CHAPTER – 1
INTRODUCTION, RESEARCH METHODOLOGY AND REVIEW OF LITERATURE

1.1: INTRODUCTION:-

Globalization has brought in border less economy into formation mainly due to liberal economic policies and opening up of domestic economies to foreign inflow of capital both in equity and direct investment form. This has had an impact on the growth and structure of domestic industrial structure especially in developing economies like India. Such an impact is felt more in the pharmaceutical sector in India, which needs study and analysis. Such studies involve two aspects:

1. Study of changing Industrial Structure
2. Analysis of Foreign Investment in the Indian domestic pharmaceutical industry

Over the past decade there have been a number of changes in the policy framework developed since the late 1990s. Beside import liberalization removal of restrictions on foreign firms, Drug Price Control Order (DPCO) has been diluted as a part of economic reforms. The Intellectual Property Rights (IPR) framework has undergone important changes as per India’s obligation under Trade Related Aspects of Intellectual Property Rights (TRIPs) Agreement of World Trade Organization (WTO) covering adoption of product patents by 2005. All these trends of past decade viz. liberalization of trade, investment and price regulation, and emerging changes in the intellectual property rights are likely to have implications for the availability and price of pharmaceutical products in India.

The industrial, trade and technology policy framework evolved over the 1950-1990 has considerably changed in the 1990s as a part of economic reforms undertaken by the government and World Trade Organization agreements. The important changes have been brought about in the industrial
policy and foreign direct investment policy, trade policy, patent protection and price controls.

The New Industrial Policy (NIP) was announced on 24th July 1991 the main aim of the new industrial policy was;

1. To unshackle the Indian industrial economy from the cobwebs of unnecessary bureaucratic control.
2. To introduce liberalization with a view to integrate the Indian economy with the world economy.
3. To remove restriction on foreign direct investment as also to free the domestic entrepreneur from the restriction of MRTP Act, and
4. The policy aimed to shed the load of the public enterprises which have shown a very low rate of return or were incurring losses over the years.¹

All these reforms of industrial policy led the government to take a series of initiatives in respect of policies in following areas:

1. Industrial Licensing,
2. Foreign Investment
3. Foreign Technology Policy,
4. Public Sector Policy, and
5. MRTP Act. (Monopolies and Restrictive Trade Practice Act)

Under the New Industrial Policy (NIP) announced by the Government of India in July 1991, under this policy licensing was abolished for all industries except 18 industries which included coal, petroleum, sugar, metro cars, cigarettes, hazardous chemicals, pharmaceuticals and some luxury goods. The industrial policy was welcome because it took the bold decision to end the licence permit raj. This step enabled Monopolies and Restrictive Trade Practice companies to established new undertaking and effects plans of expansion, mergers, amalgamations and takeovers without government approval.

Under new industrial policy it has been decided to provide approval for direct foreign investment up to 51 percent foreign equity in high priority industries. The government has further clarified that it permits 100 percent
foreign equity in the case the entire output was exported. Before 1990, India’s foreign direct investment was less compared to other developing countries. Foreign capital is permitted free entry, the distinction between high priority industries to low priority industries would gradually disappear over time and all lines of production will be opened to facilitate foreign investment. The new industrial policy was able to attract foreign investment and give a boost of domestic investment. The regulatory provision in the Monopolies and Restrictive Trade Practice Act were removed through the 1991 amendments with the view to giving effect to the new industrial policy of liberalization and deregulation aimed to achieve economies of scales for ensuring higher productivity and competitiveness.

The new industrial policy dismantled the industrial licensing system by abolishing the requirements of obtaining an industrial license from the government drugs and pharmaceutical. New industrial policy accorded a much more liberal attitude to foreign direct investment than ever in the post independent India. Another aspect of reforms has been substantial dilution of price controls. A new Drug Price Control Order (DPCO) was notified in 1995 bringing down of number of drugs under the price controls to 74 from 166 under the 1987 order. These 74 drugs covered under Drug Price Control Order 1995 account for only about 40 percent of the total market thus setting the bulk of the pharmaceutical market out of price controls. The government has followed exclusion cum inclusion criteria, excluding drugs where there is sufficient market competition and including those where there is a monopoly situation. Secondly there is a single list of drugs under the price control with a Maximum Allowable Post Manufacturing Expense (MAPE) of 100 percent. Thirdly all formulations under Drug Price Control Order drugs sold whether under branded or generics cannot price fixation. Lastly, exemption period for new drug produced by indigenous research and development expenditure has been increased from five years to ten years.

In the patent regime under the Act of 1970, India did not provide product patent protection in pharmaceutical but did recognize process patents.
Indian Patent Act of 1970, which excluded product patent coverage for pharmaceutical products completely and limited process patents to a period of seven years. With respect to process patents there are provision which substantially limit the scope of protection.

