a brand image help consumers identify those firms that are committed to higher quality products. The expenditure signals the higher quality products. Nelson (1974) brought out this correlation between the amount of 'search' advertisement and quality of a product. Since repeat purchases will reveal the true quality of the product, firms which actually undertake steps to deliver quality products like investing in R&D are the ones which will incur costs on advertising and other promotional activities. At the same time, it needs to be noted that the firms' decision to advertise and the amount to be spent on advertisement will be condition of the structure of the market they operate in. Naturally, advertisement intensity would have an important role in markets with differentiated products. Among the five categories of pharmaceutical firms considered in the analysis, formulations segment has an oligopolistic market structure with product heterogeneity while bulk drugs market is highly competitive. The impact of advertisement on R&D may therefore differ between these two categories.

It should be pointed out here that a positive relationship between advertisement intensity and R&D intensity need not always arise. If firms spend on advertisement rather than on R&D to increase their markets shares, the former substitutes the latter, and therefore a

negative relationship may arise. The nature of relationship that will actually arise between advertisement intensity and R&D intensity is therefore an empirical question. However, a positive relationship seems more likely in view of the arguments given above. Indeed, in the study of R&D behavior of Indian industrial firms undertaken by Parameswaran (2008), a significant positive relationship has been found.

4. **Firm Size:** As noted earlier, there are reasons to expect a positive relationship between firm size and R&D expenditure. A prime reason for such a relationship is that large sized firms have the resources to reap economies of scale which are associated with most of the research activities. While Kumar (1996) and Lall (1983) found a positive correlation between size and innovative activity of a firm, Mansfield (1968) found that an R&D effort was more effective in a medium-sized firm than a large one. There are other studies that have found a positive relationship between firm size and R&D intensity in Indian industries (e.g. Parameswaran, 2008). Pradhan (2003) has studied the determinants of R&D intensity in Indian pharmaceutical firms, and has found an inverted-U relationship between firm size and R&D intensity. R&D intensity increases with firm size up to some level, beyond which an inverse relationship arises between firm size and R&D intensity.

5. **Factor costs**: Higher employees' cost relative to sales could be a reflection of high skilled manpower employed in the firm. This variable is therefore expected to be positively related to R&D intensity. Similarly, high raw material import content would signify the keenness to undertake high quality production, and may be positively related to research activities. Thus, raw material import intensity is expected to bear a positive relationship with R&D intensity. Low excise duty encourages investment in R&D by making more resources available to the firm. This is a supply side link between firm resources and R&D.

6. **Regime Shift**: The impact of new patent regime is captured by taking a dummy variable for a period subsequent to the signing of TRIPS agreement in 1995. The choice of period has varied between various models estimated. In some cases, the dummy variable has been given value one for the period after 1998, and zero for earlier years, implicitly assuming that 1998 is the year since when the impact of new regime is felt. In certain other cases, other years like

2000, 2002 or 2003 has been used to ascertain the impact. In the model estimated from pooled data, all these alternatives have been tried. It needs to be pointed here that the signing of TRIPS agreement compelled India to introduce product patent protection for pharmaceuticals in 2005 and many firms started reorganizing their business strategies much earlier to be able to face the new environment.

Empirical methodology and findings

This sub-section spells out the empirical methodology used for examining the R&D behavior of firms in different categories and presents the results. The data set used for this research consists of 149 firms. The data were collated from Capitaline dataset, and relate to the period 1995-96 to 2007-08.[57] The original data had a much larger number of firms but as some firms had only one-year data, they were excluded from the analysis. Out of the set if 149 firms selected for the analysis, 52 belong to the category of bulk drugs, 34 to medium and small bulk drugs and formulation manufacturers, 26 to formulators, 22 to large sized bulk drugs and formulation manufacturers and 15 firms are MNCs.

The dependent variable in the case of Probit model is dummy variable, D, taking values 1 or 0 depending on whether the firms are undertaking any R&D or not. This represents the decision to undertake R&D. Among the five categories of firms for which the data are available, there are two categories where all firms undertook R&D. Thus, the pooled estimation of the model was done, i.e. the data for the five categories were pooled. In order to capture the dynamic behaviour of research and development, the lagged value of D was taken as an explanatory variable, with the lag of one year. The implication of this specification is that the decision of firm on whether or not to undertake R&D in a given year depends on its R&D status in the previous year. Obviously, if the firm had undertaken R&D in the previous year, it is more likely to undertake R&D in the given year.

[57] At the time this analysis of R&D behaviour was carried out, data for 2008-09 were not available. Hence, the period covered for the econometric analysis is 1995-96 to 2007-08.

The Probit model explaining the decision of the firm to undertake R&D is specified as follows:

$$D^* = \beta_0 + \beta_1 D_{-1} + \beta_2 SIZE + \beta_3 EMP + \beta_4 EXP + \beta_5 TECHMT + \beta_6 DUM + \varepsilon \ldots\ldots\ldots\ldots\ldots (6.1)$$

$D = 1$ if $D^* > 0$

$= 0$ otherwise

In this equation, D^* is a latent variable. D is the observed variable. It takes value one if the firm undertakes R&D and zero otherwise. D_{-1} is the D variable with one-year lag. The explanatory variables used in the model are:

EMP= Employee's cost as a proportion of net sales

EXP= Exports as a proportion of net sales

TECHMT = Expenditure on royalties and technical fees as a proportion of net sales (technology import intensity)

DUM (Regime Dummy)= Time Dummy to capture the impact of patent regime

Table 6.3 presents the results of model estimation. The estimated model explains the willingness of the firms to undertake R&D activity. By taking different dummies for a regime shift, the impact of the patent regime on the decision to undertaken R&D is captured.[58] The dynamic behavior of R&D is verified as the coefficient of lagged value of R&D is positive and statistically significant. The set of coefficients are statistically significant in terms of chi-square distribution at 1% level. The results clearly indicate that the large sized firms have a greater probability of undertaking R&D, as hypothesized. Firms that pay high wages (probably because they hire high skilled workers) have a higher probability of undertaking R&D. Exports do not have a significant influence on the willingness to undertake R&D. Import of technology plays the role of a substitute for firms which are considering to undertake R&D (this inference is drawn on the basis of significant negative coefficient). The coefficient on technology

[58] It is reasonable to assume that the effect of the new patent regime on R&D efforts of Indian pharmaceutical firms will be felt with a lag. But, it is difficult to say what would be the expected lag length. Time dummy variables with different starting date have therefore been tried: periods starting from 1998, 2000, 2002 and 2003.

imports fell and the coefficient of the import of technology variable was no longer significant when the firm size variable was dropped from the equation. The Schumpeterian hypothesis linking size and R&D is empirically supported in the econometric results obtained for the pharmaceutical industry. For most of the years (dummy for period starting from that year) chosen to reflect the beginning of impact of new regime of product patents, the coefficient indicates a significant positive impact of the new regime on firms' willingness to undertake R&D. [59] Improving the protection of intellectual property rights and other associated developments in recent years seem to have induced firms to undertake R&D.

Table 6.3: Estimated Probit Model, Decision to undertake R&D activity

Explanatory variables	Regressions			
	(1)	(2)	(3)	(4)
D_{-1}	1.6129(3.75)[a]	1.6970(3.94) [a]	1.6903(3.82) [a]	1.6861(3.77) [a]
SIZE	0.4115(3.21) [a]	0.3715(3.1) [a]	0.3552(2.91) [a]	0.3591(2.88) [a]
EMP	9.3862(1.87)	9.5932(1.9) [c]	10.2253(1.94) [c]	9.5097(1.82)[c]
EXP	0.1542(0.26)	0.2095(0.37)	0.3386(0.58)	0.2466(0.42)
TECHIM	-45.3968(-1.87) [c]	-40.181(-1.72) [c]	-34.015(-1.37)	-33.1002(-1.33)
DUM98	0.8070(2.21) [b]	-	-	-
DUM00	-	0.4890 (1.51)	-	-
DUM02	-	-	0.7874(1.96)[b]	-
DUM03	-	-	-	1.0823(1.89) [c]
CONSTANT	-2.1761(-3.29)[a]	-1.8365(-3.04) [a]	-1.8426(-2.99) [a]	-1.7573(-2.93) [a]
Wald chi2(6)	34.98	36.28	34.94	34.77
Log Likelihood	33.8872	35.1119	33.8868	33.3417

N=699 No. of Firms= 147

Note: t-ratios in parentheses. <a> statistically significant at one percent level; <b> at five percent level; <c> at ten percent level

The analysis based on the Probit model presented above helps in understanding the factor that have influenced the pharmaceutical firms' decision of undertake R&D. The next question to examine is how much have the firms spent on R&D. What explains the variation in the level of R&D expenditure relative to sales of the firms? The second issue is examined using a Tobit Model. The Tobit model is preferred to the Ordinary Least Squares (OLS)

[59] Considering the t-ratios for the four time-dummy variables tried, it appears that the new patent regime had an early impact on the decision to undertake R&D (say, by 1998). But, the regression results presented in Tables 6.4a-6.4e give the impression that a significant impact on the R&D expenditure incurred by the Indian pharmaceuticals industry took place later, somewhere around 2002.

regression because the dependent variable, namely R&D intensity, is zero for a large number of observations. In the Tobit model estimated, the dependent variable is R&D intensity (calculated as total R&D expenditure of each firm as a proportion of its net sales). It is regressed on the following explanatory variables: SIZE, EMP, EXP, TECHMT and DUM as in the equation above, plus a set of new variables,

Excise = Excise Duty as a proportion of net sales

RM = Raw material costs as a proportion of net sales

ADV= advertising and marketing expenditure as a proportion of net sales

The equation is specified as follows:

$$RD = \beta_0 + \beta_1 SIZE + \beta_2 Excise + \beta_3 RM + \beta_4 EMP + \beta_5 ADV + \beta_6 EXP + \beta_7 TECHMT + \beta_8 DUM + \varepsilon \ldots (6.2)$$

The model has been estimated separately for the five categories of firms. Since time-series and cross-section data are pooled for the estimation of the model, random-effects Tobit regression has been applied. The results are reported in Tables 6.4a through 6.4e.

RANDOM-EFFECTS TOBIT REGRESSION: EXPLAINING R&D INTENSITY

Table 6.4a: Bulk Drug Manufacturers

Explanatory variable	Coefficient
SIZE	0.0065(2.8)[a]
RM	0.241(19.15) [a]
ADV	0.4781(9.17) [a]
Tech MT	1.2012(1.86) [c]
D2003	0.00297(0.44)
CONS	0.18192(11.24) [a]
sigma_u	0.5302(19.46) [a]
sigma_e	0.04843 (20.94) [a]
rho	0.991724

N=238 No. of Groups= 52 Wald chi^2 (4) =93.84

Note: t-ratios in parentheses. <a> statistically significant at one percent level; <b> at five percent level; <c> at ten percent level

Table 6.4b: Bulk Drugs and Formulations - Medium & Small Firms

Explanatory variable	Coefficient
EXCISE	-0.1559 (-2.69)[a]
SIZE	0.0053 (1.6)
RM	0.046 (1.99)[b]
ADV	0.1355(2.57) [a]
Tech MT	7.5207(3.84) [a]
D2002	0.0119(2.01) [b]
CONS	-0.0148(-0.87)
sigma_u	0.0261(5.82) [a]
sigma_e	0.0257(15.06) [a]
rho	0.50719

N=152 No. of Groups= 34 Wald chi^2 (5) = 45.8

Note: t-ratios in parentheses. <a> statistically significant at one percent level; <b> at five percent level; <c> at ten percent level

Table 6.4c: MNC Pharmaceutical Firms

Explanatory variable	Coefficient
SIZE	-0.00729(-7.09)[a]
ADV	0.012199(1.6)
EXP	0.030979(2.99) [a]
Tech MT	0.086539(0.78)
D2000	-0.00261(-1.96) [b]
CONS	0.046129(7.62) [a]
sigma_u	0.012107(17.08) [a]
sigma_e	0.006323(15.4) [a]
rho	0.785681

N=123 No. of Groups= 15 Wald chi^2 (5) = 95.68

Table 6.4d: Bulk Drugs and Formulations - Large Firms

Explanatory variable	Coefficient
SIZE	0.009345(4.1) [a]
EMP	0.164002(1.74) [c]
ADV	0.263073(7.13) [a]
Tech MT	0.623878(2.21) [b]
D2002	0.006608(1.78) [c]
CONS	-0.07238(-4.67) [a]
sigma_u	0.021331(6.31) [a]
sigma_e	0.020041(18.86) [a]
rho	0.531132

N=196 No. of Groups= 22 Wald chi^2 (5) = 239.73

Table 6.4e: Formulations Manufacturers

Explanatory variable	Coefficient
EXCISE	-2.72878(-3.5) [a]
SIZE	-0.18477(-3.79) [a]
ADV	3.205509(6.1) [a]
EXP	-0.48544(-2.4) [b]
D1998	0.147736(2.15) [b]
CONS	0.433916(1.84) [c]
sigma_u	0.349819(4.71) [a]
sigma_e	0.215933(12.12) [a]
rho	0.724101

N=113 No. of Groups= 26 Wald chi^2 (5) = 72.44

Note: t-ratios in parentheses. <a> statistically significant at one percent level; <b> at five percent level; <c> at ten percent level

Size influences the R&D intensity positively for large firms as well as bulk drugs manufacturers. Even medium and small manufacturers show a positive correlation though it is statistically insignificant. Interestingly, MNCs and formulators show a negative influence of size on R&D.

There is a positive relationship between exports and R&D for large manufacturers and MNCs which shows that these firms, when diversifying into exports, are compelled to undertake R&D. MNCs which export more undertake more research activities; even the large firms which export relatively more have to do more R&D, but the significance of this factor diminishes if one includes size as the explanatory variable. This seems to be a consequence of multicollinearity, as large sized firms are also large exporters.

The impact of lower excise duty on research activities is found to be favourable in the case of medium and small bulk drug and formulation manufacturers as well as pure formulators. Many pharmaceutical firms are shifting their plants to low excise duty havens like Himachal Pradesh, Uttarakhand etc to take advantage of tax breaks in order to undertake research activities. The large and multinational firms show a positive impact of excise though it is statistically insignificant while the bulk drugs manufacturers show an insignificant negative correlation between excise duties and R&D activities.

The high import content of raw material shows a significant positive impact on the research and development activities undertaken by medium and small bulk drug and formulation manufacturers. But, it does not have a significant effect on R&D in the other categories. The not-so-large manufacturers rely on imported raw materials to undertake technology intensive production, and this could possibly explain the observed association between imports of raw materials and R&D activities among such firms. On the other hand, imports of raw materials are not found to bear any significant relationship with R&D intensity among large firms. A possible explanation could be that large firms have integrated backwards or have bulk demand from indigenous suppliers. The finding of a positive coefficient of the labor cost variable in estimated equation for large firms may signify that highly skilled workers contribute positively to the R&D undertaken by large firms. The large firms employ more skilled workers as they have resources to attract talent and given their production requirements have to hire more skilled workers as compared to say the formulators.

The promotional activities (captured by advertisement intensity) and R&D expenditure go hand in hand for all categories except MNC where it is statistically insignificant. The coefficient of the advertisement intensity variable is much higher in the regression for pure formulators than in the equation estimated for bulk drug manufacturers. One may argue that since product differentiation is a key feature of the markets faced by formulators, the impact of advertisement intensity is greater.

There is no common year from where the R&D intensity has shown an upward tendency across all the segments. Different categories have responded to the changing patent regime in different years. The most significant year dummy is selected for each of these categories. Large firms and medium and small-scale firms have started increasing their R&D expenditure around 2002. This is clear from the positive coefficient of the dummy variable with 5% statistical significance. Formulations also show a positive impact on R&D intensity after 1998. Till 1995, research and development expenditure of the domestic firms was only for process reengineering and patents that were applied were only defensive in nature. However, R&D intensity of any firm is affected not only by the patent regimes but also the market they are catering to, structural factors etc. In view of the fact that India is increasingly getting

integrated in the globalizing world, its research and development are not only going to be affected by the intellectual property (IP) regime of India but also by the IP regimes elsewhere in the world, especially in countries with whom trade and investment linkages are large and/or are growing. MNCs have shown a downward trend in their R&D intensity. This is probably because of the uncertain environment in India as the scope of flexibilities in the Indian Patent Act is deterring them to bring their technology into the industry. Novartis losing the case for its drug, Gleevec, the cancer drug in Indian courts is one glaring example. Also, in a strict patent regime, it is sufficient for MNCs to import their patented molecules without undertaking R&D or production in the country.

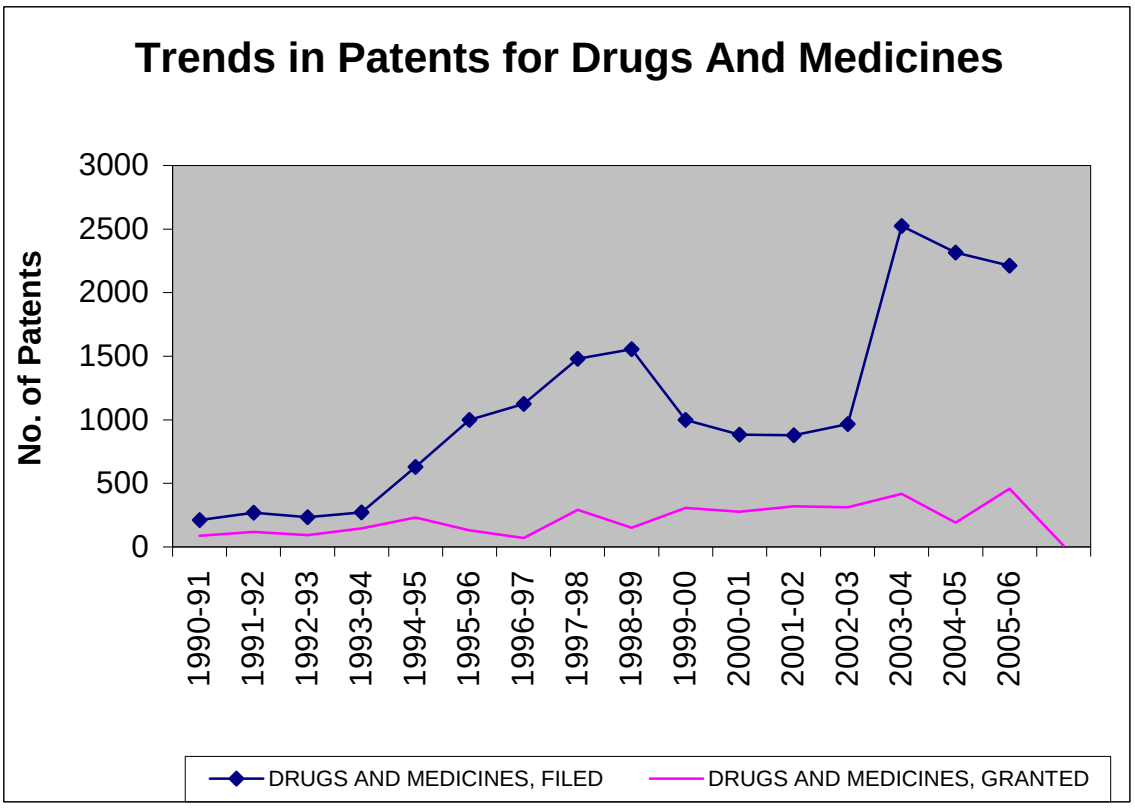
In the results presented above, imports of technology show a complementary link with R&D expenditure. One may rationalize this finding on the ground that technology imports enhance the capability of a firm to undertake indigenous research activities. The coefficient is statistically significant for bulk drugs manufacturers which are involved in the production of the basic product which is technology intensive. Even large and medium/ small manufacturers of bulk drugs and formulations show a positive relationship between R&D intensity and import of technology as they are relying on their own production base to sell medicines in final form i.e. formulations.

6.4 Impact of R&D Activity on Innovations

The main factor which is emerging as responsible for changes in the technological path that Indian pharmaceutical industry has taken since 1995 is the signing of TRIPS agreement to recognize product patents. One of the intended effects of this agreement is the changing strategies of the big pharmaceutical firms in India with respect to not only the quantum of research and development expenditure but also the direction. In the last decade the domestic companies have started filing increasing number of patents at home as well as in the international patent offices. There is also rise in number of patents filed in the Indian Patent offices by Pharmaceutical firms in the last decade or so (Figure 6.6) (detailed analysis in Chapter 8). Many domestic companies' patent filings are clustered around the 2000-03 period. They have started building capacity to develop new chemical entities. Earlier research and

development was confined to process development/innovation of existing molecules. Now, a few domestic firms like Ranbaxy, Dr.Reddy's, Glenmark and Lupin have ventured into research on new molecules. Most of the other companies are continuing with either process reengineering or somewhat less risky projects like new drug delivery system and improving already existing molecules.

Figure 6.6: Trends in Patents



Source: Annual Report of the office of the Controller General of Patents, Designs, Trademarks and Geographical Indications, various issues

The trend growth rate in the number of patent applications filed for drugs and medicines in the period 1990-91 to 2005-06 exceeds that in the total number of patent applications made. The gap is relatively larger in the growth rate of the number of patents granted. While the total number of patents granted grew at the trend rate of 3.5 percent per annum, the number patents granted for drugs and medicines grew at the trend rate of 9.9 percent per annum. This data on patents filed and granted are reported in Table 6.5. Analysis

of trends in patent applications for the period 1995-96 to 2005-06 reveals that the total number of patent applications grew much faster than the number of patent applications made for drugs and medicines. However, in regard to the number of patents granted, the growth rate was relatively faster for patents granted for drugs and medicines.

Table 6.5: Yearly Trends in Patent Filed and Granted

YEAR	TOTAL		DRUGS and MEDICINES	
	FILED	GRANTED	FILED	GRANTED
1990-91	3714	1491	211	87
1991-92	3552	1676	270	118
1992-93	3467	1272	234	94
1993-94	3869	1746	273	145
1994-95	5330	1759	629	232
1995-96	7036	1533	1000	132
1996-97	8562	907	1124	71
1997-98	10155	1844	1481	291
1998-99	8954	1800	1555	150
1999-00	4824	1881	1000	307
2000-01	8503	1318	883	276
2001-02	10592	1591	879	320
2002-03	11466	1379	966	312
2003-04	12613	2469	2525	419
2004-05	17466	1911	2316	192
2005-06	24505	4320	2211	457
Trend Rate of Growth (% p.a.)	11.9	3.5	16.2	9.9

Source: Annual Report of the office of the Controller General of Patents, Designs, Trademarks and Geographical Indications

Table 6.6 presents data on the number of patent applications made by some leading pharmaceutical companies in India. It would be noticed that these companies made applications for about 100 to 250 applications each year during the years 2000 to 2003. In this period, the overall number of applications received by the Indian Patent Office from pharmaceutical firms was over 1000, going up to 2500 in 2003. Evidently, there has been a huge flow of applications for patents from other firms, including small and medium scale firms.

Table 6.6: Database on Patent Applications filed by Select Domestic Firms in India

Firm	No.	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004
Alembic	40					6	3	17	14		
Aurobindo	48	1		3			2	5	5	15	17
Biocon	45		3	1	4	6	8	13	7	2	
Cadila	73						12	35	26		
Cipla	51		2			32	5	6	5		1
Dr. Reddy's	102			2	7			22	30	29	12
Glenmark	15						4	4	7		
Ind Swift	2								2		
IPCA	5									5	
Lupin	52	2	8	9	5	6	11	7	4		
Malladi drugs	2										2
Matrix	27								1	14	12
NichPiramal	12						9	2	1		
Orchid	94	1					2	9	23	30	29
Panacea	128	4	18	36	10	35	18	5	2		
Ranbaxy	187	3	4	17	10	28	27	47	49	2	
Reliance	8								8		
Serum	2						2				
Shasun	3							1		1	1
Sun	131	4	8	6	12	6	9	48	37	1	
Suven	9								3	1	5
Torrent	31					5	5	7	12	1	1
Wockhardt	18				5		2	5	6		
Total		15	43	74	53	124	119	133	242	101	80

Source: TIFAC, Patent Facilitating Centre. Dept of Science and Technology

In order to ascertain whether the increasing R&D expenditure is going into development of new drugs or is it still going for reverse engineering, an attempt has been made

to assess the impact of R&D undertaken pharmaceutical firms in India on the patents filed in the Indian Patent Offices. The data on patents filed by various firms, used for the econometric exercise, have been collected from the website, BigPatent India.

Analysis of data on patents filed with Indian patents offices reveals that some firms have filed around 200 patents (in the period 1995 to 2007) while some others have only one patent application in their name while incurring expenditure on research activities. Investigation of the determinants of patenting activity across the different groups classified above has been done by taking into consideration factors like size, export orientation, etc. Given that the dependent variable namely the number of patents filed ranged from 0 to around 200, and many observations are zero, the Negative Binomial Model has been used, which takes care of large range of counts. Instead of R&D intensity, the level of R&D expenditure of individual firms has been taken as one of the explanatory variable. Evidently, R&D intensity could be very high without the levels being very high, and this may not result in patents. The results of the Negative Binomial Model are shown in Table 6.7.

To explain the inter-firm differences in patent applications, R&D expenditure, size of the firm and its export orientation were included. All these variables were found to be positively related to the patenting activity of the firms but the coefficients of R&D and size were found to be statistically insignificant when both variables were included in the model. A check on their correlation coefficient revealed that it was very high at 0.84. Hence, these variables have been used in separate equations.

The size of the firm and expenditure on R&D had much larger coefficients with very high degree of significance compared to the firm's degree of export orientation. Also, firm category dummy variables representing large as well as medium and small sized bulk drug and formulation manufacturers have a larger positive coefficient at 1% and 5% degree of confidence respectively. This indicates that other things remaining the same, the firms belonging to these groups file more patent applications. By contrast, the dummy variable representing the MNC firms show a negative sign though it is not significant. This is perhaps an indication of relatively smaller number of patents filed by MNCs. As mentioned earlier the

flexibilities that TRIPS agreement provides and the earnestness with which India is resisting frivolous patents in its courts could be one reason that MNCs have not shown much enthusiasm in filing patents in India.

Table 6.7: Negative Binomial Regressions of Patent (Application) Counts

Explanatory variable	Coefficient	t	P>t
ln(R&D)	0.4249	2.84	0.004
EXP	0.3043	1.91	0.056
DLARGE	2.0544	4.11	0
DMNC	-1.1818	-1.03	0.301
DFORM	0.8540	1.11	0.269
DMS	1.0661	2.52	0.012
CONS	-2.5605	-4.94	0
ln ALPHA	0.4217		
ALPHA	1.5245		

N=143 Wald CHI^2 (6) = 253.61 log pseudolikelihood = -206.6

Explanatory variable	Coefficient	t	P>t
EXP	0.2734	1.95	0.051
SIZE	0.6943	4.43	0
DLARGE	1.6979	3.13	0.002
DMNC	-1.7535	-1.54	0.123
DFORM	1.3223	1.56	0.118
DMS	1.5799	3.09	0.002
CONS	-5.6375	-7.07	0
ln ALPHA	0.4073		
ALPHA	1.5027		

N=143 Wald CHI^2 (6) = 295.84 log pseudo likelihood = -202.3

In the analysis above, the number of patents applications filed in India has been taken as a measure of research activity outcome. A significant positive relationship has been observed between R&D expenditure and patent applications in India. It would have been interesting to see whether the results hold if the measure of outcome is the number of patents of Indian firms in the US Patent and Trademark Office (USPTO). This would make it possible to separate out the truly innovative efforts to develop global products from the efforts to introduce just local products. The number patents filed by the Indian and foreign firms and some research organizations with the US Patent and Trademark Office (USPTO) is provided in Table 6.8 to highlight the magnitude of research efforts by the Indian Pharmaceutical firms to develop drugs internationally. These data also highlight the fact that the nature of diseases for which

research is undertaken may belong to global needs rather than just local needs which would be reflected in the patents filed within India. Interestingly, the data reveals that till 1995, except Ranbaxy, no other domestic pharmaceutical firm had filed any patents with USPTO.

Table 6.8: No. of Patents filed with USPTO as a measure of Research Activity Outcome

First-Named Assignee	1969-89	1990-95	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	Total
CSIR	21	35	10	18	25	36	37	58	120	133	127	117	122	94	73	1026
Ranbaxy	0	8	1	2	5	4	4	8	7	8	11	7	12	1	2	80
Dr. Reddy's Lab	0	0	0	0	0	0	0	1	0	7	3	5	7	10	4	37
Dr. Reddy's Research Foundation	0	0	0	1	2	7	7	3	7	1	0	0	2	1	0	31
Dabur Research Foundation	0	0	0	0	0	1	3	5	5	6	1	2	3	2	0	28
Orchid Chemicals & Pharmaceuticals Ltd.	0	0	0	0	0	0	0	0	2	5	6	5	1	3	5	27
Ciba-Geigy Corporation	16	1	0	0	0	0	0	0	0	0	0	0	0	0	0	17
Panacea Biotec Limited	0	0	0	1	1	4	2	3	2	1	0	0	1	1	1	17
Wockhardt Limited	0	0	0	0	0	0	0	0	0	3	2	2	4	3	3	17
National Institute Of Immunology	1	1	0	0	2	3	1	3	2	0	0	0	0	1	0	14
Sun Pharmaceutical Industries Ltd.	0	0	0	0	0	0	0	0	2	2	0	1	4	2	3	14
Ciba-Geigy Limited	13	0	0	0	0	0	0	0	0	0	0	0	0	0	0	13
Lupin Laboratories Limited	0	0	1	1	5	2	1	1	0	0	0	1	1	0	0	13
Ciba-Geigy Ag	12	0	0	0	0	0	0	0	0	0	0	0	0	0	0	12
Hetero Drugs Limited	0	0	0	0	0	0	0	0	0	0	0	0	2	4	6	12
Usv Limited	0	0	1	0	0	0	0	1	2	1	2	1	0	1	3	12
Aurobindo Pharma Limited	0	0	0	0	0	0	0	0	2	0	3	1	3	1	0	10
Biocon Limited	0	0	0	0	0	0	0	0	0	0	0	1	0	7	2	10
Torrent Pharmaceuticals Ltd.	0	0	0	0	0	0	1	3	1	3	0	0	1	1	0	10
Cipla Limited	0	0	0	0	0	0	0	0	0	0	0	1	2	1	5	9
Lupin Limited	0	0	0	0	0	0	0	0	0	0	1	1	1	1	5	9
Reliance Life Sciences Pvt. Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	1	2	5	8

Astrazeneca Ab	0	0	0	0	0	0	0	1	1	1	0	2	0	0	2	7
Biocon India Limited	0	0	0	0	0	0	0	1	0	4	1	1	0	0	0	7
Alembic Limited	0	0	0	0	0	0	0	0	0	0	1	1	0	3	1	6
Cadila Healthcare Limited	0	0	0	0	0	0	0	0	0	1	0	0	2	0	3	6
Dabur India Limited	0	0	0	0	0	0	0	0	0	1	0	4	0	1	0	6
Department Of Science & Technology	0	0	0	0	0	0	0	0	3	1	2	0	0	0	0	6
Glenmark Pharmaceuticals Limited	0	0	0	0	0	0	0	0	0	0	0	1	0	4	1	6
Aventis Pharma Deutschland Gmbh	0	0	0	0	0	0	1	1	1	0	1	0	0	1	0	5
Ipca Laboratories Limited	0	0	0	0	0	0	0	0	0	0	0	1	0	0	4	5
Jubilant Organosys Limited	0	0	0	0	0	0	0	0	1	0	0	0	1	2	1	5
Nicholas Piramal India Limited	0	0	0	0	0	0	0	0	0	0	1	0	1	2	1	5
U & I Pharmaceuticals Ltd.	0	0	0	0	0	0	0	0	1	0	1	1	2	0	0	5

Source: Patenting By Geographic Region (State and Country), Breakout By Organization Count of 1969-2008 Utility Patents Grants By Calendar Year Of Grant from www. uspto.gov, accessed on 18th June 2010.

