

Impact of Pre and Post Patent Regime on Indian Pharmaceutical Industry: An Analytical Study

A

SYNOPSIS

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1. INTRODUCTION

The pharmaceutical industry is one of the world's most research intensive industries, which is making enormous contribution to health care. This industry is also known as the life – saving industry because that's play, a fundamental task in remedifying the pain of unhealthy persons. The United Nations include pharmaceutical industry in sustainable development goals as a key player. Pharmaceutical industry is as well the significant provider to weight any countries wealth by providing employment for millions of people and causal of foreign exchange (Gulshan Akhtar, 2013).

In 1901, the first Indian pharmaceutical company Bengal Chemical Pharmaceutical Work Ltd. was established in Kolkata by Acharya PC Roy, Alembic Chemical Works Co. Ltd and also set up by T.K Grajor in 1907. These companies began to Indian pharmaceutical industry traditional method to scientific approach.

The Indian pharmaceutical market was totally dependent on imports in 1960s. The Government policies make Indian pharmaceutical self reliance by the production of local pharma product. The 1970s saw a rip open of start-ups in the Indian pharmaceutical sector, and it is a glowing example of success over the last four and the half decades. Indian pharmaceutical industry exposed incredible growth in terms of infrastructure enlargement, technology and research base to the wide range of production. Indeed, we could say that the Indian pharmaceutical industry was actually born in the 1970s.

The Indian pharmaceutical industry was going up as a more important manufacturer of pharmaceutical commodities from mid 1980s, by growing fast in terms of production. In the year 1990 pharmaceutical companies start to development due to infrastructure creation and export initiation by the government and 2000 to 2015 Indian pharmaceutical plays a vital role in global market because of research oriented and market development approach. The Indian pharmaceutical market is dominated by branded drugs market. The share of branded and generic market is approximately 86 percent and 14 percent. The top ten Indian pharmaceutical

companies hold approximately 37 per cent of the global pharma market as beside global average of 4-7 per cent during in year 2008-2013 (DOP, 2013). According to rating, a Fitch company, The Indian Pharmaceutical industry is estimated to grow at 20 per cent (CAGR) over the next five year.

Now a day the Indian pharmaceutical sector ranks 3rd in terms of production (10 per cent of global share) and 14th largest by significance share is lowest cost of drugs in Indian ranging from 5 to 50 percent lowest as compared to other drug producer developed countries (Report Equity Master, 2015).

In the pharmaceutical industry on the basis of manufacturing, drugs can be classified in to two groups that are branded drugs and generics drugs.

1.1 Branded Drugs: A branded drug takes numerous years' for making medicine, costly scientific development and many clinical studies to get a drug approved. Manufacturers of new brand usually take on the research and development costs for new medicines with marketing costs, account for the, higher prices we pay, for most branded drugs. The brand name is protected by patent, if a branded drug has lost its patent then generic form of drug available.

1.2 Generic Drugs: Generic drugs are those drugs which are made with some dynamic ingredients in the some amount, form as a trade name, drugs but are sold to customers under their chemical name. Generic drugs has the similar active ingredients as trademark name drugs which approved by food and Drugs Administration (FDA). Generics drugs are only available in case of patent expires (20 years) on the brand name drugs (DBSA, 2007) and the cost is 30 to 80 per cent less in comparesion of branded drugs.

The domestic generic drug market may touch US \$ 27.9 billion by 2020 from the current US \$ 13.1 billion on the back of USFDA approvals to Indian pharmaceutical firms and may drugs losing their patent status. As per the ASSOCHAM and RNCOS the sector is likely to benefit from USFDA approvals to Indian pharma firms, as 21 drugs lose patent status by 2019 (The Hindu, Dec 25, 2015).

Generic drugs account for 75 percent of the domestic pharmaceutical market by value. Drugs for Cholesterol control, pain management, anti-coagulant, respiratory, liver disorders, depression and lipid regulators are highly prevalent in the global market.

The Indian generics industry got its first big break in 1984, when the US passed what is known as the Hatch-Waxman Act with this legislation the US streamlined the generic approvals, thereby making it easier for generic companies to compete in the US drug market. Observers of the pharmaceutical industry consider today's opportunity for India in generic industry. In a move, that will further inflate prices of drugs in the U.S, already burning issues. The U.S government has made it mandatory for Active Pharmaceutical Ingredients (API) to be manufactured locally. At present, nearly 80 per cent of drug raw material requirement is met by India or China.

1.3 Indian Pharmaceutical Patent Regime

The Indian Patent Regime has been instrumental for the development of the Indian Generic drugs industry, making possible the production and availability of essential drugs at affordable prices. Prior to the WTO and TRIPS the two distinct features of the Indian Patents Act, 1970, i.e. allowing only for process patent and not product patent by virtue of Section 5 of the Indian Patents Act, 1970, are the major factors, for the growth of generic industry. The then act was prepared keeping in mind the socio-economic condition of the country and was largely based on the recommendations of a report of an Ayyangar Commission.