1. First after three years from the date of sealing a pharmaceutical process patent the License of Rights clause applies. Under this clause the patent owner is obliged to license the patented process to any interested party with a maximum royalty of 4 percent payable by the licensee.

2. Second after three years from the date of sealing a pharmaceutical patent the government can grant a compulsory license if the patented drugs not available at reasonable price. The terms of a compulsory license are set by the government unless the patent owner and licensee find agreement between themselves.

3. Third a patented pharmaceutical process must be worked in India three years from the date of sealing the patent. Importation of a drug produced with the patented process is not considered as working the patent.

4. Fourth the burden of proof in case of patent infringement rests with patent owner.³

Under the 1970 Act, drugs could be patented only for a new methods or process of manufactures not for the product. It is important fact that before the introduction Trade Related Intellectual Property Rights (TRIPs) India did not provide product patent protection in pharmaceutical. Despite that the pharmaceutical industry remained under developed in India because of lack of the entrepreneurial spirit and technological skills to take advantages of the absence of product patent protection. Indian generic companies had to develop their own process patent. Another thing many of multinational companies patented drugs will come off patent by 2012-2014: this again can be seen as an opportunity to Indian pharmaceutical firms to enter the global market in a
significant way due to their cost efficiency and competitive edge more is so in the generic drug sector. Generic drugs means which patented drugs going to off patent that time every body use formula of patented drugs and reformulate them for sales. Product patent was introduced in pharmaceutical industry in India from 1st January 2005. A product patent is granted for 20 years.

Diversification is a method of investment into new markets. It is a process by which modern Corporations extend their activities beyond the current product range and markets in which they operate. Diversification can be achieved through internal expansion by investing into a new line of business activity or by external expansion through mergers. It can be classified as horizontal, vertical and conglomerate depending upon the industries in which firm is operating and the industries which want to diversify. A firm would be said to diversify horizontally if its new operations are in an industry of close substitutes. In vertical diversification, the new industry has forward or backward linkages with the firm present operations. In conglomerate diversification the new industry does not operations of the firm through diversification as shown in figure. A conglomerate merger involves a predominant element of diversification of activities. This may consist of a company deriving most of the revenue from a particular industry acquiring companies or entities operating in other industries for one or more following reasons;

- Obtain greater stability of earning through diversification,
- Obtain benefit of economies of scales,

Globalization has also given opportunity for Indian pharmaceutical industry to go for merger and acquisitions abroad. With the liberalization of Indian economy in 1991 restriction of merger and acquisitions have been lowered. As a result the government has introduced various measures to facilitate speedy clearance of merger and acquisitions deals. The Competition Bill cleared by the cabinet on June 01 is one such action for the centre. The Bill has exempted all companies from informing the government about any merger and acquisitions
deal. It would now be optional for companies to prenotify merger and acquisitions deals to the statutory body, the Competition Commission of India.
This body would review only those merger and acquisitions cases which result in post merger turnover of over Rs 30 billion and an asset base of over Rs 10 billion. The relaxation of foreign direct investment policy is another step in the right direction. Increasing foreign direct investment limit in pharmaceuticals has attracted foreign investment into the country. Out of the 73 acquisition deals announced in August 01 over 50 percent of the acquirers were foreign companies, constituting an estimated 60 percent of the total consideration of Rs 16 billion. Since 1991 Indian industries have been facing increasingly domestic as well as international competition and competitiveness has become an imperative for survival. Hence in recent times companies have started their operations around their core business activities through merger and acquisitions.

In India prior to 1991 most firms especially those belonging to large business groups undertook extensive diversification programme. The government policies dictated the timing, the size and the location of the new entrants and expansion of existing capacity. This was done to prevent dominance through the preeminent of capacity. The economy wide targeted capacity was thus split among several medium size units, which were not able to exploit scale economies. As a result, most of an Indian firm remained unfocussed due to distribution of operation.

With the New Industrial Policy of 1991, there were many changes in the regulations governing firm expansion. There was simplification in the procedural rules and regulations, industrial licensing was abolished except for a short list of related to security and strategic concerns. The pre entry scrutiny of the investment decision under the Monopolies and Restrictive Trade Practice Act 1969 was abolished. No prior approval of the central government was required for expansion establishment of new undertaking merger and takeovers. The opening up of the consequent increase in competition meant that a business group had to reassess to portfolio activities. In their public statement, the companies claimed they would concentrate on a core business reflecting a strong specialization. However, as will be seen later, the trend was towards
increased diversification in an economic environment of less government control.

Post 1991 era has witnessed the above policy changes in the Indian economy, more so the industrial sector. These policy changes are tuned to the needs of globalization, free trade and more suitable domestic policies to attract foreign capital inflows. Emphasis is also given to boost exports. These macro-economic policy changes have changed the structure of Indian Industries and such structural and policy changes need study and critical review. It is against this background that the present study is undertaken.