The pharmaceutical firms that rank high in terms of patent applications made in India, rank high also in terms of the number of patent applications filed with USPTO. There is high positive correlation between the two variables. Thus, R&D efforts of Indian pharmaceutical firms are directed both at developing global products as well as at introducing local products.

To explain the inter-firm differences in patent applications filed with USPTO, models similar to the ones presented in Table 6.7 have been estimated. In the estimated model, R&D expenditure, size of the firm and its export orientation have been included as explanatory variables. The results are presented in Table 6.9.

Table 6.9: Negative Binomial Regressions of Patent (Application) Counts, USPTO

Explanatory variable	Coefficient	t	P>t
ln(R&D)	1.3683	5.31	0.0
DLARGE	1.3126	2.01	0.045
DMNC	4.4400	4.06	0.0
CONS	-6.2503	-5.31	0.0
ln ALPHA	1.3697		
ALPHA	3.9343		

N=147 Wald CHI^2 (3) = 64.27 log pseudolikelihood = -103.2

Explanatory variable	Coefficient	t	P>t
EXP	0.4223	1.14	0.256
SIZE	0.9965	2.30	0.021
DLARGE	1.5377	2.23	0.025
DMNC	3.3419	2.40	0.017
CONS	-9.8697	-4.50	0.0
ln ALPHA	1.6129		
ALPHA	5.0174		

N=147 Wald CHI^2 (4) = 55.89 log pseudo likelihood = -107.4

The results presented in Table 6.9 are similar to those in Table 6.7. Thus, R&D expenditure bears a significant positive relationship with the number of patent application filed with USPTO. Similarly, firm size and patent application filed are found to be positively related. Interestingly, the coefficient of the MNC dummy variable is found to be positive and statistically significant.[60] It may be inferred therefore that other things remaining the same, an MNC firms tends to have a greater number of patent application filed with the USPTO. By contrast, the results reported in Table 6.7 indicate that MNCs tend to file less patent applications in India. It appears from the results that for a given level of R&D effort, an MNC pharmaceutical firm in India is more likely to file patent applications with the USPTO, while an Indian firm will file more applications in India than the number of applications it files with the USPTO.

[60] The statistical package (STATA 10) used for estimation of the model encountered problems of convergence when dummy variables for various categories of firms were used (as in Table 6.7). This is the reason why dummy variables for only two categories have been used.

6.5 Conclusions

In the Indian pharmaceutical industry, the private sector is the major spender of R&D. Due to high risks and huge investments required to develop new drugs, the Indian industry was engaged in making drugs through reverse engineering which entailed very low costs till India signed the TRIPS agreement in 1995. With the introduction of product patents in pharmaceuticals, there was considerable pressure on domestic firms to increase their investment in R&D. For some select firms, the increasing research and development expenditure appears to be going into developing new chemical entities or new processes and not simply into reverse engineering or generic manufacturing.

The empirical findings of the econometric models on R&D behaviour of different types of pharmaceutical firms and its impact on patenting by these firms show that there is a ***correlation*** over time between the new patent regime and a change in the levels and direction of R&D expenditure by some of these firms with concomitant effects on patenting.[61] Except the multinational pharmaceutical firms which show a negative trend in their research activities in India, other pharmaceutical units show an upward trend, especially large firms and medium and small bulk drugs and formulations manufacturers as well as bulk drugs manufacturers. There is clear evidence that large size firms have higher willingness to undertake R&D activities. Import of technology seems to have a negative effect on their willingness to do R&D (since imported technology tends to be a substitute). However, once they have decided to engage in research activities, imports of technology supplements and enhances their R&D activities, helping them upgrade their technological base. The Schumpeterian hypothesis linking size with R&D is found to be valid for Indian pharmaceutical industry, except for the subsidiaries of multinational corporations (who in any case do not undertake much R&D).

[61] The econometric evidence presented in the chapter established correlation, but not causation. Yet, it would not be unreasonable to treat the observed correlation as evidence of the new patent regime causing the pharmaceutical firms in India to undertake greater R&D which in turn leading to patents. If the new patent regime is not the cause of the hikes in R&D intensity in Indian pharmaceutical firms, then what else could have led to the increases in R&D? No other good explanation can be found. If the issue of patent regime is disregarded, the policy environment and other conditions in the industry has not changed so drastically in the post-1995 period to make Indian pharmaceutical firms undertake much greater R&D. There is no good reason to believe that there was a sudden rise in the requirement of R&D for reverse engineering in the 2000s, and obviously such explanation of the observed hikes in R&D intensity will not be accepted.

Greater employee cost is found to bear a positive relationship with R&D. It appears that the skilled workers which are mostly hired by large firms have been involved in building technological base of these firms. It may be inferred from the empirical findings that providing intellectual property rights in this industry has induced the firms to undertake greater R&D. Firms which undertake high investment for promoting and marketing their products are also the ones which are undertaking and increasing their R&D efforts. This establishes Nelson's thesis that expenditure on advertisement and other promotional activities signal the high quality products. Different categories of pharmaceutical units have responded to the shift in the patent regime by increasing their R&D intensity. However, the effect may have occurred at different points in time. Certain categories of firms have responded early, some others have responded a litter later. By contrast, subsidiaries of MNCs are still reluctant to take the technological jump.

Undertaking R&D and expanding the existing R&D base need not translate into doing research in developing new products or new processes for which patents are sought. The research expenditure is incurred even when the firms are doing reverse engineering or making generic versions of patented molecules or challenging patents of other firms. To look into these issues the link between R&D and patent applications has been investigated. The analysis of the link between of R&D and filing of patents has brought out that the firms that spend larger amounts on R&D and export more are the ones which file more patents than the others. It is found that the bulk drugs and formulation manufacturers, large as well as small and medium units, have filed more patents than only bulk drug manufacturers, pure formulators or multinational firms. Big sized firms are more likely to file application for patent compared to small sized firms. The number of applications filed is also likely to be higher for big sized firms.

The overall conclusion that may be drawn on the basis of the econometric analysis presented in the chapter is that there is a clear link between the new patent system and investment in R&D by the pharmaceutical firms to develop products/ processes for which they are seeking patents.

Chapter 7
Market Share of Domestic and Foreign Firms[62]

7.1 Changes in Policy Environment for Pharmaceuticals

Indian Pharmaceutical industry has achieved significant growth since 1970, when it was dominated by foreign companies (MNCs). To strengthen the indigenous manufacturing capacity and capability and to ensure for the Indian people affordable access to drugs and medicines, the Government of India formulated various policies from the 1970s and issued drug price control orders over the years. The Indian Patent Act 1970 played a major role in boosting the domestic pharmaceutical industry. Price control also played a vital role in shaping the industry and resulted in very low prices of drugs in India compared to the prices prevailing in other countries. Various Drugs price control orders (DPCOs), 1979, 1987 and 1995, have been introduced since the first Drugs Price Control Order of 1970, when most of the drugs were put under price control. The number of bulk drugs under price control was reduced to 347 as per DPCO 1979, to 142 as per DPCO 1987 and to 74 as per DPCO 1995 (Table 7.1).[63] The National Pharmaceutical Pricing Authority (NPPA) was founded in 1997 for monitoring prices. NPPA has been charged with setting prices for controlled drugs, as well as monitoring or fixing prices of decontrolled drugs. Provisions under the Drugs Price Control Order of 1995 empower NPPA to regulate drug prices for a list of 74 commonly used bulk drugs. In addition, under paragraph 10(b) of the DPCO, NPPA may "fix" prices of drugs not on the list, called non-scheduled drugs for the public interest. All these measures led to the decline in the market share of foreign companies from 80 per cent in 1970[64] to about 25 percent in 2007.

[62] This Chapter has been prepared by Anita Kumari
[63] At present, the same 74 drugs are under price control.
[64] Shanmugasundaram (2008).

Table 7.1 Market Share of Drugs under DPCOs

DPCO Order	Number of drugs	Market share (%)
1979	347	80
1987	142	60
1995	74	40
2008	74	20

Source: Ministry of Chemicals, Govt. of India

As mentioned in earlier chapters, in 1995, India signed the Agreement on TRIPS under WTO to implement product patents from January 2005. Under the new patent act, generic versions of drugs patented before 1995 and off-patent generic drugs are allowed to be produced by domestic firms to be produced for sell in the Indian market. Because of changed business environment arising from the new act, there are expectations that foreign companies will make substantial investments in India and will launch their patented products in the Indian market, which will increase their market share. Whether this has actually happened is obviously a moot question. This chapter, therefore, makes an attempt to analyse whether after the implementation of product patents in India, i.e. after 2005, the market share of foreign companies has increased. And, if this has not happened in most therapeutic segments, why so?

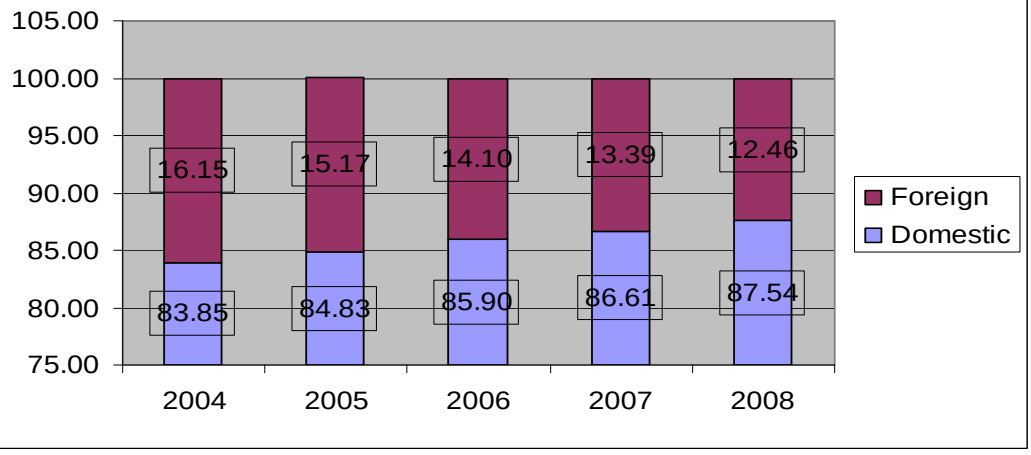
The chapter is organised as follows: Section 7.2 reviews the growth of sales of domestic and foreign companies[65] in all the therapeutic segments under consideration for this study. Section 7.3 discusses the market share of domestic and foreign companies. In Section 7.4, the market shares of top companies are discussed and in section 7.5, a detailed analysis of market share of domestic and foreign companies is done at drug level for different segments. Finally, section 7.6 summarizes the main findings of the study of trends in market shares.

[65] See footnote 35 on the classification of companies into domestic and foreign.

7.2 Growth of Sales of Domestic and Foreign Companies Since 2004

The dataset used for the study covers 11 therapeutic segments, viz, Antacid Antiflatulents, Antihelmintics, Antileukaemics, Antipeptic Ulcerants, Antirheumatic Nonstr., Broncho Inhalant & Injection, Broncho Solids & Liquid, Cephalosporins, Muscular Relaxant, Statins and Tuberculostatics Ex.. Table 7.2 shows that over the years, sales of all the segments except Tuberculostatics has increased. The same trend is observed for sales of domestic companies for all the segments. But in the case of foreign companies, apart from sales of Tuberculostatics segment, sales of Broncho Inhalant and Injection and Broncho Solids and Liquids have also declined over the years. It can be noticed from Table 7.2 that over the entire period, 2004 to 2008, the growth rate of total sales for all the segments taken together has been 14.13 percent per annum. Growth rate of sales of domestic companies has been 15.37 percent per annum whereas that for foreign companies has been 6.96 percent per annum. This naturally has lead to a fall in the market share of foreign firms between 2004 and 2008, as depicted in Fig. 7.1.

Figure 7.1
Market Share of Domestic and Foreign Companies, 2004-2008



Note: The shares shown in the graph are out of the total sales of drugs/medicines belonging to eleven therapeutic segments (selected for study).

Table 7.2: Growth of Sales of Domestic and Foreign Companies, 2004-2008

(% per annum)

THERAPEUTIC SEGMENTS	2005	2006	2007	2008	2004-2008
Domestic					
ANTACID, ANTIFLATULENTS	-7.30	6.23	1.46	0.10	0.12
ANTIHELMENTHIC	-6.20	20.18	15.96	4.05	8.50
ANTILUKEMICS	40.48	47.41	94.90	52.10	58.72
ANTIPEPTIC ULCERANTS	17.09	27.28	18.12	10.10	18.15
ANTIRHEUMATIC NONSTR.	2.72	28.20	5.63	8.00	11.14
BRONCHO INHALANT & INJ	14.06	22.93	20.12	15.32	18.11
BRONCHO SOLIDS & LIQ	-0.39	23.82	15.25	11.29	12.49
CEPHALOSPORINS	19.09	28.17	14.75	12.96	18.74
MUSCLE RELAXANTS	1.51	21.09	7.38	-2.24	6.94
STATINS	27.58	26.14	34.19	21.34	27.31
TUBERCULOSTATICS EX	-2.06	-2.69	3.05	-2.69	-1.10
TOTAL DOMESTIC	11.28	24.55	14.46	11.17	15.37
Foreign					
ANTACID, ANTIFLATULENTS	19.16	13.49	11.36	5.21	12.31
ANTIHELMENTHIC	-0.84	7.94	6.83	3.53	4.37
ANTILUKEMICS	-5.60	8.63	12.18	-3.01	3.05
ANTIPEPTIC ULCERANTS	0.63	16.32	22.16	5.53	11.16
ANTIRHEUMATIC NONSTR.	1.45	23.08	7.33	3.34	8.80
BRONCHO INHALANT & INJ	-19.17	6.38	9.86	-24.57	-6.87
BRONCHO SOLIDS & LIQ	-19.72	7.80	-6.22	-5.61	-5.94
CEPHALOSPORINS	6.50	8.79	1.35	0.21	4.21
MUSCLE RELAXANTS	28.46	12.22	17.76	13.76	18.05
STATINS	-31.37	148.93	151.87	14.82	71.06
TUBERCULOSTATICS EX	-16.15	-2.87	-0.49	-7.69	-6.80
TOTAL FOREIGN	3.31	14.34	7.82	2.36	6.96
Domestic+ Foreign					
ANTACID, ANTIFLATULENTS	5.23	10.12	6.93	3.04	6.33
ANTIHELMENTHIC	-3.97	14.92	12.27	3.85	6.77
ANTILUKEMICS	19.71	33.62	70.99	41.65	41.49
ANTIPEPTIC ULCERANTS	15.56	26.39	18.42	9.75	17.53
ANTIRHEUMATIC NONSTR.	2.44	27.10	5.98	7.02	10.64
BRONCHO INHALANT & INJ	11.68	22.07	19.66	13.67	16.77
BRONCHO SOLIDS & LIQ	-3.73	21.51	12.51	9.49	9.95
CEPHALOSPORINS	17.37	25.77	13.32	11.74	17.05
MUSCLE RELAXANTS	5.62	19.45	9.19	0.76	8.75
STATINS	27.22	26.55	34.95	21.27	27.50
TUBERCULOSTATICS EX	-3.31	-2.71	2.77	-3.06	-1.58
TOTAL DOM + FOR	9.99	23.01	13.52	9.99	14.13

Out of the eleven segments studied, the maximum (annual average) growth rate in sales, 41.5 percent, has been registered by Antileukemics followed by Statins, 27.5 percent, and then by Antipeptic ulcerant, Cephalosporins and Broncho Inhalant and Injection each having around 17 percent growth rate in sales. Other groups have grown at the rate of 6 per cent to 11 percent, except Tuberculostatics which had a decline of 1.6 percent.

Considering only the sales of domestic companies, the maximum (annual average) growth rate in sales (during 2004 to 2008) has been registered by Antileukemics segment at 58.7 percent and the minimum has been that of Antacid Antiflatulents, being 0.12 percent followed by Tuberculostatics segment showing a decline of 1.10 percent. On the other hand, maximum growth rate in sales of foreign companies has been 71.06 percent registered by Statins segment and the minimum has been of Antileukemics segment being 3.05 percent. Broncho Solids and Liquids and Broncho Inhalant and Inj and Tuberculostatic have registered a decline in sales over this period. Tuberculostatics has been showing negative growth in both domestic firms sales and foreign firms sales though the decline has been much larger for foreign firms sales, the rate being -6.80 percent per annum.

7.3 Market Share of Domestic and Foreign Companies

Table 7.3 shows shares of different segments/groups in total sales, total domestic companies sales and total foreign companies sales. A graphical presentation of market shares by segments is given in figures 7.2 and 7.3. Out of the eleven groups, Cephalosporins segment has the maximum average share of 31.56 percent in total sales followed by Antirheumatic Nonstr, 21.12 percent and Antipeptic Ulcerant, 16.07 percent. These groups together accounted for 68.74 percent share in total sales. All the remaining groups together have a share of 31.26 percent; each group having a share of less than 10 percent with Antihelmintic and Antileukemics having only a meager share of 1.5 percent and 0.6 percent respectively in total sales. Sales of domestic companies for the segments under consideration also exhibit almost the same pattern as with respect to total sales, with Cephalosporins contributing the maximum of 32.83 percent to total sales of domestic companies followed by Antirheumatic Nonstr, 19.41 percent, and Antipeptic Ulcerant, 17.21 percent, together contributing 69.5 per cent to total

sales of domestic companies. The remaining segments contributed 30.5 percent only with Antihelmintic and Antileukemics contributing very little towards total sales of domestic companies.

Table 7.3 Market Shares of Domestic and Foreign Companies, 2004-2008 (per cent)

THERAPEUTIC SEGMENTS	2004	2005	2006	2007	2008	Average
Domestic						
ANTACID, ANTIFLATULENTS	3.37	2.81	2.39	2.12	1.91	2.42
ANTIHELMENTHIC	1.27	1.07	1.03	1.05	0.98	1.06
ANTILUKEMICS	0.26	0.32	0.38	0.65	0.89	0.55
ANTIPEPTIC ULCERANTS	16.02	16.85	17.22	17.77	17.60	17.21
ANTIRHEUMATIC NONSTR.	21.31	19.67	20.25	18.69	18.16	19.41
BRONCHO INHALANT & INJ	6.62	6.79	6.70	7.03	7.29	6.93
BRONCHO SOLIDS & LIQ	5.46	4.89	4.86	4.89	4.90	4.97
CEPHALOSPORINS	30.19	32.31	33.24	33.33	33.87	32.83
MUSCLE RELAXANTS	2.34	2.14	2.08	1.95	1.71	2.00
STATINS	5.89	6.75	6.84	8.01	8.75	7.45
TUBERCULOSTATICS EX	7.27	6.40	5.00	4.50	3.94	5.17
TOTAL DOMESTIC	100.00	100.00	100.00	100.00	100.00	100.00
Foreign						
ANTACID, ANTIFLATULENTS	15.74	3.25	2.96	2.88	2.72	2.94
ANTIHELMENTHIC	4.71	4.52	4.27	4.23	4.28	4.38
ANTILUKEMICS	1.09	0.99	0.94	0.98	0.93	0.98
ANTIPEPTIC ULCERANTS	8.55	8.33	8.48	9.60	9.90	9.03
ANTIRHEUMATIC NONSTR.	30.55	30.00	32.29	32.15	32.45	31.59
BRONCHO INHALANT & INJ	2.65	2.08	1.93	1.97	1.45	1.98
BRONCHO SOLIDS & LIQ	5.92	4.60	4.33	3.77	3.48	4.34
CEPHALOSPORINS	24.71	25.47	24.24	22.78	22.30	23.78
MUSCLE RELAXANTS	2.19	2.72	2.67	2.92	3.24	2.78
STATINS	0.19	0.13	0.27	0.64	0.71	0.41
TUBERCULOSTATICS EX	3.70	3.00	2.55	2.35	2.12	2.69
TOTAL FOREIGN	100.00	100.00	100.00	100.00	100.00	100.00
Domestic+ Foreign						
ANTACID, ANTIFLATULENTS	5.37	5.13	4.60	4.33	4.06	4.60
ANTIHELMENTHIC	1.83	1.59	1.49	1.47	1.39	1.53
ANTILUKEMICS	0.39	0.42	0.46	0.69	0.89	0.61
ANTIPEPTIC ULCERANTS	14.81	15.56	15.99	16.68	16.64	16.07
ANTIRHEUMATIC NONSTR.	22.81	21.24	21.95	20.49	19.94	21.12
BRONCHO INHALANT & INJ	5.98	6.07	6.03	6.35	6.57	6.24
BRONCHO SOLIDS & LIQ	5.54	4.85	4.79	4.74	4.72	4.88
CEPHALOSPORINS	29.30	31.27	31.97	31.92	32.43	31.56
MUSCLE RELAXANTS	2.32	2.23	2.16	2.08	1.90	2.11
STATINS	4.97	5.75	5.91	7.03	7.75	6.46
TUBERCULOSTATICS EX	6.69	5.88	4.65	4.21	3.71	4.82
TOTAL DOM + FOR	100.00	100.00	100.00	100.00	100.00	100.00

Figure 7.2
Market Share of Different Therapeutic Segments in Total Sales of Domestic Companies
2004-2008

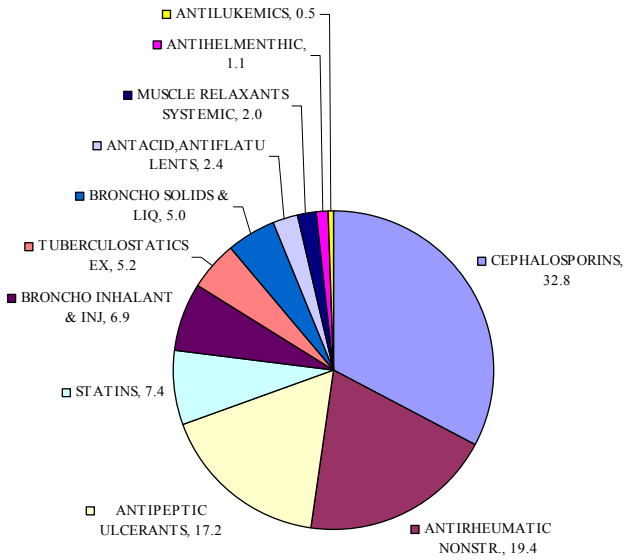
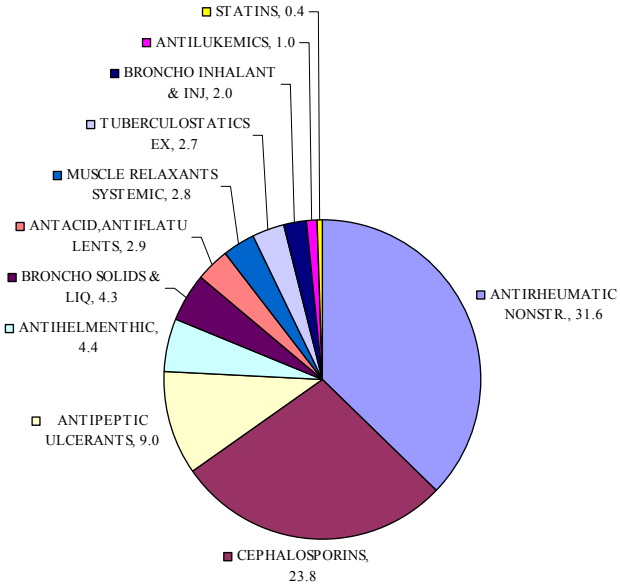


Figure 7.3
Market Share of Different Therapeutic Segments in Total Sales of Foreign Companies
2004-2008



On the other hand, in the sales of foreign companies, Antirheumatic contributed the maximum. It had a share of 31.59 percent out of the total sales of foreign companies. The next contribution comes from Cephalosporins, 23.78 percent and Antipeptic Ulcerant, 9.03 per cent. The remaining segments contributed less than 5 per cent only, with Statins segment making the lowest contribution of 0.41 percent only. Interestingly, in general, the same trend is depicted for different years, from 2004 to 2008.

Table 7.4 shows the share of domestic companies and foreign companies in total sales for each ***therapeutic*** segment from 2004 to 2008. Domestic companies on an average had a share of 85.74 percent as compared to a share of 14.26 percent of foreign companies in average total sales. In the year 2004, domestic companies had a share of 83.85 per cent as compared to 16.15 per cent of foreign companies. Over the years, the share of domestic companies has increased to 87.54 percent[66] whereas that of foreign companies has declined to 12.46 per cent.

In all the segments, except Antacid Antiflatulents, Muscle Relaxant and Statins, the share of domestic companies in total sales has increased whereas that of foreign companies has declined between 2004 and 2008. In Antacid Antiflatulents, share of domestic companies has declined significantly from 52.64 percent in 2004 to 41.23 percent in 2008 and that of foreign companies increased. However, the decline in sales of domestic companies in the other two groups, i.e., Muscle Relaxant and Statins, has been marginal only.

With respect to segments showing increase in the share of sales of domestic companies, the largest increase has been in the case of antileukemics segment, registering an increase from 54.92 percent in 2004 to 87.02 percent in 2008. In all other segments, the increase in the share of sales of domestic companies or decline in the share of sales of foreign companies has not been very large, being in the range of 2 to 6 percentage points only.

[66] Note that this relates to the share of domestic companies for the eleven segments studied. It should be noted further that this study is based on the data with the stockists in India. As per ORG-IMS (Accessed from http://www.business-standard.com/india/news/domestic-pharma-companies-dominate80-share/277299, Business Standard, Aug 4, 2009), domestic companies registered 80 percent share of the domestic prescription sales in 2006. For 2006, the share of domestic companies in the eleven segments is 86 percent. The difference in estimated shares seems attributable to differences in coverage.

Table 7.4 Shares of Domestic Companies and Foreign Companies in Total Sales for Each *Therapeutic* Segment, 2004-2008

THERAPEUTIC SEGMENTS	D/F	2004	2005	2006	2007	2008	Average
ANTACID, ANTIFLATULENTS	Domestic	52.64	46.37	44.73	42.44	41.23	45.48
	Foreign	47.36	53.63	55.27	57.56	58.77	54.52
	Total	100.00	100.00	100.00	100.00	100.00	100.00
ANTIHELMENTHIC	Domestic	58.33	56.98	59.59	61.55	61.66	59.62
	Foreign	41.67	43.02	40.41	38.45	38.34	40.38
	Total	100.00	100.00	100.00	100.00	100.00	100.00
ANTILUKEMICS	Domestic	54.92	64.45	71.10	81.04	87.02	71.70
	Foreign	45.08	35.55	28.90	18.96	12.98	28.30
	Total	100.00	100.00	100.00	100.00	100.00	100.00
ANTIPEPTIC ULCERANTS	Domestic	90.67	91.88	92.53	92.29	92.59	91.99
	Foreign	9.33	8.12	7.47	7.71	7.41	8.01
	Total	100.00	100.00	100.00	100.00	100.00	100.00
ANTIRHEUMATIC NONSTR.	Domestic	78.36	78.57	79.25	78.99	79.71	78.98
	Foreign	21.64	21.43	20.75	21.01	20.29	21.02
	Total	100.00	100.00	100.00	100.00	100.00	100.00
BRONCHO INHALANT & INJ	Domestic	92.83	94.81	95.48	95.85	97.25	95.24
	Foreign	7.17	5.19	4.52	4.15	2.75	4.76
	Total	100.00	100.00	100.00	100.00	100.00	100.00
BRONCHO SOLIDS & LIQ	Domestic	82.74	85.61	87.23	89.36	90.82	87.15
	Foreign	17.26	14.39	12.77	10.64	9.18	12.85
	Total	100.00	100.00	100.00	100.00	100.00	100.00
CEPHALOSPORINS	Domestic	86.38	87.64	89.31	90.44	91.43	89.04
	Foreign	13.62	12.36	10.69	9.56	8.57	10.96
	Total	100.00	100.00	100.00	100.00	100.00	100.00
MUSCLE RELAXANTS	Domestic	84.76	81.46	82.58	81.21	78.79	81.76
	Foreign	15.24	18.54	17.42	18.79	21.21	18.24
	Total	100.00	100.00	100.00	100.00	100.00	100.00
STATINS	Domestic	99.39	99.67	99.35	98.79	98.85	99.21
	Foreign	0.61	0.33	0.65	1.21	1.15	0.79
	Total	100.00	100.00	100.00	100.00	100.00	100.00
TUBERCULOSTATICS EX	Domestic	91.07	92.26	92.27	92.52	92.87	92.20
	Foreign	8.93	7.74	7.73	7.48	7.13	7.80
	Total	100.00	100.00	100.00	100.00	100.00	100.00
All Segments	Domestic	84.08	85.01	86.06	86.71	87.62	85.90
	Foreign	15.92	14.99	13.94	13.29	12.38	14.10
	Total	100	100	100	100	100	100.00

The other important point to be noticed here is that in 2004, the share of foreign companies in one segment, Statins, was 1 percent only. In three other segments, Broncho Inhalant and Injection, Tuberculostatics ex and Antipeptic Ulcerant, the share of foreign companies ranged from 7 percent to 9 percent. By contrast, in Antihelmintic, Antileukemics and Antacid

Antiflatulents, share of foreign companies has been quite significant, being 42 percent to 47 percent. Out of these three segments, in Antileukemics, the share of foreign companies has come down drastically over the years, a decline from 45 percent to 13 percent. In Antihelmintic as well, the share of foreign companies has declined though the decline has been relatively less, from 42 per cent in 2004 to 38 per cent in 2008. Interestingly, in antacid antiflatulent, foreign companies seem to have faced stiff competition in 2004, but have been able to increase their share over the years from 47.36 per cent in 2004 to 58.77 per cent in 2008.

Thus, out of total 11 segments considered here for the analysis, in only one segment, namely antacid antiflatulent, the share of foreign companies has increased significantly after the product patent regime came into force. In contrast, in the segment, Antileukemics, where foreign companies had 45 percent share earlier; their share has declined to 13 per cent only in 2008.

7.4 Analysis of Market Share of Top Domestic and Foreign Companies

There are, in total 377, companies covered in the sample. Out of these, 31 are foreign companies. These foreign companies accounted for on an average 16.15 per cent of total sales in 2004 (in the eleven segments covered in the study). This share has been declining over the years from 16.15 per cent in 2004 to 12.46 percent in 2008. Interestingly, top five foreign companies, namely GlaxoSmithKline (GSK), Novartis, Abbott, Sanofi-aventis and Pfizer accounted for 75.17 percent of total foreign sales in 2004. This percentage has increased marginally to 75.86 percent of total foreign sales in 2008. On the other hand, share of top 10 foreign companies has declined marginally from 95.37 percent in 2004 to 94.29 per cent of foreign sales in 2008. But as a percent of total sales the percentage has declined from 15.19 per cent to 11.67 per cent in 2008. However, five companies, namely Glaxo, Novartis, Abbott, Sanofi Aventis and Pfizer has remained at rank I, II, III, IV and Vth ranks throughout the period of study. Among top 50 companies accounting for 86.93 per cent market share, only 9 have been foreign companies: Glaxo, Novartis, Abbott, Sanofi Aventis, Pfizer, Parke Davis, Wyeth, Wallace and Sandoz. Cipla, a domestic company, has been at the top throughout the period of study. Glaxo, a foreign company, has been at 4^{th} or 5^{th} position throughout the period

of study. Hence, the above analysis shows that even after product patents came into force, top companies whether domestic or foreign have maintained their position, in general, in the Indian pharmaceutical industry. The following section discusses in detail the shares of domestic and foreign companies at drug level within each segment to find an explanation for the decline in the overall share of foreign companies.

