CHAPTER 2
LITERATURE REVIEW

2.1 INTRODUCTION

The purpose of this chapter is to report on the review of the literature made by us relevant to the present study. It helps to identify the areas where lies the scope of research and to find out the answers of the unsolved questions. Further it facilitates comparison of the findings from the current study with the result of the previous studies. A detailed review of the books, articles, Govt. reports etc, has been made to provide a framework for the present study. The present study is related to the issues and challenges of the pharmaceutical companies in India.

2.2 REVIEW OF THE PUBLISHED ARTICLES

Dasgupta and Stiglitz (1980) argue that in the model of cost-reducing R&D with nonexclusive property rights, increasing the number of competitors reduces the amount of cost reduction. The effect of competition is also monotonic in this model, although in the opposite direction. There is an intuitive argument that moderate levels of competition should be most effective in promoting innovation. In highly competitive markets the incentive to innovate may be low because the innovator’s small scale of operations may limit its benefit from a new technology.
Lunn and Martin (1986) focused on the research and development is highly associated with the market structure and performance. Competition is a stimulus to innovation. Firms in more competitive markets invest more in research and development in search of profit. There is a clear distinction between R&D inputs and R&D outputs in a research production function framework to understand the process of technology generation.

Mansfield (1986) concerns with two most important aspects, the patent system and its effects. In pharmaceuticals and chemicals the effects of the patent system are found very substantial. The large Indian pharmaceutical companies are the major R&D spenders, and they have been focusing on the larger and the more lucrative developed country markets, particularly that of the United States.

Agrawal and Thakkar (1997) have examined the strategies adopted by different companies to survive the phase of patent expiration. The authors suggest that companies should not increase the prices when the patent is about to expire, rather if the marketing strategies are well planned the costs involved in product development can be recovered even after the expiry of the patent. Companies need to have a combination of product modification, promotional and pricing strategies to save a company from losing market share on a patent expired product.
Lanjouw (1998) had analyzed how the introduction of product patents for pharmaceuticals may benefit or adversely affect India. Her analysis is based on information obtained over a period of six months, from September 1996 to March 1997. The primary data was collected by taking interviews with a wide range of people in the Pharmaceutical industry. Although the paper does not arrive at a conclusive answer to whether the introduction of pharmaceutical product patents in India will bring about heartless exploitation of the poor and suffering, still it does provide some suggestions about the way events might unfold as the policy is implemented.

Ray and Bhaduri (2001) find that the conventional determinants of R&D, like firm-size, technology import or ownership, appear significant only in explaining R&D effort in line with existing empirical studies. In fact, learning both experience-based as well as interaction (or spill over) based, proved to be the only important determinant of the research production process. Therefore, technological learning has been the most important determinant of technology generation in Indian industry.

The study by Zuniga & Combe (2002) focused on the economic impact of patent protection of pharmaceuticals in the Mexican industry. The researchers have tried to make a brief evaluation of the static and dynamic effects of the introduction of patent protection for pharmaceuticals in
Mexico and to compare them to those predicted by economic literature. Although the static effects might have been limited since multinationals already controlled the private market before the reforms, dynamic gains are still far from being felt. Reinforcing patent protection will not automatically change the access and the ways to finance R&D projects. They suggest that other factors besides patent protection must be taken into account before expecting an increased R&D activity in the Mexican pharmaceutical sector.

**Buckley (2003)** focuses on the Need to Develop Responsible Marketing Practice in the Pharmaceutical Sector. This paper identifies and discusses current marketing practice in the pharmaceutical sector, as it relates to therapeutic pharmaceuticals. It examines the potential risks associated with certain marketing practices, such as the impact of misleading advertising and the possibility of disease mongering. The methods currently used to regulate industry promotion practice are critiqued and suggestions are made for improvements, including a move from industry self-regulation to an independently monitored code of practice for pharmaceutical marketing.

**Madanmohan and Rishikesh (2003)** have dwelt upon the adaptive strategies in the Indian pharmaceutical industry. They have analyzed several adaptive strategies to be used by the Indian pharmaceutical companies to cope up with the WTO product patent law. They have also analyzed the
factors driving the movement towards consolidation and augmentation in the sector.