1.2: PERIOD OF STUDY:-

The present study attempts to review the growth and composition of Indian pharmaceutical industry, during the period 1991 to 2006. The period of study spans seventeen years because we have studied the progress and changes after New Economic Policy was introduced in India since 1991.

1.3: TITLE OF STUDY:–

The present thesis is entitled, “A STUDY OF THE CHANGING PROFILE OF THE INDIAN PHARMACEUTICAL INDUSTRY IN POST ECONOMIC REFORM PERIOD (1991 ONWARDS)”

1.4: SCOPE OF THE STUDY:–

The period of study is from 1991 to 2006 for which comparable data is available The New Economic Policy was introduced in India from 1991 onwards and hence the period of study starts from 1991. The study is limited to the Indian Pharmaceutical Industry only and where ever necessary inter country comparison is attempted.

1.5: OBJECTIVES OF THE STUDY:–

The following are the main objectives of the proposed study.
1. Review the growth of the Pharmaceutical Industry in India since 1991 and highlight the emerging structural changes.

2. Highlight the nature of Acquisition and Mergers taking place in the Indian Pharmaceutical Industry.

3. Analyze the growth performance of Indian Pharmaceutical Industry and its likely consequences on the drug market and prices of drugs in the domestic market.

4. Based on the above mentioned objectives, draw conclusions and make suitable suggestions.

1.6: RESEARCH METHODOLOGY:-

The present study is essentially based on published secondary data collected from official sources. Secondary data is analyzed with help of appropriate statistical tools of analysis. Based on statistical tabulation of the data interpretation is done in appropriate chapter scheme followed by pooling suggestions based on conclusions of the study. Secondary data is collected from the annual reports of major Pharmaceutical companies as well as Government publications. The secondary data is collected by visiting the following libraries:-

1. Late D.R. Gadgil Library, Gokhale Institute of Politics and Economics, Pune.
3. Jaykar Library, University of Pune
4. Library of Maratha Chambers of Commerce of Agriculture and Industry, Pune
5. National Chemical Laboratory, Pune.
7. Tata Institute of Social Sciences, Mumbai
8. Indira Gandhi Institute of Development Research, Mumbai.
9. Jawaharlal Nehru Library. University of Mumbai
10. Centre For Monitoring Indian Economy Pvt Ltd (CMIE), Mumbai
11. Federation of Indian Chambers of Commerce and Industry (FICCI), Mumbai
12. Organisation of Pharmaceutical Producer of India (OPPI), Mumbai

Necessary secondary data is collected from following official sources.

7. Organisation of Pharmaceutical Producer of India.
8. Pharmaceutical Research and Manufacturers of America, PhRMA Annual Membership Survey.
10. Indian Planning Experience – A Statistical Profile; Planning Commission, Government of India, New Delhi

Data collected from the above sources is tabulated and interpreted with the help of appropriate statistical tools. Compound growth rate, ratio analysis
and percentage methods are used for data analysis. Graphical presentation of data is made wherever necessary.

1.7: HYPOTHESIS OF THE STUDY:-

The Indian Pharmaceutical Industry has witnessed many structural changes in post-economic reform period. The period of reform has witnessed increased entry of Multinational Pharmaceutical Company into the Indian market resulting in a number of Acquisition and Mergers taking place. The marketing strategy hence needs analyses as it is probable that by capturing a sizeable share in the market, a few large pharmaceutical industrial firms many succeed to control supply of drug in the market and it the process manipulate price when the Government is also bringing in price decontrol policy. Such a situation also has large social consequences.

1.8: LIMITATION OF THE STUDY:-

In the process of the data tabulation certain limitations were noted. Data pertaining to total global sales and country wise, region wise, global sales of global pharmaceutical industry was not available on the year to year basis. Hence, data for specific years only is analyzed. The year wise figures of production of pharmaceutical formulation for the years 2004-05 to 2006-07 was not available and hence not studied. Similarly, export of finished formulation and bulk drugs and import of pharmaceutical finish formulation, bulk drugs and intermediaries for the years 1999-2000 to 2006-07 were not available.
The data tabulated from the above source is analyzed according to the following chapter scheme.

**CHAPTER – 1**

INTRODUCTION, RESEARCH METHODOLOGY AND REVIEW OF LITERATURE

**CHAPTER – 2**

EMERGING TRENDS IN GLOBAL AND INDIAN PHARMACEUTICAL INDUSTRY SINCE 1991

**CHAPTER – 3**

GROWTH AND CHANGING PROFILE OF THE INDIAN PHARMACEUTICAL INDUSTRY SINCE 1991

**CHAPTER – 4**

EMERGING STRUCTURAL CHANGES IN INDIAN PHARMACEUTICAL INDUSTRY

A) ENTRY OF MULTINATIONAL COMPANIES
B) STUDY OF ACQUISITION AND MERGERS
C) COMPARATIVE ANALYSIS OF THE SHARE OF MAJOR PHARMACEUTICAL COMPANIES IN PRODUCTION AND MARKET SHARE STUDIES
D) EXPORT PROFILE
E) REVIEW OF MARKETING POLICY

**CHAPTER – 5**

REVIEW OF PRICING POLICY AND GOVERNMENT POLICY ON PRICE CONTROL SOCIAL CONSEQUENCES STUDY.

