CHAPTER II
REVIEW OF LITERATURE

This section intends to review the literature related to the pharmaceutical industry, pricing, market structure, research and development (R&D), patents and the impact these factors have on overall healthcare in India. An incisive examination of empirical and theoretical literature can be expected to throw up rich views on this subject, which will be of immense help in drawing conclusions later in the analysis part of this thesis. This chapter is divided into 4 sub-sections: 1) Literature on the economics of pharmaceutical industry; 2) Past studies on drug policies; 3) Issues relating to pharmaceutical research and development; 4) Studies on patent and its consequences in healthcare sector.

2.1. Literature on the Economics of Pharmaceutical Industry:

2.1.1 Studies on the Market Structure

The drug industry is a unique one, with an unusual demand structure and a typical supply function. The industry has attracted attention from across the globe for its larger-the-size influence and dubious practices. Now, first let us turn our attention to the studies dealing with growth and structure and other features of the industry.

Pharmaceutical production structure throughout the world seems to follow similar patterns, as following studies bare testimony to this pattern. Globally, way back in 1979, a study by the United Nations (1979) brings out the dominance of few firms in this industry. For instance, in the international market with over 10,000 firms, the share of 50 leading pharmaceutical corporations stood at around two-thirds of the total market while about half of the total market share is accounted for by a handful of 25 giant transnational corporations. Among the top firms, U.S. based companies dominate both in terms of numerical strength and sales volume followed by German and Swiss enterprises.

In one of the pioneering works dealing with the third world drug industries, Lall (1974) observes that across countries, the market for pharmaceutical products generally comprises of a large number of small-scale units with 10-15 percent
Review of Literature

share of the total market, while the rest 85-90 percent of the market is held by a handful of large firms (mostly transnational corporations). Lall attributes technological concentration and peculiar marketing practices as reasons for this typical production structure. Chaudhuri (1999) too acknowledges the dominance of multinational drug corporations in the Indian market. But the dominance of drug multinationals and import dependence in the early 1970s gave way to the emergence of an indigenous sector which became a favourable net exporter of drugs. According to him, encouraging drug policies partly enabled domestic sector to climb up the ladder to become a vital player in the market. Besides, improved technological efforts of private domestic companies and public research laboratories greatly helped the industry to develop drugs at relatively cheaper cost and therefore market the products at a fraction of global prices.

To lend credence to what the aforementioned studies assert, a casual look at the market share of leading companies would show concentration in the drug industry, whether they are local or foreign subsidiaries. Such a market structure has become possible because the market for drugs is fragmented into a number of therapeutic classes, which has no close substitutes, like the market for anti-biotics, vitamins, anti-hypotensives, etc.¹

Firms in this situation tends to out-compete rivals in sub-therapeutic segments, rather than take on them on drug market as a whole, [Lall (1974) and Chaudhuri (1999)]. The other vital element of pharmaceutical industry is that it does not enjoy any economies of scale, that is largeness (dominated particularly by transnational corporations) does not have any special advantage over small firms.

2.1.2 Product Concentration Studies in Drug Industry

Product concentration and oligopoly is an omnipresent phenomenon in the drug industry across the globe. One of the earliest studies on product competition and concentration in U.S drug industry was made by Comanor & Jemin (1964) and later by Comanor (1986). Lall’s (1974) attempt was also in this direction but focussed on developing countries, particularly the Indian conditions. Lall (1974)
asserts that pharmaceutical market is highly product concentrated, made possible because of its heterogeneous character and comprises of a number of sub-markets within which, firms have tended to specialise.

It is claimed that the drug industry provides an excellent case of product competition. Studies by Comanor (1964) and Cocks (1975) found that introduction of New Chemical Entities (NCEs)\(^2\) and product obsolescence in drug industry was high among all industries. The dynamics of product competition is brought out by the former study, wherein it reported that roughly 44 percent of the total sales is derived from products introduced within last five years. In addition, the market share underwent enormous shifts within individual therapeutic classes in a short span of time\(^3\). In a study of product competition in U.S by the UN (1979), the share of few top drugs in the total sales of firm shows that six of these leading drug firms made half of their sales on five drugs or less. Shifting share of drugs within individual therapeutic categories were also reported. This is made possible by the successful introduction of new drugs and a corresponding decline in the share of old drugs. But it must also be made clear that such ‘new drug’ are mostly in the category of ‘me-too’ drugs wherein by introducing few cosmetic changes in the already existing old drug, drug companies market it as a new drug. Although this strategy is common among all product markets, drug market stand out as an illuminating case due to the fact that ‘copying’ the product is easy and through a assorted sales and distribution methods, drug companies engage in such tactics to compete out the competitors and retain their market share.

2.1.3. Price Trends and Price Behaviour Studies

Moving a step further, the issue of introduction of a new product introduction and its influence on price was probed by many scholars. Comanor and Jemin (1964) suggests that restrictions on the rate of new product introduction leads to dwindling of share of patented drugs. As established drugs face greater competition, prices are lowered. Therefore, the price of new products will be fixed

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\(^1\) For a thorough analysis of market structure and concentration in the pharmaceutical market, see Section 3.8 of Chapter III.

\(^2\) NCE refers to a new chemical entity tested for the first time in human-beings.
at a lower rate. But Peltzman (1973) contests this view. He holds that competition between the old and new products would reduce the price overall.

The relationship between the degree of competition and price behaviour has aroused interest and has been a topic of intense debate. For instance, price rigidity is associated with oligopoly (Cocks and John Virts 1974). As far as pharmaceutical price behaviour is concerned, Cock’s finding confirms the view that pharmaceutical prices are relatively high at the initial stage and peters out later. Agreeing with this view, Reekie (1978) observed that though the Consumer Price Index for drugs in U.S declined, average prescription price moved in the opposite direction. Further, he found that higher the therapeutic improvement in drugs, higher the price of the new products. Considering the peculiar structure of the industry, such as: high product concentration ratio at sub-market levels; competition pursued through innovation and product differentiation in conjunction with high selling costs and patent protection. Moreover, the other features of the drug market are: price inelastic nature of demand for drugs; complete dichotomy between the real purchaser and sellers. All these factors, according to most researchers has left the industry to resort to price differentiation indiscriminately.

Hudson’s work (1992) develops both theoretical and empirical models to analyse pharmaceutical price behaviour in a dynamic setting. In an industry characterised by continually changing market environment, due to rapid innovation and expiry of patents, the issue of pricing assumes enormous significance.