7.5 Analysis of Market Share of Domestic and Foreign Companies at Drug Level in Different Segments

In India, the new patent act providing for product patents has come into force since January 2005. In the previous regime, foreign companies have been hesitant to launch their patented products in India because of lack of product patent and risk of copying. But, it has been noticed in the sections above that share of foreign companies has declined in 8 segments out of the 11 segments considered. The segments in which the share of foreign companies has increased are Antacid, Muscle Relaxant and Statins. There can be several reasons for the decline in the market share of foreign companies given the complexity in which the pharmaceutical industry operates. One of the reasons may have to do with the government control on prices of some drugs assuming that control on prices of drugs has a role to play in the value of sales of companies. Thus the share of foreign companies may decline in those drugs and hence in the related segments which have been under price control. Its intensity may be different for different segments. Other possible reasons for the decline in the share of foreign companies may be connected with the introduction of new products and the differential growth of different molecules in the segments. An attempt is made in this section to analyse the trend in the share of domestic and foreign companies for major drugs in each segment to find out the reasons for decline in the share of foreign companies in each segment in the period 2004-2008.

Impact of Drug Price Control and Ceiling Price

As mentioned above, in India, price controls on certain drugs are carried out through drug price control orders (DPCO) by Ministry of Chemicals and Fertilisers with in the framework of Essential Commodities Act. There had been 347 drugs under price control under DPCO 1979 which were brought down to 142 in DPCO 1987. Under DPCO 1995 these have been brought

down further to 74 bulk drugs. Till present, these 74 drugs and all the formulations based on these 74 drugs are under price control (See Annexure 7.1). National Pharmaceutical Pricing Authority (NPPA) is an organization of the Government of India established to fix/ revise the prices of controlled bulk drugs and formulations and to enforce prices and availability of the medicines in the country, under the Drugs (Prices Control) Order, 1995. NPPA determines the ceiling prices for controlled bulk drugs in intra-industry transactions and the retail ceiling prices of controlled formulations from time to time. To examine the impact of these controls, an effort has been made to identify the drugs within each segment, which has been under price control. Then, the share of domestic and foreign companies has been compared for the controlled drug vis a vis other drugs out of price control in the same segment. If in a segment, there has been no drug under price control, then an effort has also been made to find out what could have been the probable reasons (other than price control) for the decline in the market share of foreign companies.

Antileukemic

With regard to Antileukemics segment, it may be noted that there have been in total six compounds: Capecitabine, Doxorubicin, Gefitinib, Hydroxycarbamide, Imatinib, Methotrexate, and one miscellaneous group (Table 7.5). None of these drugs has been under price control. It may be noted that this is the segment where the share of sales of foreign companies has come down drastically from 45 percent to 13 percent. Then, the reason for a massive decline in the share of foreign companies in this sector seems to lie in factors other than price control.

In 2004, Methotrexate had the maximum share of 52.71 percent and Doxorubicin, the next highest share of 10.40 percent. All other compounds had a share of less than 10 percent only. Surprisingly, the share of all the compounds except Doxorubicin and Methotrexate increased over the years. Share of both these compounds declined for domestic as well as foreign companies, the decline being sharpest for foreign companies in Methotrexate which had the large share of sales of foreign companies. Hence, the increase in the share of domestic companies has been contributed by Imatinib, Capecitabine and Gefitinib where foreign

companies were not there. Together the share of these three compounds increased from 6.57 percent in 2004 to 42.44 percent in 2008 in the sale of domestic companies.

Table 7.5: Share of Drugs in Antileukemic Segment, 2004-2008

DRUGS	2004	2005	2006	2007	2008
DOMESTIC					
CAPECITABINE	0.32	2.12	4.87	4.49	13.05
DOXORUBICIN	6.57	10.47	8.58	9.49	7.29
GEFITINIB	0.76	1.94	5.24	25.26	11.54
HYDROXYCARBAMIDE	3.70	3.34	3.42	1.85	4.35
IMATINIB	5.49	9.94	9.78	6.09	17.85
METHOTREXATE	27.55	26.90	24.58	18.33	16.09
OTH.ANTILEUKAEMICS	10.54	9.74	14.63	15.52	16.85
TOTAL DOMESTIC	54.92	64.45	71.10	81.04	87.02
FOREIGN					
DOXORUBICIN	3.83	3.24	3.12	2.73	1.60
GEFITINIB	0.00	0.00	0.21	2.06	0.63
METHOTREXATE	25.17	19.33	13.97	8.41	5.42
OTH.ANTILEUKAEMICS	16.08	12.98	11.61	5.77	5.34
TOTAL FOREIGN	45.08	35.55	28.90	18.96	12.98
TOTAL					
CAPECITABINE	0.32	2.12	4.87	4.49	13.05
DOXORUBICIN	10.40	13.72	11.70	12.22	8.88
GEFITINIB	0.76	1.94	5.45	27.32	12.17
HYDROXYCARBAMIDE	3.70	3.34	3.42	1.85	4.35
IMATINIB	5.49	9.94	9.78	6.09	17.85
METHOTREXATE	52.71	46.23	38.55	26.75	21.51
OTH.ANTILEUKAEMICS	26.62	22.72	26.23	21.29	22.19
TOTAL DOM + FOR	100.00	100.00	100.00	100.00	100.00

Thus, one of the reasons for decline in the share of foreign companies in antileukemic segment seems to be the introduction of new cost effective cancer drugs[67] by major Oncology[68] players in India, Gefitinib and Imatinib by Natco Pharma, Capecitabine by Nicholas Piramal and Dabur. Already existing players in Methotrexate drug have been domestic companies viz. IPCA labs, Sun Pharma, Zydus Cadila, Biochem and Cipla and only one foreign company Glaxo. In Doxorubicin, the major domestic companies have been Dabur and Sun Pharma and

[67] Also see "Indian Collaborations in Pharmaceuticals-A special emphasis on Anti Cancer Medication," Indo-Africa, Asian & GCC Pharma and health care conference, 1-2 Dec 2005, http://www.pharmexcil.com/V1/Docs/IndiaAfrica/Dr_P_Khadgapathi_Natco_Pharma14.pdf

[68] *Oncology* is the branch of medicine dealing with cancer.

only one foreign company, Pharmacia. Though there has been a rise in the number of cancer patients in India[69] foreign companies have not been in a position to capture their slice of the expanding market as the prices of multinational firms' drugs are much higher than those of domestic companies. Hence the main reason for the decline in the share of foreign companies in this segment seems to be the introduction of new, cost effective generic cancer drugs. This is explained in detail in Box 7.1.

Box 7.1: Supply of Cancer Drugs in India

Glivec tablet contains the active ingredient imatinib mesilate, a type of anti cancer medicine. It is used to treat a cancer of the blood cells called chronic myeloid leukemia and is also used to treat a rare cancer of the stomach and intestine. A month's therapy of Glivec costs Rs. 1.10 lakhs[70] as compared to Rs. 11,000 for a generic equivalent. A year's therapy with Gleevac costs $27000, compared with $2700 for a generic firm's imatinib product. In 1998, Novartis filed a patent application in India for a product patent on beta-crystalline form of imatinib mesylate (imatinib mesylate). As India did not recognize product patents for pharmaceuticals this patent application was to be examined only after 2005.

In 2003, Novartis obtained exclusive marketing right (EMR) for imatinib mesylate based on this patent application. By the time the EMR was granted, a number of Indian manufacturers, namely CIPLA, Ranbaxy, Sun and Natco had launched generic imatinib. Based on the EMR, Novartis obtained orders from the Madras High Court to stop several generic pharmaceutical companies from manufacturing generic versions of imatinib mesylate. Novartis obtained an injunction from the Madras high court, restraining six domestic firms from manufacturing imatinib but not Natco. The court order resulted in the reduction of the supply of generic versions from other companies, and hence, the share of Natco has increased significantly from 2004 to 2008 whereas share of other companies, for example, Sun pharma, Cipla, Ranbaxy declined. This explains the decline in the share of foreign companies in Antileulemics segment.

Further the antileukemic drug Capecitabine, manufactured by domestic companies only, had a small presence in 2004 with a share of 0.32 per cent only but increased to 13.05 per cent in 2008. In 2004 only two players had been there, Dabur and Ranbaxy. But later on other new players entered, Dr Reddy's, Shantha Biotech and Sun Pharma in 2005, Nicholas Piramal in 2006 and Wockhard in 2007, with Nicholas having the third highest share in domestic companies sales of Antikleukemic segment in 2008 with a share of 12.63 per cent. The reason for such a large share of capecitabline seems to be the significant improvement in overall survival by the addition of capecitabine to gemcitabine over gemcitabine alone in advanced pancreatic cancer with acceptable levels of toxicity.[71]

[69] Oncology market is valued at Rs. 100 crores with a gr rate of 20 %. http://www.pharmexcil.com/V1/Docs/IndiaAfrica/Dr_P_Khadgapathi_Natco_Pharma14.pdf

[70] http://timesof India, accessed on September 3, 2009.

[71] Gemcitabine and Capecitabine Improved Overall Survival in Patients with Advanced Pancreatic Cancer, ScienceDaily (Nov. 3, 2005) http://www.sciencedaily.com/releases/2005/11/051103080143.htm

Antipeptic Ulcerant

In antipeptic ulcerant segment, there have been 5 drugs: Esomeprozol, Omeprazol, Pantoprozol, Rabeprazol, and Ranitidine and the others group. It may be noted here that Ranitine drug is under the list of 74 drugs under price control. And, there have been a ceiling price of all formulations based on this drug. Within the domestic companies sales of this segment, in 2004, the share of Omeprazol and Pantoprozol have been more than that of Ranitidine (Table 7.6). Share of Ranitidine had remained constant till 2006 but with further revision in the ceiling price of Ranitidine drug since 21.03. 07[72], its share started declining since 2007 and declined to 13.39 per cent in 2008. But, the shares of other competing drugs in this segment that is, Pantoprazol and Rabeprazol increased significantly since 2004.

Share of foreign companies in this segment is small being 9.33 per cent in 2004 which declined further to 7.41 per cent in 2008. Foreign companies have been there in Ranitine drug mainly with a share of 8.63 per cent in 2004 which declined further to 5.50 percent in 2008. Share of other drugs, Esomeprozol, Pantoprozol and Rabeprazol though negligible in 2004 increased over the years, though the shares still remained small.

In Ranitine drug, Glaxo is the main foreign company but its share has declined over the years. Since Ranitidine is under price control, some companies entered in the drugs that have not been under price control and increased their share in the aggregate sales in the segment. For instance, Eisai Pharma launced Raberprazole in 2005 and Abbott launched Pantaprazole in 2006 and increased their share. Thus, it is found that drug price control or ceiling price do have an impact on the share of companies, resulting in the decline in the share of drug under price control. But, it affects the share of both domestic as well as foreign companies. As a result, sometimes, new players enter in other competing drugs that have been out of price control resulting in an increase of the share of drugs out of price control. Thus, while the share of Ranitidine has declined, this has adversely affected both domestic and foreign firms. The share

[72] National Pharmaceutical Pricing Authority: List of Price control Bulk Drugs, http://nppaindia.nic.in/bulkdruglist.html accessed on 31.08.09

of other drugs in the same segment has increased; both domestic and foreign firms have gained but the gain being more for domestic companies.

Table 7.6: Share of Drugs in Antipeptic Ulcerant Segment, 2004-2008

DRUGS	2004	2005	2006	2007	2008
DOMESTIC					
ESOMEPRAZOLE	5.29	5.97	5.28	4.87	4.53
OMEPRAZOLE	23.22	20.48	18.08	16.31	17.05
PANTOPRAZOLE	20.72	21.70	21.29	23.34	24.44
RABEPRAZOLE	11.97	16.04	20.11	22.44	24.76
RANITIDINE	16.92	16.53	16.94	15.68	13.39
OTHERS	12.56	11.15	10.82	9.65	8.42
TOTAL DOMESTIC	90.67	91.88	92.53	92.29	92.59
FOREIGN					
ESOMEPRAZOLE	0.00	0.00	0.01	0.34	0.41
OMEPRAZOLE	0.02	0.07	0.04	0.04	0.03
PANTOPRAZOLE	0.10	0.05	0.03	0.45	0.64
RABEPRAZOLE	0.04	0.10	0.64	0.77	0.71
RANITIDINE	8.63	7.51	6.49	5.92	5.50
OTHERS	0.54	0.39	0.26	0.18	0.13
TOTAL FOREIGN	9.33	8.12	7.47	7.71	7.41
TOTAL					
ESOMEPRAZOLE	5.29	5.97	5.29	5.21	4.94
OMEPRAZOLE	23.25	20.56	18.12	16.35	17.08
PANTOPRAZOLE	20.81	21.75	21.32	23.80	25.08
RABEPRAZOLE	12.01	16.14	20.75	23.21	25.47
RANITIDINE	25.54	24.04	23.43	21.61	18.89
OTHERS	13.09	11.54	11.08	9.83	8.55
TOTAL DOM + FOR	100.00	100.00	100.00	100.00	100.00

Antirheumetic

There are five drugs/compounds in this segment in the data set: Aceclofenac, Diclofenac, Etorecoxib, Ibuprofen and Nimesulid. Out of these five drugs, only one drug, namely Ibuprofen, has been under price control. The share of Ibuprofen has been declining gradually from 16.74 per cent in 2004 to 13.33 percent in 2008. Among drugs other than Ibuprofen, the share of two drugs, Aceclofenac and Diclofenac, has increased, whereas the shares of other

drugs has declined over the years. The increase in the share of Aceclofenac has been quite marked, from 1.81 percent in 2004 to 12.62 percent in 2008 (Table 7.7).

Table 7.7: Share of Drugs in Antirheumetic Segment, 2004-2008

DRUGS	2004	2005	2006	2007	2008
DOMESTIC					
ACECLOFENAC	1.81	6.91	11.62	12.51	12.46
DICLOFENAC	15.32	17.77	20.11	19.97	20.11
ETORECOXIB	5.47	7.67	5.95	5.25	4.47
IBUPROFEN	7.85	8.07	7.55	6.51	6.01
NIMESULIDE	20.47	21.78	20.95	20.01	19.48
OTHERS	27.45	16.37	13.07	14.75	17.18
TOTAL DOMESTIC	78.36	78.57	79.25	78.99	79.71
FOREIGN					
ACECLOFENAC	0.00	0.00	0.03	0.14	0.15
DICLOFENAC	7.72	8.42	8.01	8.51	8.61
IBUPROFEN	8.89	8.51	8.05	8.08	7.32
NIMESULIDE	0.10	0.08	0.07	0.05	0.04
OTHERS	4.93	4.41	4.60	4.23	4.16
TOTAL FOREIGN	21.64	21.43	20.75	21.01	20.29
TOTAL					
ACECLOFENAC	1.81	6.91	11.65	12.65	12.62
DICLOFENAC	23.04	26.19	28.11	28.47	28.72
ETORECOXIB	5.47	7.67	5.95	5.25	4.47
IBUPROFEN	16.74	16.58	15.60	14.59	13.33
NIMESULIDE	20.56	21.86	21.02	20.06	19.52
OTHERS	32.38	20.78	17.68	18.98	21.35
TOTAL DOM + FOR	100.00	100.00	100.00	100.00	100.00

With respect to sales for domestic companies also, the share of Ibuprofen has declined over the years. Among other drugs, the share of Aceclofenac and Diclofenac has increased with the increase for Acelofenac being large, from 1.81 per cent to 12.46 per cent in 2008 whereas share of other drugs has declined over the years. Foreign companies in this segment has mainly been operating in two drugs only: Diclofenac and Ibuprofen. Out of these, the share of Ibuprofen, the drug under price control, has declined marginally over the years whereas share of Diclofenac, which has been approximately the same as that of Ibuprofen in

2004, has increased marginally. Share of Nimesulide and other drugs has also declined over the years.

In anti-rheumatic segment, there have been many players within the domestic companies. But the major players have been Dr. Reddy's, IPCA Labs, Piramal health care, Alkem, Zydus Cadila, Intas, Aristo pharma, Sun Pharma, Cipla and Ranbaxy. Within the foreign companies, Novartis, Sanofi Aventis, Pfizer, and Abbott have been the main players throughout in this order of share accounting for 88.72 per cent of total foreign sales in this segment. This share has increased to 90.76 per cent in 2008. The analysis shows that the price control on a drug has caused the decline in the share of this drug for both the domestic and foreign companies. However, it seems that the share of foreign companies in this segment has declined only marginally because of all major well known foreign players have their brand name in this segment. On the other hand, the share of domestic companies increased because of launch of other most effective drugs by domestic companies. There are several other reasons for the observed trends in the shares of various drugs belonging to this segment, as drugs in this segment belong to non-steroidal anti-inflammatory drugs **(**NSAIDs). Further, the trend may also be traced to the different side effects of different drugs or the habit of medical doctors in prescribing a particular medicine. This has been explained in some detail in Box 7.2.

Box 7.2: Non-steroidal anti-inflammatory drugs – effectiveness and risks

In the Antirheumetic segment, Ibuprofen has been under price control. Though price control does have an impact on the share of a drug, other factors also seem to be important. Therefore, an overview of drugs belonging to this segment, based on reports cited on various sites, might be useful in understanding the trend in the share of drugs. All drugs of this segment, Acelofenac, Diclofenac, Etorecoxib, Ibuprofen and Nimesulide, belong to non-steroidal anti-inflammatory drugs **(**NSAID)[73]. NSAIDs are used in the treatment of pain, fever and inflammation, occurring alone or in any combination. All NSAIDs have analgesic, antipyretic and anti-inflammatory effect. However the potency and the price of the various NSAIDs vary. Pain and fever being the most common problems, these drugs are in great demand and are often sold as Over-The-Counter (OTC) products.

[73] Non-steroidal means they are not steroids, which often have similar effects. As analgesics, NSAIDs are generally non-narcotic (do not cause insensibility). The NSAID market is growing at the rate of 20% per annum and its size is about Rs 2700 crores (Source: IMS ORG June MAT '07).

(Box 7.2 continued)

Benefit/risk profile of Nimesulide has been mentioned to be controversial. Nimesulide is, like most NSAIDs, not indicated in children. In response to a Report, Alembic Ltd.in 2003 asked wholesalers and retailers to withdraw all stocks of Nimegesic Drops (a pediatric dosage form of nimesulide). But in India, the marketers of Nimesulide were unwilling to acknowledge any of its side effects. The prescription of this drug by doctors to children below 12 years of age continued. The marketers of Nimesulide alleged that since Nimesulide is taking the market share for analgesics away from Paracetamol and Ibuprofen, the marketers of Paracetamol and Ibuprofen have been engaging themselves in misrepresenting Nimesulide.

Diclofenac originated from Novartis (Ciba-Geigy earlier) in 1973. It has been marketed in India for more than 15 years and it is widely used for pain management[74]. There have been certain risk factors associated with the use of this drug. Therefore it has been advised to be used only as prescribed by Doctors.

Ibuprofen was derived during 1960 and was patented in 1961 by Boots Company, UK. In 1969 it was launched as a medication for the treatment of rheumatoid arthritis in the UK and in 1974 in USA. The World Health Organization (WHO) includes ibuprofen in its "Essential Drugs List"; a list of minimal medical needs for a basic health care system.

In case of Etorecoxib belonging to celecoxib[75] group, Pfizer linked celecoxib to a risk of heart attacks. Therefore, doctors as precaution reverted to the traditional and tested anti-inflammatory drugs in the same family Therefore, In India, drug companies started coming out with improved versions of the drug molecule, resulting in the decline of celecoxib market.

Aceclofenac is assumed to be superior to other NSAIDs with high efficacy like traditional NSAIDs, but no adverse cardiovascular effects. The combination of aceclofenac, paracetamol and chlorzoxazone is emerging as one of the widely prescribed combination in single dosage form.

These facts about the drugs belonging to this segment illustrate the impact of factors other than price control on the trend in the share of different drugs.

Source: Various Websites

Broncho-dilator Inhalant and Injection

In the Broncho-dilator Inhalant and Injection segment, two drugs, namely Salbutamol and Etophylline, have been under price control. The share of Salbutamol drug is the highest in this segment, being 42.93 percent in 2004. By contrast, the share of Etophylline drug is the lowest,

[74] See: http://www.drugs.com/diclofenac.html

[75] Celecoxib is an estimated Rs 13 crore market in India and Zydus Cadila, Sun, Lupin, Unichem and Cipla are some of the companies that produced the drug locally.
http://www.hinduonnet.com/thehindu/thscrip/print.pl?file=2004122103280300.htm&date=2004/12/21/&prd=bl&

being 3.17 per cent only in 2004 (Table 7.8). Share of Salbutamol has declined for domestic as well as foreign companies. Share of Etophylline drug has also declined for domestic companies; foreign companies have not been there in this drug. However, the share of all other drugs in this segment has increased over the years for domestic companies but not for foreign companies whose share in this segment is very low being 7.17 per cent only in 2004, which declined further to 2.75 per cent in 2008

Table 7.8: Share of Drugs in Broncho-dilator Inhalant and Injection, 2004-2008

DRUGS	2004	2005	2006	2007	2008
DOMESTIC					
BUDESONIDE	6.75	6.33	6.38	6.44	6.60
ETOPHYLLINE	3.17	3.12	3.64	3.55	2.85
FORMOTERAL	11.74	13.19	14.43	15.30	16.02
SALBUTAMOL	40.43	38.79	37.84	35.23	34.66
SALMETEROL	19.46	21.72	21.32	21.55	21.38
OTHERS	11.28	11.65	11.87	13.78	15.72
TOTAL DOMESTIC	92.83	94.81	95.48	95.85	97.25
FOREIGN					
BUDESONIDE	0.65	0.47	0.38	0.26	0.18
FORMOTERAL	0.35	0.06	0.03	0.11	0.08
SALBUTAMOL	2.49	1.82	1.67	1.44	0.75
SALMETEROL	2.55	2.03	1.85	2.02	1.62
OTHERS	1.12	0.82	0.59	0.33	0.12
TOTAL FOREIGN	7.17	5.19	4.52	4.15	2.75
TOTAL					
BUDESONIDE	7.41	6.80	6.76	6.70	6.78
ETOPHYLLINE	3.17	3.12	3.64	3.55	2.85
FORMOTERAL	12.10	13.25	14.45	15.41	16.10
SALBUTAMOL	42.93	40.61	39.51	36.67	35.41
SALMETEROL	22.01	23.75	23.17	23.56	23.00
OTHERS	12.40	12.47	12.46	14.11	15.85
TOTAL DOM + FOR	100.00	100.00	100.00	100.00	100.00

It may be noted here that in Salbutamol, Cipla has been the main player among the domestic companies with a share of 96 per cent in 2004 out of total sales of domestic companies, which has declined to 90 per cent in 2008. Glaxo has been the main player among

foreign companies, having a share of 86 per cent in 2004 out of total sales of foreign companies, which has not declined much probably because of brand name.

Hence, in this segment, price control on major drugs has affected the share of both the domestic companies and foreign companies, but because of the increase in the share of other competing drugs in the case of domestic companies, the share of domestic companies in overall sales in the segment has increased whereas that of foreign companies has declined.

Broncho-dilators Solids and Liquids

In this segment, the drug Ephedrine has been under price control. Further for all the formulations based on this drug there have been a ceiling price which has been revised for Ephedrine resinate since 21.12.94 and Ephedrine HCL since 21.3.07. Share of this drug has declined over the years for both domestic as well as foreign companies (Table 7.9). As noted above, Salbutamol and Etophylline, are also under price control. Foreign players do not have presence in Etophylline, and relatively a smaller share in the sales of Salbutamol than domestic firms. The share of both Salbutamol and Etophylline in total sales of Broncho-dilator Solids and Liquids has fallen.

The overall conclusion that may be drawn is that the market share of domestic companies in the segment has increased and that of foreign companies has declined over the years. It is also seen that drug price control has led to a fall in the shares of drugs under price control for both the domestic as well as foreign companies. But, at the aggregate level, the share of domestic companies has increased because of the increase in the share of other competing drugs that have been out of purview of price control.

Table 7.9: Share of Drugs in Broncho Solids and Liquids, 2004-2008

DRUGS	2004	2005	2006	2007	2008
DOMESTIC					
AMINOPHYLLINE & COMB.	0.00	0.00	0.00	0.16	0.73
AYURVEDIC	0.58	0.48	0.42	0.25	0.30
BAMBUTEROL	1.27	0.89	0.76	0.62	0.48
BROMHEXINE	0.88	0.77	0.72	0.80	0.81
CARBOCISTEINE	0.37	0.32	0.30	0.25	0.22
EPHEDRINE	3.86	3.25	2.62	2.39	2.24
ETOPHYLLINE COMB.	10.45	11.06	12.01	11.11	9.46
MONTELUKAST COMB.	11.95	13.12	13.80	15.11	16.09
SALBUTAMOL COMB.	38.34	38.38	37.58	36.62	35.60
TERBUTALINE COMB.	1.04	1.22	1.25	1.18	1.55
THEOPHYLLINE COMB.	10.66	12.14	11.65	9.78	7.63
OTHERS	3.34	3.96	6.13	11.09	15.73
TOTAL DOMESTIC	82.74	85.61	87.23	89.36	90.82
FOREIGN					
AYURVEDIC	0.05	0.04	0.01	0.00	0.00
BAMBUTEROL	0.36	0.27	0.18	0.12	0.11
BROMHEXINE COMB.	0.01	0.04	0.05	0.03	0.02
EPHEDRINE COMB.	2.93	2.60	2.08	1.70	1.56
MONTELUKAST COMB.	0.18	0.06	0.00	0.00	0.00
SALBUTAMOL COMB.	6.82	4.67	4.91	4.57	3.98
TERBUTALINE COMB.	3.46	3.45	2.60	2.30	2.06
THEOPHYLLINE COMB.	2.36	2.12	1.84	1.19	0.86
OTHERS	1.09	1.14	1.10	0.74	0.59
TOTAL FOREIGN	17.26	14.39	12.77	10.64	9.18
TOTAL					
AMINOPHYLLINE & COMB.	0.00	0.00	0.00	0.16	0.73
AYURVEDIC	0.63	0.52	0.43	0.25	0.30
BAMBUTEROL	1.62	1.15	0.93	0.74	0.59
BROMHEXINE	0.90	0.82	0.77	0.82	0.84
CARBOCISTEINE	0.37	0.32	0.30	0.25	0.22
EPHEDRINE	6.79	5.85	4.70	4.09	3.80
ETOPHYLLINE COMB.	10.45	11.06	12.01	11.11	9.46
MONTELUKAST COMB.	12.13	13.19	13.80	15.11	16.09
SALBUTAMOL COMB.	45.16	43.05	42.49	41.19	39.57
TERBUTALINE COMB.	4.50	4.67	3.85	3.48	3.61
THEOPHYLLINE COMB.	13.02	14.26	13.49	10.98	8.48
OTHERS	4.42	5.10	7.23	11.83	16.32
TOTAL DOM + FOR	100.00	100.00	100.00	100.00	100.00

Cephalosporins

In this segment, there are six drugs including a miscellaneous group. Out of these, two drugs, Cefadroxyl and Cefotaxime, have been under price control and for all formulations based on this drug there have been a ceiling price, which has been revised since 21.3.07. Shares of both these drugs have declined over the years. In Cefotaxime, foreign companies have not been there, and the share of domestic companies has declined from 9.74 per cent in 2004 to 6.80 percent in 2008 (Table 7.10). In Cefadroxyl, share of foreign companies is very small, being 0.38 percent only as against the relatively larger share of domestic companies at 10.77 per cent in 2004, and the shares of both domestic as well as foreign companies have declined over the years.

Share of all other compounds in this segment, except cefixime, has declined[76] over the years. Cefixime had a share of 16.80 percent in 2004 and it has increased to 25.24 percent in 2008. Share of foreign companies in this compound is very small, being 0.53 percent, which declined to 0.21 percent in 2008. Since Cefixime belongs to 3rd generation Cephalosporins that are considered to be more effective than preceding generation Cephalosporins, it seems that some companies started launching these new generation compounds and captured the market. To give an example, Alembic company launched Cefixime in 2006 and had the largest share 20.50 per cent in the launch year out of the total sales of cephalosporin segment and increased its share to 37 per cent in 2008. On the other hand, Alkem had the largest share of cefotaxime out of total cephalosporin segment, 43.51 percent in 2004, which declined to 32.22 per cent in 2008. Cefotaxime is a parental cephalosporin belonging to 3rd generation.

[76] The 'others' group had a share of 24.40 per cent in 2004 out of total sales of Cephalosporins. The compounds belonging to the 'others' group have not been clearly specified in the data set. And, this group's share has increased to 35.27 per cent in 2008. The market share of foreign companies has, however, declined over the years in this case too.

Table 7.10: Share of Drugs in Cephalosporins Segment, 2004-2008

DRUGS	2004	2005	2006	2007	2008
DOMESTIC					
CEFADROXIL	10.77	9.51	8.19	7.11	6.21
CEFIXIME	16.27	19.36	22.70	25.35	25.03
CEFOTAXIME	9.74	8.74	7.93	7.26	6.80
CEFTRIAXONE	15.40	14.90	13.53	11.49	11.41
CEFUROXIME	5.67	5.16	4.98	5.32	5.70
CEPHALEXIN	8.16	7.29	5.80	4.74	4.24
OTHERS	20.37	22.68	26.18	29.17	32.03
TOTAL DOMESTIC	86.38	87.64	89.31	90.44	91.43
FOREIGN					
CEFADROXIL	0.38	0.22	0.22	0.09	0.01
CEFIXIME	0.53	0.32	0.27	0.21	0.21
CEFOTAXIME	0.00	0.00	0.00	0.00	0.00
CEFTRIAXONE	0.43	0.29	0.21	0.15	0.16
CEFUROXIME	4.07	3.54	3.08	2.94	2.51
CEPHALEXIN	4.19	3.91	3.37	2.88	2.44
OTHERS	4.02	4.08	3.54	3.29	3.24
TOTAL FOREIGN	13.62	12.36	10.69	9.56	8.57
TOTAL					
CEFADROXIL	11.15	9.73	8.41	7.20	6.22
CEFIXIME	16.80	19.68	22.97	25.56	25.24
CEFOTAXIME	9.74	8.74	7.93	7.26	6.80
CEFTRIAXONE	15.83	15.20	13.74	11.64	11.58
CEFUROXIME	9.73	8.70	8.06	8.26	8.21
CEPHALEXIN	12.35	11.20	9.17	7.62	6.68
OTHERS	24.40	26.76	29.72	32.47	35.27
TOTAL DOM + FOR	100.00	100.00	100.00	100.00	100.00

Hence, in this segment as well, it is noticed that drug price control has affected the market share of two drugs. Adverse effect is observed for both for the domestic companies as well as foreign companies. But, because of launch of other competing generic drugs by domestic companies, which helped in capturing a slice of the market of this segment, the share of domestic companies has increased whereas that of foreign companies has declined.

Antihelmintic

In Antihelmintic segment, there are five drugs and a miscellaneous group, namely, Albendazole, Levamisol, Mebendazole, Piperazine, Pyrental Pamoate and other antihelmintic combinations. Out of the total sales of domestic companies in the segment in 2004, Albendazole had the largest share of 34.76 percent, followed by Mebendazole, 11.98 percent, Pyrental Pamoate 5.22 percent, other combinations 3.26 percent and Levamisol, 3.11 percent (Table 7.11). Pyrental Pamoate has been under price control. Over the years, the share of Pyrental has declined, and so have the shares of all the drugs except the category 'other antihelmintic combinations' which has contributed to the overall increase in the share of domestic companies in this segment from 58.33 per cent in 2004 to 61.66 percent in 2008. Within the set of domestic companies, there have been many domestic players with Cipla having the largest average share of 14.79 per cent out of a total share of 58.33 per cent in 2004 of domestic companies. There has been a stiff competition within the domestic companies in this segment. Albendazole, though a market leader in this segment, has had a high price[77] and this is possibly the reason why the sales and market share of 'other antihelmintic combinations' group has increased over the years.