**CHAPTER – 6**

CONCLUSIONS AND POLICY SUGGESTION

**1.9: REVIEW OF LITERATURE:**

1 – Pradeep Agrawal, and P. Saibaba, in their paper “TRIPS and India’s Pharmaceuticals Industry”, Economic and Political Weekly, September 29,
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2001, undertake a broad review and present a brief analysis of how the Indian Pharmaceuticals industry might have been affected new patent laws that came into force from January 1, 2005 as a part of the Trade Related Intellectual Property Rights (TRIPS) agreement, negotiated under the World Trade Organisation regime.

In this paper the authors have built up an important argument offered by the supporters of Trade Related Aspects of Intellectual Property Rights agreement regarding the world welfare in the medium to long run. It is that increased patent protection for inventors is necessary in the increasingly globalised world economy where flow of products among countries may have serious consequences for the overall profits of pharmaceutical firms. In the long run the Trade Related Aspects of Intellectual Property Rights agreement may bring benefits for developing countries like India in the form of research and development expenditure in inventing drugs for diseases that are specific to developing regions.

The authors are of the opinion, that India is relatively better off than many other developing countries because it has a reasonably well developed pharmaceuticals sector. They argue that we must do our best to help make Indian firms more capable of undertaking research and development and to be more competitive in exports. This can be facilitated by providing generous tax incentives for undertaking research and development and by allowing liberal imports of raw materials with minimum import duties. Export procedures should also be further simplified so that they do not become a hindrance to the growth of export. We should also actively encourage technological collaboration with foreign firms and the inflow of foreign direct investment, in the pharmaceutical industry as ways to brings new technology, research and managerial capabilities into this important sector of the economy.

2 – Nilesh Zacharias and Sandeep Farias,\textsuperscript{7} in their paper “Patent and the Indian Pharmaceutical Industry” argue that the process of liberalization initiated in 1991 has helped develop policies that are focused on attracting capital from overseas and making India a global industrial base. The resultant inflows of
foreign direct investment and technology transfers have created an environment for dynamic growth and increased competitiveness of Indian industry.

They concluded that India is slowly moving into global markets and competing with international quality standards and prices. Although research and development is an important factor to ensure a competitive edge in the international arena. The future of the pharmaceutical industry hinges on patent protection.

3 – Kalpana Chaturvedi and Jonna Chatawy, in their special paper “Strategic integration of knowledge in Indian pharmaceutical firms: creating competencies for innovation”, have given to much stress on the effects of TRIPS on the research and innovation strategies of the Indian pharmaceutical firms. The most common strategic concern that Trade Related Aspects of Intellectual Property Rights has raised for Indian firms is them perceived need for research and development and technological strength.

The present paper analyses the gradual reorientation of the Indian firms towards innovation-based research and development. Focusing at the firm level, the paper looks at research and innovation strategies that are being devised by the top Indian firms to attain leadership in the domestic market and carve a niche for them in the international market in the post-TRIPs regime.

They observed that Indian pharmaceutical firms are involving from reverse engineering outfits catering to domestic market to technologically advanced and sophisticated organizations capable of catering to diverse markets.

4 - Gehl Sampath, Padmeshree, in their paper “Indian Pharma Within Global Reach?” deal with The Indian pharmaceutical industry and its strengths have been conceptualized broadly from two perspectives: one analyses the potential of the sector to offer price-based competition to the global pharmaceutical industry, by producing cost-effective generic versions of patented drugs. The other seeks to explore how the Indian experience can be replicated in other developing and least developed countries. These perspectives stress upon the
strengths of the Indian pharmaceutical sector to compete globally and help provide price competition in the generics sector to the multinational firms.

The analysis conducted in the paper has shown that firms in the Indian pharmaceutical sector vary considerably in their innovative capabilities.

The author concludes that, consistent with what is know about sectoral systems behavior everywhere, innovation processes of Indian firms are strongly shaped by their specific knowledge base, qualifications and skills, required organizations and institutions involved, as well as specific competitive challenges from a globalizing economy.