The model assumes that price growth in the pharmaceutical market is influenced by market characteristics like the age of the market, brand loyalty and the degree of competition. The model is estimated based on the data relating to leading 25 therapeutic class in four front markets - the U.S., U.K., W.Germany and France. The above hypothesis that price growth gets influenced by market features receives empirical acceptance in U.S., West Germany and France while in U.K in view of the regulation on maximum profits, pharmaceutical prices are distorted. However, this is only a partial view, according to the author. As far the impact of brand loyalty on price growth, Hudson observes, “that products with high levels of

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3 Comanor (1964), pp. 376-77.
brand loyalty tend to see a fall, or at least a slowing down in price growth, which is not so evident in markets with low levels of brand loyalty." This implies that

"the introduction of new products in markets characterised by high levels of brand loyalty is more likely to provoke a price war as these new products will have to be priced more aggressively to gain market share and the established products have greater medium-term viability which firms will want to protect by keeping prices competitive. Firms with products with low levels of brand loyalty on the other hand will be more likely to raise price on new competition emerging to make the most of any short-term sales".

Regarding the influence of regulations on pricing behaviour, market power is equated with high price growth in U.S and West Germany whereas in France and U.K it appears to have eroded the ability of firms to benefit from short-term market power.

As regards technology, it is claimed that the industry is highly research-oriented, as majority of drug multinationals in developed economies devote nearly 10 percent of its sales value to R&D during the 1960s. However, Lall (1974) questions the efficiency of spending this magnitude on R&D as it may not turn out to be socially beneficial. Moreover, as pharmaceutical products enjoy patent protection, a large amount of money is devoted to R&D for subsequently reaping extraordinary profits. In addition, patenting on the imitative products actually swells the profit of the firm while it amounts to a cost on the society, since it involves ‘molecule manipulation’ rather than real research. Interestingly, public/government sector also equally spends a substantial amount of money on R&D but unfortunately they are not geared towards producing the final product. In fact, private firms benefit considerably from the public research and utilise it to give final shape. And as stated earlier, patent protection basically confers monopoly status to firms, leading to its abuse and excessive profits.

Another characteristic feature of the drug industry is that it is highly research-oriented. Kefauver Committee, though conceded to this view, argued however, that the research was more duplicative in nature involving “molecule manipulations” and moreover commercial laboratories, which provided new drugs,

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5 See Hudson (1992), p.111
were of little social values. To the question of what determines research expenditures, Comanor (1964) reaches the conclusion that firm size cannot be treated as a determinant of research spending. And as to another controversy that drug industry spends considerable share of its costs on promotional expenses, it was argued that in view of frequent introduction of new products, advertising costs also had to be enhanced.

2.1.4 Literature on Marketing and Advertising Practice of Drug Industry

The pharmaceutical industry is always in the thick of controversy over its marketing practices, as it spends nearly one-third value of total sales on promotional expenses. The reasons are not far to seek. Since the purchaser (the patient) does not have any role in choosing the good, it is the doctor who on behalf of the former prescribes and is effectively instrumental in influencing choices. Therefore, there is no pressure on doctors to economise on prices and are influenced by salesmen's tactics. Advertising helps drug firms to push through its high-priced drug brand names in the market thereby challenging low-priced generic drugs. Rapid product obsolescence, proliferation of various brand names in the same therapeutic categories and its related information campaigns lead to utter confusion while deciding the purchase of drugs. Lall (1974) asserts that all these factors along with strong patent protection have resulted in price anomalies in the drug market. To capture the role of sales representatives, in the words of Lall, "Not only do their visits save doctors the trouble of having to read, but their conversations are unrecorded, they use such tactics as gifts and fast-talk gimmicks to win over nurses and receptionists, they sometimes gain access to confidential files to discover doctors prescribing practices and they subject recalcitrant doctors to 'concentrated sales assaults' to win them over to their products". Private drug marketing, according to Lall, is "a peculiar configuration of private profitability, doctor's convenience and official inaction".

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6 Ibid, p.111
7 See Lall (1974), p.1953
8 Ibid, p.1953
Asserting on similar lines, Panikar et al. (1990) brings out unholy alliances between pharmaceutical companies and physicians. Quoting Canadian experience, Panikar, et al (1990) expresses concern and notes that price competition does not exist while it is other forms of competition that is sustained by brand names. They also assert that pharmaceutical companies spend enormous amount on brand promotion. According to them, “Promotional expenditure as a proportion of sales came to 13 percent in India, 5 to 20 per cent in Thailand, to mention a few examples”\(^9\). Drug corporates not only indulge in heavy promotional expenditure but are also involved in dubious methods while marketing their products. In the words of Panikar, et. al (1990), “they exaggerate the claims on the efficacy of particular products but underplay the adverse side effects, i.e., misrepresentative advertising”\(^10\).

In an industry marked by product competition, information asymmetry and other extreme features of market, product advertising and exceptionally high promotional expenditures leads to undesired consequences on the price of product. In a pioneering study by Rizzo (1999), he examines the issue of whether advertising puts downward pressure on price elasticity of demand in pharmaceutical industry. This hypothesis is tested in the market for anti-hypertensive drugs for the period covering 1988-93 in the U.S.

Advertising is supposed to lower price elasticity of demand and raise prices. Evidence presented by Rizzo suggests that advertising put limits on price competition, by lowering price elasticities and resulting in higher prices. However, even without any brand promotion, product sales are found to be responsive enough to price. In this context, arrival of drug detailing lowers this price sensitivity considerably. The other finding also corroborate with earlier results about the effect of promotional expenditure on physician prescribing behaviour. Hence, the author concludes that detailing strategy of drug firms is socially undesirable and need to be arrested.

2.1.5 Profitability Studies in Pharmaceutical Industry

Echoing others view, Lall (1974) claims that pharmaceutical industry is one of the most profitable industry and records sustained growth momentum. In fact, it consistently recorded profits substantially higher than the average for all-industries put together. A U.N (1979) study on pharmaceutical firms in U.S. also goes to point that drug firms have consistently maintained its top first or second rank in terms of relative profitability. The rate of return on investment has averaged 18 percent for pharmaceutical companies as against 11 percent registered for all-manufacturing industries since 1960. A persistently high profit rates in this industry is a manifestation of oligopolistic market structure characterised by: significant seller concentration, high entry barriers and a unique demand pattern. Evidence from Comanor (1986) for U.S. and Gupta (1994) for India suggest that profitability has been higher compared to most of all other industries. It is claimed that in view of a highly research-oriented risky operation, it is acceptable to have excessive profit. But econometric tests have consistently disproved this contention. Moreover, international pharmaceutical firms, whose operations are quite enormous in this industry, reaps extra profits through transfer pricing mechanism, as it is required to buy and sell intermediate chemical inputs between its subsidiaries. Transfer pricing through over-invoicing and under-invoicing of imports and exports has played a major role in deepening the pockets of multinational drug companies situated in developing countries. Vaitsos (1974), Chandrasekhar & Purkayastha (1982) and Nogues’ (1993) report the magnitude and pattern of transfer pricing followed by drug transnationals in Colombia, India and Argentina respectively. In the former case, effective profit earned through

\[ \text{Transactions involving global shipments of commodities (including capital, intermediates, finished goods) between branches or affiliates under the control of one company is termed as transfer pricing. Particularly, in the context of drug firms, the tied purchase of intermediates permits the transnationals to charge prices on the sale of intermediates far in excess of the ruling global prices. In the intra-firm transactions, the price is only an accounting device and the two parties are trying to maximize joint profits. On other hand, 'over pricing' indicate (as the name itself suggests) prices charged in excess of the cost of each unit of the commodity in question. From the firms point of view, while transfer price could be seen as a device of 'avoidance' of taxes, but from the host countries' view it is treated as an 'evasion' of taxes.} \]
overpricing worked out to 82.6 percent while for the latter overpricing of imports reached an alarming 126.52 percent. An estimate made for a span of six years for a sample of 26 pharmaceutical multinational corporations, Chaudhari’s (1999) findings suggest that over pricing was calculated at 66.8 percent.