**Singh and Surendar (2003)** in their article have focused upon the strategies used by small and medium scale pharmaceutical companies to meet the challenges of the patent regime. The larger companies like Ranbaxy and Cipla etc. were preparing for the new patent regime since 1995 onwards, however the small and medium scale pharmaceutical companies did not make much of an effort and now realizing that their toplines and bottom-line are going to be impacted because of product patent they have devised few strategies: Toll Manufacturing, Bottom fishing, In-licensing, Niche plays and contract manufacturing. The article is based on interviews with top executives of small and medium Pharmaceutical companies who have implemented with success the above mentioned strategies.

**Saranga and Phani (2003)** have found out that there is evidence that there appears to be a direct relationship between internal efficiencies and higher growth. They have concluded that irrespective of the growth strategies adopted by the individual firms, internal efficiencies will have a higher probability of survival and growth. Thus the internal efficiencies would help firms in the Indian Pharmaceutical Industry to overcome any new challenges arising out of the change in patent process from the year 2005.
Dey (2006) focused on the strategies adopted by global pharmaceutical majors in India in view of the product patent in India. Among the various vigorously being pursued by MNC pharmaceutical companies are accelerating patented product launches, Mergers & acquisitions, reducing R&D expenditure by outsourcing clinical trials, sourcing their manufacturing requirements for API from independent manufacturers in India. However MNC’s in India are faced with host of problems like price control, competition from big domestic Indian Pharmaceutical companies and data Exclusivity. The author concludes that MNC’s should go in for innovation, thereby slowly developing newer molecules and at the same time becoming price sensitive.

Gelei (2003) focused on competitiveness is basically a function of two factors. Firstly, it is determined by the value dimensions which are basically for their customer’s satisfaction. The second factor of firm competitiveness is the sum of resources and capabilities that make a firm capable to create and deliver the identified important value dimensions for the customer.

Chittor and Ray (2003) focused on the internationalization paths of emerging economy firms through a strategic group analysis of internationalizing firms in the Indian pharmaceutical industry. This study
analyzed proprietary data set of strategic variables from forty firms and the analysis revealed significant variation in their internationalization strategies. **The study** by Lanaszka (2003) highlighted that WTO rules on IPRs are controversial because of the persistence of the asymmetry in the level of development and research capacities between the developed and developing countries. It is of course true that exploitative business practices are possible only to the extent that monopoly positions are tolerated. Many developing countries, however, lack the necessary financial resources and have not yet developed appropriate competition rules to deal effectively with the challenges presented by TRIPS agreement. The leading industrialized countries must pay attention to the social and economic needs of the developing countries for which a change of attitude is necessary. It should begin with the idea of fairness as one of the principles governing the dialogue between the developed and developing countries. Farness entails sensitivity to the special needs of developing countries and one important dimension of this sensitivity is the recognition of the problems posed by human needs, such as health.

**Kaviraj Singh (2004)** in his paper Basic of Patent Law India has discussed the evolution of Indian Patent Laws, Patentable, not patentable Inventions

**Saji (2004)** focuses on multinationals from all over the world are accelerating the pace of their direct investments in overseas R&D and strategic alliances. Previously, companies expanded their R&D operations overseas primarily to support local manufacturing and marketing operations. But now, companies are making overseas investments to complement their domestic research, technology, and product portfolios. They are integrating their domestic and overseas R&D facilities into global R&D networks thereby achieving cost reductions and price advantages.

**Dr. kumar and G Nair (2005)** focused on Indian Patent Law and Pharmaceutical Industry has concluded that the Indian Patent Act 1970 was instrumental in providing the impetus for laying foundations of a strong manufacturing base of both formulations and bulk actives (as well as intermediates) in India and it helped National pharmaceutical industry to grow at a double digit pace. Author has also discussed post TRIPS development in Indian Patent Laws and it’s Impact of Indian pharmaceutical Industry.