5 – Larry Davidson and Gennadiy Greblov,10 in their article “The Pharmaceutical industry in the Global Economy”, summarizes the results of our global pharmaceutical industry analysis and is intended to increase awareness of the general public investors, policy makers, managers, employees of the companies about its current developments. The paper has the following major goals:

1) To analyze the current situation, major challenges and the prospects of the pharmaceutical industry;

2) To identify major players of the global pharmaceutical industry and make a comparative analysis of their business practices and financial results;

3) To determine the relative position of the U.S. pharmaceutical companies in the global pharmaceutical industry, as well as to reveal opportunities for further strengthening of their positions.

The paper consists of three major parts. In the first part present an overview of the pharmaceutical industry as a whole its major players, current trends and challenges. The second part focuses on a more detailed analysis of major pharmaceutical companies. These major companies are divided into two major groups:

a) Companies with headquarters in the U.S.,
b) Foreign pharmaceutical companies with headquarters outside of the U.S. Pharmaceutical companies are compared with other companies in the same group; and major trends within each group are analyzed.

6 - Richard M. Scheffler and Vikram Pathania, the study of Richard M. and Vikram Pathania “Medicines and vaccines for the world's poorest: Is there any prospect for public-private cooperation?” review the current status of the global pharmaceutical industry and its research and development focus in the context of the health care needs of the developing world. The study considers the attempts to improve access to critical drugs and vaccines, and increase the research effort directed at key public health priorities in the developing world. In particular, it will consider prospects for public-private collaboration.

   The opines study that there are huge potential benefits if even a fraction of the industry's vast resources laboratories, scientists, and databases can be harnessed to look for solutions to developing country health needs. As the partnerships strive to make the drug companies allies in the war on disease in developing countries, coordination across multiple partners will be a key challenge.

7 – Suma Athreye and Dinar Kale, in their study “Experimenting with strategy in the Indian Pharmaceutical Sector”, highlight the role of new economic opportunities in inducing experimentation in strategy. This paper describes and analyzes the variation in the strategy-mix of established Indian pharmaceutical firms in response to the economic opportunities generated by three big policy changes- two of these involved changes in national regulation but perhaps the most important change was the change in US regulations governing the production of generics. It explored the different strategies adopted by the four firms to target the generics market and the subsequent attempts to transition to a drug discovery company.

   They find the only significant capability that the four firms have developed thus far is the capacity to integrate technologies acquired from diverse technological sources and operate on reasonably large scales. Later
firms have found less costly modes of technology acquisition than the earlier entrants in the market for firm acquisitions.

Thus, the paper highlights the role of new economic opportunities in inducing experimentation in strategy and in inducing strategic change. While managerial vision appears to direct strategy when there is uncertainty about which strategy best targets the economic opportunity, imitation is rapid when uncertainties disappear. The paper shows that incumbent firms drew upon firms’ own strengths, vision and managed risk in different ways. They also showed considerable entrepreneurial behavior in pursuing new opportunities.

8 - Keshab Das, 13 in his paper “The Domestic Politics of TRIPs: Pharmaceutical Interests, Public Health, and NGO Influence in India, examine some of the political implications of the coming into force, in 2004 of provisions of the World Trade Organization Agreement on Trade Related Aspects of Intellectual Property Rights. These are serious implications for India’s pharmaceutical industry, as well as for the political environment within which pro-poor policy change can be effected. The historical backdrop to this change is an important contextual feature: operating within India’s homegrown patent system which covers not the product itself, but only the process by which it was made India’s pharmaceutical industry managed, over the course of several decades, to make the country self-sufficient in the production of a considerable range of drugs and (crucially for the poor) to make them widely available at affordable prices.

The World Trade Organisation provisions now coming into force are likely to have different impacts on different groups associated with the pharmaceutical sector. Some of this stems from the nature of the provisions themselves, but an important part of the story concerns attempts by state elites to co-opt external stakeholders. This latter development is itself an important change in the nature of trade policy formulation in India.

The author observes that as part of a global campaign to loosen the strictures of the Trade Related Aspects of Intellectual Property Rights Agreement, in the interest of making medicine more widely available to the
poor, India’s more activist-oriented non Governmental organization (NGOs) have increased their influence over this aspect of trade policy. One outcome has been to make India's trade policymaking process more democratic and participative, though the outcomes for the poor remain, for the moment, unclear.

9 – Product Patent: In this special article “Implication of Pharmaceutical Industry and Consumers”, stress on the impact of product patent regime on the Indian pharmaceutical sector. This paper attempts to examine the potential price hikes in certain drug segment using the econometric approach. The paper also examines some of the flexibilities provided in the new Indian patent Act, 2005.

The present study attempts to analyse the possible effects of the imposition of the product patent on the pharmaceutical sector in India. The author has observed, the impact of such impositions, a comprehensive examinations of the market structure of the pharmaceuticals, market accessibility and price of the drugs as well the preparedness of the country to face such product patent regime has been focused upon. Thus, econometric analysis shows that the Trade Related Aspects of Intellectual Property Rights regime affects the Indian consumers to an extent, since there appears to be certain welfare loss for them. This welfare loss is not only in terms of higher of lower drug prices, but also in terms of less product variety in near future.