In a comprehensive review of the literature on pharmaceutical industry, Comanor (1986) traces out the genesis of public outcry in U.S. regarding skyhigh prices and profits of pharmaceutical industry. Based on substantial differences between price and production costs and high profit rates in the pharmaceutical industry, the Kefauver Committee concluded that the industry is characterised by monopoly power. Steele (1962 & 1964) also concurs with this submission and supplements his argument with Lerner Index indicating a cost-price ratio at 5-15 per cent for individual products. As to the issue of abnormal rates of return in the pharmaceutical industry, the Kefauver Committee and other scholars (Comanor, 1964, p.380; Schifrin, 1967, pp.908-912) estimated that average profit rates were higher compared to all other manufacturing industry.

However, the above contention was vehemently refuted by the industry in U.S and others who asserted that the Lerner Index cannot be an appropriate measure because direct production costs cannot be a proper index of marginal cost and moreover the assumption of stable technology and constant returns to scale cannot be applied to the pharmaceutical industry. Regarding the alleged excess profit of the industry, it was contended that since costs on marketing and R&D were excluded from accounting profits, it seemed to be high on a casual glance.

Drug corporations in India have continued to claim that drug policies including the Drug Price Policy, 1978 has dented profitability quite substantially since the 1970s. In an attempt to unravel this issue, Sarkar, et al (1986) analysed drug price policy of 1979 which assigned four levels of mark-up on different categories of drugs.

Before we proceed to examine the results of Sarkar, et al (1986), we need to give an account of pricing of formulation in India. This is calculated as under.\textsuperscript{12}

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R.P. = (M.C. + C.C. + P.M. + P.C.) \times (1 + \text{MAPE}/100) + E.D.
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Where R.P. denote retail price of formulation;
M.C. indicate material cost including the cost of drugs and other pharmacuetical aids used;
C.C. connote conversion cost worked out in accordance with established procedures of costing;
P.M. refers to cost of the packing material used in the packing of concerned formulation;
P.C. means packing charges;
E.D. indicate excise duty; and
MAPE denote Maximum Allowable Post-Manufacturing Expenses including trade margin.

The analysis was done based on the most popular brands of selected 17 companies. The results, which emerged from the study, suggest that the policy hardly had any effect on the fast moving drugs. It is to be noted that the share of two or three of top fast moving products of each company is around 35 percent of the value of total sales. Despite price controls, drug companies are reported to have offered huge discounts to chemists. For instance, in the case of Category II drug group\textsuperscript{13}, the study shows that companies offered up to 15 percent cash discount to chemists where the mark-up allowed is 55 percent.

Analysing profits and sales turnover of leading drug companies in India in the early 1990s, Gupta (1994) argues that both sales and profits of leading companies are showing large increase over the previous years. Further, handsome dividends paid out by these large companies are a clear indication of robust growth of the industry despite the existing controls. Over and above, he adds that pharmaceutical industry is less capital-intensive. Relative comparison, therefore, with other capital-intensive industries is meaningless. Even if one goes for inter-industry comparison, Gupta (1994) concludes, the ratio of gross profits to sales is almost equal to the average ratio registered for all-industry groups.

\textsuperscript{12} See DPCO (1987), p.5-6.
Another study conducted in the wake of the Drug Policy 1978 in India reached a diametrically opposite conclusion from other studies. Narayana (1984) while tracing pre-tax profit on formulation activities of sampled companies in the immediate post-1978 period conclude that profitability took a beating continuously from 8.8 percent in 1978 to 7.29 percent in 1979 and further to 4.25 percent in 1980.

2.2 Studies Dealing with Drug Policies

Mote and Pathak's (1972) paper is a sequel to the Drug Price Control Order, 1970. They first developed a framework to analyse price control and harnessed the framework to find out whether there is a conflict between the short and long-term advantage of price control to the consumer. Apparently, this contradiction stems from the fact that industry opposed price control, for it would mean less profit while the consumers would benefit from such a control is all too obvious.

The framework takes into account the interests of the consumer, the industry, apart from the retail trade. This is carried out by allowing a reasonable price to the consumer, a satisfactory return to the manufacturing and to the retail agents. However, due to paucity of data the authors skipped the objective of resolving the conflict between short-term and long-term benefits of price control. Evidence emerging from the study indicates that surprisingly sales volume of drugs has gone up manifold. The authors consider this to be a positive aspect of the policy, as profitability could be maintained by firms reigning in price through higher sales.

An analysis of 1978 Drug Policy in India by EPW (1978) was immediately carried out after its announcement. The note attempts to examine primary objectives of the policy, namely, self-reliance in drug technology, self-sufficiency in drugs production and availability of adequate and quality drugs at reasonable prices.

13 One among the four category of drugs according to DPCO, 1979. Category II drugs allows for 55 percent mark-up over costs.
It states that even after two decades of a supposed strategy of self-sufficiency in the drugs industry in the late 1970s, India had an uncomfortable situation of importing drugs to the extent of 60 percent. It is in this context, that this research note calls for a stronger role of the public sector in the production of bulk drugs since during that period, the Indian private drug industry was at a nascent stage.

In response to the decision of the government’s policy of shifting from brand name to a generic name in the case of five commonly consumed drugs, the study favoured the idea since this would put a downward pressure on drug prices. At the same time the government, the note states, must ensure a ban on spurious drugs and also take care to assure quality generic drugs.

It is to be noted that the Indian private sector accounted for nearly 50 percent in the case of formulations and only 26 percent of the total bulk drug production during the mid-70s, while foreign sectors’ contribution remained quite high. The note, in this regard, called for the reversal of the trend in order to achieve self-sufficiency in drug production. Moreover, the public sector was also called up to perform its key role in providing drugs at reasonable rates and ensure its efficient functioning.

The Drug Policy of 1986, like its earlier policy had come under sharp focus. Bal (1986) while tracing the impact of the Drug Price Control Order (DPCO) 1979 came down heavily on ‘the corrupt and inefficient drug control machinery and the unhelpful, mercenary attitude of the pharmaceutical industry’\(^\text{14}\). This view was later attested by Gupta (1994). The industry appear to have reacted by sharply underproducing and shifting production of essential drugs (from Category I and Category II) towards production of inessential but highly profitable (Category III and Category IV)\(^\text{15}\) from the industry’s viewpoint. Between 1978 and 1980, the value of production of Category I and Category II drugs dropped from 4.5 percent to 3.6 percent and 16.7 percent to 13.2 percent respectively. During the same period, respective production of other two categories of drugs


\(^{15}\) For a detailed account of different categories of drugs under DPCO 1979, see Chapter IV of this thesis.
registered an upward movement from 67.1 percent to 68.6 percent and 11.7 percent and 14.6 percent.