The share of foreign companies has declined from 41.67 percent in 2004 to 38.34 percent in 2008. It may be noted here that foreign companies in this segment have mainly been there in only one drug, namely Albendazole. The share of Albendazole has, however, increased from 30.76 percent in 2004 to 31.50 percent in 2008. That too has been captured by the Glaxo which has increased its share from 28.60 percent in 2004 to 30.88 percent in 2008.

[77] See The Times of India, 19 May 2008, http://timesofindia.indiatimes.com/NEWS/Business/India-Business/Key-drug-prices-hit-the-roof-govt-in-a-fix/articleshow/3051593.cms
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Table 7.11: Share of Drugs in Antihelmintic Segment, 2004-2008

DRUGS	2004	2005	2006	2007	2008
DOMESTIC					
ALBENDAZOLE	34.76	34.03	33.12	32.52	32.62
LEVAMISOL	3.11	3.14	2.40	2.39	2.15
MEBENDAZOLE	11.98	11.75	11.82	10.56	9.94
PIPERAZINE	0.01	0.02	0.03	0.02	0.02
PYRENTAL PAMOATE	5.22	4.77	5.01	4.30	4.21
ANTIHELMINTIC, OTH. & COMB	3.26	3.27	7.20	11.75	12.74
TOTAL DOMESTIC	58.33	56.98	59.59	61.55	61.66
FOREIGN					
ALBENDAZOLE	30.76	32.02	31.28	30.99	31.50
LEVAMISOL	4.32	4.65	4.35	3.34	2.61
MEBENDAZOLE	0.64	0.57	0.24	0.00	0.00
PIPERAZINE	5.60	5.41	4.19	3.83	3.90
PYRENTAL PAMOATE	0.00	0.00	0.01	0.01	0.01
ANTIHELMINTIC, OTH. & COMB	0.35	0.37	0.34	0.29	0.32
TOTAL FOREIGN	41.67	43.02	40.41	38.45	38.34
TOTAL					
ALBENDAZOLE	65.52	66.04	64.40	63.51	64.11
LEVAMISOL	7.43	7.79	6.75	5.73	4.76
MEBENDAZOLE	12.62	12.32	12.06	10.56	9.94
PIPERAZINE	5.61	5.43	4.22	3.84	3.91
PYRENTAL PAMOATE	5.22	4.78	5.02	4.31	4.22
ANTIHELMINTIC, OTH. & COMB	3.60	3.64	7.54	12.05	13.06
TOTAL DOM + FOR	100.00	100.00	100.00	100.00	100.00

In part, this may be attributed to the brand name of the foreign company that has a dominant position in the segment. It will be noticed further that while the overall share of Albendazole has declined, and there has been a decline in respect of this drug for domestic companies, the foreign companies have not suffered any set back. The domestic companies have been able to off-set the fall in the market shares of Albendazole, Levamisol, Mebendazole and pyrental pamoate through an increase in the sales of 'other antihelmintic combinations'.

Muscle Relaxant

There have been five compounds in this segment: Baclofen, Chlormezanone, Chlorzoxa, Methocarbamol and Tizanidine, and one others group. Among these, no drug seems to be under price control. It may be noted that this is one of those three segments where the share of foreign companies has increased between 2004 and 2008. In 2004, Chlorzoxa had the maximum share of 41.39 per cent, followed by Tizanidine, 21.08 per cent and 'others' group, 10.61 per cent in the sales of domestic companies. Rest of the compounds had a share of less than 10 per cent (Table 7.12). Decline in the share of domestic companies seems to have occurred because of decline mainly in the share of two compounds, Chlorzoxa and Tizanidine. Similarly in the case of sales of foreign companies as well the share of these compounds has declined. But, it appears that since the share of some other compounds in this segment has increased for domestic as well as foreign companies, the increase being the larger for foreign companies, the share of foreign companies have increased in this segment. Further, the increase in the share of foreign companies seems to be due to launch of some other compounds continuously since 2004 by Sanofi Aventis which increased its share from 0.48 per cent in 2004 to 10.68 per cent in 2008, the maximum by any company in this segment in 2008.

Table 7.12: Share of Drugs in Muscle Relaxant Segment, 2004-2008

DRUGS	2004	2005	2006	2007	2008
DOMESTIC					
BACLOFEN & COMB	2.93	3.36	3.26	3.41	3.84
CHLORMEZANONE & COMB.	3.93	4.46	4.62	4.18	3.69
CHLORZOXA & COMB.	41.39	43.75	48.04	47.57	38.90
METHOCARBAMOL & COMB.	4.81	4.64	4.28	4.06	4.24
TIZANIDINE & COMB.	21.08	18.43	18.78	15.98	14.49
OTHERS	10.61	6.81	3.59	6.02	13.63
TOTAL DOMESTIC	84.76	81.46	82.58	81.21	78.79
FOREIGN					
BACLOFEN & COMB	3.94	3.64	3.37	3.81	4.01
CHLORMEZANONE & COMB.	0.03	0.17	0.13	0.13	0.08
CHLORZOXA & COMB.	2.32	2.02	1.44	1.16	0.87
TIZANIDINE & COMB.	6.24	6.63	5.39	4.32	2.88
OTHERS	2.72	6.08	7.09	9.37	13.37
TOTAL FOREIGN	15.24	18.54	17.42	18.79	21.21
TOTAL					
BACLOFEN & COMB	6.87	7.00	6.63	7.21	7.85
CHLORMEZANONE & COMB.	3.95	4.63	4.76	4.30	3.77
CHLORZOXA & COMB.	43.70	45.77	49.48	48.73	39.78
METHOCARBAMOL & COMB.	4.81	4.64	4.28	4.06	4.24
TIZANIDINE & COMB.	27.32	25.07	24.18	20.30	17.36
OTHERS	13.33	12.90	10.68	15.39	27.00
TOTAL DOM + FOR	100.00	100.00	100.00	100.00	100.00

Statins

In this segment, the share of foreign companies was very low at 0.61 percent in 2004 and has increased marginally to 1.15 per cent in 2008. The marginal presence of foreign companies has been in the Atorvastatin drug only, out of three drugs belonging to this segment: Atorvastatin, Rosuvastatin and Simvastatin. Increase in the share of Atorvastatin from a share of 0.61 per cent only in 2004 to a share of 1.08 per cent in 2008 has led to an increase in the share of foreign companies in this segment. Domestic companies with a share of 99.39 per cent in 2004 have had a decline their share marginally to 98.85 per cent in 2008. In 2004, the share of

Atorvastatin was the highest at 69.81 percent followed by Simvastatin, 18.26 percent and Rosuvastatin, 8.32 percent only[78] (Table 7.13). The share of Atorvastatin has increased significantly over the years to 86.48 per cent whereas that of other two drugs has declined, the decline being much larger for Simvastatin.

Table 7.13: Share of Drugs in Statins Segment, 2004-2008

DRUG	2004	2005	2006	2007	2008
DOMESTIC					
ATORVASTATIN	69.81	77.67	82.65	84.93	86.48
ROSUVASTATIN	8.32	6.28	4.41	3.34	3.11
SIMVASTATIN	18.26	12.32	8.76	6.30	5.15
OTHERS	2.99	3.41	3.53	4.22	4.11
TOTAL DOMESTIC	99.39	99.67	99.35	98.79	98.85
FOREIGN					
ATORVASTATIN	0.61	0.33	0.65	1.19	1.08
OTHERS	0.00	0.00	0.00	0.02	0.07
TOTAL FOREIGN	0.61	0.33	0.65	1.21	1.15
TOTAL					
ATORVASTATIN	70.42	78.00	83.30	86.13	87.56
ROSUVASTATIN	8.32	6.28	4.41	3.34	3.11
SIMVASTATIN	18.26	12.32	8.76	6.30	5.15
OTHERS	2.99	3.41	3.53	4.24	4.18
TOTAL DOM + FOR	100.00	100.00	100.00	100.00	100.00

Share of Atorvastatin seems to have been the highest because it has been found to be more effective than other drugs without increasing adverse effects[79]. Statins vary in cost from $32 to $150 a month in the USA. Generics have been recommended as being cost-efficient alternatives to more expensive branded drugs, for those to whom it is suitable.[80] Hence, in India, domestic generic companies seem to have a monopoly because of the low cost of the drug. Because worldwide statin market is of about $20 billion with a growth of 30 per cent annually[81], Indian pharmaceutical companies are thronging the statin market creating competition within the domestic companies in India. Under these circumstances, foreign

[78] There is also an 'others' category with a small share. It was 2.99 percent in 2004, which increased over the years to 4.18 per cent.
[79] Jones, Kafonek, Laurora and Hunninghake D (1998). doi:10.1016/S0002-9149(97)00965-X. PMID 9514454.
[80] See http://en.wikipedia.org/wiki/Statin
[81] http://www.pharmabiz.com/article/detnews.asp?articleid=24139&sectionid=50

companies having a very low share in the domestic market of stains is not surprising and this also explains why foreing firms have not been able to raise their market share in recent years despite the new patent act imposing product patents.

Tuberculostatics Ex

In this segment, total sales have declined over the years. Growth rate of sales of all companies taken together has been negative at -1.58 percent per annum during 2004 to 2008. It has been negative for both the domestic as well as foreign companies though the decline has been much larger for foreign companies being -6.80 percent per annum. Negative growth for this segment seems to have occurred because of the successful implementation of Revised National Tuberculosis Control Programme (RNTCP) for over ten years.[82] As a result of this programme, TB mortality in the country has reduced from an estimated 42/lakh population in 1990 to 28/lakh population in 2006, and prevalence of TB in the country has reduced from 568/lakh population in 1990 to 299/lakh population by the year 2006.

Therefore, before analyzing the trends in market shares of this segment, a brief overview about the treatment of tuberculosis will provide a useful insight for the analysis. Treatment of Tuberculosis is very complex one though anti-TB treatment can cure all patients. This is so because the treatment has to be uninterrupted and taken for the prescribed duration. In India, to meet this objective, Revised National Tuberculosis Control Programme (RNTCP) has been framed. This programme is a comprehensive package for TB control for implementing the DOTS (Directly Observed Treatment, Short-Course) strategy along with other components of stop TB strategy. In India, DOTS strategy is cost-effective and is the international standard for TB control programme. But those unwilling to participate in DOTS are offered different drug regimens depending on the type of TB (Category I, II or III) and its characteristics. Various regimens of anti-TB drugs consists of the following drugs: Streptomycin (S), Para-amino salicyclic acid (P), Isoniazid (H), Thiacetazone (T), Ethambutol (E), Rifampicin (R) and Pyrazinamide (Z). Out of these, the dataset used for this study shows

[82] For details see: TB India 2009, RNTCP Status Report, Central TB Division, Directorate General of Health Services, Ministry of Health and Family Welfare, Nirman Bhawan, New Delhi-110011, http://www.tbcindia.org

the sales figures for Ethambutol, Pyrazinamide, RH (Rifampicin and Isoniazid), RHEZ (Rifampicin, Isoniazid, Ethambutol and Pyrazinamide) and RHEZ Kits.

Table 7.14: Share of Drugs in TUBERCULOSTATICS EX Segment, 2004-2008

DRUG	2004	2005	2006	2007	2008
DOMESTIC					
ETHAMBUTOL	9.35	8.40	7.93	7.82	7.85
PYRAZINAMIDE	5.16	5.43	5.16	5.18	5.98
RH	18.20	17.81	16.76	15.96	15.38
RHEZ	38.02	40.25	41.97	42.30	42.42
RHEZ KITS	9.36	9.29	9.32	9.36	8.96
OTHERS	10.97	11.07	11.13	11.90	12.29
TOTAL DOMESTIC	91.07	92.26	92.27	92.52	92.87
FOREIGN					
ETHAMBUTOL	0.09	0.07	0.04	0.01	0.01
PYRAZINAMIDE	2.19	1.99	2.05	2.61	2.36
RH	2.22	2.02	2.11	1.88	1.98
RHEZ	2.27	1.58	1.46	1.20	1.21
RHEZ KITS	0.76	0.63	0.64	0.64	0.63
OTHERS	1.40	1.44	1.44	1.14	0.93
TOTAL FOREIGN	8.93	7.74	7.73	7.48	7.13
TOTAL					
ETHAMBUTOL	9.44	8.47	7.97	7.83	7.87
PYRAZINAMIDE	7.35	7.42	7.20	7.79	8.35
RH	20.42	19.84	18.87	17.84	17.36
RHEZ	40.30	41.83	43.43	43.49	43.63
RHEZ KITS	10.13	9.92	9.96	10.00	9.58
OTHERS	12.37	12.52	12.57	13.05	13.22
TOTAL DOM + FOR	100.00	100.00	100.00	100.00	100.00

Rifampicin is a bactericidal antibiotic drug used in the treatment of tuberculosis. It was introduced in 1967 as a major addition to the cocktail-drug treatment of tuberculosis along with isoniazid, ethambutol, and streptomycin. This drug is used in combination with other drugs. For example, in India, R-Cinex 600 by Lupin, the largest manufacturer of antituberculostic drugs, is a combination of Rifampicin and Isoniazid. Rifampicin has been under price control in India. But despite this, the marker share of largest manufacturer, Lupin lab, has increased over the years. Next comes Macleods Pharma, whose share has also increased. Hence,

domestic companies in this segment seem to have significant market domination. In consequence, despite the drug Rifampicin being under price control, the share of domestic companies has increased in this segment. Given the complexity in the treatment of TB, drug wise analysis seems to be less relevant. However, Table 7.14 shows the share of different drugs in this segment. It may be noticed that the share of foreign companies is low and it has not increased between 2004 and 2008

Antacid Antiflatulents

The dataset used for the analysis does not mention the name of the molecules/drugs in this segment. However, if one considers total sales of foreign and domestic firms in this segment, one will find that the share of foreign firms has increased during 2004-08. As Table 7.4 shows, the share of foreign companies increased from 47 percent in 2004 to 59 percent in 2008.

Out of the top 5 companies in this segment, in 2004, three were foreign (Table 7.15). All these three companies increased their market share between 2004 and 2008. These companies, Abbott, Parke Davis and Wyeth became the three top companies in the segment in 2008 with a combined share of about 51 percent, up from a share of 41 percent in 2004. The next two were domestic companies, Himalaya Drug and Alembic, with a combined share of 16 percent in 2008 (down from a combined share of 24 percent in 2004). The rising share of the three foreign companies seems to be attributable largely to their branded products in India.

Table 7.15: Share of Top Five Companies in Antacid Antiflatulents Segment

TOP FIVE COMPANIES IN 2004			TOP FIVE COMPANIES IN 2008		
Type	**Company**	**Share**	**Type**	**Company**	**Share**
Foreign	ABBOTT	19.82	Foreign	ABBOTT	22.60
Domestic	ALEMBIC	13.74	Foreign	PARKE DAVIS	18.46
Foreign	PARKE DAVIS	12.06	Foreign	WYETH LIMITED	10.39
Domestic	HIMALAYA DRUG	10.03	Domestic	HIMALAYA DRUG	10.16
Foreign	WYETH LIMITED	8.96	Domestic	ALEMBIC	5.81
	TOTAL	64.61		TOTAL	67.42

7.6 Main Findings

The new patent act has enforced product patents in India from 2005. However, despite this major change in the patent regime, the market share of foreign companies has declined during 2004-08 in eight of the eleven segments analysed in this study. The exceptions are Antacid Antiflatulents, Muscle Relaxant and Statins. Among these in one segment, namely Antacid Antiflatulent, the share of foreign firms has been substantial which increased further. In case of Statins, the share of foreign firms has, however, been negligible only. Foreign firms have been able to increase their market share in Antacid Antiflatulents. But, this is not because of the product patent regime. It seems to be primarily caused by the brand name of the products sold by leading foreign companies in this segment.

The analysis reveals that drug price control does have an impact on the market shares. The market share of the drugs under price control tends to get reduced over time, though there are exceptions. However, price control tends to reduce the market shares of both domestic and foreign companies, and this factor by itself should not definitely cause the relative share of foreign companies to decline. At the same time, it needs to be noted that in certain ways,

domestic companies are able to off-set to some extent the adverse effect of price control on their market share. By increasing the sales of other low cost generic drugs or by introducing new products within the same segment, the domestic companies are able to increase their market share at the aggregate level of segments. Another important finding which has come out of the above analysis is that though the share of foreign companies as a group has declined, the shares of major foreign companies have increased in general because their branded products are well known and accepted in the market and help them raise their share in the Indian market.

The main reason why the new patent regime has not seen an increase in the market share of foreign companies is that the existing foreign companies have mostly been operating in the generic segments only where the domestic companies dominate. Relaxation of drug price controls and provisions of the Indian product patent Act 2005 has made Indian market favourable to the launching of patented drugs. But, foreign companies have not yet launched their patented products in India.[83] This is indicated by newspaper reports: (a) "MNCs fail to launch patented drugs in India" mentioned in the Business Standard of January 1, 2007. [84] This report notes that none of the major foreign companies have launched their patented products in India even after 21 months of product patent regime but they have launched the original brands of already existing Indian Generics; (b). "MNC pharmas firms told to launch latest drugs in India" mentioned in The Economic Times of September 29, 2008. According to this report, most of the MNCs pharma companies have stopped launching latest products in India after 1995 though they have been introducing them in other parts of the world. The reason mentioned for this is the grant of marketing approval of the same patented drug to a generic manufacturer by Drug Controller General of India. Interestingly, even though the MNCs have not been launching their latest drugs, many new foreign players have entered in the Indian domestic market (Bristol Myers Squibb, Boehringer ingelheim and Eisai (Source: Richard Gerster-Report on Indian Pharmaceutical Industry).

There are a number of other reasons for the increasing market share of domestic companies. First, the performance of the domestic drug companies has been driven by increased penetration to smaller towns and villages by domestic pharmaceutical companies

[83] This aspect has been discussed earlier in Chapter 4. It was noted that only a small portion of the new patented drugs launched globally during 1995-2003 were subsequently launched in India,and that there was a downward trend in the launching of new patented drugs in India.
[84] Business Standard, January 1, 2007

with a deep trenched distribution network (ORG-IMS). Indian firms have tied up with the foreign companies to manufacture in-license drugs. For instance, Dr Reddy's has a license from Merck & Co. to sell simvastatin as an authorized generic drug. Secondly, significant foreign investment has taken place in the drugs and pharmaceutical industry mainly to aid the growth of contract research and manufacturing in the country. As a result of this opportunity, domestic companies seems to have gained by learning by doing and have increased their competitiveness and hence sales in the process. Thirdly, a number of patented drugs have gone off-patent in recent years and their generic versions have been manufactured by Indian companies.

Chapter 8

Impact of the new patent regime on public health in India[85]

8.1 Introduction

Patents are essentially legal instruments for protecting intellectual property rights, and confer to an inventor the sole right to exclude others from economically exploiting the innovation for a stipulated time. From an economic point of view, patents offer a second-best solution to the market failure arising from the public good nature of knowledge. Thus, while patents have been devised to create incentives for innovations and R & D, its very design creates "market power positions that can adversely affect the economic performance of the system" (Langinier and Moschini 2002). This feature of the patents system has been the reason why so much discourse, discussions and debates have arisen around the effect of patents on the health system and health outcomes in especially developing country.

The role of science and technology in improving health conditions has been remarkable, especially in the recent past, with a variety of new and improved drugs as well as technology to detect as well as treat health conditions. The need to make quality health care available, accessible and affordable to those who need it the most continues to be the main aim of a well-functioning health system. In this context, patents are seen as a tool to further this objective of the health sector. According to the World Intellectual Property Organisation[86] (WIPO) "the patent system is designed to promote innovation and, at the same time, offer a mechanism ensuring that the fruits of that innovation are accessible to society. In the contexts of public health, the challenge for policy makers is to find an optimal balance between the rights of patent owners, who provide technological innovations to improve health conditions, and the

[85] This Chapter has been prepared by Indrani Gupta, Pradeep Guin, and Mayur Trivedi.
[86] http://www.wipo.int/patent-law/en/developments/publichealth.html

needs of the general public". Among the three conditions for a patent, viz. novelty (must not be already known to the public), usefulness (must provide identifiable benefit which is not merely aesthetic or descriptive) and non-obviousness (not obvious to person of ordinary skill in a particular field), the first two are extremely relevant for pharmaceutical products, which need to be continuously evolving to be of use to human beings.

Prior to the World Trade Organization (WTO), many developing countries - including India - allowed no patents on pharmaceutical inventions or only allowed process patents, which meant that the market for generic drugs could flourish. While this helped domestic pharmaceutical companies producing generic drugs to grow at a tremendous rate in countries like India, it also helped make essential drugs available at significantly lower prices globally. For example, a study shows that the price differentials between branded and generic drugs could be as much as 90 percent (Zaka Ur Rehman, 2007). The WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), which made the availability of product patents compulsory for eligible inventions in all member countries, meant that the entire market for generic drugs was out of bounds for manufacturing till the time the products went off-patent. The availability of generic drugs at a much later period, it was argued, was not very useful from the perspective of public health, which required drugs be available as and when these were invented to be affordable to all those who needed them. It was also argued that the commercial incentives provided by the patent system were not sufficient to ensure the development of new products in certain areas like neglected diseases. The argument is that patent rights, which are enforced on the basis of commercial and market-based considerations, prevent access to, or by increasing prices of, essential medicines

As discussed earlier, the "flexibilities" in TRIPS like compulsory licensing and parallel trade – which were supposed to be the channels available to needy countries to address their public health concerns – have also given rise to debates, dissent and discussion. There has also been a serious on-going debate among economists on the usefulness of patents in promoting R&D in diseases prevailing mostly in developing countries. The traditional view held by economists that patents and other such arrangements are a way of rewarding the successful innovators and, therefore, such measures are a kind of necessary evil one has to put up with

despite their market-distorting characteristics (Tirole1988, Barro and Sala-i-Martin 1999, Cohen et al 2002) has now been repeatedly questioned. A significant volume of literature has emerged which seriously raises the issue of efficacy of patents as a mechanism to stimulate R&D. Some earlier analysis of alternative data sources like worldwide patenting, biomedical citations and National Institute of Health grants (Lanjouw and Cockburn, 2001) had indicated that neglected infectious and tropical diseases of developing countries were not attracting sufficient R&D that is expected with a reasonably sound IPR system. Follow-up research with longer post-TRIPS time horizon confirmed these findings (Lanjouw and MacLeod 2005, Kyle and McGahan 2009), and indicated that the level of innovative activity related to diseases specific to poor countries remained very low relative to pharmaceutical research overall, though there were some slight upward movement in R&D in some of the diseases that were important in the developing world (Lanjouw and MacLeod, 2005).

Boldrin and Levine 2008 in their book *Against Intellectual Monopoly* (Boldrin and Levine, 2008) argue that patents and copyrights create an intellectual monopoly, lower availability and raise prices. The argument is that the current patent, copyright system and other regulations discourage and prevent inventions from entering the marketplace by driving up the cost of creation, and therefore, slows down the rate of diffusion of new ideas. The slow but steady stream of analysis and research raise the possibility that patents are neither necessary nor sufficient to encourage R&D in neglected diseases affecting the developing world, There are many other structural issues including weak demand, domestic market distortions through pricing and tariff policies, weak generic competition from domestic producers etc, that reduce incentives to invest in R&D, despite patents (Maskus, 2009). Also, some have argued that in the context of informative advertising, overinvestment incentives are likely to be always present, leading to a larger share of the patent rent to be spent on marketing, relative to R&D (Brekke and Straume, 2008).

On 20 February 2007, a joint United Nations Conference on Trade and Development (UNCTAD) and Stockholm Network event was held in Geneva, which debated the issue of pharmaceutical intellectual property rights (IPR). Some of the issues discussed were (UNCTAD 2007):

- Are pharmaceutical IPRs a barrier to access to medicines or are they essential to it?
- Do pharmaceutical patents prevent or enhance pharmaceutical research and development?
- Is there any hope at all for multilateral IP negotiations, and for whom?
- Are compulsory licenses a legitimate tool for price negotiations or are they a predatory mechanism aimed at circumventing the rights of developers?
- Are pharmaceutical IPRs a zero sum game or can they lead to win-win results?

The contents of the discussion point to divided opinions on the usefulness of patents for meeting the twin objectives of innovation and affordable medicines. In fact, the impact of global treaties like TRIPS continues to be a major controversial area especially with respect to public health issues. The 2006 case of Novartis filing an appeal over the Indian rejection of an application for a cancer drug was only the beginning of a series of conflicts and controversies arising out of the fact the national patent laws are often not aligned to the TRIPS and WTO rules. India's position was that the proposed drug only represented a new form of a known substance, and was therefore not an innovation that could be patented under the Indian patent law (EurActiv.com PLC 2007). An alternate view around this can be gleaned from the fact that the humanitarian aid group Médecins Sans Frontières (MSF) has urged the European Union (EU) to support the Indian government over the confrontation with Norvartis. Their argument is that if Novartis were to win the case, it will open the flood gate for drugs that are not really new but are either combinations or derivatives of existing drugs, killing the generic production of drugs essential for the developing countries. Finally, of course Novartis did lose the case in the Indian court, but there remain two sides of the sharply drawn argument regarding the new patent regimes and national patent laws (Ollier, 2007).

The perceived trade-off between public health priorities and supply of patented drugs has been continuously generating global controversies around TRIPS. For example, recently, India officially put in complaints at the WTO council regarding seizure of generic drugs at EC ports, including the latest one by the Dutch government on the grounds of violation of domestic patents and trademarks. According to India, "measures of this nature have an adverse

systemic impact on legitimate trade of generic medicines, south-south commerce, national public health policies and the principle of universal access to medicines" (Knowledge Ecology Notes 2009).

Another issue being seriously debated is about data exclusivity, whereby the developed countries, especially US and EU countries, want India to include data exclusivity in its domestic legislation, which would mean that the patent holder can have additional years till which the process will become public knowledge. This would essentially discourage generic production (Bhatnagar and Garg, 2009). India's interests are twofold: India: it has been a net exporter of some of the more important generic products with public health relevance on the one hand, and in need of essential drugs and medicines to combat significant burden of diseases from both communicable and non-communicable diseases within the country, on the other.

While the evidence is mounting to indicate that patents are probably not the best instruments to encourage medical innovation in areas that benefit developing countries, it was deemed worth the effort to analyze the existing patents applications in India, to see to what extent the evidence is consistent with this view. In particular, the attempt was to assess the broad category of diseases the patents applications are targeting, and whether or not these were consistent with the disease burden in the country.

This is the first known attempt in India, when data on pharmaceutical patents applications have been collected, collated, cleaned and classified according to International Patent Classification (IPC) codes, to enable preliminary understanding of the nature and type of the applications. Broadly, the patents applications received and ultimately granted would be beneficial to a country if it is more or less aligned with the disease priorities of the country. This hypothesis is the main rationale of the present research.

The remaining chapter is arranged as follows: Section 8.2 presents a snapshot of the pharmaceutical market in India. Section 8.3 gives an overview of the current disease burden in India to contextualize the remaining discussion around the implications of patents for public

health in India. Source of data on patent applications and methodology adopted to build a database are discussed in Section 8.4. Section 8.5 gives an overview of the data received from the primary source (BigPatents India), which is essential for proper understanding of the remaining analysis. The data is analyzed from the perspective of geographical distribution, disease classification and ownership categories in Section 8.6. Finally, in Section 8.7, the implications of the preliminary findings in terms of their impact on the public health scenario in the country are presented.

8.2 Pharmaceutical market in India

By the end of 2006, The Indian Pharmaceutical Market (IPM) was estimated to be valued at more than Rs. 27,000 crores. The market saw an average annual growth of around 8 percent between 2003 and 2006 as the total business grew from Rs. 20,013 crores in 2003 to Rs. 27,333 crores in 2006. However, between 2005 and 2006, the market grew at more than 17 percent. Table 8.1 presents the composition of the market by the top 10 therapeutic segments.

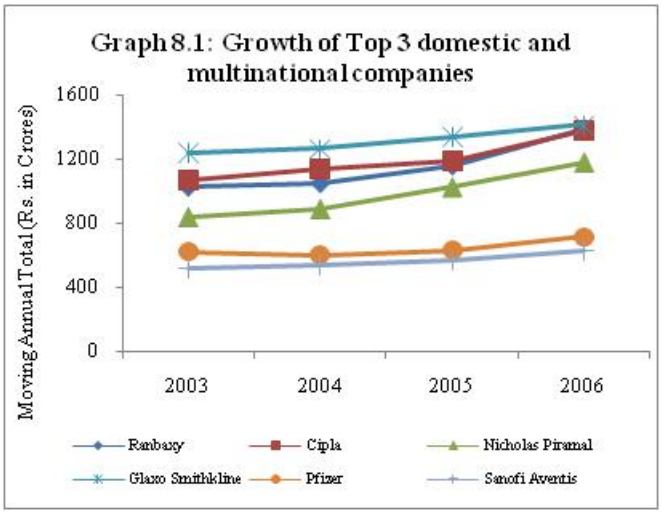
During 2006, the anti-infective drugs had the highest market share, around two-fifth of the total, followed by those related to gastro intestinal (11%) and cardiac disease (10%). As can be seen from the last column, the lifestyle diseases segment like diabetes, cardiac (both 10%) and Neuro/CNS (9%) have witnessed maximum growth in the last few years reflecting the emerging market for non-communicable diseases. At a sub-class level, the three segments that experienced maximum growth in the market were those of anti-malarial (17 %), Parenteral and vaccines (15 % each), indicating increase in demand in these sectors in the recent years. While the market for drugs relating to HIV grew by 10 percent in the four year period, the same for tuberculosis (TB) drugs showed a negative growth of around 3 percent (see Annex 8.1).

Table 8.1: Composition of Indian Pharmaceutical Market (IPM) and its growth by major therapeutic segments, 2003-06

Therapeutic segment	Moving annual total of sales *(in Rs. Crores)*				Proportion (in percent)				Avg. annual growth rate
	2003	2004	2005	2006	2003	2004	2005	2006	
Anti-infective	3568	3680	4110	4926	17.8	17.2	17.7	18.0	8.4
Gastro Intestinal	2170	2324	2547	3002	10.8	10.9	11.0	11.0	8.5
Cardiac	1895	2161	2418	2738	9.5	10.1	10.4	10.0	9.6
Pain / Analgesics	1877	1977	2071	2554	9.4	9.3	8.9	9.3	8.0
Respiratory	2022	2064	2157	2549	10.1	9.7	9.3	9.3	6.0
Vitamins / Minerals Nutrients	1882	1973	2091	2354	9.4	9.2	9.0	8.6	5.8
Dermatological	1079	1152	1272	1500	5.4	5.4	5.5	5.5	8.6
Gynecological	1116	1191	1272	1479	5.6	5.6	5.5	5.4	7.3
Neuro / CNS	1036	1106	1244	1469	5.2	5.2	5.4	5.4	9.1
Anti Diabetic	821	901	1008	1202	4.1	4.2	4.3	4.4	10.0
Others	2546	2836	3054	3559	12.7	13.3	13.1	13.0	8.7
IPM	**20013**	**21364**	**23243**	**27333**	**100**	**100**	**100**	**100**	**8.1**

Note: Others include Hormones, Ophthalmological / Otologicals, Anti-TB, Hepatoprotectives, Vaccines, Blood Related, Sex stimulants / Rejuvenators, Anti-Parasitic, Anti malarials, Stomatologicals, Parenteral, HIV and others

The domestic companies account for nearly 80 percent of the total IPM during 2006; this is a slight increase from 76.6 percent in 2002. The GlaxoSmithKline was the top performer with 5.2 percent of total share, with two Indian companies - Ranbaxy and Cadila – following closely, with 5.1 percent of total shares. The top-3 Indian pharmaceutical companies in 2006 were Ranbaxy, Cipla and Nicholas Piramal, while GlaxoSmithKline, Pfizer and Sanofi Aventis among the major MNCs. Together, these companies contributed one-fourth of the Indian pharmaceutical market



(Graph 8. 1). However, rates of growth were higher among the smaller companies like Lupin Labs (12.8%), Aristo Pharma (11.4%) and Alkem (10.3%) among the Indian, and Solvay Pharma (8.5%), Abbott (7.5%) and Novartis (6.2%) among the multinationals.