10 – D.P. Dubey, in the article "Globalisation and its Impact on the Indian Pharmaceutical Industry”, this to show how the workers of the drug industry and the people of our country are affected by the impact of globalisation. Considering the wide gap of industrial and technological development between developed and developing countries monopoly rights through the patent system should not be allowed to the rich nations. Today 85 percent of the patents are being controlled by the Transnational Companies of the rich nations. Globalization is hurting poor people not just the poor countries. In this process poor countries and poor people will become increasingly marginalized, says the 1997 world development report of United Nation Development Programme.
The author concludes that the main aim is to impose the conditional ties of World Trade Organization and to change the Indian Patent Act as Multinational Companies need more markets and are eyeing Asia which is the largest continent of the world where 60 percent of the world population lives but contributes only 20 percent of the world pharmaceuticals business. With a high rate of population growth it is expected that the need of drugs will tremendously increase in the third world countries including India in the next millennium. India contributes 16.1 percent of the world population, but it produces only 1.2 percent of world drug production. Hence the Multinational Companies are trying to have more control over the pharmaceutical markets of the developing nations. Developed countries are backing their own big companies to capture markets in other countries even at the cost of the interest of the people there. The United States has successfully battled for the inclusion of strict intellectual property rules in international trade agreements such as NAFTA and GATT. Often the U.S. position has literally been drafted by PhRMA. These trade agreements disregard public health considerations and have forced dramatic changes in the intellectual property rules the world over. Still PhRMA is not satisfied. And when PhRMA is not happy the office of U.S. Trade Representative (USTR) is not happy, says the editorial comment of multinational monitor.

11 - Aradhna Aggarwal, in the study entitled "Strategic Approach to Strengthening the International Competitiveness in Knowledge Based Industries: The Indian Pharmaceutical Industry;” identifies the factors that determine the export competitiveness of firms in the Indian pharmaceutical industry. Her findings suggest that the competitiveness of firms depends not only on firm specific advantages but also on government fiscal incentives. Among the firm specific factors own research and development efforts emerged as one of the prime factors influencing export competitiveness. Technology imports on the other hand did not play a significant export-enhancing role. Brand promotion and lower costs were other important determinants of the export competitiveness. The study also finds that the
determinants of export competitiveness differ across firms of different size and ownership. High transaction and production costs are found to be major constraints faced by Indian exporters. Based on the quantitative and qualitative analysis, the study draws useful policy implications to strengthen the export competitiveness of the industry.

Mary Cain and Susannah Kirsch, in their article “The Future of Pharmaceuticals” put forth broad themes that emerge in the pharmaceutical marketplace of the future: an increase in the segmentation of products and markets, and the importance of relationships. They view that of the new drugs to people have to be based on their preferences and will have to give tailor specific treatment regimens supporting their lifestyles and behaviors. Consumers will receive highly targeted and specific marketing messages based on their use of technology, health status, ethnic and racial background, gender, age, and interests and activities.

As a result of this segmentation, the relationships maintained by players up and down the supply and demand chains among pharmaceutical companies and their suppliers, their customers (both patients and providers), and public regulatory agencies, as well as between patients and their providers and health plans, to name just a few of the permutations will become more important to the success of all parties, both individually and collectively. Partnering with consumers and providers will allow the industry to advance to its next phase of providing more targeted and appropriate health care by helping pharmaceutical companies learn more about their customers.

The study concludes that segmentation and the importance of relationships in business are not big news. Pharmaceutical companies, scientists, and marketers have all been focusing on segmenting their research and markets to better understand separate trends before integrating them into a multidimensional context. Companies have always been concerned about the business relationships they form with their suppliers and their consumers. Technology is allowing customization and targeted research on a broad scale. Industry is integrating increasingly specific information about consumers to
narrowcast messages and information, whereas in the past they were constrained to broadcasting techniques. Science and industry are developing a portfolio of highly targeted drugs that better suit the needs of a diverse patient population.

13 - Dr Alka Chadha in her study “Destination India for the Pharmaceutical Industry, undertakes a broad overview of the patent law, TRIPs regulations, market structure, Foreign Direct Investment, exports, joint ventures and alliances. The twin dose of economic liberalization and strong patent regime has rejuvenated the Indian pharmaceutical industry. The export focus of Indian firms, propelled by the recognition of process patents in different countries, has made them penetrate a number of countries based on their low cost structure. They are now concentrating not only on off-patent drugs but also on undertaking contract research. The pharmaceutical industry is in the transition phase ready to face new challenges that could bring major changes in its business environment. For long-term solutions, the industry will have to build up its research and development facilities as well as make sustained efforts to attract foreign direct investment for technical collaborations. Moreover, it is imperative that the deregulation and decontrol of the industry should proceed in such a manner that prices of essential drugs remain affordable to consumers since this industry has direct implications for healthcare and social welfare.