Bal (1986) further calls the bluff of the industry's claim of a reduced bottomline in the wake of the drug policy of 1978 and DPCO of 1979. Marshalling growth rate and share prices of 20 leading companies, in the post-1979 period, he shows that the companies' growth rate has never been less than 55 percent while a sustained upward rise in share price was recorded during this period. Notwithstanding this evidence, the government responded by substantially delicensing. The author points to the dangerous rise in the import of these delicensed drugs which is a cause for concern on the objective of self-sufficiency.

In yet another critique of drug policies of the late 1970s, Gupta (1994) brings out the lacunae in policy initiatives and comes down heavily on policy reversals that were ushered in later in the mid-1980s and mid-1990s. The graded pricing structure without proper production control actually led to distortion in drug production. Transnational corporations responded by hiking production of inessential formulations in low technology areas. 'In essence they continued to play the role of trading centres.'

On the other hand, bulk drugs were mainly in the hands of small scale sector, public sector units and domestic private players. Equity divestment that was sought from multinationals was readily complied with as 40 percent equity holding was enough for them to control firms. The idea of sectoral reservation was thus diluted ultimately cremating it later in the following years. The havoc played by drug transnationals in the shift to generic names from brand names (and that too only in minuscule number of drugs) was a classic case of how global drug players wield power to scuttle any rational drug policy.

Price decontrol along with a reduction in the number of categories to two from four with higher mark-up in the policy of 1986, according to Gupta (1994), has only belied the expectation of upswing in production and lower drug price.

Rane (1996), who has been consistently analysing the drug prices over the years, in yet another study, examines comprehensively the percentage changes in the prices of drugs due to deregulation, decontrol and delicensing of the drug

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17 For an analysis of drug price in India over the years, see Rane (1990), (1992), (1993a), (1993b).
industry in the recent past by the Indian state. Rane (1996) states that the pharmaceutical industry which had stringent controls in the 1970s, had to give way to a more liberal policy in the 1980s, resulting in considerable growth of domestic pharmaceutical industry along with MNCs. Medicine prices too have gone up sharply along with this. In fact the recent policy of 1986 and later in 1994, has brought down the number of drugs under control from a staggering 347 to a minimal 73 bulk drugs. These changes have led to a phenomenal increase in the price of drugs particularly in the last 15 years, surpassing the general index of prices.

Rane (1996) makes use of the data for the period starting from 1980 to 1995, culled from MIMS India. He considered 778 product packs accounting for nearly 53 per cent of all products sold in India on June 1990. A simple comparative percentage-wise analysis reveals that on an average there is a substantial rise of nearly 200 per cent in the prices of all drugs for the period from 1980 to 1995. Anti-Cancer treatment drugs accounted for the largest and sharpest increase of 336 percent for the same period, followed by anti-allergic drugs (259 percent), drugs for the respiratory system also recorded the same percentage increase, closely followed by alimentary system drugs (243 percent). The only silver lining in all rising trend of prices, the prices of antibiotics registered a very 'modest' increase of 64 percent, but strangely enough, most of the antibiotics were not in commercial circulation. The other drugs whose prices have gone up significantly are as follows: drugs for heart disease (135 percent); drugs acting on the central nervous system (trebled); rigidity and tremor control drugs (335 percent); drugs for hormone (214 percent); pharmaceutical price on genito-urinary system (97 percent); anti-infective drugs (59 percent); nutrition enriching products (225 percent), etc.

2.3. Issues Relating to Research and Development in the Drug Industry

Rapid product obsolescence and subsequent new product introduction is the key, which drug firms use in order to retain and consolidate their monopoly market. To achieve this objective, research and development of 'new' drugs forms
the core of any drug firm. This section amalgamates diverse literature on this subject and dissects it.

2.3.1 Studies of Competition and Drug Research

The pharmaceutical industry rode high since the 1950s with stunning medical advances around the world. In order to sustain profitability, the leading drug players started guarding their market positions by some sort of product differentiation. Advances in the medical field offered the industry potentially promising drugs, which tended to differentiate from other close products. The number of newly introduced product in 1960 in the U.S. was put at around 380 per annum, and by 1960 over 3,800 new products were already introduced into the market. Only 11 of the new introduction every year turned out to be new chemical entities. Dishing out these figures, Comanor (1964) probes the relationships that exist among market structure and research effort. He sums up thus:

"The growth of competitive product differentiation has been associated with substantial outlays on research and development; but equally significantly, it has been associated with a specific emphasis in its direction. Research is a generic term which covers a broad spectrum of activities, and thus the type or character of the research activities undertaken as well as their volume are important factors in an analysis of the relationships among market structure, research and technical change." 18

2.3.2. Private-Public Research Effort in the Drug Industry

Historically, effort in industrial research has been unambiguously aided and promoted by public institutions. Research laboratories, universities and other government institutions in developed countries were pioneers in basic research. The role of firms, particularly multinationals in the drug industry, largely revolved around developing and marketing drugs.

The history of research and development (R&D) efforts in developed market economies like Germany and the U.S in the initial stage of development of
the industry could be traced to public laboratories. Liebenau (1985) while describing and assessing innovational character of drug firms in the UK., the U.S and Germany shows that public institutions played a leading role in Germany. In the US, on the other hand, the lesson is a little different in the sense that regulators with public assistance ultimately collaborated with a few leading private firms in bringing out new breakthrough products.

On the origin and direction of industrial R&D in India, Desai (1980) surveys the vital issue of the reported lack of a relationship between public laboratories engaged in basic R&D and large private firms. The stylised facts of R&D in India since 1958 reveal that the expenditure on R&D registered rapid growth. Although R&D spending in 1958 showed that the entire expenditure was incurred by government laboratories like Council for Scientific and Industrial Research (CSIR) and the industrial associations, the share of public laboratories had gone down to 70 per cent by 1965 and drastically to just less than 25 percent by 1974.

One of the important reasons for the erosion in the share of public R&D was its inability to turn basic research into a commercially viable solution. For example, in 1974, the amount of expenditure incurred on R&D by CSIR research institutions was as high as Rs. 194 million. As against this, the sale proceeds of know-how and technical services generated by National Research Development Corporation, the sole agency of CSIR involved in selling technology, was a meagre Rs. 4.3 million. This lack of foresight in transforming basic R&D effort into commercial sale venture has put a financial burden on the government while private industrial institutions continued to thrive, for they bought technology from the former for a reasonable price. The role of pharmaceutical public institutions like Indian Drugs and Pharmaceuticals Limited (IDPL) and Hindustan Antibiotics Limited (HAL) in their introduction and production of essential and life-saving drugs at a cheaper rate is a laudable initiative. However, as a result of lack of initiative on the part of the public authorities, the venture turned out to be a loss-making project whose closure is imminent.