**Sampath (2006)** in her research paper analyzed her survey of 103 Indian pharmaceutical firms. The scope of her study was limited to analyzing
emerging firm strategies of Indian firms as a response to a gradual transition to product patent protection. The study has categorized firms in the Indian Pharma Industry into 3 main groups based on empirical data collected and identified the main strategies and their triggers in each one of the 3 firm groups. The survey found that Indian firms are adapting a combination of cooperative and competitive strategies, in order to adapt and as well as capitalize on opportunities created by the new patent regime. The Indian domestic pharmaceutical companies have faced the international competition and although product patent has thrown up lot of opportunities, still consolidation will happen in the industry in coming years. The study also found a high correlation between export intensity and R&D investments in the Indian Pharmaceutical sector. Firms that had greater revenues from exports were able to invest a larger amount on R&D.

Pradhan (2006) in his paper explained that Govt. of India has taken national policy time to time for making competitive in the global market. The Indian policy regime has succeeded in bringing out its pharmaceutical sector as among the fastest growing in the world, but it has also created its own limitations in pushing forward its productivity and technological activities. The fragmented nature of policy that had encouraged a large number of small and medium sized pharmaceutical firms appears to have placed a
constraint on the scale of production and capabilities to further upgrade the technological strength.

**Sunil (2006)** in his working paper undertakes a detailed mapping out of the sectoral system of innovation of India’s pharmaceutical industry. He concludes that the TRIPS compliance of the intellectual property right regime has not reduced the innovation capacity of the domestic pharmaceutical industry which has visualized an increase in both research budget and patenting. But at the same time it has not made them work on R&D projects that may lead to the discovery of drugs for neglected diseases of the developing world. He feels that this is an area where public policy support is still required.

**Praveen Dalal (2006)** in his paper Indian Patent Law – Some Reflections has discussed Intellectual Property Rights, TRIPS coverage of IPR. He has further discussed salient features of Indian Patents Act 1970.

**Bhaduri (2006)** has tried to examine the justification of some of the arguments advanced to implement TRIPS in India. She argues that extending monopoly rights up to 20 years can lead to a situation, where complacency effect of a monopolist, arising out of a secure market, could lead to a decline in R&D expenditure because it will have no incentive to search for more efficient processes of the same product during the patent life. The consumers
may, therefore, have to pay higher prices for inefficient processes of the novel drugs under the TRIPS which is in sharp contrast with the stated objectives of the WTO, which propagates to raise global cost efficiency and thereby consumer welfare.

Nair (2007) has stressed upon the fact that if visionary strategies are adopted by Indian pharmaceutical companies then the future will be bright for these companies. Strategies such as Drug Discovery, Para IV filings, focus on production of high quantum and moderately priced generics, strengthening API/drug intermediates production, outsourcing to MNC’s upgrading manufacturing facilities to USFDA standards and investing in Pharma support services such as analytical services, diagnostic services, data management services and clinical research operations will prove worthwhile in the long run and help India to move up to the top of the global Pharmaceutical Industry.

Chaudhuri (2007) explores that R&D expenditure has dramatically increased for a segment of the Indian pharmaceutical industry after TRIPS came into effect. It is not only that the amount of R&D expenditure has increased, but there has been a drastic shift in the structure of R&D activities of the Indian companies. Earlier they were primarily engaged with the development of new processes for manufacturing drugs, now they are also
involved in R&D for new chemical entities (NCE). Although, the R&D activities have diversified, the Indian pharmaceutical firms have yet to prove their competence in innovating new products. No NCE has yet been developed.

**Manthan D, et.al. (2007)** in their paper Patents Regime in India: Issues, challenges and opportunities in pharmaceutical Sector have given a brief history of Indian Patent Laws. Authors have concluded that; Indian pharmaceutical industry has benefited tremendously from the liberal patent law of 1970. It ranks very high in the third world, in terms of technology, quality and range of medicines manufactured. From simple pills to complex medicines requiring complex steps to manufacture, medicines for almost all type of ailments are manufactured in India.