8.3 Burden of disease in India

To understand the effect of the new patent regime on the public health situation in the country, it is important to first understand the disease priorities in the country. The latest available data on Burden of Diseases (BoD) is from the 'Global Burden of Disease – 2004 updates' report compiled and published in 2008 by the World Health Organization (WHO). This report builds on an earlier WHO report on BoD in 2002, and like the previous one, uses the Disability Adjusted Life Years (DALYs) as a metric for estimating BoD for diseases, injuries and risk factors. The Global Burden of Disease (GBD) cause categories are divided in three step classification viz. group, sub-group and diseases. The 3 major groups are a) Communicable, maternal, peri-natal and nutritional conditions, b) Non communicable diseases, and c) Injuries. The three groups are classified into 213 sub-groups and further into 182 disease causes. .

In Table 8.2, the 2004 data on BoD for major sub groups is presented for India and the world. The data shows that India contributes around one-fifth to the total DALYs lost globally, with almost an equivalent proportion of DALYs lost due to communicable, maternal, perinatal and nutritional conditions as well as injuries (22%); India's contribution in non-communicable diseases is slightly lower at 18%.

The burden of disease due to both communicable and non-communicable category in India is around 43 percent; the corresponding figures for 2002 were 45.3 percent and 41.4 percent, respectively. Among communicable diseases, while the share of burden due to infectious and parasitic diseases is more or less same in the country as well as in the world (around 20%), there is a disproportionate share in the world DALY of other diseases like perinatal conditions, respiratory infections, maternal conditions and nutritional deficiencies (21% -28%).

Table 8.2: DALYs ('000) by major causes in India and World, 2004

Cause	India*		World DALY	Proportion of India to World DALY
	DALY	Proportion		
Communicable, maternal, perinatal and nutritional conditions	**134078**	**43.9**	**603993**	**22.2**
Infectious and parasitic diseases	58836	19.3	302144	19.5
Perinatal conditions	35468	11.6	126423	28.1
Respiratory infections	21703	7.1	97786	22.2
Nutritional deficiencies	9854	3.2	38703	25.5
Maternal conditions	8217	2.7	38936	21.1
Noncommunicable diseases	**131256**	**43.0**	**731652**	**17.9**
Neuropsychiatric conditions	35981	11.8	199280	18.1
Cardiovascular diseases	28960	9.5	151377	19.1
Sense organ diseases	19209	6.3	86883	22.1
Respiratory diseases	11198	3.7	59039	19.0
Digestive diseases	8705	2.9	42498	20.5
Malignant neoplasms	8487	2.8	77812	10.9
Other**	18717	6.1	114762	16.3
Injuries	**39779**	**13.0**	**187614**	**21.2**
Unintentional injuries	32047	10.5	138564	23.1
Intentional injuries	7732	2.5	49050	15.8
All Causes	**305112**	**100**	**1523259**	**20.0**

Notes:
* Estimated total
** Other includes musculoskeletal diseases, congenital anomalies, diabetes mellitus, genitourinary diseases, endocrine disorders, oral conditions, skin diseases and other neoplasms
Source: WHO 2009

Overall, the top five disease causes among infectious and parasitic diseases and respiratory infections by estimated DALYs lost are lower respiratory infections, diarrhoeal diseases, childhood-cluster diseases, tuberculosis and HIV & AIDS. Clearly, India is dealing with the dual burden of communicable and non-communicable diseases, with vaccine preventable diseases still being an important source of DALYs lost. While routine vaccinations seem to have reached high levels in many countries, India still has long way to go in achieving full coverage; in fact, India remains the country with the most unvaccinated infants (Okwo-Bele and Salama, 2009), given its large population base. Additionally, there remains the issue of newer vaccines that are as yet out of reach of many countries. For example, Rotavirus is by far the most common cause of severe diarrhoea and diarrhoeal deaths in infants and young children, especially in developing countries where it disproportionately strikes the poor (WHO 2009). WHO has recommended that rotavirus vaccination be included in all national immunization programmes of countries, but there remain issues of costs and

feasibility that need to be resolved before that can be done. Similarly, streptococcus pneumoniae, or pneumococcus, is a leading cause of morbidity and mortality among children worldwide and particularly in developing countries including India, with vaccines still not easily available as a preventive tool. The issue of patents and pricing are also applicable to newer vaccines, with most of the innovations happening in the developed world.

The only way one can reasonably analyze whether the patent applications are aligned to these disease realities is to study the patent applications received; without this, any conclusion is merely hypothetical. In this analysis, we attempt to analyze the pharmaceutical related patent applications that have been filed since India became a signatory to the WTO. In the next section, the data sources and methodology for compiling the database for analysis is presented.

8.4 Data and Methodology

Finding appropriate data for this analysis has been as important a part of the research as the analysis itself, and therefore, we explain in some detail below, the steps involved in compiling the data.

International Patent Classification (IPC) codes

The main source of information on patent applications in India is the Official Journal of the Patent Office, which provides information, both for those in the mailbox (1995-2004), and under the new patent regime (2005 onwards). While the mailbox applications are not coded in technological classes, it was mandatory under the new patent regime for patents applications to describe its technological domain according to the International Patent Classification (IPC) codes. International Patent Classification is a hierarchical classification system that is being used to classify and search patent documents according to their technical domains. The codes are made up of hierarchical alphanumeric combinations. The IPC codes are classified into a)

Sections, b) Sub sections (which do not have specific codes), c) Classes, d) Sub-classes, e) main/major groups and f) sub-groups. The five important levels are described below

- Sections – 1st level - Denoted by an Alphabets (A-H)
- Classes - 2nd level- Denoted by an Alphabet + two digits (A61)
- Subclasses - 3rd level - Denoted by an Alphabet + two digits + an Alphabet (A61P)
- Main groups - 4th level - Denoted by an Alphabet + two digits + an Alphabet + one to three digits/'00' (A61P 01/00)
- Subgroups - 5th level - Denoted by an Alphabet + two digits + an Alphabet + one to three digits/a number of at least two digits other than 00 (A61P 01/02)

There are eight sections from Section A to Section H; the section A is called 'human necessities'. There is a sub-section on Health and Amusement under section A, under which 'A61' includes health related products and is called CLASS a 61 Medical or Veterinary Science; Hygiene. The class A 61 has 12 sub classes, out of which two are relevant classes for pharmaceutical preparations viz. A61 K (Preparations for medical, dental, or toilet purposes) and A61 P (Therapeutic activity of chemical compounds or medicinal preparations). The list of groups under both these class is attached as Annex 8.2. As far as pharmaceutical products are concerned, the 'groups' indicates the major therapeutic categories; for example, A61P01/00 indicates the category called 'Drugs for disorders of the alimentary tract or the digestive system**'.**

Applications with codes A61K or A61P are classified at 4-digit subclass level and hence cannot be deciphered for their therapeutic class. Almost all other applications have classification symbol at least up to the main group. For example, A61Kab/cd can be either A61K31/00 at the main group level or A61K31/40 at the subgroup level. A61Kab/cd also means that applications are classified under only one IPC code. On the other hand, A61Kab/cd, wx/yz represents two or more IPC codes for a single application, thereby implying that such molecules may have multiple usage. Other types of multiple usage IPC coding patterns are combination of A61K and A61P viz. A61Kab/cd+A61Pab/cd, A61Kab/cd, wx/yz + A61Pab/cd, wx/yz, A61Kab/cd+A61Pab/cd, wx/yz or A61Pab/cd+A61Kab/cd, wx/yz.

Patent Application data

The official journal of patent provides information on applications in three categories: a) application filed for grant of a patent, b) application notified for opposition, and c) granted patents. However, the patent application information available from the journals is descriptive and not in database format, making merely the data collection process a time consuming and tedious exercise. The Technology Information, Forecasting and Assessment Council (TIFAC), a registered society under Department of Science & Technology has addressed this problem by compiling the information of both the periods in a database format, albeit with a few limitations. The patent application information from TIFAC is available in a series of three CD-ROMs: Ekaswa – A, B and C.

Ekaswa A provides information on applications filed and B on those notified for opposition; the information in both these CDs, pertains to the mailbox applications (1995-2004. Ekaswa C on the other hand contains information on applications that have been filed in the new patent regime i.e. from 2005 onwards.

However, the IPC coding of applications in CD C are restricted to 4-digit sub-class level, making it impossible to segregate them further into therapeutic classes. It was, therefore, necessary to search for alternative sources of data, and the web- based database called BigPatents India was a critical source of information on patent applications[87]. Unlike other sources, BigPatents India (henceforth BPI) provides information on the applications filed, and those for which patents have been issued as well as issued patents

[87] Professor Bhaven Sampat, Mailman School of Public Health, has created a dataset of all published Indian patent applications and patents, which is now available on a free website (india.bigpatents.org) where people can search for pending applications. The raw data – in a database format - was supplied to this research team by Prof. Sampat.

Pharmaceutical patent applications

The database of patent applications for pharmaceutical products provided by BPI containing 12029 row entries was cleaned[88] and classified under five heads: application number, title of the application, applicant, abstract and IPC codes. This process led to the loss/deletion of 95 records leaving 11934 applications for analysis.

Table 8.3 presents a distribution of the pharmaceutical applications across IPCs. As can be seen, most of the applications (around 68%) are classified as A61Kab/cd, followed by A61Kab/cd, wx/yz (13%). Together the two groups form a major proportion of the data (81%), and hence we restrict the next stage of our analysis to these two groups only.

Table 8.3: Distribution of IPC codes

8 or less digit coded	Frequency	Percentage
A61K	646	5.4
A61Kab/cd	8097	67.8
A61P	9	0.1
A61Pab/cd	248	2.1
A61Kab/cd, wx/yz	1510	12.7
A61P ab/cd, wx/yz	20	0.2
A61Kab/cd+ A61Pab/cd	662	5.5
A61Kab/cd, wx/yz + A61Pab/cd, wx/yz	189	1.6
A61Kab/cd+A61Pab/cd, wx/yz	194	1.6
A61Pab/cd+A61Kab/cd, wx/yz	359	3.0
Total	**11934**	**100**

Table 8.4 describes the 8097 A61Kab/cd application types at the next lower level – the group level (at 6-digit) - which comprises the main group (like A61K31/00) and subgroup (like A61K31/40) level. Almost half (49 percent) of the applications filed for grant of patent were under the category 'medicinal preparations containing organic active ingredients' (A61K31/cd), followed by 'medicinal preparations characterized by special physical form' (A61K09/cd) comprising around 15 percent of the total applications at the subclass level A61K.

Looking at these applications at the lowest level of their classifications, i.e. at the group level would help to understand the exact category for which patent is sought. The last column of Table 8.4 presents the contribution of top-10 IPC codes (at 8 or higher digit) to their immediate higher level (at 6-digit). For example the top-10 IPC codes like A61K31/00, 31/40,

[88] Keeping in mind the objective of the study, the research team decided to consider only those applications which has IPC codes A61K (preparations for medical, dental, or toilet purposes), and A61P (therapeutic activity of chemical compounds or medicinal preparations).

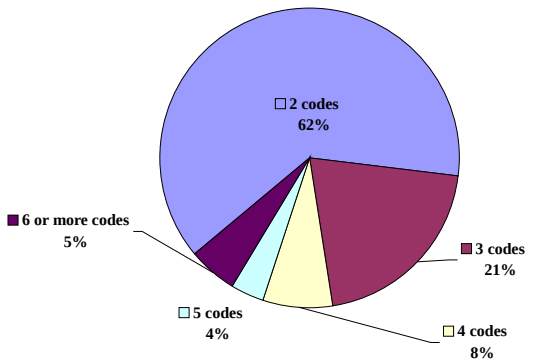
31/44, 31/445, etc., comprised around one-third of the total applications under A61K31; while those like A61K9/00, 9/20, 9/16, 9/14, etc., contributed nearly 80 percent of the total applications under the category A61K09. The percentage figures in this column should however be interpreted with caution; lower percentage indicates a higher variation in IPC code as compared to higher percentage where such variations within the top-10 are less. Thus, in the IPC code type A61K31/cd, there is more variation in the number of applications at the group level (8 or more digit) as compared to A61K35/cd.

Table 8.4: Sub classification of code A61Kab/cd at 6-digit level

IPC code (at 6-digit)	Description	No. of application	Proportion	Contribution of top-10 IPC codes at 8-digit (%)
A61K31/cd	Medicinal preparations containing organic active ingredients	3923	48.5	33.5
A61K09/cd	Medicinal preparations characterised by special physical form	1172	14.5	79
A61K38/cd	Medicinal preparations containing peptides	590	7.3	68.1
A61K07/cd	Cosmetics or similar toilet preparations	523	6.5	89.5
A61K39/cd	Medicinal preparations containing antigens or antibodies	470	5.8	81.3
A61K35/cd	Medicinal preparations containing material or reaction products thereof with undetermined constitution	431	5.3	93.3
A61K47/cd	Medicinal preparations characterised by the nonactive ingredients used, e.g. carriers, inert additives	268	3.3	88.1

The next large application volume is A61Kab/cd, wx/yz, which includes applications that have sought patents in more than two different IPC codes under the subclass A61K. With 1510 such applications, this category comprises around 13 percent of total applications. Graph 8.2 gives the distribution of such applications by the

Graph 8.2: Distribution of applications across number of IPC codes under A61Kab/cd, wx/yz



number of times different IPC codes appear (ranging from 2 to 17). As obvious, 1510 applications have at least 2 IPC codes, and the number reduces to 494 applications with 3 IPC codes mentioned in the patent application filed for grant of patent.

Linking the applications with its potential use

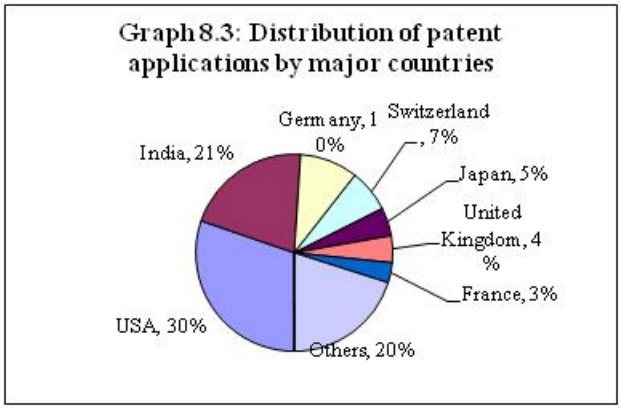
These applications were classified on the basis of their possible end use as gleaned from their abstracts and titles of the applications, and accordingly aligned with the BoD as laid down by the WHO. This exercise entailed reading the abstracts in detail and classifying the drugs in the proper disease categories by a medical professional. Wherever group classification was not possible due to their non-specificity to a particular disease cause like perfume, usage in inhibiting vascular permeability, fusion proteins, etc. they were separately labeled and grouped under the category 'other'.

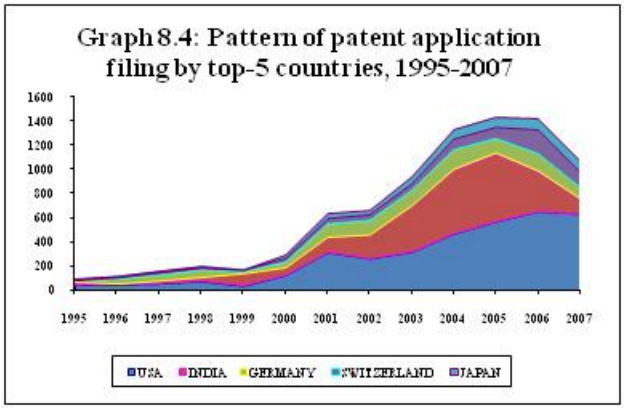
8.5 Analysis of BigPatents India data: An Overview

The only available parameters on the application forms are geographical distribution, disease classification and ownership categories. Thus, only these parameters have been analyzed for the pharmaceutical related applications from BigPatents India: the more detailed disease analysis will be discussed in the next section.

Graph 8.3 gives the distribution of patent applications by major countries. As can be seen, most of the applications filed during 1995-2008 were from USA (30%), followed by India (21%), Germany (10%) and Switzerland (7%). The trend in applications received from each of the top 5 countries between 1995 and 2007[89] (in total applications) is given in Graph 8.4 below. Patent applications from these countries aggregated to 6668 out of a total of 9891. Applications saw a steady rise beginning in 2000, particularly for USA and India. From the figure it seems as though there was a decline in the number of applications from all the countries; even if we allow for incomplete data for 2007, there still is a downward trend for India after 2005. Overall USA has been able to keep its place on the top.

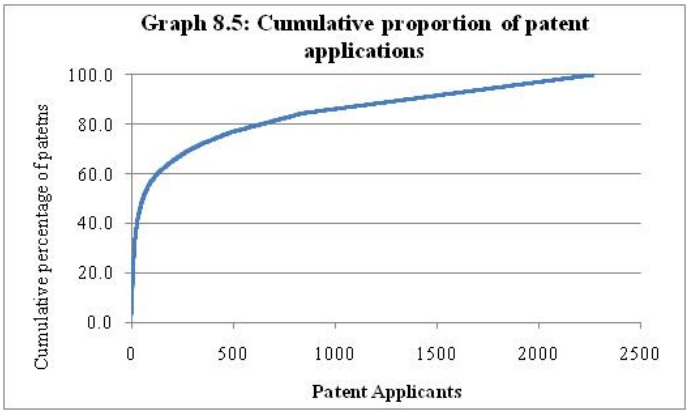
[89] Since there was only one patent application in 1992, none in 1993 & 1994, and very few in 2008, figures for these years were not considered while constructing the graphs.





A total of 2902 applicants have filed for pharmaceutical patents in India, out of which 1804 applicants - i.e. more than 62 percent of total applicants - have only single application; another 458 applicants (16%) have filed only two applications. Thus, overall, more than three-forth (78%) applicants are either individuals or small firms that may not have much R & D capabilities. In other words, from the application perspective, there seems to be a kind of oligopoly with a group of few applicants together having a higher share of total applications. Only 12 applicants account for nearly one-fourth of applications, and while there are nearly 3000 applicants, half of the applications are from only 75 applicants.

The skewed distribution of applicants and patent applications can be better understood from Graph 8.5, which plots cumulative proportion of patent applications across the number of applicants. Nealry 60 percent of all applications are from around 100 applicants. The next table presents the list of the top-20 applicants (Table 8.5). Novartis AG - the Swiss pharmaceutical giant - topped the list with 329 applications during this period, which comprised 3.6 percent of the total pharmaceutical applications. This was followed by Sanofi-Aventis and GlaxoSmithKline for the second and third spots. Ranbaxy Laboratories Limited and the Council of Scientific and Industrial Research (CSIR) are the two Indian applicants among the top-10. The top-10 applicants



together comprise around one-fourth of the total patent applications in the pharmaceutical sector in India.

Table 8.5: Distribution of patent application by top-20 companies

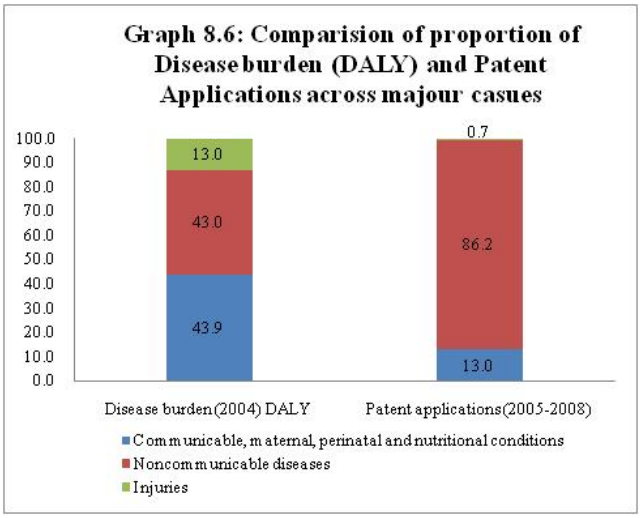
Group company	No. of applications	Percent
Novartis AG	329	3.6
Sanofi-Aventis	290	3.2
GlaxoSmithKline	288	3.1
Pfizer	287	3.1
Merck	269	2.9
Unilever	204	2.2
F. Hoffmann-La roche AG	191	2.1
Ranbaxy Laboratories Limited	187	2.0
AstraZeneca International	156	1.7
Council of Scientific and Industrial Research	138	1.5
Wyeth	138	1.5
Dr. Reddy's Laboratories Ltd	124	1.3
Novo Group	113	1.2
Boehringer Ingelheim	103	1.1
Elililly and Company	100	1.1
Janssen Pharmaceutica N.V.	89	1.0
Teva Pharmaceutical	76	0.8
Bristol-Myers Squibb Company	72	0.8
Nycomed	70	0.8
Schering-Plough Corporation	68	0.7
Other	5897	64.2
Total	**9189**	**100.0**

8.6 Patent applications: an analysis of disease categories

As explained above, the disease classifications were done on the patent applications to understand where the emphasis has been in terms of invention and innovation, and whether it broadly aligns with the health priorities in the country. To achieve this, a medical doctor studied every application – based on IPC code as well as the abstract – and assign possible disease categories. Attempts were made to at least assign disease category if the exact disease cause could not be ascertained. A classification of all applications based on the frequency of their possible use – in terms of disease category – is given in Table 8.5. Around 72 percent applications had only one possible use; however, more than 150 applications have five or more uses. To really understand the public health implications, it is important to take into account the multiple uses as well. The last column in Table 8.6 indicates the cumulative possible uses; 9189 applications thus, yield 13759 possible uses, in terms of the three major disease categories. This would be taken into consideration to discuss the public health implications of the patent applications in the subsequent sections.

Table 8.6: Distribution of patent applications by frequency of possible uses

Frequency of potential use	Applications	Percent	Cumulative Uses
One	6641	72.3	6641
Two	1306	14.2	2612
Three	647	7.0	1941
Four	434	4.7	1736
Five	137	1.5	685
Six	24	0.3	144
Total	**9189**	**100**	**13759**



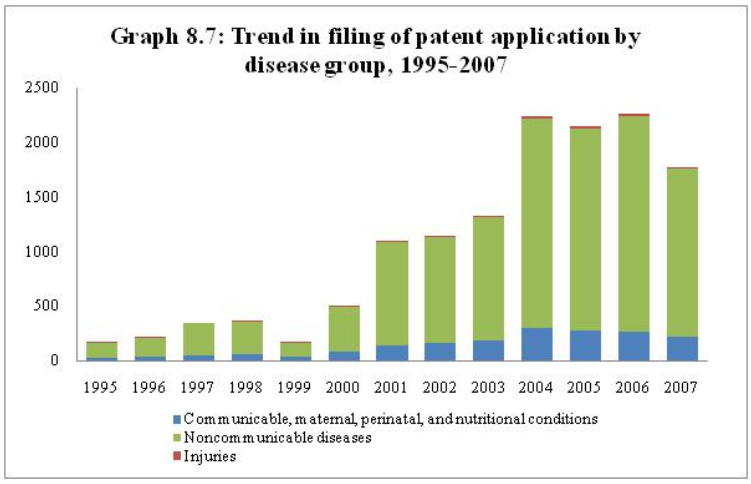
Graph 8.6 shows classifications of disease burden and potential uses of patent applications by three major disease causes - communicable, non-communicable and injuries. As much as 86 percent of the potential uses of the applications are for non-communicable diseases (NCDs), which comprise 43 percent of the total BoD. To further understand the

nature of the applications, Table 8.7 presents the disease sub-groups the applications are meant for. The top five sub groups under the non-communicable diseases - Malignant neoplasms (cancer), Neurological conditions, Cardiovascular and circulatory diseases, Mental and behavioural diseases, and musculoskeletal disorders – together comprise nearly half of the total (48.7%) applications. Among the communicable diseases, HIV/AIDS (1.9%) and Hepatitis (1.2%) top the list.

Table 8.7: Distribution of patent application by disease group and sub-group

Group	Sub-group	Applications	Percent
Communicable, maternal, perinatal, and nutritional conditions	HIV AIDS	255	1.9
	Hepatitis	163	1.2
	Malaria	86	0.6
	Parasitic and vector diseases	86	0.6
	Intestinal infectious diseases	74	0.5
	Tuberculosis	60	0.4
	Selected VaccinPreventablChildhood Diseases	56	0.4
	Respiratory infections	49	0.4
	Nutritional deficiencies	26	0.2
	Maternaconditions	22	0.2
	STDs excluding HIV	21	0.2
	Meningitis and encephalitis	18	0.1
	Perinatal and infant causes	15	0.1
	Sub group not specified	29	0.2
	Other infectious diseases	834	6.1
Sub-total		**1794**	**13.0**
Non-communicable diseases	Malignant neoplasms	1673	12.2
	Neurological conditions	1377	10.0
	Cardiovascular and circulatory diseases	1339	9.7
	Mental and behavioural disorders	1280	9.3
	Musculoskeletal diseases	1029	7.5
	Skin diseases	974	7.1
	Diabetes mellitus	901	6.5
	Respiratory diseases	859	6.2
	Digestive diseases	788	5.7
	Endocrine nutritional blooanimmune disorders	771	5.6
	Genitourinary diseases	473	3.4
	Sense organ diseases	221	1.6
	Oral conditions	119	0.9
	Other neoplasms	15	0.1
	Congenital anomalies	7	0.1
	Respiratory infections	1	0.0
	Sub group not specified	38	0.3
Sub-total		**11865**	**86.2**
Injury	Unintentional injuries	74	0.5
	Sub group not specified	26	0.2
Sub-total		100	0.7
Grand Total		**13759**	**100**

What has been the trend in filing application across disease categories over the years? As Graph 8.7 indicates, the non-communicable diseases have always been dominating the patent applications. While the proportion of communicable (on an average 13.7%) and non-communicable diseases (on average 85.7%) has remained more or less the same over the last decade, there are two phases of sharp increase in non-communicable diseases during 2000-01 and 2003-04.



8.7 Pattern of patent applications and their likely impact on public health

Table 8.8 gives the estimated total DALYs lost by cause for the world and India. The last two columns indicate India's contribution to the global burden and the percentage of applications received for patents in each category.

Apart from the category of neuropsychiatry – where India contributes about 18 percent to global DALYs and has received about 21 percent of the applications in this category – most of the other applications are not in proportion to the patterns of disease burden. Diseases from the non-communicable category attract most number of patent applications which is clearly not aligned to the disease priorities in the country. Broadly, the country needs to see more invention and innovation in dealing with communicable diseases that impact on IMR and under-5 mortality rates, as well as on maternal mortality rates. Of course, many of these diseases are vaccine-preventable, making vaccines key to prevention, with simple treatment protocols. But in many cases of parasitic and vector borne diseases, especially in recent outbreaks like HIN1, there seems to be a dearth of treatment options, which could benefit greatly from newer inventions In actuality, and as has been brought out clearly in the debate among economists discussed earlier regarding patents, these are targeted at markets that have

the ability to pay; thus, cardiovascular diseases, neurological disorders, mental illness are categories where there is a big demand, making the markets extremely lucrative. The patent applications are, therefore, mostly meant for these categories. As has been contended, "the cost of researching and developing medicines is paid for through high drug prices. This means that research is steered towards areas where the profit rewards are the greatest, so diseases which predominantly affect the developing world are neglected"[90].

Table 8.8 : Estimated total DALYs ('000), by cause World and India

Group	GBD cause name	World	India	% (India to World)	% application received: 1995- 2008 (N=12346) (same as in last column of Table 8.7)
I	Leprosy	194	91	46.9	0
I	Childhood-cluster diseases[2]	30226	10570	35	0
I	Tropical-cluster diseases[3]	12113	3815	31.5	0.1
I	Dengue	670	193	28.8	0
I	STDs excluding HIV	10425	3001	28.8	0.2
I	Perinatal conditions[5]	126423	35468	28.1	0.1
I	Nutritional deficiencies	38703	9854	25.5	0.2
I	Diarrhoeal diseases	72777	17445	24	0.5
I	Hepatitis B	2068	487	23.6	0.3
III	Unintentional injuries	138564	32047	23.1	0.5
II	Congenital anomalies	25280	5741	22.7	0.1
I	Meningitis and Japanese encephalitis[1]	12108	2720	22.5	0.1
I	Respiratory infections	97786	21703	22.2	0.4
II	Sense organ diseases	86883	19209	22.1	1.6
I	Tuberculosis	34217	7286	21.3	0.4
I	Maternal conditions	38936	8217	21.1	0.2
II	Oral conditions	7875	1656	21	0.9
II	Digestive diseases	42498	8705	20.5	5.7
II	Genitourinary diseases	14754	2885	19.6	3.4
II	Cardiovascular diseases	151377	28960	19.1	9.7
II	Respiratory diseases	59039	11198	19	6.2
II	Neuropsychiatric conditions[7]	199280	35981	**18.1**	**19.3**
II	Skin diseases	3879	626	16.1	7.1

[90] http://www.msfaccess.org/main/access-patents/introduction-to-access-and-patents/what-needs-to-happen/

III	Intentional injuries	49050	7732	15.8	na
I	Intestinal nematode infections[4]	4013	610	15.2	0.5
II	Musculoskeletal diseases	30869	4557	14.8	7.5
II	Diabetes mellitus	19705	2701	13.7	6.5
II	Other neoplasms	1953	246	12.6	0.1
II	Malignant neoplasms	77812	8487	10.9	12.2
I	HIV/AIDS	58513	3852	6.6	1.9
II	Endocrine disorders[6]	10446	304	2.9	5.6
I	Malaria	33976	603	1.8	0.6

Notes:
Groups: I Communicable, maternal, peri-natal and nutritional conditions; II Non-communicable diseases; III Injuries

[1] Meningitis and encephalitis

[2] Of the selected vaccine preventable childhood diseases there is 1 applicant against Poliomyelitis (childhood-cluster disease)

[3] 13 patent applications have been filed for two disease - leishmaniasis, and trypanosomiasis - in this category

[4] Intestinal infectious diseases

[5] Perinatal and infant causes

[6] Endocrine nutritional blood and immune disorders

[7] Neurological conditions and mental & behavioural conditions

Source: WHO (2009), micro-data from BigPatents India

These findings confirm earlier findings (Boldrin & Levine 2008, Lanjouw and Cockburn 2002, Lanjouw 2005, Lanjouw 2002) that the current system of TRIPS and patents is not geared towards the goal increasing the production of necessary and more effective medicines at affordable prices.

The discussion among economists around the alternatives to patents or optimal patenting has been equally vibrant, with many ideas proposed to make useful medicines affordable and accessible to the developing world. Some economists have argued for innovative subsidies that are designed to be least distortionary for innovation and creation in place of IPR (Boldrin and Levine 2008, Gallini and Scotchmer 2001, Hellwig and Irmen 2001). Others have offered suggestions within the framework of patents; for instance, it has been suggested that the segmented market for diseases allows patents to operate differently, so that developing countries do not lose out on newer innovations and at the same time are able to access essential medicines at affordable prices (Lanjouw, 2001). Direct government investment in R&D for newer and more effective medicines has also been suggested as an

obvious alternative (Baker, 2007). Another suggestion is that a system of drug insurance – similar to systems prevailing in developed countries – may help avoid the dead weight loss due to patents (Lakdawalla and Sood, 2009).