Do stringent laws and procedures relating to clinical testing of drugs have a pronounced impact on research productivity? The amendments brought by Kefauver-Harris in 1962 are said to have caused a rapid decline in the rate of innovation and a sharp drop on R&D investment in U.S drug firms. Schnee (1979) undertook a probe into these issues and had identified considerable changes that are taking place on the economic and technological feature of the industry. His results suggest that since the amendment, the drug industry in the U.S is said to be incurring rapid cost escalation, lengthening of time-period and rising risk in R&D ventures. In view of this, the leading role of U.S firms in the global market seems to be eroding. A comparison of R&D productivity between U.S and U.K firms goes to show that both the countries had seen their innovation levels falling, but the former had indeed seen intensification of decline due to a regulatory effect. Also in view of stringent regulatory laws, U.S. firms has started shifting their R&D base to foreign countries and have chosen foreign locations for initial testing of new chemical entities. As a result of these developments, Schnee calls for 'enlightened and responsive R&D strategies' in order to survive and take the road of success in a challenging and competitive market environment.

2.3.3 The Issue of Cost and Returns on Drug R&D

The issue of cost and returns of pharmaceutical R&D assumes importance in view of alleged overestimation of costs and underestimation of returns, particularly in the backdrop of calls for strengthening the patent regime. Studies such as Joglekar & Paterson (1986) and Di Masi, et al (1991) are recent and worth taking up for discussion here. Joglekar & Paterson's (1986) article examines the contentious issue of whether returns from R&D in the pharmaceutical firms are excessive or inadequate. This is evaluated by means of three criteria using historical data projecting the future cash outflows and inflows of a New Chemical Entity (NCE) with R&D. These criteria are: Net Present Value (NPV), Internal Rate of Return (IRR) and Break-Even Point (BEP). The analysis includes 218 NCEs introduced in the U.S from 1962 through 1977.
The estimate of average and median earnings show that in the ninth year after marketing for an average NCE, the cumulative earnings change from negative to positive, which is termed as the recovery year of cost. However, the median NCE never recovers expected costs. Moreover, according to the author, based on a conservative 2.3 per cent capitalisation rate, the median NCE seems unlikely to ever break-even. As a result, two out of three NCEs does not seem to break-even after marketing for 24 years.

As for Internal Rate of Return (IRR), the estimate reveals that if one takes into consideration the real IRR (prices indexed), nearly 65 per cent of NCEs generate IRRs less than those of the opportunity investment. That is, "the real IRR advantage for the average NCE is 2.2 per cent points through year 24". Further, "the median's real IRR represents a 5.5 and 4.0 percentage point disadvantage relative to the bond's IRR for these years". In the case of Net Present Value (NPV), for a 36-year period, the study indicates that only one out of every three NCEs represents any NPV advantage.

Despite a gloomy projection as above, the authors end on an optimistic note for those who invest in the portfolio of pharmaceutical firms. Because according to them, in view of several peculiarities of the drug industry the return on pharmaceutical investment continues to be considerably higher than the estimate of this study and in addition, "returns in the pharmaceutical industry are likely to be recession-proof; a stock in a pharmaceutical firm complements other more volatile investments". On the negative side, however, the authors fear that significant substitution of generic drugs in the event of the expiry of patents would threaten returns on R&D.

Di Masi, et al.'s (1991) work is an addition to the existing empirical literature on the analysis of costs to discover and develop NCEs. Specifically, this study focuses its attention on R&D costs incurred by the pharmaceutical industry. For this an estimate was made to arrive at pre-tax average cost of new drug

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19 Break-even here relates the time required for an New Chemical Entities (NCE) investment to equal and surpass the earnings of the opportunity investment.
21 Ibid, p. 175.
development from 93 randomly selected NCEs obtained from a survey of 12 U.S owned pharmaceutical firms spanning a time period of 1970-82.

The estimate showed that for development of a single NCE, the cost incurred on an average is put at U.S. $231 million in 1987. The time period required for an NCE to reach the stage of marketing approval starting from synthesis is calculated to be 12 years. In real terms, when compared with a previous study (Hansen 1979), the total cost seems to have gone up 2.3 times. Some of the reasons attributed to the skyrocketing of development costs are: i) the duration of development, approval and clinical trial are getting lengthier; ii) adoption of expensive technologies; iii) a gradual shift in the development of drugs towards treatment for chronic and degenerative diseases.

2.3.4. Studies on Determinants of Drug Research

The pharmaceutical industry has been going through massive mergers and acquisition since the early 1990s throughout the world and in India as well. Allegedly an apparent advantage of larger size in research activities is cited as a major inducement for drug firms to go in for major consolidations. It would be interesting to peep into the literature particularly on firm size-research intensity relationship and other associated factors that affect domestic R&D effort as it would unravel claims of the industry.

Firm size has been the main focus of determinants among various factors influencing R&D of a firm. Literature on this relationship has been vast but inconclusive as well. Studies dealing with Indian industries reported both ways. While Lall (1983), Goldar and Ranganathan (1996) found a positive and significant influence of firm size on R&D intensity of firms, Katrak (1985, 1989, 1990) demonstrated that size increase results in less than proportionate rise in R&D spending.

In a recent study, Kumar and Saqib (1996) examine this issue across 291 industries by employing Probit and Tobit models by harnessing RBI data for the period spanning 1977-78 to 1980-81. Apart from other factors the focus was also
on the influence of firm size on R&D. Results emerging from the study point to an inverted ‘U’ shape for firm size-R&D relationship. To be specific, as firm size goes up the probability of undertaking R&D rises up to a certain limit after which it tends to decline. But, as far as R&D intensity is concerned, R&D spending is reported to rise in a linear fashion with firm size.

The other vital factor, which is assumed to affect R&D, is market concentration. Market concentration is assumed to retard or push up R&D effort of a firm. Comanor (1967) notes that concentration do not promote innovation when entry barriers are strong in an industry. Kumar (1987) obtained a negative association implying that market concentration adversely affects R&D efforts of industries in the backdrop of policy-induced entry barriers. Kumar and Saqib (1996) upheld the earlier contention that poor R&D activity in industries is mainly the result of strong entry barriers across industries.