**Dixit (2008)** focuses on the Indian pharmaceutical industry is one of the leading industries not only in India but also in the world. This industry meets approximately 95 per cent of the country’s pharmaceuticals needs. The present turnover of the Indian pharmaceutical industry is US $ 9 billion of which share of exports is 40 per cent. Compared to the global picture the Indian pharmaceutical industry ranks 4th position in terms of volume which is highly significant and it is growing at the compound growth rate 13.7 per cent per annum.
2.3 REVIEW OF THE GOVERNMENT ACT AND REPORTS

DRUGS PRICE CONTROL ORDER, 1995

This Provide that in the case of an imported formulation, the landed cost shall form the basis for fixing its price along with such margin to cover selling and distribution expenses including interest and importer’s profit which shall not exceed fifty percent of the landed cost. This is the cost-plus fixed percentage approach. The problem with this approach is with regards to the ability to obtain accurate information on production marketing and other costs as reported costs can be manipulated. Such an approach also promotes inefficiency as producer has no incentive to reduce production costs and thereby affects competition. Similarly, while computing the price to be fixed, the cost of manufacture of generic drugs should be taken into account. In no case should the notified price be more than the average price of generic manufacture. This calculation also ignores the volatility in prices of raw materials, or the additional cost of ensuring quality.

Price of imported medicines is calculated on the basis of declared landed cost. However, there is no mechanism to verify whether the declared cost is true. One study revealed that MNCs are more interested in importing to India rather than producing in India because the transfer pricing loophole would give them an incentive to produce drugs elsewhere and then import
them into India. This provision can therefore be abused by them to gain an advantage over others. Under Section 8(2) of DPCO, 1995: Where the Government fixes or revises the price of any bulk drug under the provisions of this Order and a manufacturer utilizes such bulk drug in his Scheduled formulations he shall, within thirty days of such fixation or revision, make an application to the Government, in Form-III for price revision of all such formulations and the Government may, if it considers necessary, fix or revise the price of such formulation.

However, in the case of downward revision in bulk drug prices, manufacturers seldom apply for price revision. It observes that —drug companies fail to furnish information as prescribed under DPCO ‘95, but no specific provision for punitive actions are there in DPCO’95 to take action against errant companies/units. As a result the manufacturers lack sufficient incentive to lower the drug prices.

Sections 3, 8 and 9 of DPCO, 1995 deal with the fixing prices of Scheduled drugs: There are no provisions of fixing prices of substitutes of scheduled drugs as a result; companies continue to charge high prices through creating substitutes thereby hurting consumers who could otherwise gain through lower prices. An example of such a practice is the substitution of Psuedoephedrine with Phenylpropanolamine (PPA). Actifed, an
international brand of Glaxo for cough and cold, contains specialized wine. However, in India it contains PPA. In high doses, PPA has been found to enhance the risk of cerebrovascular accidents. Glaxo preferred to use PPA in India because while specialized wine is under price control, PPA is not. It observes in some cases, it has been noticed that whenever Government/NPPA fixes/revises ceiling or non-ceiling price of medicines/formulations some drug companies change the composition of the medicines/formulations and obtain new licenses from respective State Drug Controller/Licensing Authority. The State Drug Controller/Licensing Authority should not allow change in composition without any valid ground and without consulting DCGI and NPPA.

INDIAN MEDICAL COUNCIL (PROFESSIONAL CONDUCT, ETIQUETTE AND ETHICS) REGULATIONS, 2002

In exercise of the powers conferred under section 20A read with section 33(m) of the Indian Medical Council Act, 1956, the Medical Council of India, with the previous approval of the Central Government, provides for regulations relating to the Professional Conduct, Etiquette and Ethics for registered medical practitioners as under these Regulations. Unfortunately, despite the serious medical malpractices that go on, there is little regulation on the actions of health care providers.
According to Regulation Indian Medical Council (Professional conduct, Etiquette and Ethics) Regulations, 2002: Use of Generic names of drugs: Every physician should, as far as possible, prescribe drugs with generic names and he/she shall ensure that there is a rational prescription and use of drugs.

Generic drugs are essential for effective competition and making medicines available at low prices to consumers. However, due to the various collusive arrangements, doctors often end up prescribing branded and expensive drugs instead of the cheaper generics.