The discussion among economists has been somewhat separate from the global initiatives and action around drugs and patents. Also, while the suggestions have been interesting, these still require a high degree of collaboration and cooperation globally, and an explicit analysis and recognition of the needs of developing countries. Some new initiatives like the WHO's global strategy on public health, innovation and intellectual property indicates that there is global awareness that the TRIPS and patents issues remain largely unresolved for developing countries. The strategy "aims to promote new thinking on innovation and access to medicines, as well as, provide a medium-term framework for securing an enhanced and sustainable basis for needs driven essential health research and development relevant to diseases which disproportionately affect developing countries, proposing clear objectives and priorities for R&D, and estimating funding needs in this area." [91]

Organizations like UNITAID have been set up with a mission of contributing to scaling up access to treatment for HIV & AIDS, TB and Malaria, "primarily for people in low-income countries, by leveraging price reductions for quality diagnostics and medicines and accelerating the pace at which these are made available". [92] Recently, with WHO's approval, UNITAID has launched the setting up of a medicines patent pool, which is defined as the "Portfolio of assets of the entire set of patents and other relevant IP held by various actors made available on a non-exclusive basis to third parties, (e.g. generic manufacturers) against the payment of royalties". While this was meant mainly for ARVs, the WHO in its 17th Essential Medicines List Expert Committee meeting pointed out the potential of applying the patent pool approach to other major public health problems so that generic versions of medicines can be made accessible to the countries with the greatest needs.

Hopefully, some of these initiatives would snowball into major actions that can in turn make new health innovations available to needy countries at affordable prices without delay.

[91] http://apps.who.int/gb/ebwha/pdf_files/A61/A61_R21-en.pdf
[92] http://www.unitaid.eu/en/UNITAID-Mission.html

This means not only innovations like the patent pooling but global recognition and cooperation to ensure greater flexibilities in the patent laws and easier exercising of options like compulsory licensing so that affordable medicines for relevant disease are available to the developing world. Finally, there remains the need to examine and question the very basis of TRIPS and patents, and analyze and understand whether and how the world actually benefits from such agreements in critical areas like public health.

Chapter 9

Impact of TRIPS: Policy Issues

The broad area of intellectual property rights, innovation and public health continue to generate serious debates, discussions and controversies, and there does not seem to be any right or generalizable answer to the question: are developing countries going to gain from the new patent regime?

From the disease burden perspective, communicable diseases continue to disproportionately affect developing countries and within these countries, the poor relative to the non-poor. At the same time, there is an increasing trend in non-communicable diseases as well, with evidence mounting around the rising prevalence of diseases like CVD, diabetes, and cancer among the poor. There is some agreement now that the innovation cycle in biomedical R&D present in developed countries is lacking in developing countries. As the Commission of Intellectual Property Rights, Innovation and Public Health (WHO 2006) indicates, there is a large gap between demand and supply of appropriate medicines and other health care products suitable for the disease patterns and health system realities of developing countries. The need for health and bio-medical research that addresses the health needs of developing countries is therefore an important priority in the context of public health. At the same time, it is not sufficient to produce the right products, it is also important to provide these at prices that are affordable, through a system that is accessible.

There are two questions that arise in this context that are relevant to developing countries like India. The first question is: will the TRIPS help in furthering research appropriate for the disease burden of developing countries? Secondly, will the prices of essential medicines rise due to the new patent system and prove to be a barrier to access for the vast majority of the poor in such countries?

An important point to bear in mind in all such discussions is that while it is tempting to club all developing countries in one group, there are wide variations in both disease conditions as well as capabilities of production/R&D in pharmaceutical products among the countries clubbed as developing countries. India, in fact, stands out among this group as a country with advanced capabilities in production and R&D on the one hand, and a vast market for pharmaceutical products due to its sheer size on the other. At the same time, it is a country with a large poor population, making the concerns around pricing and availability urgent in the context of public health.

The answer to both the questions for India lie in the pattern of patent applications it has received so far: the majority of the applications are for NCD (non-communicable diseases) making it immediately apparent that patent applications follow the market trends closely, and applications are mainly targeting the diseases that translate into market shares and profits. Currently, the increasing trends of NCD in the country – as also globally – is making the market lucrative for drugs that treat heart diseases, diabetes, neurological disorder, cancer, mental illness etc. Only a small number of applicants are aiming for communicable diseases in any case, indicating that the grant of patent by itself cannot distort the market for priority diseases.

As for R&D, which the new patent system is supposed to encourage, it is a much more complex issue, and product patenting system may not necessarily encourage innovations, especially in priority diseases. The size of the market and adequate scientific and technological capabilities of firms ultimately determine the level of R&D, and not the presence of a mere patent. While no thorough analysis could be done on this issue, it does seem as though the Indian as well as foreign firms applying for patents in India are targeting big markets with products that are not really in line with the public health priorities of the country. In fact, to that extent there does not seem to be much of a difference between the foreign and the domestic players.

Secondly, as was clear from the empirical analysis, there does not seem to be any immediate cause for concern as far as price rise is concerned. The econometric results indicate

that there is probably only limited substitutability between domestic and foreign products; essentially, this means that when prices of domestic drugs rise, providers/consumers do not necessarily switch to the foreign drugs, and vice versa. Mostly, the demand for drugs is driven by what the physicians prescribe, especially in developing countries like India where regulation standards are quite low. There is a slow but increasing body of evidence on physician behaviour that indicate that physicians behave as imperfect agents in the presence of asymmetric information. For instance, evidence indicates that within systems where physicians both prescribe and dispense, there is a tendency towards rent-seeking behvaiour, with physicians prescribing brand-name drugs instead of generic ones (Liu et al, 2009; Lizuka, 2007). Another study indicates that both physicians' habits and patients' preferences are the most important factors in choice of drugs (Coscelli, 2000).

While these studies are based on health systems with strong reimbursement mechanisms, in India, the high out-of-pocket expenditure of households on health may not necessarily lead to the same outcomes in terms of prescriptive behaviour of physicians, and may minimize the agency problem. On the other hand, evidence of kickback and other unfair practices that pharmaceutical firms engage in to influence physicians, has the potential of introducing another wedge between 'what ought to be' and 'what is' in drug prescriptions. Clearly, larger the firms, larger would be the volume of kickbacks, indicating the potential of over-prescription of branded more expensive drugs over generic – relatively cheaper - drugs. There is no evidence of the extent of such practices in India, and on balance it can be safely said that so far, the market is largely being driven by consumer and physician preferences rather than other kinds of incentives. The findings of this research is consistent with the view that in case of price rise of a certain drug, physicians probably recommend a slightly different formulation, rather than recommend switching to more costly branded drugs. At the same time, there is market segregation in drug usage and supply, with the market for the upper-end drugs mostly confined to urban cities and towns. Even if prices rise for some drugs primarily meant for these markets, the consumers are better able to absorb the price rise, compared to the rural markets. In fact, there is no evidence of patent-protected high-cost drugs flooding the market in India, nor a major shift away from the type of diseases these drugs are meant for.

On balance, there does not seem to be any immediate danger of price rise due to the new patent system, especially because much of these patented applications/drugs are very similar to the off-patent drugs and offer possibilities of substitution. However, there may be some medium to long run effects of the new patent system, when far superior patent protected drugs come into the market, whether from Indian or foreign firms. Also, if there is a shift in the type of drugs in terms of the kind of diseases these patented drugs are meant for, there may be a danger that the more needy and vulnerable may be affected. For example, if there is a sudden jump in research into the diseases affecting the developing world like water-borne diseases, vector-borne diseases like malaria & dengue, pneumonia, TB etc, and more efficient drugs under patent come into the global market, this is certainly going to affect prices and the availability of essential medicines. However, given the patterns of R&D, this also does not seem very likely in the immediate future.

However, there is always merit in being prepared for eventualities. The government must be open and explore all the possibilities of furthering the cause of public health by exercising the many flexibilities of the TRIPS, like compulsory licensing, government use, parallel imports etc. It also has to guard against the dilution of these flexibilities through the many bilateral and free trade agreements that offer a higher level of protection (WHO 2006). At the end, no national government can go it alone in the fight to protect public health when numerous global, multilateral and bilateral treaties and agreements are involved. Patents are the other side of R&D, and the best argument for cooperation in R&D – especially in neglected health diseases - is that it is a typical global public good. While India need not immediately fear affordability issues around essential drugs, it will have to ensure that more suitable drugs come into the market for diseases, and that these are available, affordable and accessible for the vast majority of the population. For that a high level engagement with global players – government, pharmaceutical companies, and international bodies - would be required in a more pro-active manner. It may be added here that there is a vast scope for further policy research in this area, which is at present lacking; the government can be a lead player in calling for and partnering in research into the key issues around TRIPS, public health and innovations.

Gopakumar (2010) points out that while TRIPS flexibilities have been incorporated in the new (amended) patent law in India (to address the concerns of future of domestic industry and affordable access to medicines in India), India is facing legal, policy and institutional challenges in implementing TRIPS flexibilities. He goes on to argue that mere incorporation of TRIPS flexibilities in the domestic legislation alone is not enough and the domestic legislation needs to be complemented with policy and institutional framework

Impact on Domestic Industry

The available evidence indicates that the domestic pharmaceuticals industry has so far not been adversely affected by the new patent regime. Rather, the relatively large firms in the domestic industry have adopted strategies to meet the challenges of the new regime and have been successful in taking advantage of the regime. The market share of the domestic firms have gone up in recent years instead of going down even though a tougher patent regime, more favourable to the MNCs, has been put in place. An important reason for the continuing fall of the market shares of foreign companies in India is that they have not launched many of their new patented products in India. According to a report published in the Economic Times (September 29, 2008), most of the MNCs pharma companies have stopped launching latest products in India after 1995 though they have been introducing them in other parts of the world. Also, whenever they have launched their patented product in India, it has been priced much lower than the prices being charged for the same product in developed and other developing countries.

In the discussion on the effect of TRIPS, serious concerns are raised that the subsidiaries of multinational companies would substantially raise prices of drugs once alternate sources of supply are removed. However, the worry about a large price rise in drugs is there also with the large domestic firms in India. For a vast majority of drugs, the market in India is oligopolistic. The pharmaceuticals market is highly concentrated and there is not much effective competition. The top 3 or 4 firms account for a large share of the market. Commonly, there are a large number of small and medium firms supplying the same drug at a considerably lower price offering some degree of competition to the market leaders. In this environment, the

emergence of the Indian firms in the international arena as cheap and quality generic medicine suppliers, may cause the domestic prices to get aligned with the export prices, which would lead to hike in drug prices and affect a large section of the population. The small and medium scale firms operating the drug markets create a competitive pressure and thus prevent to some extent the large firms from hiking the prices. However, for some reasons, the small-scale pharmaceutical firms in India have lately been facing considerable difficulties (not really connected with TRIPS) and one cannot rule out the possibility that a sizeable part of the small-scale pharmaceutical firms in India may close down in course of time. This development, if it occurs, will obviously strengthen the forces leading to hike in drug prices in India. Needless to say, supportive policy for continuance of small-scale pharmaceutical firms in India is important for ensuring affordability of drugs. In terms of patent applications too, individual small players are a significant proportion of total players, indicating that there is still a chance to turn things around, so that small-scale firms may get incentivized to stay in the market.

To enable the small and medium pharmaceutical companies to face the stiff challenges posed by big pharmaceutical companies the government has planned to make available financial assistance up to Rs.1 crore with 15% capital subsidy to small scale drug and pharmaceutical units for technology up-gradation under the credit linked capital subsidy scheme of Ministry of Micro, Small and Medium Enterprises (MSME). There is a proposal of Department of Chemicals and Petrochemicals to extend 5% interest subsidy to small scale units for technology up-gradation on the basis of Schedule 'M' of Drugs and Cosmetic Rules, 1945 and to provide support to high-risk research and late stage development in small and medium companies.

Apart from the government support, the small-scale units have to upgrade their production facilities to the international standards; otherwise they would lose not only the international market but also the generic segment of the domestic market because large firms in the process of meeting the good manufacturing standards would usurp small units' share in the domestic market. Thus despite their large share in terms of output and employment in the pharmaceutical industry, the existence of the small scale units is threatened by increasing competition and need for adherence to good manufacturing practices. Thus unless efforts are

made to provide adequate resources and finance to upgrade their plants, technical skills, good laboratory practices and good clinical practices, their contribution in manufacturing and research will be wiped out.

Impact on Consumers

Econometric analysis presented in Chapter 5 (based on demand function estimation and counterfactual simulation) indicated that a comprehensive enforcement of the product patents and consequent large-scale displacement of domestic manufacturing of drugs (which may be treated as a possible scenario that would develop in the course of next 15 to 20 years) may cause the prices of drugs/medicine produced by foreign firms to go up by about 260 percent (than what it would have been otherwise) and thus may lead to a loss of consumer welfare by about Rs 237 billion annually. The loss could be greater than Rs 237 billion if the large domestic pharmaceutical firms in India substantially increase their exports over time and try to align the prices at which they sell their products in India to the price they get from the export market. Another factor that may enhance the consumer welfare loss is connected with the elimination of a large section of the domestic small and medium scale pharmaceutical firms in India. That there is such a possibility has been mentioned above. At present the presence of such firms keeps a check on the prices that large Indian firms and MNCs can charge. In case a large number of small and medium scale pharmaceutical firms close down, this source of cheap supply of drugs is no longer available to the consumers, and the increase in prices of products of foreign firms following enforcement of product patenting may be greater than the estimate obtained. Naturally, the consumer welfare loss will be greater than the estimate of Rs 237 billion per year. Evidently, support is found for the argument that the new patent regime will impose a significant cost on the consumers, but little support is found for the counter-argument that such a regime will encourage R&D activity for the development of drugs in the priority areas for developing countries (which could have been a benefit to the consumers).

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Annexes

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Annex 5.1: Coefficient Estimates of Lower Level AIDS System

A5.1(a): Statins

Share\Price	Atorvastatin_d	Atorvastatin_f	Rosuvastatin_d
at_pr_d	0.24 (2.81)	0.014 (1.07)	-0.13 (-4.52)
at_pr_f	0.014 (1.07)	-0.002 (-0.53)	0.006 (1.02)
ros_pr_d	-0.13 (-4.52)	0.006 (1.02)	0.032 (1.93)
si_pr_d	-0.124 (-1.56)	-0.017 (-1.33)	0.092 (3.19)
reaexp	0.027 (1.97)	0.006 (2.88)	-0.019 (-3.24)
_cons	0.911 (14.62)	-0.011 (-1.11)	0.24 (2.81)

Note:1) at_pr: Atorvastatin price; ros_pr : Rosuvastatin price; si_pr : Simvastatin price; _d: Domestic; _f: Foreign

2) t- ratios in parentheses

A5.1(b): Beta Blockers

share/price	sate_d	sate_f	scar_d	smet_d	smet_f	sneb_d	spro_d
ate_pr_d	-0.156 (-15.72)	0.012 (2.67)	0.081 (10.01)	-0.012 (-1.8)	0.031 (5.26)	0.037 (5.38)	0.014 (1.64)
ate_pr_f	0.012 (2.67)	0.012 (1.4)	0.012 (2.3)	0.016 (2.9)	-0.002 (-0.38)	-0.001 (-0.12)	-0.016 (-4.32)
car_pr_d	0.081 (10.01)	0.012 (2.3)	-0.13 (-10.94)	0.028 (4.09)	0.05 (6.68)	-0.069 (-7.74)	0.011 (1.31)
met_pr_d	-0.012 (-1.8)	0.016 (2.9)	0.028 (4.09)	-0.151 (-17.97)	0.009 (1.27)	0.017 (2.83)	0.072 (8.62)
met_pr_f	0.031 (5.26)	-0.002 (-0.38)	0.05 (6.68)	0.009 (1.27)	-0.038 (-4.4)	0.025 (3.51)	-0.042 (-7.24)
neb_pr-d	0.037 (5.38)	-0.001 (-0.12)	-0.069 (-7.74)	0.017 (2.83)	0.025 (3.51)	-0.029 (-3.42)	-0.013 (-1.84)
pro_pr_d	0.014 (1.64)	-0.016 (-4.32)	0.011 (1.31)	0.072 (8.62)	-0.042 (-7.24)	-0.013 (-1.84)	0.005 (0.4)
pro_pr-f	-0.006 (-0.58)	-0.033 (-2.95)	0.017 (1.22)	0.02 (1.57)	-0.032 (-2.78)	0.033 (3.05)	-0.03 (-2.71)
realexp	-0.103 (-19.88)	-0.001 (-0.41)	0.015 (3.2)	0.033 (6.35)	0.001 (0.34)	-0.024 (-5.27)	0.069 (10.21)
_cons	0.605 (29.21)	-0.039 (-3.46)	0.078 (3.67)	0.38 (18.73)	-0.048 (-2.66)	0.139 (8.09)	-0.084 (-3.79)

Note:1) ate_pr: Atenlol price; car_pr : Carvedilol price; met_pr : Metoprolol price; ; neb_pr: Nebivolol price; pro_pr: Propranolol price _d: Domestic; _f: Foreign

2) t- ratios in parentheses

A5.1(c): Muscular Relaxant

Share\Price	Baclofen & comb_f	Baclofen & comb_d	Chlormezanone & comb_f	Chlormezanone & comb_d	Chlorzoxa & comb_f	Chlorzoxa & comb_d	Methocarbamol & comb_d	Tizanidine & comb_f
bac_pr_f	0.058 (3.88)	0.009 (0.73)	-0.002 (-0.4)	0.012 (0.71)	0.000 (-0.11)	0.153 (2.12)	-0.039 (-3.28)	-0.017 (-7.36)
bac_pr_d	0.009 (0.73)	-0.064 (-1.57)	-0.028 (-1.71)	0.057 (2.69)	0.006 (2.16)	0.175 (0.58)	0.045 (4.18)	-0.021 (-8.12)
cne_pr_f	-0.002 (-0.4)	-0.028 (-1.71)	0.018 (2.1)	0.013 (1.65)	-0.001 (-1.42)	-0.353 (-2.09)	0.008 (2.41)	0.002 (2.55)
cne_pr_d	0.012 (0.71)	0.057 (2.69)	0.013 (1.65)	-0.17 (-4.1)	0.018 (3.04)	0.17 (1.13)	0.135 (6.8)	-0.017 (-3.35)
cxa_pr_f	0.000 (-0.11)	0.006 (2.16)	-0.001 (-1.42)	0.018 (3.04)	0.013 (5.1)	0.068 (4.44)	0.003 (0.61)	-0.005 (-2.4)
cxa_pr_d	0.000 (-0.11)	0.006 (2.16)	-0.001 (-1.42)	0.018 (3.04)	0.013 (5.1)	-0.171 (-3.79)	0.018 (1.2)	0.062 (6.15)
met_pr_d	-0.039 (-3.28)	0.045 (4.18)	0.008 (2.41)	0.135 (6.8)	0.003 (0.61)	0.018 (1.2)	-0.055 (-2.49)	-0.019 (-4.9)
tiz_pr_f	-0.017 (-7.36)	-0.021 (-8.12)	0.002 (2.55)	-0.017 (-3.35)	-0.005 (-2.4)	0.062 (6.15)	-0.019 (-4.9)	-0.004 (-1.39)
tiz_pr_d	-0.020 (-1.03)	-0.009 (-0.41)	-0.01 (-1.63)	-0.065 (-1.6)	-0.045 (-3.92)	-0.122 (-1.1)	-0.095 (-4.06)	0.019 (1.99)
realexp	-0.026 (-4.17)	-0.046 (-7.43)	0.002 (1.1)	-0.05 (-3.55)	-0.024 (-3.55)	0.228 (8.13)	-0.014 (-1.34)	-0.081 (-10.54)
_cons	0.059 (4.11)	0.103 (4.74)	0.014 (1.45)	0.04 (1.23)	0.069 (4.82)	-0.244 (-1.26)	0.128 (5.8)	0.276 (17.91)

Note:1) bac_pr: Baclofen & comb price; cne_pr: Chlormezanone & comb price; cxa_pr: Chlorzoxa & comb price; met_pr: Methocarbamol& comb_price; tiz_pr: Tizanidine & comb_price ; _d: Domestic; _f: Foreign

2) t- ratios in parentheses

A5.1(d): Anthelmintics Ex.Schis

Share\Price	Albendazole_d	Albendazole_f	Ivermectin& comb_d	Ivermectin & comb_f	levamisol_d	levamisol_f	Mebendazoe_d	Mebendazole_f	Pyrental Pamoate_d
ad_pr_d	0.05 (0.57)	-0.109 (-1.39)	-0.452 (-9.71)	-0.041 (-1.26)	-0.123 (-4.88)	-0.028 (-0.68)	0.167 (4.08)	0.041 (1.18)	0.352 (6.31)
ad_pr_f	-0.109 (-1.39)	0.219 (1.71)	0.38 (8.3)	-0.01 (-0.27)	0.042 (1.26)	-0.059 (-1.25)	-0.173 (-3.13)	-0.097 (-2.34)	-0.2 (-3.3)
anocd_pr_d	-0.452 (-9.71)	0.38 (8.3)	-0.243 (-4.11)	-0.083 (-3.79)	0.121 (6.79)	0.11 (4.77)	0.041 (1.34)	-0.098 (-5.36)	0.199 (8.38)
anoc_pr_f	-0.041 (-1.26)	-0.01 (-0.27)	-0.083 (-3.79)	-0.004 (-0.18)	-0.013 (-0.94)	0.005 (0.24)	0.111 (5.3)	0.037 (2.3)	0.074 (3.07)
iev_pr_d	-0.123 (-4.88)	0.042 (1.26)	0.121 (6.79)	-0.013 (-0.94)	0.016 (1.11)	0.04 (1.71)	-0.098 (-5.49)	0.012 (0.77)	-0.028 (-1.35)
iev_pr_f	-0.028 (-0.68)	-0.059 (-1.25)	0.11 (4.77)	0.005 (0.24)	0.016 (1.11)	-0.001 (-0.02)	-0.098 (-5.49)	0.012 (0.77)	-0.028 (-1.35)
mebd_pr_d	0.167 (4.08)	-0.173 (-3.13)	0.041 (1.34)	0.111 (5.3)	-0.098 (-5.49)	-0.037 (-1.18)	0.07 (1.64)	0.068 (3.03)	-0.03 (-0.95)
mebd_pr_f	0.041 (1.18)	-0.097 (-2.34)	-0.098 (-5.36)	0.037 (2.3)	0.012 (0.77)	0.186 (1.64)	0.068 (3.03)	0.107 (1.2)	-0.028 (-0.79)
pyd_pr_d	0.352 (6.31)	-0.2 (-3.3)	0.199 (8.38)	0.074 (3.07)	-0.028 (-1.35)	-0.165 (-2.91)	-0.03 (-0.95)	-0.028 (-0.79)	-0.222 (-3.45)
pyd_pr_f	0.142 (2.83)	0.007 (0.12)	0.026 (0.73)	-0.076 (-3.46)	0.053 (2.52)	0.022 (0.73)	-0.059 (-1.64)	-0.015 (-0.62)	-0.089 (-3.13)
realexp	-0.039 (-1.55)	-0.027 (-1.49)	0.078 (3.88)	-0.004 (-0.43)	0.014 (1.74)	-0.013 (-1.42)	0.034 (2.56)	-0.017 (-2.09)	0.008 (0.84)
_cons	0.688 (5.4)	0.12 (1.08)	-0.032 (-0.31)	0.173 (3.28)	-0.2 (-4.02)	-0.344 (-0.79)	0.031 (0.38)	-0.033 (-0.11)	0.018 (0.3)

Note: 1) ad_pr: Albendazole price; anocd_pr: iev_pr: Ivermectin& comb price; l evd_pr:l evamisol price; mebd_pr: Mebendazole price; pyd_pr: Pyrenta Pamoate price; _d: Domestic; _f: Foreign

2) t- ratios in parentheses

A5.1(e): Antileukaemics

Share\Price	Capecitabine_d	Doxorubincin_d	Doxorubicin_f	Gefitinib_d	Imatinib_d	Methotrexate_d
cape_pr_d	0.415 (9.81)	-0.016 (-0.44)	-0.026 (-0.96)	-0.2 (-3.39)	0.005 (0.1)	-0.084 (-2.62)
doxo_pr_d	-0.016 (-0.44)	0.035 (0.55)	-0.019 (-0.62)	0.174 (2.49)	-0.052 (-0.93)	-0.037 (-0.98)
doxo_pr_f	-0.026 (-0.96)	-0.019 (-0.62)	0.069 (0.85)	-0.2 (-1.52)	0.253 (2.94)	-0.246 (-3.21)
giff_pr_d	-0.2 (-3.39)	0.174 (2.49)	-0.2 (-1.52)	0.62 (1.5)	-0.123 (-0.63)	-0.05 (-0.26)
ima_pr_d	0.005 (0.1)	-0.052 (-0.93)	0.253 (2.94)	-0.123 (-0.63)	-0.456 (-2.35)	-0.053 (-0.49)
meth_pr_d	-0.084 (-2.62)	-0.037 (-0.98)	-0.246 (-3.21)	-0.05 (-0.26)	-0.053 (-0.49)	-0.495 (-3.3)
meth_pr_f	-0.094 (-2.05)	-0.084 (-1.6)	0.17 (1.53)	-0.22 (-0.82)	0.428 (2.79)	0.966 (6.12)
realexp	0.014 (0.85)	0.039 (1.88)	-0.006 (-0.46)	0.169 (6)	0.071 (3.35)	-0.141 (-9.39)
_cons	-0.481 (-1.96)	-0.439 (-1.56)	0.069 (0.13)	-1.361 (-0.85)	1.545 (1.93)	1.281 (1.54)

Note: 1) cape_pr: Capecitabine price; doxo_pr: Doxorubincin price; giff_pr: Gefitinib price; ima_pr: Imatinib price; meth_pr: Methotrexate price; _d: Domestic; _f: Foreign

2) t- ratios in parentheses

A5.1(f): Antirheumatic nonstr.

Share\Price	aceclofenac_d	aceclofenac_f	Diclofenac_d	Diclofenac_f	Etorecoxib_d	Ibuprofen_d	Ibuprofen_f	Nimesulide_d
acec_pr_d	-0.19 (-1.71)	-0.064 (-3.76)	-0.011 (-0.23)	0.07 (2.04)	-0.233 (-12.34)	0.334 (7.25)	0.153 (3.63)	-0.017 (-0.22)
acec_pr_f	-0.064 (-3.76)	0.008 (1.59)	-0.01 (-1.29)	0.027 (3.84)	0.011 (2.8)	-0.035 (-4.05)	0.005 (0.62)	0.022 (1.72)
dic_pr_d	-0.011 (-0.23)	-0.01 (-1.29)	-0.017 (-0.63)	0.08 (4.46)	-0.065 (-5.25)	0 (0.01)	-0.132 (-6.03)	0.13 (3.06)
dic_pr_f	0.07 (2.04)	0.027 (3.84)	0.08 (4.46)	0.036 (1.55)	0.012 (1.12)	-0.011 (-0.56)	-0.066 (-3.21)	-0.139 (-3.97)
eto_pr_d	-0.233 (-12.34)	0.011 (2.8)	-0.065 (-5.25)	0.012 (1.12)	0.006 (0.39)	0.029 (2.58)	0.075 (5.92)	0.102 (4.6)
ibu_pr_d	0.334 (7.25)	-0.035 (-4.05)	0 (0.01)	-0.011 (-0.56)	0.029 (2.58)	-0.011 (-0.32)	-0.16 (-7.28)	-0.043 (-1.1)
ibu_pr_f	0.153 (3.63)	0.005 (0.62)	-0.132 (-6.03)	-0.066 (-3.21)	0.075 (5.92)	-0.16 (-7.28)	-0.027 (-0.93)	0.051 (1.31)
nim_pr_d	-0.017 (-0.22)	0.022 (1.72)	0.13 (3.06)	-0.139 (-3.97)	0.102 (4.6)	-0.043 (-1.1)	0.051 (1.31)	0.061 (0.63)
nim_pr_f	-0.043 (-0.69)	0.036 (3.25)	0.025 (0.89)	-0.01 (-0.4)	0.064 (3.77)	-0.104 (-3.43)	0.102 (3.59)	-0.167 (-3.39)
realexp	0.014 (0.84)	-0.007 (-2.2)	0.043 (3.92)	0.022 (2.62)	-0.065 (-5.68)	0.025 (2.95)	0.007 (0.7)	-0.011 (-0.68)
_cons	0.495 (4.93)	0.014 (0.72)	0.064 (1)	-0.06 (-1.23)	0.432 (7.06)	-0.056 (-1.05)	-0.141 (-2.44)	0.199 (2.16)

Note:1) acec_pr: Acelcofenac price; dic_pr: Diclofenac price; eto_pr: Etorecoxib price; ibu_pr: uprofen price, nim_pr: Nimesulide price; _d: Domestic; _f: Foreign

2) t- ratios in parentheses

A5.1(g): Broncho Dilator Solids & liquid

Share\Price	Etophylline _d	Montelukast_ d	Montelukast_ f	Salbutamol _d	Salbutamol _f	Terbutaline _d	Terbutaline _f
etop_pr_d	0.061 (1.34)	-0.009 (-0.3)	0.079 (4.67)	0.211 (5.16)	-0.108 (-4.12)	0.177 (9.51)	0.052 (3.07)
mont_pr _d	-0.009 (-0.3)	-0.08 (-1.78)	0.036 (1.77)	-0.262 (-7.39)	0.24 (7.5)	0.079 (4.27)	0.139 (7.36)
mont_pr _f	0.079 (4.67)	0.036 (1.77)	0.05 (2.37)	-0.122 (-6.98)	-0.025 (-1.09)	0.007 (0.6)	0.003 (0.27)
sab_pr _d	0.211 (5.16)	-0.262 (-7.39)	-0.122 (-6.98)	-0.241 (-3.32)	0.005 (0.2)	-0.239 (-11.1)	0.011 (0.54)
sab_pr _f	-0.108 (-4.12)	0.24 (7.5)	-0.025 (-1.09)	0.005 (0.2)	-0.06 (-1.37)	0.026 (1.45)	-0.042 (-2.25)
terb_pr _d	0.177 (9.51)	0.079 (4.27)	0.007 (0.6)	-0.239 (-11.1)	0.026 (1.45)	0.011 (0.77)	-0.049 (-4.78)
terb_pr _f	0.052 (3.07)	0.139 (7.36)	0.003 (0.27)	0.011 (0.54)	-0.042 (-2.25)	-0.049 (-4.78)	-0.03 (-2.02)
theo_pr _d	-0.463 (-14.2)	-0.143 (-4.97)	-0.029 (-1.63)	0.637 (12.95)	-0.036 (-1.57)	-0.012 (-0.5)	-0.083 (-5.06)
Realexp	0.014 (1.21)	0.018 (1.91)	-0.006 (-1.03)	-0.038 (-2.03)	0.001 (0.18)	-0.007 (-0.93)	0.016 (2.94)
_cons	0.41 (3.7)	0.349 (2.92)	-0.123 (-1.54)	0.866 (5.49)	-0.409 (-3.33)	-0.056 (-0.71)	-0.282 (-4.26)

Note: 1) etop_pr: Etophylline price; mont_pr: Montelukast price; sab_pr: Salbutamol price; terb_pr: Terbutaline price ; theo_pr: Theophylline price; _d: Domestic; _f: Foreign