R&D activity is mostly considered to be complimented by technology imports. Strong empirical evidence emerging from various studies indicates this trend. Desai (1980) asserts that developing countries which are dependent on industrialised economies for their technology, apart from importing technology also undertake supplementary research in order to adapt it to local conditions. Later studies too followed this hypothesis of a complementary relationship. Lall (1983), Kumar (1987), Katrak (1989) and Siddharthan (1992) found a complementary association. Going a step further, Kumar’s (1987) study reveals that the R&D-technology import association is also seem to be affected by the mode of technology import. Findings of Kumar and Saqib (1996) suggest that the probability of undertaking R&D is not influenced by import of technology. Goldar and Rangathan (1998) found technology imports to adversely affect R&D activity of firms. In a comprehensive study of the question of technology import and in-house technological effort, Katrak (1990) says:

"Multiple regression analysis showed that the technological effort (measured by the R&D expenditures) is higher in enterprises whose technology imports include those intended to strengthen their in-house technological capabilities, but lower in the enterprises that have negotiated an exclusive right of sale in the home market. An increase in the number of technology agreements leads to a higher level of R&D expenditures, but the
Firms aiming to capture the export market are necessarily constrained by poor quality, price and taste of products. In order to diversify into the global arena, firms are required to constantly adapt and upgrade products according to market conditions. R&D are considered to play a dominant part in fashioning the required change. The results of Kumar and Siddharthan (1994) reveal a significant and positive association between export orientation and R&D of medium and low technology industries. High technology industries seem to have bucked the trend. Confirming this relationship, a statistically strong and positive influence between export orientation and R&D activity is reported by Kumar and Saqib (1996).

2.4 Literature Relating to Patent Rights and Its Influence

Patent regimes across countries have come into sharp focus in recent times. The issue of pharmaceutical patents particularly has been the bone of contention in the eighth Uruguay Round of multilateral negotiations, wherein developing countries stoutly resisted measures to introduce strong product patent regimes by industrialised nations, but in vain. Before examining the studies relating to patents, we place below the difference between product and process patents.

A product patent is one in which a patent is issued for a product (such as a medicine) that confers exclusive rights to the patent-owner. This is intended to prevent others from making, using for sale, selling or importing the product. While on the other hand, a process patent is one in which a patent is issued for a process (such as a method of producing the chemical ingredients for a medicine) that confers exclusive rights to the patent-owners. The legal right is provided in order to prevent others from using, offering for sale, selling, or importing for these purposes at least the product obtained directly by that process.

India has been following the system of process patent since 1970 and is supposed to shift to product patent system from 2005 onwards. The outcry against process patent in India was created by drug multinationals who argue that process patent...
Review of Literature

A patent allows the domestic pharmaceutical companies to indulge in 'reverse engineering'. By 'reverse engineering' means the domestic companies were able to 'copy' or 'imitate' the product marketed by transnational corporations by incorporating different process methods in manufacturing a drug, particularly a new drug. This issue has been brought forward by the multinational corporations successfully in the negotiations that preceded the conclusion of GATT/WTO agreements of 1995. Under the WTO agreement, developing countries like India has to shift towards product patent regime from 2005 and continuation of process patent beyond this period would be treated as illegal under the agreement.

Rich literature has appeared thoroughly analysing various aspects of patent system both in developed and third world economies. The following section intends to examine each one of them. Some of the aspects that are being analysed here are: i) patent trends and their functions; ii) cost and benefit of introducing strong product patent regimes in developing economies; iii) studies on post-patent entry barriers.

2.4.1 Patent Trends, Pattern and Their Functions in Developing Countries

What is the vital function of a patent system in a developing country and what are its overall implications on them? Vaitsos (1972) attempts to evaluate these issues in great detail. To analyse these issues one needs first to understand the underlying features of patents system in developing countries. A predominant trend that is emerging from the analysis of patents in developing countries suggests that over the years, patents granted in these countries increasingly show that they are concentrated around a few foreign business houses operating in developing countries. Hence, the claim that patents stimulate domestic inventive activity is not borne out by statistical facts. And, moreover, patents only strengthen the hands of monopolists in their greed to maximise profit. Apart from being predominantly foreign-owned, most of these patents are left idle for some reasons. For instance,

"In the Republic of Columbia, out of a total of 3,513 patented processes or products examined (2,534 of which belonged to the pharmaceutical industry and the rest mainly to the textile and chemical industries) only 10 were actually produced in the country in 1970. In Peru from a sample of
4,872 patents granted between 1960 and 1970 in major industrial sub-sectors (including electronics, textiles, machinery and equipment, chemicals, food processing, pharmaceuticals, fishing industry, metal processing, air transportation), only 54 were reported as exploited, i.e., only about 1.1 percent of the total. The motive for taking out patents in developing countries and leaving them unexploited is two-fold: first it preserves secure import markets for large foreign corporations without necessitating foreign investment, and second it blocks potential competition from other close substitutes which can neither be produced nor imported. Thus, patents granted by developing countries are not only almost all foreign-owned but they are almost totally unexploited.23

Evidence from developing countries points out clearly that patents are not stimulant in securing foreign investment. In fact, the foreign patent-holder leaves the developing country as a captive export market. If at all such investment flows, it is only through mergers and acquisition. The author further concludes that patents act as impediment in the flow of technology to the third world economies subsequently retarding local technological progress. Granting and activating patents lead to monopoly consolidation, which is against the anti-monopoly legislation of sovereign nations. As has already been noted, patents in developing nations are largely controlled by foreign corporations and hence import the products under patent control. The imported product is usually over-priced mainly due to transferpricing causing terms of trade to turn adversely against the host third world countries.

Arguably the most vital economic function of a patent is that it motivates useful invention. But how far is this empirically proven? Available evidence, [Scherer et. al. (1959), Taylor and Silberston (1973), Mansfield (1986), Levin et. al. (1987), Cohen et al. (1997), Goto and Nagata (1996)], indicates apparently that patents were neither necessary nor effective. Except pharmaceutical sector, patents do not appear to have triggered-off any substantial innovative activity.

Patent regimes across the world differ widely in terms of its coverage, effective life time, membership to international patent agreements, enforcement mechanisms, etc. In order to facilitate comparisons of patent regimes across the world, an index is developed by Ginarte and Park (1997) covering 110 countries

23 See, Vaitsos (1972), p. 78.
running quinquennially from 1960-90. With the aid of this index, the authors further explore the determinants of patent rights.

The mean value of patent rights index shows that during the period under consideration, it had increased by 15 per cent. But the protection levels have been quite varied across countries. The standard deviation worked out based on these indices reveals that protection levels have tended to differ quite considerably. Another interesting point captured by the authors goes to show that, as economies move forward from the ladder of less developed to developing and developed categories, protection levels tend to get either strengthened or weakened.

Regarding the question of determinants of patent rights, the model assumed by the authors relate patent rights to independent variables, such as, per capita income, investments in human and R&D capital, openness, political and market freedom. This relationship is put to test with a panel data set constructed for 48 countries for four years: 1965, 1975, 1985 and 1990. Results of the model exhibit a better fit for richer countries. For them a lagged R&D variable is a better measure to argue for a stronger protection while for the poorer economies lagged openness of the economy seems to have a significant impact on patent protection. The insignificance of R&D in explaining patent protection is said to be due to the fact that the public sector still accounts for a sizeable amount of research work which are not patentable and more of their research is of an imitative or adaptive nature and does not require strong patent protection. The other important conclusions of this study are that political freedom and human capital turned out to be insignificant factors in arguing for a strong patent protection.