This provision tries to guard against that is weak and lacks teeth as it does not prescribe any punishment for failure to comply. One way, often suggested, of checking the rent-seeking behavior of the doctors, as has been successfully experimented, even in neighboring Bangladesh, is to mandate doctors to prescribe drugs with generic names. However, given the enormous clout of the pharmacists in India, this mandate has not worked. What is, thus, desperately required in India, is an effective mechanism to contain the rent-seeking behavior of the doctors and pharmacists so as to check the anti-competitive practices in this market.
INDIAN PATENT ACT, 1970 AND THE TRIPS AGREEMENT

One of the main impediments to competition in the pharmaceuticals market is strategies employed by big players to delay generic entry into the market. Ever-greening has oft been used as a routine business strategy by monopolistic patentees to delay generic competition. Patents are issued on pharmacological compounds quite early in the drug development process, which sets the clock running. The EC conducted a pharmaceutical sector inquiry under the EC Competition Rules in 2008, based on information that suggested restriction of competition in these markets leading to a reduction in the number of innovative medicines reaching the market and delays in generic entry. The inquiry found that originator companies used a range of strategies to extend exclusivity and delay generic entry as long as possible such as filing up to 1300 patents for a single medicine (creating —patent thickets"), and engaging generic companies in costly litigation, even though the courts upheld originator patent litigation claims in only 2% of cases. It estimated that faster generic entry could reduce public expenditure on medicines by over 5%. Such strategies have been witnessed in India as seen in the number of litigations filed under Section 3 (d) which has been held as a pro-competitive provision to safeguard ever greening of patents. For instance, Delhi High Court rejected the petition of Bayer Healthcare
(German) preventing the Drug Controller General of India giving marketing approval to Indian company Cipla for the generic version of the cancer drug Nexavar. Similarly, Cipla in another case won the right to manufacture and market the generic version of the anti-cancer drug Tarceva originally patented by the Swiss pharmaceutical company Hoffman La Roche both in Delhi High Court and the Supreme Court. And finally, the much controversial case of Novartis which had challenged Section 3(d) of the Indian Patents Act, 1970 claiming immunity for their drug Gleevic, a major drug for leukemia on the pleas that the new Gleevic was a major improvement over older version whose patent was over. This was disputed by Indian companies such as Natco Pharmaceuticals. The plea of Novartis was rejected consequently enabling manufacture by Indian generic companies.

**Concerns regarding the Drug Price Control Regime** There have been growing concerns in the decrease in the number of drugs under price control as well as the shift in production by drug manufacturers from scheduled to non-scheduled drugs. This is a grave issue as it has adversely impacted the availability of essential drugs to the public at large. Currently there are 37 drugs out of 348 in the National List of Essential Drugs that are under the control of the National Pharmaceutical Pricing Authority (NPPA).
present price control regime, the prices of Non-Scheduled drugs are monitored, and in the case the prices of such drugs increase by more than 10% in a year, the NPPA is empowered to fix the prices of such drugs. Non-essential drugs should not be under a controlled regime and their prices should be fixed by market forces. There is a separate committee for finalizing the pricing of Patented Drugs, and decisions on pricing of patented drugs would be taken based on the recommendations of the Committee.

2.4 THE RESEARCH GAP AND OBSERVATION

From the literature review this has been observed that many research work were done on Indian pharmaceutical industry to know the developments and future prospects but the study on issues like increasing span of price control, price erosion in generics, low research and development productivity etc and Challenges like growing export, expanding presence in regulated market, rise in new product launches etc in this respect was neglected. Indian companies need to attain the right product mix for sustain future growth. Core competencies will play an important role in determining the future of many Indian pharmaceutical companies in the post product patent regime after 2005. Indian companies in an effort to consolidate their position will have to increasingly look at merger acquisition options of either companies or product. This would help them to offset loss of new product options,
improve their research and development efforts and improve distribution to penetrate markets.

Research and development has always taken the back seat amongst Indian pharmaceutical companies. In order to stay competitive in the future, Indian companies will have to refocus and invest heavily in Research and development. That is why researcher is also interested to know the factors behind the issues and challenges in Indian pharmaceutical industry.

2.5 CONCLUSION

The careful and minute review of the above literatures clearly depicts that there is no such comprehensive research with respect to the Indian Pharmaceutical industry issues and challenges after 2008. Therefore, this humble attempt has been made in this study. We think that our study will try to bridge the gap of the present studies and will contribute further knowledge to the issues and challenges of the pharmaceutical industry in India.