2) t- ratios in parentheses

A5.1(h): Cephalosporins

Share\Price	Cefadroxil_d	Cefadroxil _f	Cefixime_d	Cefixime_f	Cefotaxime_d	Ceftriaxone_d	Cefuroxime_d	Cefuroxime_f	Cephalexin_d
cefa_pr_d	0.063 (4.88)	-0.005 (-0.65)	-0.058 (-3.39)	0.001 (0.26)	-0.04 (-2.76)	0.016 (2.29)	0.05 (3.83)	0.017 (2.05)	-0.108 (-5.92)
cefa_pr_f	-0.005 (-0.65)	0.031 (4.16)	-0.068 (-5.94)	0.008 (1.76)	0.042 (3.67)	-0.014 (-2.29)	-0.021 (-2.02)	-0.003 (-0.4)	0.034 (2.37)
cefi_pr_d	-0.058 (-3.39)	-0.068 (-5.94)	-0.418 (-9.18)	-0.042 (-5.17)	0.042 (1.88)	0.029 (2.79)	0.053 (2.47)	-0.026 (-1.97)	0.069 (2.52)
cefi_pr_f	0.001 (0.26)	0.008 (1.76)	-0.042 (-5.17)	-0.007 (-1.39)	0.038 (3.91)	0.017 (3.07)	-0.028 (-3.24)	0.002 (0.45)	0.044 (3.82)
cefo_pr_d	-0.04 (-2.76)	0.042 (3.67)	0.042 (1.88)	0.038 (3.91)	0.125 (3.57)	0.035 (2.46)	-0.013 (-0.55)	-0.069 (-4.64)	0.146 (4.59)
ceft_pr_d	0.016 (2.29)	-0.014 (-2.29)	0.029 (2.79)	0.017 (3.07)	0.035 (2.46)	-0.023 (-1.64)	-0.091 (-7.56)	-0.015 (-1.99)	-0.046 (-2.46)
cefu_pr_d	0.05 (3.83)	-0.021 (-2.02)	0.053 (2.47)	-0.028 (-3.24)	-0.013 (-0.55)	-0.091 (-7.56)	-0.063 (-2.2)	0.063 (5.02)	-0.041 (-1.37)
cefu_pr_f	0.017 (2.05)	-0.003 (-0.4)	-0.026 (-1.97)	0.002 (0.45)	-0.069 (-4.64)	-0.015 (-1.99)	0.063 (5.02)	0.044 (4.02)	-0.028 (-1.63)
ceph_pr_d	-0.108 (-5.92)	0.034 (2.37)	0.069 (2.52)	0.044 (3.82)	0.146 (4.59)	-0.046 (-2.46)	-0.041 (-1.37)	-0.028 (-1.63)	0.032 (0.59)
ceph_pr_f	0.064 (2.5)	-0.004 (-0.22)	0.418 (8.37)	-0.034 (-2.02)	-0.307 (-6.34)	0.092 (2.98)	0.09 (2.24)	0.014 (0.59)	-0.102 (-1.52)
realexp	-0.006 (-0.76)	-0.023 (-4.7)	-0.022 (-1.25)	-0.014 (-4.66)	-0.001 (-0.17)	0.002 (0.47)	0.005 (0.56)	-0.001 (-0.24)	-0.082 (-7.66)
_cons	0.133 (2.86)	0.23 (7.21)	0.202 (2.12)	0.171 (7.19)	0.417 (5.29)	0.117 (3.82)	-0.014 (-0.21)	-0.122 (-3.28)	0.677 (7.84)

Note: 1) cefa_pr_d: Cefadroxil_price cefi_pr_d: Cefixime_price; cefo_pr_d: Cefotaxime_price; ceft_pr_d: Ceftriaxone_price; cefu_pr_d: Cefuroxime_price ; ceph_pr_d: Cephalexin_price _d: Domestic; _f: Foreign

2) t- ratios in parentheses

A5.1(i): Antipeptic Ulcerants

Share\Price	Esomeprazole_d	Esomeprazole_f	Omeprazole_d	Omeprazole_f	Pantoprazole_d	Pantoprazole_f	Rabeprazole_d	Rabeprazole_f	Ranitidine_d
eso_pr_d	0.068 (2.24)	0.017 (2.68)	-0.055 (-1.64)	-0.002 (-0.19)	0.016 (0.81)	0.021 (1.76)	0.006 (0.15)	-0.022 (-2.96)	-0.144 (-2.92)
eso_pr_f	0.017 (2.68)	-0.008 (-3.35)	0.018 (1.87)	0 (-0.02)	-0.014 (-2.37)	-0.01 (-3.4)	-0.019 (-1.65)	0.003 (1.23)	0.005 (0.42)
ome_pr_d	-0.055 (-1.64)	0.018 (1.87)	0.142 (1.96)	-0.024 (-1.5)	-0.027 (-0.63)	-0.022 (-1.32)	-0.201 (-3.26)	-0.069 (-6.13)	0.213 (2.93)
ome_pr_f	-0.002 (-0.19)	0 (-0.02)	-0.024 (-1.5)	0.001 (0.09)	0.027 (2.9)	0.005 (0.74)	-0.116 (-5.4)	0.006 (1.74)	0.111 (5.14)
pan_pr_d	0.016 (0.81)	-0.014 (-2.37)	-0.027 (-0.63)	0.027 (2.9)	0.021 (0.62)	0.006 (0.61)	0.069 (1.8)	0.014 (1.97)	-0.016 (-0.37)
pan_pr_f	0.021 (1.76)	-0.01 (-3.4)	-0.022 (-1.32)	0.005 (0.74)	0.006 (0.61)	0.02 (1.85)	-0.026 (-1.13)	0.002 (0.45)	0.002 (0.08)
rab_pr_d	0.006 (0.15)	-0.019 (-1.65)	-0.201 (-3.26)	-0.116 (-5.4)	0.069 (1.8)	-0.026 (-1.13)	-0.038 (-0.33)	0.078 (5.26)	0.319 (3.26)
rab_pr_f	-0.022 (-2.96)	0.003 (1.23)	-0.069 (-6.13)	0.006 (1.74)	0.014 (1.97)	0.002 (0.45)	0.078 (5.26)	-0.004 (-1.2)	0 (0.02)
ran_pr_d	-0.144 (-2.92)	0.005 (0.42)	0.213 (2.93)	0.111 (5.14)	-0.016 (-0.37)	0.002 (0.08)	0.319 (3.26)	0 (0.02)	-0.325 (-2.63)
ran_pr_f	0.094 (4.44)	0.009 (1.57)	0.025 (0.78)	-0.007 (-0.77)	-0.097 (-4.26)	0.003 (0.26)	-0.072 (-1.86)	-0.008 (-1.17)	-0.165 (-3.96)
realexp	0.022 (2.94)	0 (0.05)	-0.05 (-3.77)	-0.008 (-2.25)	-0.007 (-0.7)	0.004 (1.35)	-0.037 (-2.54)	0.006 (2.03)	0.06 (3.79)
_cons	0.061 (0.98)	0.056 (3.17)	0.671 (6.25)	0.029 (1.02)	-0.032 (-0.35)	-0.012 (-0.43)	0.284 (2.23)	-0.08 (-3.52)	-0.682 (-5.26)

Note: 1eso_pr_d: Esomeprazole price; ome_pr_d: Omeprazole price pan_pr_d: Pantoprazole price; rab_pr_d: Rabeprazole price; ran_pr_d: Ranitidine price

_d: Domestic; _f: Foreign

2) t- ratios in parentheses

Annex 5.2: Estimate of the Upper Level Demand Equation Parameters

Items	Antihe-lmintics	Antileu-kaemics	Antirehumatic nonstr	Broncho dilator solids & Liquids	Cephalo-sporins	Muscle relaxant	Statins	Beta Blockers	Antipeptic Ulcerants
Coefficient of price index	-2.388 (-9.06)	-0.818 (-3.45)	-2.133 (-8.54)	-1.5*	-1.952 (-15.20)	-0.818 (-5.14)	-2.105 (-5.86)	-1.245 (21.14)	-1.300 (-3.14)
Coefficient of per capita income	-0.208 (-2.31)	0.781 (2.34)	0.769 (9.06)	0.043 (0.26)	0.954 (8.48)	0.862 (11.61)	1.598 (14.97)	1.036 (4.71)	0.133 (1.00)
Constant	-0.255 (-0.24)	-8.268 (-2.47)	-6.504 (-6.87)	5.187 (4.04)	-7.348 (-5.83)	-7.276 (-8.68)	-14.893 (-14.09)	-8.657 (-3.98)	1.329 (1.11)
R^2	0.595	0.163	0.726		0.794	0.690	0.827	0.881	0.208
Adj R^2	0.582	0.135	0.717		0.787	0.680	0..821	0.878	0.182

*** Not estimated. Taken as average of the estimates for other molecules (after leaving out one relatively high value).**

Annex 5.3: Price Elasticity Estimates

A5.3 (a): Antileukaemics

Product group	Elasticity with respect to:						
	Domestic groups' prices					Foreign groups' prices	
East-Zone	Cape_pr	Doxo_pr	Giff_pr	ima_pr	Meth_pr	Doxo_pr	Meth_pr
Cape_d	9.30	-0.18	-7.83	0.04	-0.22	-0.48	-0.29
Doxo_d	-0.41	-0.65	6.15	-0.89	-0.06	-0.34	-0.23
Giff_d	-4.96	1.83	22.51	-1.96	-0.13	-3.76	-0.72
Ima_d	0.11	-0.56	-5.02	-8.23	-0.12	4.78	1.47
Meth_d	-2.12	-0.45	-3.71	-1.10	-2.24	-4.55	3.44
Doxo_f	-0.66	-0.21	-7.91	3.94	-0.68	0.31	0.60
Meth_f	-2.35	-0.93	-9.92	6.52	2.92	3.29	-4.73
West Zone							
Cape_d	5.02	-0.09	-2.10	0.02	-0.32	-0.69	-0.42
Doxo_d	-0.23	-0.81	1.53	-0.68	-0.04	-0.47	-0.28
Giff_d	-2.90	0.95	5.12	-1.44	-0.15	-5.40	-1.03
Ima_d	0.07	-0.29	-1.35	-6.22	-0.17	6.88	2.23
Meth_d	-1.22	-0.20	-0.79	-0.72	-3.01	-6.61	5.05
Doxo_f	-0.38	-0.11	-2.06	2.85	-1.05	0.88	0.89
Meth_f	-1.36	-0.46	-2.46	4.76	4.36	4.68	-6.73
North Zone							
Cape_d	21.57	-0.19	-1.60	0.02	-0.30	-0.43	-0.55
Doxo_d	-0.92	-0.61	1.30	-0.29	-0.09	-0.29	-0.43
Giff_d	-10.92	2.01	3.80	-0.66	-0.11	-3.24	-1.21
Ima_d	0.17	-0.65	-1.15	-3.42	-0.08	4.18	2.75
Meth_d	-4.69	-0.49	-0.65	-0.31	-2.68	-3.96	6.07
Doxo_f	-1.46	-0.24	-1.64	1.32	-0.88	0.14	1.08
Meth_f	-5.16	-1.01	-1.90	2.23	3.69	2.83	-7.89
South Zone							
Cape_d	2.43	-0.18	-1.85	0.00	-0.24	-2.86	-0.30
Doxo_d	-0.12	-0.66	1.40	-0.53	-0.08	-2.09	-0.27
Giff_d	-1.63	1.74	4.23	-1.19	-0.12	-22.31	-0.81
Ima_d	0.05	-0.54	-1.17	-5.32	-0.14	28.36	1.80
Meth_d	-0.67	-0.41	-0.70	-0.60	-2.72	-27.37	4.09
Doxo_f	-0.22	-0.20	-1.74	2.37	-0.93	6.71	0.70
Meth_f	-0.75	-0.88	-2.15	3.92	3.83	19.24	-5.56

Note: cape_pr: Capecitabine price; doxo_pr: Doxorubincin price; giff_pr: Gefitinib price; ima_pr: Imatinib price; meth_pr: Methotrexate price; d: Domestic; f: Foreign

A5.3 (b): Antihelmentics

Antihelmentics	Elasticity with respect to:									
Product group	Domestic groups' prices						Foreign groups' prices			
east	ad_pr	ived_pr	evd_pr	mebd_pr	pyd_pr	af_pr	ivef_pr	evfs_pr	mebfs_pr	pyf_pr
ad_d	-1.18	-13.72	-9.90	0.55	3.04	-0.72	-3.79	-1.02	39.31	-
ive_d	-1.49	-7.58	8.44	0.21	1.93	1.18	-7.36	3.53		-
lev_d_	-0.41	3.06	0.09	-0.70	-0.30	0.12	-1.13	0.52	9.40	-
meb_d	0.38	0.18	-7.49	-0.80	-0.53	-0.73	9.74	-3.21		-
py_d	1.02	4.56	-2.33	-0.41	-3.38	-0.76	6.47	-0.93	-18.16	-
af_f	-0.69	7.98	1.82	-1.80	-2.49	-0.66	-1.06	-2.05		-
ive_f	-0.14	-2.24	-0.95	0.75	0.72	-0.05	-1.32	0.14	28.09	-
lev_f	-0.12	2.67	2.74	-0.31	-1.70	-0.23	0.38	-1.03	.-	-
meb_f	0.13	-2.56	0.86	0.47	-0.29	-0.31	3.30	0.39	.-	-
py_f	0.46	0.67	2.09	-0.83	0.48	0.02	-6.74	2.27	.-	-
west										
ad_d	-1.24	-7.25	-3.92	0.60	13.25	-0.74	-	-0.88	10.77	-
ive_d	-1.40	-4.49	2.92	0.17	7.73	1.04	-	2.53	-19.54	-
lev_d_	-0.40	1.44	-0.67	-0.84	-1.18	0.08	-	0.35	2.75	-
meb_d	0.34	0.05	-2.79	-0.71	-1.48	-0.67	-	-2.38	14.74	-
py_d	0.99	2.51	-0.76	-0.29	-9.87	-0.63	-	-0.66	-5.63	-
af_f	-0.69	3.71	0.32	-2.03	-8.67	-0.75	-	-1.62	-17.48	-
ive_f	-0.12	-1.09	-0.33	0.87	2.94	-0.03	-	0.11	7.67	-
lev_f	-0.13	1.28	0.93	-0.37	-6.65	-0.23	-	-1.04		-
meb_f	0.11	-1.31	0.30	0.52	-1.14	-0.29	-	0.28		-
py_f	0.41	0.34	0.75	-0.94	1.92	0.02	-	1.65		-
north										
ad_d	-1.19	-7.40	-3.78	1.47	9.62	-0.67	-31.85	-0.71	21.52	-
ive_d	-1.51	-4.60	2.86	0.38	5.63	0.92		1.61		-
lev_d_	-0.43	1.49	-0.68	-1.42	-0.88	0.06	-10.30	0.21	5.55	-
meb_d	0.45	0.27	-2.61	-0.24	-1.03	-0.55	92.54	-1.56	28.75	-
py_d	1.08	2.57	-0.77	-0.50	-7.52	-0.57		-0.45	-11.04	-
af_f	-0.75	3.70	0.21	-3.28	-6.55	-0.88	-5.89	-1.26	-33.74	-
ive_f	-0.13	-1.14	-0.32	1.50	2.15	-0.03	-3.95	0.07	15.30	-
lev_f	-0.16	1.24	0.86	-0.66	-4.93	-0.24	4.16	-1.07	-	-
meb_f	0.13	-1.35	0.30	0.91	-0.83	-0.26		0.18	-	-
py_f	0.45	0.35	0.74	-1.62	1.40	0.02	-63.18	1.07	-	-
south										
ad_d	-1.40	-7.46	-7.10	0.53	13.69	-0.87	-	-1.19	13.12	-
ive_d	-1.13	-4.43	5.48	0.19	8.09	1.19	-	4.52	-22.33	-
lev_d_	-0.31	1.48	-0.30	-0.89	-1.19	0.12	-	0.66	3.01	-
meb_d	0.25	0.09	-4.97	-0.64	-1.52	-0.72	-	-4.04	16.80	-
py_d	0.78	2.47	-1.37	-0.31	-10.28	-0.70	-	-1.14	-6.44	-
af_f	-0.60	3.77	1.11	-2.11	-8.97	-0.61	-	-2.49	-20.24	-
ive_f	-0.09	-1.07	-0.60	0.96	3.08	-0.03	-	0.19	8.78	-
lev_f	-0.09	1.32	1.83	-0.37	-6.92	-0.23	-	-1.03		-
meb_f	0.09	-1.28	0.56	0.58	-1.19	-0.33	-	0.50	24.14	-
py_f	0.33	0.33	1.39	-1.03	2.01	0.02	-	2.89		-

Note: ad_pr: Albendazole price; ive_pr: Ivermectin &comb*; evd_pr: Levamisol price mebd_pr: Mebendazole price; pyd_pr: Pyrental Pamoate price; d: Domestic; f: Foreign*
Elasticity are not define because share is very low

A5.3(c): Antirheumatic nonstr.

Product group	Elasticity with respect to:								
	Domestic groups' prices					Foreign groups' prices			
East-Zone	acec_pr	dic_pr	eto_pr	ibu_pr	nim_pr	acec_pr	dic_pr	ibu_pr	nim_pr
acec_d	-2.68	-0.26	-2.46	3.71	-0.19		0.76	1.96	-
dic_d	-0.34	-1.39	-0.64	-0.32	0.24	-6.21	0.80	-2.09	-
eto_d	-1.98	-0.51	-0.90	0.18	0.24	10.91	0.01	0.91	-
ibu_d	2.53	-0.14	0.35	-1.28	-0.23		-0.31	-2.35	-
nim_d	-0.54	0.23	1.19	-1.02	-1.11		-2.48	0.31	-
acec_f	-0.51	-0.05	0.12	-0.42	0.07	5.78	0.37	0.06	-
dic_f	0.46	0.32	0.16	-0.26	-0.54		-0.62	-1.01	-9.58
eto_f	1.12	-0.84	0.82	-2.01	0.10	5.15	-1.05	-1.48	
ibu_f	-0.34	0.14	0.68	-1.22	-0.56		-0.14	1.42	
nim_f									
West -Zone									
acec_d	-0.40	-1.42	-0.73	-0.38	0.21	-10.81	0.60	-1.76	
dic_d	-2.20	-0.41	-0.86	0.23	0.27	20.56	0.03	0.74	
eto_d	2.89	-0.13	0.47	-1.28	-0.23		-0.28	-1.89	
ibu_d	-0.57	0.13	1.64	-1.04	-1.11		-2.19	0.18	
nim_d	-0.58	-0.05	0.15	-0.42	0.07	12.03	0.32	0.05	
acec_f	0.52	0.24	0.23	-0.28	-0.56		-0.70	-0.84	-7.07
dic_f	1.25	-0.74	1.10	-2.08	0.08	10.45	-0.95	-1.42	
eto_f	-0.39	0.11	0.88	-1.25	-0.56		-0.12	1.14	
ibu_f	-2.68	-0.26	-2.46	3.71	-0.19		0.76	1.96	
nim_f	-0.34	-1.39	-0.64	-0.32	0.24	-6.21	0.80	-2.09	

Continued…

North -Zone									
acec_d	-3.49	-0.18	-3.70	2.68	-0.15		0.90	0.87	-
dic_d	-0.44	-1.41	-0.83	-0.32	0.32	-10.45	0.82	-1.09	-
eto_d	-3.00	-0.42	-0.84	0.15	0.35	18.93	0.07	0.39	-
ibu_d	3.98	-0.19	0.61	-1.28	-0.30		-0.38	-1.15	-
nim_d	-0.58	0.25	1.93	-0.74	-1.01		-2.52	0.02	-
acec_f	-0.80	-0.05	0.18	-0.30	0.09	11.17	0.39	0.03	-
dic_f	0.78	0.29	0.28	-0.20	-0.64		-0.58	-0.50	-23.37
eto_f	1.67	-0.90	1.39	-1.60	0.04	11.42	-1.27	-1.37	
ibu_f	-0.53	0.12	1.03	-0.87	-0.68		-0.15	0.64	
nim_f									
South -Zone									
acec_d	-0.35	-1.41	-0.67	-0.39	0.32	-6.39	0.48	-2.18	17.66
dic_d	-1.65	-0.44	-0.88	0.25	0.34	11.91	-0.01	0.95	
eto_d	2.12	-0.11	0.39	-1.28	-0.25		-0.23	-2.39	
ibu_d	-0.43	0.24	1.35	-1.03	-0.99		-1.81	0.41	
nim_d	-0.42	-0.05	0.13	-0.49	0.09	6.48	0.27	0.07	17.45
acec_f	0.34	0.22	0.20	-0.34	-0.69		-0.78	-1.07	-2.13
dic_f	0.92	-0.73	0.94	-2.35	0.14	5.66	-0.79	-1.48	
eto_f	-0.29	0.11	0.77	-1.44	-0.71		-0.11	1.46	
ibu_f	-3.49	-0.18	-3.70	2.68	-0.15		0.90	0.87	
nim_f	-0.44	-1.41	-0.83	-0.32	0.32	-10.45	0.82	-1.09	

Note: acec_pr: Aceclofenac price; dic_pr: Diclofenac price; eto_pr: Etorecoxib price; ibu_pr uprofen price; nim_pr: Nimesulide price; d: Domestic; f: Foreign -: Elasticity are not defined because share is very low

A5.3 (d): Antipeptic Ulcerants

Product group	Elasticity with respect to:									
	Domestic groups' prices					Foreign groups' prices				
East -Zone	eso_pr	ome_pr	pan_pr	rab_pr	ran_pr	eso_pr	ome_pr	pan_pr	rab_pr	ran_pr
eso_d	0.37	-0.30	0.06	0.03	-0.79	15.09	-14.01	7.21	-4.60	1.14
ome_d	-1.31	-0.21	-0.16	-1.05	0.98	15.22		-7.92	-14.37	0.23
pan_d	0.13	-0.13	-0.98	0.35	-0.26	-12.13		1.36	2.48	-1.30
rab_d	-0.04	-1.09	0.24	-1.21	1.53	-16.97		-9.45	15.55	-0.98
ran_d	-3.15	1.18	-0.12	1.64	-2.84	4.44		0.24	-0.30	-2.12
eso_f	0.36	0.10	-0.06	-0.10	0.03	-7.91	-0.56	-3.52	0.53	0.11
ome_f	-0.04	-0.13	0.11	-0.60	0.58	-0.06	5.59	1.59	1.27	-0.09
pan_f	0.44	-0.12	0.02	-0.14	0.01	-8.92		6.00	0.35	0.03
rab_f	-0.46	-0.38	0.06	0.40	0.00	2.29		0.59	-1.88	-0.10
ran_f	1.88	0.14	-0.42	-0.38	-0.92	7.56		0.74	-1.85	1.66
West -Zone										
eso_d	0.13	-0.25	0.06	0.02	-0.98	11.20	-0.97	7.76	-4.63	1.95
ome_d	-1.13	-0.36	-0.18	-0.89	1.20	11.28	-14.08	-8.64	-14.47	0.41
pan_d	0.11	-0.12	-0.96	0.28	-0.28	-9.03	18.99	1.54	2.54	-2.15
rab_d	-0.07	-0.91	0.26	-1.19	1.88	-12.64		-10.29	15.51	-1.65
ran_d	-2.61	0.96	-0.11	1.37	-3.23	3.30		0.35	-0.23	-3.55
eso_f	0.30	0.08	-0.06	-0.08	0.03	-6.13	-0.04	-3.80	0.53	0.18
ome_f	-0.04	-0.11	0.12	-0.50	0.72	-0.05	-0.51	1.72	1.27	-0.15
pan_f	0.37	-0.10	0.03	-0.11	0.01	-6.63	3.07	6.56	0.35	0.05
rab_f	-0.39	-0.31	0.07	0.34	0.00	1.70	4.12	0.64	-1.88	-0.18
ran_f	1.59	0.11	-0.46	-0.32	-1.11	5.62	-4.51	0.88	-1.78	3.57

Continued…

North -Zone										
eso_d	0.27	-0.26	0.06	0.03	-1.05	9.47	-4.32	6.63	-4.87	1.17
ome_d	-1.26	-0.34	-0.18	-0.97	1.30	9.53		-7.37	-15.26	0.22
pan_d	0.13	-0.13	-0.96	0.31	-0.30	-7.64		1.29	2.66	-1.33
rab_d	-0.06	-0.94	0.26	-1.20	2.05	-10.68		-8.75	16.41	-1.01
ran_d	-2.91	0.99	-0.11	1.51	-3.39	2.78		0.31	-0.22	-2.16
eso_f	0.33	0.08	-0.06	-0.09	0.03	-5.34	-0.16	-3.24	0.56	0.11
ome_f	-0.04	-0.11	0.12	-0.55	0.77	-0.04	1.08	1.47	1.34	-0.09
pan_f	0.41	-0.10	0.02	-0.13	0.01	-5.60	13.33	5.45	0.37	0.03
rab_f	-0.43	-0.32	0.06	0.37	0.00	1.44	17.90	0.55	-1.93	-0.11
ran_f	1.76	0.12	-0.45	-0.35	-1.22	4.74	-18.60	0.68	-1.95	1.74

South-Zone										
eso_d	-0.05	-0.25	0.06	0.03	-1.08	12.80		8.51	-4.12	1.02
ome_d	-0.97	-0.36	-0.19	-1.00	1.32	12.90		-9.50	-12.83	0.18
pan_d	0.09	-0.12	-0.95	0.33	-0.29	-10.30		1.72	2.25	-1.17
rab_d	-0.05	-0.91	0.28	-1.20	2.10	-14.41		-11.24	13.78	-0.89
ran_d	-2.21	0.97	-0.11	1.55	-3.43	3.78		0.43	-0.18	-1.89
eso_f	0.25	0.08	-0.07	-0.09	0.04	-6.86	-5.15	-4.18	0.47	0.10
ome_f	-0.03	-0.11	0.13	-0.57	0.79	-0.05		1.89	1.12	-0.08
pan_f	0.31	-0.10	0.03	-0.13	0.01	-7.57		7.32	0.31	0.03
rab_f	-0.33	-0.31	0.07	0.38	0.00	1.94		0.70	-1.78	-0.09
ran_f	1.32	0.11	-0.49	-0.36	-1.25	6.41		0.86	-1.66	1.39

Note: esod_pr: Esomeprazole price; omed_pr: Omeprazole price; pand_pr: Pantoprazole price; rabd_pr: Rabeprazole price; rand_pr: Ranitidine price d: Domestic; f: Foreign

-: Elasticity is not defined because share is varying low

A5.3 (e): Statins

Product group	Elasticity with respect to:			
	Domestic groups' prices			Foreign groups' prices
East-Zone	at_pr	ros_pr	si_pr	at_pr
ator_d	-1.76	-2.99	-2.42	-0.53
rosu_d	-0.20	-0.33	1.33	1.63
sim_d	-0.22	1.95	-0.32	-5.72
ator_f	0.01	0.13	-0.26	-1.74
West Zone				
ator_d	-1.67	-3.34	-1.66	-0.61
rosu_d	-0.21	-0.20	0.66	0.68
sim_d	-0.31	2.31	-0.75	-2.63
ator_f	0.01	0.15	-0.14	-1.33
North Zone				
ator_d	-1.70	-2.51	-2.07	-0.72
rosu_d	-0.23	-0.50	1.01	0.50
sim_d	-0.25	1.49	-0.51	-2.10
ator_f	0.01	0.10	-0.20	-1.28
South Zone				
ator_d	-1.67	-2.54	-1.77	-0.66
rosu_d	-0.23	-0.49	0.75	0.49
sim_d	-0.29	1.51	-0.67	-2.12
ator_f	0.01	0.10	-0.16	-1.27

Note: at_pr: Atorvastatin price; ros_pr : Rosuvastatin price; si_pr : Simvastatin price; d: Domestic; f: Foreign

A5.3 (f): **Beta Blockers**

Elasticity with respect to								
	Domestic groups' pricess					foreign groups' pricess		
East	ate_prd	car_prd	met_prd	neb_prd	pro_prd	ate_prf	met_prf	pro_prf
sate_d	-1.34	0.97	-0.19	1.91	-0.38	3.09	1.44	-36.71
scar_d	0.19	-2.96	0.05	-2.76	0.04	2.95	2.56	53.54
smet_d	-0.01	0.23	-1.55	1.04	0.39	4.11	0.32	54.24
sneb_d	0.09	-1.04	0.04	-2.16	-0.18	-0.15	1.25	-
spro_d	0.04	0.12	0.17	-0.43	-1.05	-4.14	-2.19	-
sate_f	0.03	0.17	0.04	-0.02	-0.20	1.99	-0.11	-
smet_f	0.07	0.74	0.02	1.02	-0.52	-0.53	-2.94	-
spro_f	-0.02	0.25	0.06	1.36	-0.36	-8.28	-1.66	-
West								
sate_d	-1.39	0.43	-0.23	0.31	-0.19	-	1.40	-
scar_d	0.03	0.08	0.09	-0.01	-0.10	-	-0.10	-
smet_d	0.24	-1.97	0.09	-0.58	-0.04	-	2.43	-
sneb_d	-0.01	0.13	-1.92	0.14	0.30	-	0.36	-
spro_d	0.09	0.35	0.04	0.21	-0.27	-57.84	-2.86	-
sate_f	0.12	-0.53	0.04	-1.24	-0.17	-13.07	1.17	-
smet_f	0.06	0.01	0.32	-0.11	-1.10	-	-2.13	-
spro_f	-0.02	0.12	0.11	0.28	-0.18	-	-1.59	-
North								
sate_d	-1.41	0.83	-0.45	0.42	-0.12	-	2.72	-71.84
scar_d	0.04	0.14	0.23	-0.01	-0.04	-	-0.19	
smet_d	0.25	-2.64	0.34	-0.74	-0.01	-	4.64	-
sneb_d	-0.02	0.32	-3.19	0.19	0.15	-	0.77	-
spro_d	0.09	0.62	0.11	0.27	-0.11	-80.42	-4.50	-
sate_f	0.12	-0.90	0.16	-1.31	-0.07	-19.28	2.24	-
smet_f	0.09	-0.06	0.69	-0.11	-1.17	-	-4.07	-
spro_f	-0.02	0.21	0.29	0.36	-0.08	-	-3.00	-
South								
sate_d	-1.98	0.33	-0.07	0.65	-0.02	-	8.51	-
scar_d	0.08	0.05	0.03	-0.01	-0.19	-	-0.59	-
smet_d	0.70	-1.67	-0.01	-1.10	-0.14	-	13.93	-
sneb_d	0.23	-0.03	-1.47	0.41	0.23	-	2.06	-
spro_d	0.21	0.23	0.02	0.41	-0.49	-	-11.55	-
sate_f	0.29	-0.34	0.02	-1.47	-0.22	-	6.81	-
smet_f	0.15	0.02	0.12	-0.19	-1.05	-	-11.85	-
spro_f	-0.04	0.08	0.04	0.56	-0.35	-	-9.06	-

A5.3 (g): Muscular Relaxant

Product group	Elasticity with respect to:								
	Domestic groups' prices					Foreign groups' prices			
East-Zone	bac_pr	cne_pr	cxa_pr	met_pr	tiz_pr	bac_pr	cne_pr	cxa_pr	tiz_pr
bac_d	-2.24	1.02	0.00	1.09	-0.02	0.20	-	0.51	-0.19
cne_d	1.19	-3.87	0.03	3.24	-0.21	0.27	-	1.38	-0.13
cxa_d	3.89	3.28	-1.54	0.62	-0.36	3.37	-	5.58	1.07
met_d	0.94	2.35	0.03	-2.30	-0.32	-0.77	-	0.25	-0.17
tiz_d	-3.30	-3.47	0.06	-2.14	0.23	-3.36	-	-6.79	0.49
bac_f	0.22	0.24	-0.01	-0.92	-0.06	0.21	-	0.06	-0.14
cne_f	-0.55	0.23	0.00	0.19	-0.03	-0.03	-	-0.08	0.02
cxa_f	0.13	0.32	0.03	0.07	-0.15	0.00	-	-0.04	-0.05
tiz_f	-0.34	-0.21	0.13	-0.40	0.08	-0.29	-	-0.25	-0.97
West -Zone									
bac_d	-3.16	1.01	0.01	0.90	-0.04	0.25	-11.41	0.31	-0.35
cne_d	2.04	-3.90	0.02	2.70	-0.28	0.35	5.42	0.88	-0.23
cxa_d	6.77	3.41	-1.42	0.57	-0.46	4.42	-	3.68	1.88
met_d	1.61	2.39	0.03	-2.07	-0.41	-1.00	3.31	0.17	-0.27
tiz_d	-5.79	-3.57	0.07	-1.80	0.56	-4.41		-4.35	0.68
bac_f	0.35	0.24	-0.01	-0.76	-0.08	0.56	-0.64	0.03	-0.26
cne_f	-0.94	0.23	0.00	0.16	-0.04	-0.04	6.38	-0.05	0.04
cxa_f	0.24	0.33	0.02	0.06	-0.19	0.01	-0.44	-0.39	-0.07
tiz_f	-0.64	-0.24	0.11	-0.35	0.09	-0.40	0.75	-0.19	-1.00