Her opinion is that the, with stronger patent laws, contract research, joint ventures and clinical trials at a fraction of the cost in India, as compared to developed countries, India is the right choice for pharmaceutical foreign direct investment in the near future.

14 - Sean Eric Smith, in his study “Opening Up to the World:India’s Pharmaceutical Companies Prepare for 2005”, highlights the following points;

1. First, around 80 percent of the Indian drug market consists of off-patent drugs. These, and other drugs whose patents expire by 2005, will continue to be available to Indian firms with no intellectual property rights of their own. It is striking that over 95 of the top 100 drugs listed by the World Health Organisation are off-patent.
2. Second, the price-control regime means that Indian firms are highly efficient manufacturers, as is shown by the 40 percent share of output being exported.

3. Third, a few Indian firms have determinedly moved away from their origins as reverse-engineers of patented medicines, and are now investing a growing research and development budget in their new drug discovery programs, aimed at building their own internationally patented intellectual property rights. Two firms, Ranbaxy Laboratories and Dr. Reddy’s Laboratories (DRL), have already filed their first molecules internationally, and in 1999, received the all-important Food Drug Administration approval to conduct clinical trials upon them. These companies have also indicated that they have discovery pipelines that enable them each to file for one molecule per year.

4. Fourth, mergers and acquisitions have become increasingly common. By matching companies with complementary strengths, the merger and acquisitions process promises to better equip Indian companies to compete with Multinational Companies in years ahead. To the extent that merger and acquisitions activity has occurred between Indian and multinational firms, the distinctions between the two groups are increasingly blurred.

5. Fifth of the twelve firms in the sample for this paper were Multinational Companies subsidiaries. Accordingly, the paper also offers insights into these companies’ 2005 related strategies. Most Multinational Companies that already have a presence in India are building up the capacity to localize further their post 2005 Indian operations, pending the specific nature of the new patent environment.

The study in the final analysis, feels that changes in the Indian pharmaceutical sector will permanently alter its structure. Fears that Multinational Companies will capitalize on increased patent protection and wipe out local competition appear to be exaggerated, although consolidation is inevitable with 16,000 companies, the Indian pharmaceutical industry is
currently one of the most fragmented in the world. However, the industry is certain to grow increasingly efficient and productive in the coming years. India may become a center of global importance in pharmaceutical production and research and thereby, enhance its position in the world economy.

15 – Sunil Mani, 20 in the study of “The Sectoral System of Innovation of Indian Pharmaceutical Industry”, undertakes a detailed mapping out of the sectoral system of innovation of India's pharmaceutical industry. The industry is one of the most innovative industries in the Indian manufacturing sector. The innovation system of the industry has three strong pillars: very proactive government policy regime especially with respect to intellectual property right, strong government research institutes and private sector enterprises which have invested in innovation. The Trade Related Aspects of Intellectual Property Rights compliance of the intellectual property right regime making it mandatory for pharmaceutical products to be patented has not reduced the innovation capability of the industry although it has not made them work on research and development projects that may lead to the discovery of drugs for neglected diseases of the developing world.

The study concludes that, India's innovation system is dominated by the pharmaceutical industry. The industry has achieved self sufficiency in most drugs, although a number of active pharmaceutical ingredients are still being imported. It is very well understood that the old patents regime has enabled the pharmaceutical industry to enhance its domestic technological capability. This capability to reverse engineer known pharmaceutical products have given some of the firms sufficient learning to engage in the development of new chemical entity (NCEs) in a Trade Related Intellectual Property Rights compliant product patent regime. However, none of the firms is doing research on the neglected diseases. In sum, the Trade Related Intellectual Property Rights compliant patent regime does not appear to have dampened the innovation capability of the domestic pharmaceutical industry, and on the contrary, they have both increased their research budgets and patenting.
16 - Patricia M. Danzon, Andrew Epstein and Sean Nicholson, in their study “Mergers and Acquisitions in the Pharmaceutical and Biotech Industries”, examine the determinants of merger and acquisitions activity in the pharmaceutical-biotechnology industry and then study effects of mergers using propensity scores to control for merger endogeneity. Among large firms, we find that mergers are a response to excess capacity due to anticipated patent expirations and gaps in a company’s product pipeline. For small firms, mergers are primarily an exit strategy for firms in financial trouble, as indicated by low Tobin’s q, few marketed products, and low cash-sales ratios.