The growth of generic pharmaceutical industry due to the favourable patent regime not only had impact in India but also well beyond its borders. India is the main supplier of essential medicines for developing countries. As per the Annual Supply Report of UNICEF, India was the largest supplier country in 2012. UNICEF procured \$558 million worth of services and supplies from India. Further as per the reports of Campaign for Access to Essential Medicines, around 67 % of medicines exports from India go to developing countries, around 75-80% of all medicines distributed by the International Dispensary Association (IDA) to developing

countries are manufactured in India. In Zimbabwe, 75% of tenders for medicines for all public sector health facilities come from Indian manufacturers. The state procurement agency in Lesotho, NDSO, states it buys nearly 95% of all ARVs from India. This is the reason why India is known as the doctor without borders. But the recent change in the Patents Act, 2005 in order to harmonize it with the Trade Related Intellectual Property Rights (TRIPs) Agreement, may leave least developing nations and the developing ones in a big trouble, who were dependent on India's generic pharmaceutical industry.

The Patents Amendment Act, 2005, introduced "Product Patent" in India. The product patent was granted for the new product for a period of twenty years. Earlier due to absence of product patent, only process patents are granted for a new process of manufacturing an already known product or for manufacturing a new product. This has helped Indian pharmaceutical industry to develop generic versions of the new medical drugs without having fear of infringement of patent. This has also helped in achieving a key-objective of policymakers in the developing world to ensure the availability of new medical treatments to save millions of lives by production of cheap generic versions of on-patent drugs. The introduction of product patents is considered as a major incentive for developing new medicines, especially for tropical diseases, not focused upon by the developed nations; it has a snowball effect on the Generic industries with only one saving clause.

1.4 Indian Pharmaceutical Manufacturing Units

As per the Directory of pharmaceutical manufacturing units in India 2014, published by National Pharmaceutical Authority, Government of India. There are 10563 pharma manufacturers across the country. Out of the total 10563 pharmaceutical manufacturers in the country, 8174 unit (77.4 per cent) manufacturing formulation drugs and 2389 units (22.6 per cent) are engaged in manufacturing of bulk drugs. The state wise distribution of no. of formulation and bulk drugs manufacturing show that, the five states like Maharashtra (29.7 per cent), Gujarat (14.4 per cent), West Bengal (7.2 per cent) Andhra Pradesh (6.9 per cent) and

Tamil Nadu (5.4 per cent) which accounts for more than 60 per cent of the total no of manufacturers in the country.

Table- 1.4.1

Classification of Indian Pharmaceutical Manufacturing Units

State	No. of Manufacturing Unit			Per cent Share	Cumulative Per cent
	Formulation	Bulk Drugs	Total		
Maharashtra	1928	1211	3139	29.7	29.7
Gujarat	112	397	1526	14.4	44.1
West Bengal	694	62	756	7.2	51.3
Andhra Pradesh	528	199	727	6.9	58.2
Tamil Nadu	472	98	570	5.4	63.6
Others	3423	922	3845	36.4	100.0
	7157	2389	10563	100.0	-

Source: Bulk Drugs Manufacturing Association

Top ten exporter companies of Indian pharmaceutical industries on the basis of, sales revenue rated by Business Standard (2015), they are Dr. Reddy Lab, Cipla Ltd, Ranbaxy Ltd, Aurobindo Ltd, Lupin Ltd, Matrix Lab Ltd, Orchid Pharma, Cadila Healthcare, Divi's Lab Ltd, Sun Pharma Ltd. Top ten firm exported approximately 50 per cent of the total pharmaceutical products exports, they registered a boost in their share over the period of time despite some upheavals.

The Indian pharmaceutical industry is one of the leading and largely advanced industries among the developing nations. Indian pharmaceutical industry is also the world-largest, in term of volume, supplier of the 20 per cent global market for generic medicines.

The Indian pharmaceutical industry has been achieved extraordinary expansion in recent year and also gets a reputed global position in pharmaceutical sector. In present era India is rising as a world leader in generic drugs production.

Indian Pharmaceutical Industry also meets up to 70 per cent of the domestic requirement of bulk drugs and almost all the demands for formulations. It may also be pertinent to point out that although branded pharmaceutical products accounted for nearly two-third of global spending on medicine.

1.5 Export of Indian Pharmaceutical Industry

The Indian pharmaceutical industry has publicized unbelievable escalation in exports of generic drugs market. The Indian pharmaceutical industry is the mainly important facts- base industry, which has recorded a compound growth rate 19.22 per cent in exports in the last decade (UNTAD, April 2013). India has 17th rank in the World for the export of pharmaceutical products. India ranks fourth in terms of the total pharma market share in the Asia Pacific. India's currently exports around US\$ 15 billion worth medicines and the stipulations of China were estimated to be affecting Indian drug exports in nearly a fifth in some markets in Africa, Asian and Eastern Europe.