Continued…

North -Zone									
bac_d	-2.84	4.56	0.01	1.02	-0.04	0.21	-12.99	0.84	-0.34
cne_d	1.69	-14.30	0.03	3.03	-0.32	0.26	6.19	2.26	-0.29
cxa_d	5.91	15.34	-1.37	0.66	-0.52	3.75		10.09	1.95
met_d	1.37	10.72	0.02	-2.21	-0.46	-0.83	3.76	0.44	-0.28
tiz_d	-4.98	-16.34	0.07	-2.05	0.74	-3.68		-12.00	0.63
bac_f	0.31	1.07	-0.01	-0.86	-0.09	0.31	-0.73	0.08	-0.24
cne_f	-0.81	1.04	0.00	0.18	-0.05	-0.03	7.40	-0.13	0.04
cxa_f	0.19	1.42	0.02	0.06	-0.22	0.00	-0.50	0.63	-0.09
tiz_f	-0.55	-1.12	0.10	-0.39	0.10	-0.33	0.85	-0.54	-1.00
South -Zone									
bac_d	-2.20	0.75	0.00	0.65	-0.06	0.21		0.24	-0.31
cne_d	1.17	-3.10	0.02	1.92	-0.42	0.29		0.65	-0.20
cxa_d	3.85	2.51	-1.43	0.43	-0.75	3.43		2.68	1.85
met_d	0.93	1.76	0.02	-1.75	-0.62	-0.75		0.14	-0.24
tiz_d	-3.31	-2.65	0.08	-1.29	1.32	-3.44		-3.19	0.56
bac_f	0.21	0.18	-0.01	-0.54	-0.13	0.21		0.03	-0.24
cne_f	-0.53	0.17	0.00	0.11	-0.06	-0.03		-0.03	0.03
cxa_f	0.14	0.25	0.02	0.05	-0.30	0.01		-0.55	-0.06
tiz_f	-0.36	-0.17	0.11	-0.24	0.13	-0.31		-0.14	-1.00

Note: bac_pr: Baclofen & comb price; cne_pr: Chlormezanone & comb price; cxa_pr: Chlorzoxa & comb price; met_pr: Methocarbamol & comb_price; tiz_pr: Tizanidine & comb_price ; d: Domestic; f: Foreign

-: Elasticity is not defined because share is very low

A5.3 (h): Cephalosporins

Product group	Elasticity with respect to:									
	Domestic groups' prices						Foreign groups' prices			
East-Zone	cefa_pr	cefi_pr	cefo_pr	ceft_pr	cefu_pr	ceph_pr	cefa_pr	cefi_pr	cefu_pr	ceph_pr
cefa_d	-0.47	-0.29	-0.49	1.01	0.54	-1.23	-0.43	0.78	0.30	0.88
cefi_d	-0.80	-2.73	0.17	1.71	0.40	1.14	-29.94	-7.59	-0.84	9.17
cefo_d	-0.47	0.07	0.15	2.31	-0.28	1.92	24.75	8.51	-1.70	-9.36
ceft_d	0.15	0.10	0.34	-2.63	-1.21	-0.56	-7.21	3.71	-0.37	2.42
cefu_d	0.43	0.13	-0.20	-6.40	-1.91	-0.43	-9.27	-5.44	1.41	1.83
ceph_d	-1.13	0.19	1.38	-3.30	-0.63	-0.52	19.98	9.74	-0.73	-3.53
cefa_f	-0.05	-0.25	0.42	-0.99	-0.27	0.43	15.63	1.65	-0.06	-0.14
cefi_f	0.01	-0.16	0.38	1.19	-0.37	0.56	4.22	-2.49	0.05	-0.98
cefu_f	0.13	-0.13	-0.73	-1.11	0.78	-0.31	-0.43	0.70	-0.01	0.01
ceph_f	0.60	1.49	-3.09	6.34	1.14	-1.23	-1.54	-7.00	0.29	-7.70
West -Zone										
cefa_d	-0.71	-0.29	-0.69	0.99	0.50	-1.67	0.30	1.38	0.28	0.40
cefi_d	-0.70	-2.46	0.26	1.69	0.33	1.97	-15.65	-9.33	-0.94	7.50
cefo_d	-0.33	0.06	0.68	2.43	-0.25	2.81	13.29	11.02	-1.75	-8.14
ceft_d	0.10	0.07	0.48	-2.68	-1.23	-0.82	-4.00	4.87	-0.39	2.16
cefu_d	0.27	0.09	-0.25	-6.62	-1.92	-0.61	-5.17	-7.13	1.48	1.63
ceph_d	-0.77	0.15	1.99	-3.39	-0.61	-0.31	10.70	12.65	-0.74	-2.95
cefa_f	-0.04	-0.19	0.59	-1.03	-0.28	0.63	8.21	2.17	-0.07	-0.14
cefi_f	0.01	-0.12	0.53	1.23	-0.37	0.82	2.32	-2.97	0.05	-0.87
cefu_f	0.08	-0.11	-1.00	-1.15	0.80	-0.44	-0.28	0.93	0.05	0.02
ceph_f	0.39	1.13	-4.33	6.56	1.16	-1.79	-0.81	-9.16	0.30	-7.01

Continued…

North -Zone										
cefa_d	-0.52	-0.29	-0.49	0.61	0.60	-1.09	-0.24	0.91	0.39	0.70
cefi_d	-0.77	-2.70	0.15	1.01	0.46	0.98	-27.85	-8.23	-0.99	7.96
cefo_d	-0.45	0.07	0.12	1.47	-0.30	1.68	23.20	9.32	-2.09	-8.26
ceft_d	0.13	0.09	0.32	-2.07	-1.33	-0.49	-6.58	4.09	-0.46	2.07
cefu_d	0.40	0.13	-0.19	-4.18	-1.98	-0.40	-8.83	-5.97	1.77	1.65
ceph_d	-1.06	0.17	1.34	-2.19	-0.69	-0.58	18.92	10.71	-0.90	-3.19
cefa_f	-0.05	-0.24	0.41	-0.64	-0.30	0.38	14.56	1.80	-0.08	-0.12
cefi_f	0.01	-0.15	0.37	0.77	-0.40	0.49	3.94	-2.63	0.06	-0.86
cefu_f	0.12	-0.12	-0.70	-0.73	0.88	-0.28	-0.59	0.73	0.25	0.07
ceph_f	0.55	1.44	-3.02	4.11	1.25	-1.09	-1.33	-7.62	0.37	-6.92
South -Zone										
cefa_d	-0.53	-0.27	-0.47	1.26	0.86	-0.86	-0.17	0.83	0.37	0.33
cefi_d	-0.79	-2.58	0.10	2.15	0.70	0.70	-17.74	-7.37	-1.00	4.06
cefo_d	-0.45	0.05	0.07	2.89	-0.38	1.27	15.08	8.52	-2.04	-4.56
ceft_d	0.14	0.08	0.32	-3.02	-1.81	-0.38	-4.42	3.68	-0.44	1.17
cefu_d	0.40	0.13	-0.17	-7.91	-2.30	-0.33	-6.01	-5.55	1.74	0.96
ceph_d	-1.07	0.12	1.26	-4.14	-0.95	-0.69	12.62	9.90	-0.90	-1.91
cefa_f	-0.05	-0.22	0.39	-1.23	-0.41	0.29	9.12	1.65	-0.08	-0.07
cefi_f	0.01	-0.14	0.35	1.48	-0.55	0.37	2.56	-2.49	0.06	-0.47
cefu_f	0.12	-0.11	-0.68	-1.37	1.21	-0.22	-0.38	0.67	0.22	0.02
ceph_f	0.51	1.26	-2.94	7.85	1.69	-0.83	-0.42	-6.79	0.33	-4.41

Note: cefad_pr: Cefadroxil_price ; cefid_pr: Cefixime_price; cefod_pr: Cefotaxime_price; ceftd_pr: Ceftriaxone_price; cefud_pr: Cefuroxime_price ; cephd_pr: Cephalexin_price _d: Domestic; _f: Foreign

A5.3 (i): Broncho Dilator Solids & Liquid

Product group	Elasticity with respect to:							
	Domestic groups'prices					Foreign groups'prices		
East-Zone	letop_pr	lmont_pr	lsalb_pr	lterb_pr	ltheo_pr	lmont_pr	lsalb_pr	lterb_pr
etop_d	0.20	-0.09	0.36	7.16	-3.25		-2.08	2.53
mont_d	-0.32	-1.63	-0.53	3.18	-1.07		4.50	6.69
salb_d	3.83	-2.09	-1.64	-9.70	4.14		-0.19	-0.38
terb_d	3.61	0.50	-0.44	-0.55	-0.10	10.94	0.49	-2.50
theo_d	-9.63	-1.04	1.09	-0.50	-0.17		-0.77	-4.39
mont_f	1.62	0.24	-0.22	0.29	-0.20		-0.47	0.17
salb_f	-2.25	1.55	-0.01	1.06	-0.28		-2.18	-2.20
terb_f	1.05	0.90	0.01	-1.99	-0.59	5.40	-0.82	-2.55
theo_f								
West -Zone	-0.63	-0.15	0.38	19.67	-3.38		-2.07	1.24
etop_d	-0.16	-1.67	-0.59	8.79	-1.09		4.38	3.53
mont_d	1.29	-2.20	-1.67	-26.07	4.31		-0.15	-0.25
salb_d	1.33	0.56	-0.49	0.24	-0.09		0.48	-1.32
terb_d	-3.59	-1.12	1.25	-1.25	-0.14		-0.75	-2.36
theo_d	0.60	0.26	-0.25	0.79	-0.21		-0.46	0.09
mont_f	-0.85	1.68	-0.01	2.94	-0.29		-2.15	-1.18
salb_f	0.37	0.97	0.01	-5.41	-0.61	21.87	-0.81	-1.85
terb_f	0.20	-0.09	0.36	7.16	-3.25		-2.08	2.53
theo_f	-0.32	-1.63	-0.53	3.18	-1.07		4.50	6.69

Continue…

North -Zone								
etop_d	-0.81	-0.18	0.46	15.15	-3.25		-2.26	1.63
mont_d	-0.14	-1.58	-0.72	6.77	-1.06		4.71	4.82
salb_d	0.84	-1.80	-1.74	-20.16	4.13	1	-0.10	-0.14
terb_d	0.89	0.46	-0.61	-0.05	-0.09	19.23	0.52	-1.80
theo_d	-2.44	-0.94	1.55	-0.97	-0.19		-0.80	-3.21
mont_f	0.40	0.21	-0.31	0.61	-0.20		-0.50	0.13
salb_f	-0.58	1.39	0.00	2.25	-0.27		-2.23	-1.61
terb_f	0.25	0.80	0.02	-4.17	-0.58	9.80	-0.86	-2.14
theo_f								
South -Zone	-0.63	-0.12	0.51	12.46	-3.27		-1.54	0.94
etop_d	-0.20	-1.51	-0.76	5.57	-1.09	36.11	3.18	2.65
mont_d	1.35	-1.50	-1.76	-16.66	4.21		-0.12	-0.14
salb_d	1.33	0.37	-0.63	-0.21	-0.09	7.00	0.35	-1.03
terb_d	-3.58	-0.78	1.63	-0.82	-0.18		-0.57	-1.84
theo_d	0.59	0.17	-0.32	0.50	-0.20		-0.34	0.07
mont_f	-0.86	1.12	-0.01	1.86	-0.29	-23.32	-1.86	-0.94
salb_f	0.36	0.64	0.01	-3.43	-0.60	3.71	-0.60	-1.67
terb_f	-0.81	-0.18	0.46	15.15	-3.25		-2.26	1.63
theo_f	-0.14	-1.58	-0.72	6.77	-1.06		4.71	4.82

Note: 1) Letop_pr: Etophylline price; lmont_pr: Montelukast price; lsalb_pr: Salbutamol price; lterb_pr: Terbutaline price ; ltheo_pr: Theophylline price; _d: Domestic; _f: Foreign

Annex 5.4: Summary of Estimates of Own and Cross Price Elasticity, and Expenditure Elasticity, (East Zone)

A5.4 (a): Statins

East Zone	Own Price Elasticity		Cross Price Elasticity		Positive Cross Price Elasticity with Other Compound (+ve cases)			Expenditure Elasticity	
Molecule	Domestic	Foreign	Domestic#	Foreign@		d/d	f/f	Domestic	Foreign
Atorvastatin	-1.76	-1.74	(-)	(+)	6/8	4/4	-	1.03	3.02
Rosuvastatin	-0.33	-	-	-	2/6	2/4	-	0.59	-
Simvastatin	-0.32	-	-	-	4/6	2/4	-	0.79	-

A5.4 (b): Beta Blockers

East Zone	Own Price Elasticity		Cross Price Elasticity		Cross Price Elasticity with Other Compound (+ve cases)	d/d	f/f	Expenditure Elasticity	
Molecule	Domestic	Foreign	Domestic	Foreign				Domestic	Foreign
Atenolol	-1.34	1.99	(+)	(+)	11/24	5/8	np/4	0.76	0.76
Carvedilol	-2.96	-	-	-	12/14	6/8	-	1.23	-
Metoprolol	-1.55	-2.94	(+)	(+)	16/24	6/8	np/4	1.09	1.07
Nebivolol	-2.16	-	-	-	8/14	4/8	-	0.03	-
Propranolol	-1.05	101.64	(-)	(-)	11/24	5/8	np/4	1.82	29.75

A5.4 (c): Cephalosporins

East Zone	Own Price Elasticity		Cross Price Elasticity		Positive Cross Price Elasticity with Other Compound (+ve cases)	d/d	f/f	Expenditure Elasticity	
Molecule	Domestic	Foreign	Domestic#	Foreign@				Domestic	Foreign
Cefadroxil	-0.47	15.63	(-)	(-)	16/32	4/10	2/6	0.94	-11.15
Cefixime	-2.73	-2.49	(-)	(-)	22/32	7/10	4/6	0.92	-1.97
Cefotaxime	0.15	-	-	-	10/18	6/10	-	0.99	-
Ceftriaxone	-2.63	-	-	-	10/18	6/10	-	1.12	-
Cefuroxime	-1.91	-0.01	(+)	(+)	12/32	4/10	4/6	1.06	0.97
Cephalexin	-0.52	-7.70	(-)	(-)	18/32	4/10	2/6	-0.01	4.97

A5.4 (d):Antipeptic Ulcerants

East Zone	Own Price Elasticity		Cross Price Elasticity		Positive Cross Price Elasticity with Other Compound (+ve cases)	d/d	f/f	Expenditure Elasticity	
Molecule	Domestic	Foreign	Domestic#	Foreign@				Domestic	Foreign
Esomeprazole	0.37	-7.91	(+)	(+)	15/32	3/8	4/8	1.45	1.09
Omeprazole	-0.21	5.59	(-)	(-)	14/32	2/8	4/8	0.73	-70.78
Pantoprazole	-0.98	6.00	(+)	(+)	18/32	4/8	6/8	0.97	2.52
Rabeprazole	-1.21	-1.88	(+)	(+)	13/32	5/8	6/8	0.81	2.25
Ranitidine	-2.84	1.66	(-)	(-)	18/32	4/8	4/8	1.31	1.12

A5.4 (e): Broncho-dilators Solids & Liquid

East Zone	Own Price Elasticity		Cross Price Elasticity		Positive Cross Price Elasticity with Other Compound (+ve cases)	d/d	f/f	Expenditure Elasticity	
Molecule	Domestic	Foreign	Domestic#	Foreign@				Domestic	Foreign
Etophylline & comb.	0.20	-	-	-	8/14	4/8	-	1.28	-
Montelukast & comb.	-1.63	73.75	(+)	(+)	12/24	2/8	2/4	1.12	-7.46
Salbutamol & comb.	-1.64	-2.18	(-)	(-)	9/24	4/8	np/4	0.93	1.03
Terbutaline & comb.	-0.55	-2.55	(-)	(-)	15/24	4/8	2/4	0.71	1.78
Theophylline & comb.	-0.17	-	-	-	2/14	2/8	-	1.02	-

A5.4 (f):Antileukaemics

East Zone	Own Price Elasticity		Cross Price Elasticity		Positive Cross Price Elasticity with Other Compound (+ve cases)	d/d	f/f	Expenditure Elasticity	
Molecule	**Domestic**	**Foreign**	**Domestic#**	**Foreign@**				**Domestic**	**Foreign**
Capecitabine	9.30	-	-	-	2/12	2/8	-	1.35	-
Doxorubincin	-0.65	0.31	(-)	(-)	6/20	2/8	2/2	1.41	0.89
Gefitinib	22.51	-	-	-	2/12	2/8	-	7.45	-
Imatinib	-8.23	-	-	-	6/12	2/8	-	2.11	-
Methotrexate	-2.24	-4.73	(+)	(+)	4/20	np/8	2/2	0.60	0.51

A5.4 (g):Antirheumatic Nonstr.

East Zone	Own Price Elasticity		Cross Price Elasticity		Positive Cross Price Elasticity with Other Compound (+ve cases)	d/d	f/f	Expenditure Elasticity	
Molecule	**Domestic**	**Foreign**	**Domestic#**	**Foreign@**				**Domestic**	**Foreign**
Aceclofenac	-2.68	5.78	(-)	(-)	16/28	2/8	6/6	1.11	-5.59
Diclofenac	-1.39	-0.62	(+)	(+)	10/28	2/8	2/6	1.23	1.31
Etorecoxib	-0.90	-	-	-	12/16	4/8	-	0.31	-
Ibuprofen	-1.28	-1.48	(-)	(-)	14/28	4/8	4/6	1.29	1.10
Nimesulide	-1.11	158.35	(-)	(-)	16/28	4/8	4/6	0.96	-44.72

A5.4 (h):Antihelmentics

East Zone	Own Price Elasticity		Cross Price Elasticity		Positive Cross Price Elasticity with Other Compound (+ve cases)	d/d	f/f	Expenditure Elasticity	
Molecule	**Domestic**	**Foreign**	**Domestic#**	**Foreign@**				**Domestic**	**Foreign**
Albendazole	-1.18	-0.66	(-)	(-)	14/32	4/8	2/8	0.87	0.91
Ivermectin & comb.	-7.58	-1.32	(-)	(-)	20/32	6/8	4/8	3.02	0.64
Levamisol	0.09	-1.03	(+)	(+)	16/32	2/8	6/8	2.00	0.59
Mebendazole	-0.80	78.46	(+)	(+)	14/32	4/8	4/8	1.24	-11.51
Pyrental Pamoate	-3.38	NC	(-)	(+)	16/32	4/8	4/8	1.08	NC

A5.4 (i):Muscular Relaxant

East Zone	Own Price Elasticity		Cross Price Elasticity		Positive Cross Price Elasticity with Other Compound (+ve cases)	d/d	f/f	Expenditure Elasticity	
Molecule	**Domestic**	**Foreign**	**Domestic#**	**Foreign@**				**Domestic**	**Foreign**
Baclofen & comb	-2.24	0.21	(+)	(+)	13/28	6/8	2/6	0.08	0.47
Chlormezanone & comb	-3.87	NC	(+)	(+)	15/28	6/8	2/6	0.14	NC
Chlorzoxa & comb	-1.54	-0.04	(+)	(+)	18/28	7/8	2/6	1.56	-0.76
Methocarbamol & comb	-2.30	-	-	-	10/16	6/8	-	0.67	-
Tizanidine & comb	0.23	-0.97	(+)	(+)	6/28	1/8	2/6	1.04	0.09

Note-NP (not positive), NA (not available), NC elasticity not computed because the share of molecule is very low, #change in demand for produce of domestic firms due to change in price of foreign firms; @change in the demand for produce of foreign firms due to change in price of domestic firms.

Annex 5.5: Changes in the Prices of Producs of Foreign Firms after Withdrawal of Products of Domestic Firms followng Petent Enforcement (alternate estimates)

Segment	Molecules	Change in Price (%)	
		All domestic products of the segment withdrawn	One domestic product of the segment withdrawn
Antihelmintics	Albendazole	406	-37
	Ivermectin & comb.	1585	16
	Levamisol	237	52
	Mebendazole	300	300
	Pyrental pamoate	35	29
Antileukaemics	Doxorubicin	300	300
	Methotrexate	66	36
Antirheumatics Nonstr	Aceclofenac	300	78
	Diclofenac	290	197
	Ibuprofen	31	-7
	Nimesulide	262	159
Bronchodilators solid & liquid	Montelukast comb.	300	300
	Salbutamol comb.	17	68
	Terbutaline comb.	303	23
Cephalosporins	Cefadroxil	300	300
	Cefixime	77	27
	Cefuroxime	300	300
	Cephalexin	60	-14
Muscular relaxant	Baclofen & comb	135	144
	Chlormezanone &	300	102
	Chlorzoxa & comb.	110	89
	Tizanidine & comb.	9	-21
Statins	Atorvastatin	9	10
Beta Blockers	Atenolol	99	228
	Metoprolol	50	13
	Propranolol	300	300
Antipeptic Ulcerants	Esomeprazole	-5	13
	Omeprazole	75	72
	Pantoprazole	48	300
	Rabeprazole	85	8
	Ranitidine	130	300

Note: (1) For a number of products, the price elasticity of demand is positive, or negative but less than one. The equation system cannot be used to determine their price. For those products, the price rise consequent upon product patent enforcement has been exogenously fixed at 300 percent (based on the results of Chaudhuri at al. (2006) for Fluoroquinolones. (2) For these estimates, it has been assumed that the price elasticity of demand for the firm is two times that for the industry.

Annex 7.1

The First Schedule

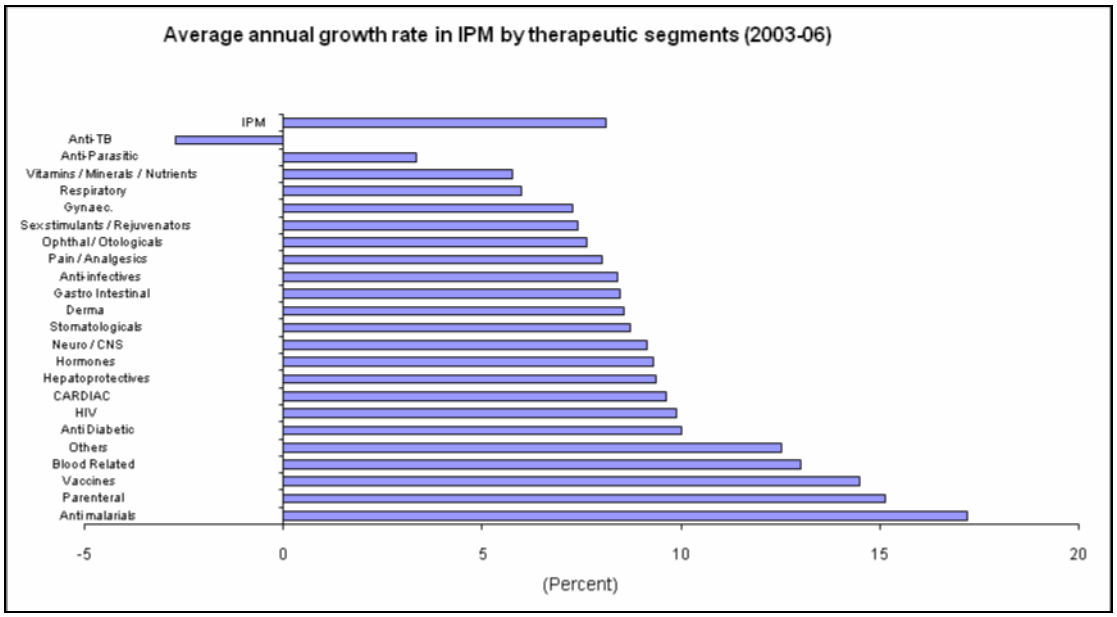
List of Price Controlled Drugs (DPCO 1995)

1. SULPHAMETHOXAZOLE
2. PENICILLINS
3. TETRACYCLINE
4. RIFAMPICIN
5. STREPTOMYCIN
6. RANITIDINE
7. VITAMIN C
8. BETAMETHASONE
9. METRONIDAZOLE
10. CHLOROQUINE
11. INSULIN
12. ERYTHROMYCIN
13. VITAMIN A
14. OXYTETRACYCLINE
15. PREDNISOLONE
16. CEPHAZOLIN
17. METHYLDOPA
18. ASPIRIN
19. TRIMETHOPRIM
20. CLOXACILLIN
21. SULPHADIMIDINE
22. SALBUTAMOL
23. FAMOTIDINE
24. IBUPROFEN
25. METAMIZOL (ANALGIN)
26. DOXYCYCLINE
27. CIPROFLOXACIN
28. CEFOTAXIME
29. DEXAMETHASONE
30. EPHEDRINE
31. VITAMIN B1 (THIAMINE)
32. CARBAMAZEPINE
33. VITAMIN B2 (RIBOFLAVIN)
34. THEOPHYLLINE
35. LEVODOPA
36. TOLNAFTATE
37. VITAMIN E
38. NALIDIXIC ACID
39. GRISEOFULVIN
40. GENTAMICIN
41. DEXTROPROPOXYPHENE
42. HALOGENATED HYDROXYQUINOLINE
43. PENTAZOCINE
44. CAPTOPRIL
45. NAPROXEN
46. PYRENTAL
47. SULPHADOXINE
48. NORFLOXACIN
49. CEFADROXYL
50. PANTHONATES & PANTHENOLS
51. FURAZOLIDONE
52. PYRITHIOXINE
53. SULPHADIAZINE
54. FRAMYCETIN
55. VERAPAMIL
56. AMIKACIN SULPHATE *
57. GLIPIZIDE
58. SPIRONOLACTONE
59. PENTOXYFYLLINE
60. AMODIAQUIN
61. SULPHAMOXOLE
62. FRUSEMIDE
63. PHENIRAMINE MALEATE
64. CHLOROXYLENOLS
65. BECAMPICILLIN
66. LINCOMYCIN
67. CHLORPROPAMIDE
68. MEBHYDROLINE
69. CHLORPROMAZINE
70. METHENDIENONE
71. PHENYL BUTAZONE
72. LYNESTRANOL
73. SALAZOSULPHAPYRINE
74. DIOSMINE
75. TRIMIPRAMINE
76. MEFENAMIC ACID *

* deleted vide so 626(E) dated 2.9.97

Source: Government of India, National Pharmaceutical Pricing Authority, Department of Pharmaceutical, Ministry of Chemicals and Fertilizers; http://nppaindia.nic.in/index1.html

Annex 8.1



Annex 8.2

❖ **SUBCLASS A 61 K Preparations for medical, dental, or toilet purposes**

This subclass covers: a) Compositions which are

- Used as preparations for dentistry, e.g. for artificial teeth, for filling or for capping teeth, or for taking dental impressions.
- Used for cosmetic purposes for treating the skin, hair, nails, teeth or oral cavity with a view to cleaning them, changing their appearance, correcting body odours, protecting them or keeping them in good condition.
- Used for medicinal purposes, e.g. drugs, biological compositions, when they are capable of:
  - preventing, alleviating, treating or curing abnormal or pathological conditions of the living body by such means as destroying a parasitic organism, or limiting the effect of the disease or abnormality by chemically altering the physiology of the host or parasite;
  - maintaining, increasing, decreasing, limiting, or destroying a physiological body function, e.g. vitamin compositions, sex sterilants, fertility inhibitors, growth promotors, or the like;
  - diagnosing a physiological condition or state by an in vivo test, e.g. X-ray contrast or skin patch test compositions.

And b) Processes of preparing these compositions, and of using these compositions or single compounds for medical, dental, or toilet purposes. **Therapeutic activity of medicinal** preparations **is further classified in subclass** A61P

Major groups under subclass A61K

1. A61K 6/00 Preparations for dentistry
2. A61K 7/00 Cosmetics or similar toilet preparations
3. A61K 9/00 Medicinal preparations characterized by special physical form
4. A61K 31/00 Medicinal preparations containing organic active ingredients
5. A61K 33/00 Medicinal preparations containing inorganic active ingredients
6. A61K 35/00 Medicinal preparations containing material or reaction products thereof with undetermined constitution
7. A61K 38/00 Medicinal preparations containing peptides
8. A61K 39/00 Medicinal preparations containing antigens or antibodies
9. A61K 41/00 Medicinal preparations obtained by treating materials with wave energy or particle radiation
10. A61K 45/00 Medicinal preparations containing active ingredients not provided for in groups
11. A61K 47/00 Medicinal preparations characterized by the non-active ingredients used, e.g. carriers, inert additives
12. A61K 48/00 Medicinal preparations containing genetic material which is inserted into cells of the living body to treat genetic diseases; Gene therapy
13. A61K 49/00 Preparations for testing in vivo
14. A61K 51/00 Preparations containing radioactive substances for use in therapy or testing in vivo

❖ **SUBCLASS A 61 P Therapeutic activity of chemical compounds or medicinal preparations**

This subclass covers Therapeutic activity of chemical compounds or medicinal preparations. This subclass covers therapeutic activity of chemical compounds or medicinal preparations already classified as such in A61K or C12N (especially Therapeutic activity of single-cell proteins or enzymes), or in classes C01 (INORGANIC CHEMISTRY), C07 (INORGANIC CHEMISTRY) or C08 (ORGANIC MACROMOLECULAR COMPOUNDS). The classification symbols of this subclass are not listed first when assigned to patent documents.

Major groups under subclass A61K

1. A61P 1/00 Drugs for disorders of the alimentary tract or the digestive system

2. A61P 3/00 Drugs for disorders of the metabolism (of the blood or the extracellular fluid
3. A61P 5/00 Drugs for disorders of the endocrine system
4. A61P 7/00 Drugs for disorders of the blood or the extracellular fluid
5. A61P 9/00 Drugs for disorders of the cardiovascular system
6. A61P 11/00 Drugs for disorders of the respiratory system
7. A61P 13/00 Drugs for disorders of the urinary system (diuretics)
8. A61P 15/00 Drugs for genital or sexual disorders (for disorders of sex hormones; Contraceptives
9. A61P 17/00 Drugs for dermatological disorders
10. A61P 19/00 Drugs for skeletal disorders
11. A61P 21/00 Drugs for disorders of the muscular or neuromuscular system
12. A61P 23/00 Anaesthetics
13. A61P 25/00 Drugs for disorders of the nervous system
14. A61P 27/00 Drugs for disorders of the senses
15. A61P 29/00 Non-central analgesic, antipyretic or anti-inflammatory agents, e.g. antirheumatic agents; NSAIDs
16. A61P 31/00 Anti-infective, i.e. antibiotics, antiseptics, chemotherapeutics
17. A61P 33/00 Antiparasitic agents
18. A61P 35/00 Antineoplastic agents
19. A61P 37/00 Drugs for immunological or allergic disorders
20. A61P 39/00 General protective or antinoxious agents
21. A61P 41/00 Drugs used in surgical methods, e.g. surgery adjuvants for preventing adhesion or for vitreum substitution
22. A61P 43/00 Drugs for specific purposes, not provided for in groups A61P 1/00-A61P 41/00

- All these major groups contains sub groups and further levels, details of which are available in PDF files that are available at (http://www.wipo.int/classifications/ipc/ipc8/)