Narin and Noma (1987) in their study on 17 U.S. pharmaceutical firms analysed the underlying link between patents and corporate performance. The broad corporate performance variables are profits, sales and equity. While patent indicators were represented by such measures as: average cites received per patent, and changes in the number of patents and citations received. Patent data, according to the study, is a powerful indicator of overall firms' technological strength. A high correlation exists between 'expert opinion of pharmaceutical company technical strength, and the number of U.S. patents granted to the companies, the correlation coefficient working out to 0.82 per cent. As far as the
association between rise in profits and sales of firms and both patent citation frequency and concentration of the company patents within a few patent classes, Pearson product moment correlation coefficient is put in the range of 0.6 to 0.9 per cent.

2.4.2 Impact of Changeover to TRIPS

Empirical work on the consequences of a changeover to a product patent regime has earnestly started on time before the conclusion of the last Uruguay Round (the eighth round). Since pharmaceutical patent was one of the contentious issue, studies have appeared focusing more on the Indian pharmaceutical industry apart from other developing countries. The earliest study was undertaken by Challu (1991) followed by Nogues (1993), Redwood (1994), Subramanian (1994), Watal (1995, 2001), Lanjouw (1998), Fink (2000). The central theme that runs through all these studies is the consequence of shifting over to product patent on domestic pharmaceutical market structure, drug price and overall welfare costs and benefits to society.

Besides providing estimates of costs due to adoption of product patent system, Challu (1991) puts to test a different theoretical statement. Harnessing Yule's coefficient for all countries spanning a half a century, results indicate that the motivation for invention does not necessarily arise from the existence of the patent system. Further, the study shows that as an economy developed the number of inventions made in that country also went up. The study rejected the assertion that the existence of a strong patent regime is a prerequisite for higher economic development. In fact, it was shown that product patent was ultimately the culmination of economic development rather than a prerequisite. The other assertion that a third world economy having a patent system for pharmaceutical products would promote more inventions was outrightly rejected with the help of Yule's coefficient.

The estimated cost of adopting to product patent regime on Argentina, according to Challu (1991) would be as follows: i) price of drugs under patent is expected to skyrocket by 273.2 percent; ii) the estimated fall in drug consumption
would be to the extent of nearly 45 percent; iii) the welfare loss on account of consumers would be a staggering U.S $ 309 million per year.

Nogu’es (1993) in a stimulating analysis attempts to simulate the net result on social costs arising out of the introduction of patent protection based on certain assumptions and data on pharmaceutical drug market. The results of his analysis reveal that patents have acted as a key factor for high medicine prices, the effect of which could be felt when generic versions were introduced in the market. On the overall net result of patents, the author, assuming different figures of market demand, finds that losses in developing countries from consumer misallocation owing to policy transition could reach as high as US $ 7.7 billion. For India, based on certain market assumptions, the reported consumer misallocation worked out to a high of US $ 3,055.2 million.24

The author further observes that when the pre-transition period is characterised by severe competition, the change-over is likely to be catastrophic in terms of high drug prices and welfare loss to the consumers. However, if a market enjoyed monopoly condition in a pre-patent era, then the consumers are expected to net additional gain in terms of new drug introduction.

Lanjouw’s (1997) paper primarily deals with the theoretical implications of introducing product patents in developing countries. When a patent-owning drug manufacturer fixes a price that could ensure maximum profit, it results in consumers’ welfare loss. The other associated costs of this dead-weight loss are the costs of administrating the patent system and enforcing patentee rights through courts.

The net gains of granting patent protection are brought about through an enhanced welfare by stimulating additional R&D investment. In view of the disclosure requirement under patents regime, others could make use of these technologies as input in their own R&D. However, product patents are unlikely to bring dramatic changes in R&D choices of big TNCs.

The author concludes on the basis of interviews that since only 10 per cent of drugs marketed in India at present are actually on-patent in Europe and since

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only roughly 30 per cent of the population consumes allopathic medicine, the author does not expect adverse influence on consumers.

Further, the ‘first-mover advantage’ into the global generic market by Indian firms may come under fire in view of patent introduction. India, as a competitor in the world pharmaceutical market, will continue to maintain due to its low manufacturing cost advantage.

What would eventually result in the post-TRIPS era on Indian pharmacy market – its prices, TNC profits and consumer welfare? These issues are taken up in a simulation exercise, calibrated on a theoretical model by Fink (2000). Harnessing 1992 brand-level data for 2 therapeutic groups, the author assumes different estimates of market demand and market structure to determine the implications of product patent regime.

As far as the impact on price is concerned, estimates suggest that if the product to be patented is a ‘breakthrough’ new drug, the price of those products may be fixed exorbitantly higher than what competitive levels would allow and eventually static welfare losses are supposed to be large.

With the change-over to product patent regime, introduction of any new product would mean price-elasticity of demand is likely to exhibit relatively inelastic demand for therapeutic groups of medicine. This would result, however, in higher profits of patent holders. In a situation when the number and weight of patent-less chemical entities are considerable then this would entail lower profits for multinationals introducing patented product. This is mainly due to a shift that occurs from on-patent to off-patent bio-equivalence.

In view of the above, Fink (2000) calls for a simultaneous attack on rising prices through the grant of compulsory license and price controls, which are permissible under the TRIPS agreement. Alternatively, price increase and welfare losses can be minimised if the patented product happens to have close substitutes in a therapeutic category.

In a recent revision of the earlier estimate made in 1996, Watal (2001) re-estimates social costs and drug price increase accruing in the Indian pharmaceutical market in the post-patent period. The study uses ORG data on the pharmaceutical retail market survey for 1994 assuming a different demand and
market structure. When a linear demand function is adopted in the model, the price rise is estimated to be a minimum of 26 percent only [an understatement which was recorded in Watal's (1996) study]. But if one assumes a constant-elasticity demand function, drug price is likely to go up by a phenomenal 242 percent. The simulated price rise is essentially predicated upon 'the values of demand elasticity at the pre-patent stage and, by assumption, on the availability of credible and effective substitute pharmaceuticals in each therapeutic category'\(^{25}\).

On the question of welfare loss, a shift from the current market structure to patent monopoly could either be $50 million or $140 million, depending on different assumption.

Watal suggests a judicious use of price controls and compulsory licensing to tackle price rise and other welfare losses that would accrue to consumers. Although the latter, according to the author, is more beneficial since it involves less administrative and enforcement costs. Despite these measures, the patented market in future can never be the same as it was in the pre-patent regime.

In a simple but comprehensive analysis of change over to TRIPS, Gupta (2001) examines the implications on health care, self-reliance and pharmaceutical prices. Given the market situation that would arise in the wake of a changeover to a new patent system, there is every possibility of the present Indian market falling back to pre-1970 levels wherein the market was largely held by a handful of few MNCs across all therapeutic segments.