The study further finds that it is important to control for a firm’s prior propensity to merge. Firms with relatively high propensity scores experienced slower growth of sales, employees and research and development regardless of whether they actually merged, which is consistent with mergers being a response to distress. Controlling for a firm’s merger propensity, large firms that merged experienced similar changes in enterprise value, sales, employees, and research and development relative to similar firms that did not merge. Merged firms had slower growth in operating profit in the third year following a merger. Thus, mergers may be a response to trouble, but they are not an effective solution for large firms. Neither mergers nor propensity scores have any effect on subsequent growth in enterprise value. This confirms that market valuations on average yield unbiased predictions of the effects of mergers.

Small firms that merged experienced slower research and development growth relative to similar firms that did not merge.

17-P.G.K.Panikar, in the study of “Multinational Enterprise in Pharmaceutical Industry and Less Developed Countries”, in this paper main focuses on the multinational enterprise in pharmaceutical industry, because;

1 – Pharmaceutical industry is perhaps the most multinational of all manufacturing industries,

2 – The product of this industry has certain distinct characteristics, which differentiate it from others.
The multinational drug firm shares the generic characteristics of Multinational Companies size of investment, scale of turnover, structure and organization, method of control and operations, etc. But then the pharmaceutical industry is the most multinational of all manufacturing industries; it is the most profitable of all.

The researcher concludes that, the less developed countries cannot afford the luxury of allowing multinational enterprise to thrive in this business of disease and death, whatever be the avowed advantages.

18 – H.A.C. Prasad, 23 in his study “The New Patent Regime: Implication for India’s Pharmaceutical Sector” examines the implication of new patent system as stated in the Trade Related Aspects of Intellectual Property Rights agreement on Indian pharmaceutical sector. It also examines certain provisions, which have not been included in the Trade Related Aspects of Intellectual Property Rights agreement but have an important bearing on India’s pharmaceutical sector. While emphasizing that the new patent system under World Trade Organisation is not really for India, the author underlines the need to take some immediate steps to reap the benefits of a strengthened patent regime, in the sphere of foreign investment and technology transfer.

The study concludes that, the new patent system under World Trade Organisation is not really has no adverse impact on India’s pharmaceutical sector, though it may not also be very rosy in terms of foreign investment and technology transfer, unless India makes some intelligent moves. There are also many clauses within and outside the Intellectual Property Rights agreement which can be used to India’s advantages. Finally India should also invest in which is at an abysmally low level, to get more foreign patents for Indian products.

19 – J.P.Pradhan, 24 in the study “Strengthening IPR Rights Globally: Impact on India’s Pharma Exports”, focuses on Intellectual Property Rights impact on Indian pharmaceutical exports. In the post trip period Multinational Companies in developed nations make a demand that across countries patented protection regimes need to be harmonized so that trade distortions and barriers to trade are
reduced. Strong patent regimes are always helpful to exports of developed nations as long as patent cover is in force. The movement patents time span gets over then strong patent policies also give scope for exports of developing nations to increase their presence in developed nations market.

Against the above background the present paper makes an attempt to study the possible impact of a stronger Patent regime on a country like India whose better technology gives scope for India to expand and diversity its pharmaceutical exports. The against that Indian pharmaceutical producer stand to benefit from the stronger patent regime. This is so because the generic drug market offers a lot of scope for that Indian pharmaceutical. Producers where research and development efforts are better in this market segment. The paper also sounds a condition that the potential benefits from a strong patent regime is for pharmaceutical industry only and the same comment be said other sectors of the industry for other sectors of the industry for which further studies need to be conducted.

20 – S.S.Pattnagak and S.M.Thangarelm, 25 in their study “Linkages, Spillovers and Foreign Ownership: Evidence from the Indian Pharmaceutical firms” are of the opinion that post globalization policy changes have seen a increase in the flow of foreign direct investment into developing countries. Other forms of foreign capital inflows also have come across borders. Domestic policy changes trade, industrial as well as capital market and financial reform have made entry of Multinational Companies into countries that India, China, SE Asia easier. This has had and impacts domestic industrial structures of developing countries where in domestic firms have for gent linkages with foreign firms. Such linkages both forward and backward result in spillovers, which benefit domestic firms.

The present study makes a critical examination of such spillover effects of the entry of Multinational Companies on domestic Indian Pharmaceutical industry. The study make data analysis of the study reveals that there is a positive impact as far as horizontal spillovers are concerned. Negative
spillovers of backward linkages with foreign firms care noticed. The reason for this is the large technological gaps between domestic firms are foreign firms.

The paper emphasis that if firm in all countries has to gain from a globally competitive scenario then it is very necessary to reduce the technology collaboration across nations from technological efficient firms to less efficient firms. However, this the paper feels will not happen, if the patent regime is strong.
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5 - Ibid


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16 - Aradhna Aggarwal, (2004), Strategic Approach to Strengthening the International Competitiveness in Knowledge Based Industries: The Indian Pharmaceutical Industry, Research and Information System for the Non-Aligned and Other Developing Countries, Discussion Paper.