As far as the implications for health care are concerned, the resurgent transnational corporations are expected to charge high price and capture monopoly market thereby putting many patented drugs out of reach of poor consumers.

On the price front, a relative comparison of international drug prices was made. Analysis apparently makes a few points clear. In the case of drugs (which are product patented in other countries because India do not follow product patent regime currently and moreover such products account only for 10-12 percent of total pharmaceutical sales in India) prices are estimated to be lower in India while for other non-patented drugs (which are off-patent in most other industrialised countries who otherwise follow product-patent regime), drug prices reportedly

show a higher price as compared to prices prevailing in industrialised developed economies.\(^{26}\) Such higher price trend is logically a strange situation since India is considered to have a superior domestic technological capability to develop drugs. Gupta further argues that given the larger size of the market, economies of scale must necessarily be to the advantage of Indian drug producers. The other advantage that Indian drug companies enjoy is that of lower labour and infrastructure costs. With secular decline in the number of drugs under price control, the profitability of pharmaceutical firms has gone up considerably while the industry has failed to pass on this measure to consumers.

Market forces have failed to reign in drug prices over the years. Deregulation and delicensing carried out savagely in drug industry has only resulted in an unjustifiable increase in prices. Unfortunately, emerging conditions appear to relegate us to a situation as obtained in the 1950s.

In another study of patent protection and pharmaceutical industry, Keayla (1994) traces the salient feature of the Indian Patent Act 1970, praising its balanced approach of encouragement to invention and technical progress and simultaneously excluding certain sectors like drugs and food from strong protection with limited patent term.

The Indian Patent System of 1970 has placed Indian pharmaceutical industry as one of the most advanced among developing countries. In terms of technology, quality and range of medicines produced, the patent regime has played an overwhelming part. Near self-sufficiency in formulations, enough bulk drug production, substantial export of formulations has been made possible by an enabling framework provided by the patent system. However, recent developments in the international arena in the form of TRIPS have thrown enormous challenges before Indian pharmaceutical industry.

Drug prices are set to skyrocket, the share of transnationals is expected to increase manifold, and overall the objective of self-sufficiency is likely to take a beating. According to the author, a relative drug price comparison of India vis-à-vis other patent offering countries, reveals that whether patented or off-patent, drug price in both developed and developing countries having a strong patent system are

\(^{26}\) See Gupta (2001), p. 3.
experiencing comparatively high price. Developed countries led by U.S vehemently argued that patented drugs sold in India comprise only five-ten percent of the Indian drug market. And therefore, apprehensions created in India are misplaced. However, Keayla (1994) marshals data dug out from Indian Drug Manufacturers Association (IDMA) to counter underestimation of patented products turnover. Accordingly, if one were to consider the IDMA study, the average turnover of patented drugs may go up to 60 percent or more in the first 10 years of implementation of product patent system. Therapeutic-wise, the sales turnover of patented drugs under certain categories like antibacterials and contraceptive hormones is expected to reach as high as 98.80 and 88.97 percent respectively. The other therapeutic classes whose patented drugs turnover is likely to rise over 60 percent or more are: Anti-Leprotics – 69.96 percent; Tranquilizers – 74.42 percent; Anti-Convulsants – 65.93 percent; Antipeptic Ulcer Drugs – 65.92 percent.

It is in the backdrop of above analysis, Keayla (1994) calls for a thorough re-negotiation of TRIPs agreement. 'The re-negotiated patent regime could provide for adequate royalty payment for the product patent holder, whose patented product abroad might be produced by other enterprises, by developing innovative process technology even during the product patent regime. This would provide continuity in our current research efforts.'

4.2.3 Patents and Post-patent Barriers

Intellectual Property Rights (IPRs) in the form of patent protection is accorded to the inventing firm to recoup its investment on R&D and thus avoid dynamic welfare losses accruing to the firm. On the other hand, patent protection would also result in static welfare loss to the society in view of its monopoly power. But even after the product goes off-patent, the inventing firm still enjoys its market power sustained by its brand image, effectively acting as a post-patent

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28 This section intends to show the implications that would arise in the event of a change-over to new patent regime, i.e., the post-product patent era. The resulting post-patent barriers due to product patent regime is a chilling illustration of things that would shape up in India too. And it is in this context the experiences of other countries are cited here.
entry barrier. Therefore, this 'composite' factors (patent plus trademark protection) may end up as an entry barrier extending indefinitely into the future. Mc Rae and Tapon (1985) probe into these aspects for the Canadian drug industry using the data of pharmaceutical price, market shares and market power of 21 first entrant drugs.

Interestingly, the results reveal that 16 (76%) out of 21 first entrants did not report price decline with the entry of competitors. In fact, the first entrant's prices have either remained stable for a long-period or were hiked. Expectedly, patent holders charged the highest price. Evidence reported in the study indicate considerable price differentials between the one charged by patent-holders and generic competitors subsequently failing to reflect differences in provincial drug reimbursement rules and loss of market share of patent-holders. To sum up,

"for various reasons (fear of law suit, belief in price inelasticity of product, etc.) first entrants typically do not engage in price competition after generic competitors enter the market. Having established a relatively inflexible price structure over the years of monopoly supply, first entrants maintain or increase price despite lower-priced generic competition." 29

An analysis of market shares throws up different results. In Quebec, 30 the first entrants were able to retain their market shares better than in the other two provinces, such as, Ontario and Saskatchewan. This is due to intense generic competition in the later two provinces, with brand names suffering heavily and are able to retain only a very low market share in Ontario.

Findings regarding market power 31 suggest that market power in Quebec for the first entrants remained intact. Whereas, Saskatchewan and Ontario provides contrary results. In Saskatchewan, in view of guarantee provided to the late entrants to their products as bio-equivalent along with protection from liability by the provincial government has contributed to the erosion of market-power. In Ontario only two first entrants could retain their market power.

29 See Mc Rae and Tapon (1985), pp. 53-55
30 Quebec, Ontario and Saskatchewan are the provinces of Canada.
31 Market power is defined here as a situation in which the patent-holding first entrant is in a position to charge higher prices and maintain higher market shares compared to the generic entrants, despite the latter providing similar products at reasonable prices.
Provincial controls are attributed as reasons for the difference in results obtained from the three provinces. The authors conclude that both compulsory licensing and provincial regulations are necessary and sufficient to erode the patent-holder's market position.

In response to the findings of Mc Rae & Tapon (1985), Gorecki's (1987) work provides additional evidence on the impact of varying provincial regulations in Canada on the market share of generics. More specifically, Gorecki examines the significance of differing rules on drug price, product selection and quality issue on the market share of licensee. On analysing the change in reimbursement rules in the Quebec province of Canada, Gorecki concludes that the patentee's market share cannot be eroded until concomitant changes are made at the retail level along with changes in the effective patent life and easing of regulatory requirements for health and safety. However, he suggests that an active intervention of governments and a properly structured set of rules on price, product selection and quality can considerably reduce the market share of the patentee.