1.6 Merger & Acquisitions in Indian Pharmaceuticals Industry

The Increasing cross border merger and acquisition (M&A) activities in the pharmaceutical industry facilitated a liberal credit regime, probable has added to the export intensities of Indian firms. This, not only, exposed Indian firms to new technologies and best managerial practices, leading to substantial improvement in operational efficiency, but also helped them to expand in the overseas markets with relative ease. It pointed out that post product patent period also witnessed major structural shift in India's pharmaceutical industry in terms of shareholding stakes with a movement towards foreign controls. In 2012, there were 72 outbound acquisitions by Indian firms worth US\$ 11 billion, which is twice the US\$ 6 billion in 2011. Some Indian

pharmaceutical firms were acquired by MNCs for example Piramal Healthcare (by Abbott Labs), Dabur (by FreseniusSE), Matrics Lab (by Mylan), Shantha Biotech (by Sanofi Aventis) Orchid Chemicals (by Hospira) etc. Pharmaceutical forms within India have also initiated acquisition and mergers of Ranbaxy with Sun Pharmaceuticals at the cost of US\$ 3.2 billion in 2014 Tyagi Shilpi et al. (2014).

1.7 FDI in Indian Pharma Sphere

India has a population with a limited access to affordable healthcare. In this regard, some of the primary concern in allowing foreign investment in the Indian pharma industry including ensuring continuous availability and supply of drugs, non discontinuance of essential medicines and an increased supply of drugs over a period of time. Therefore, the policy allowing foreign investment in to the Indian pharma sector has to play a balancing act between meeting the need of the people and the capital needs of the industry. Presently FDI up to 100 per cent is permitted in brown field investment, with prior approval of the Foreign Investment Promotion Board (FIPB) and green field investment, FDI up to 100 per cent is permitted with no requirement of prior FIPB approval. Since 2000, the pharma sector has attracted one of the highest foreign direct investment inflows of US \$12,689 million (April 2000 to September 2014).

1.8 Contract Research and Manufacturing Services Regarding Pharmaceuticals

Manufacturing of pharmaceutical products through contract has emerged as a growth move towards many Indian pharmaceutical companies, in offering contract services like data management, marketing, clinical research trials, and laboratory services provide to international pharmaceutical companies. The procedure of outsourcing brings wide profitable gains to universal firms as they packed the production of their core competencies and far above the ground value like research and encouragement. The grounds behind the success of the Indian contract research and manufacturing services is harsh expenditure stress on global market. India is recognized as the fastest rising outsourcing objective by means of 43 per cent increasing rate (Ernst & Young, 2014).

The Indian pharmaceutical industry is able to be accessed on the basis of the nature of pharmaceutical technology and the degree of self-reliance in comparison with other drugs producing countries. India is not only self-sufficient but also self-reliant in the production of drugs. India not only has the technology to produce chemical intermediaries and raw materials for their need but also exports them at various competitive prices. At present, India has the maximum number of US-FDA plants of US and massiveness drug filling feature with lesser production cost. The UNIDO has classified India as a country with inventive capabilities and also the Ministry of Chemicals and the Ministry of Commerce have permitted the principals for export encouragement council 'Pharmexcil'. It will play a dynamic role as a quality supplier of pharma materials, resources and finished goods.

1.9 New Bulk Drug Policy in India

Department of pharmaceuticals under the Ministry of Chemicals and Fertilizers is expected to come out with a new bulk drugs policy with an objective to grow the Indian pharmaceutical sector to a US \$ 200 billion industry by 2030.

Until 1970 India was dependent on other countries for its pharmaceutical requirements and in 20 year's time it becomes self-sufficient to meet its own requirement.

The industry is growing at 9 per cent per annum at present, and even if we maintain the same growth rate, we can reach US \$ 110 billion by 2030; we need to overcome several challenges to achieve this herculean task. In excess of the quality problems, we need to have our own Active Pharmaceutical Ingredients (API) manufacturing capacities. The new bulk drug policy will help in increasing the domestic bulk drug production and reduce dependence on Chinese imports. The new policy is aiming at bringing down imports of bulk drugs and increasing the domestic output. Bulk drugs otherwise called APIs are Active raw materials that provide beneficial effect to drugs. India is dependent on China for API and there is a concern on quality.

India has potential pharmacy hub for the world if we make a few changes in the way we do and manage business in India we accelerate that process. The regulatory frame work must be strengthened and brought on par with international practices.

1.10 Government Initiatives

On behalf of Ministry of Health & Family Welfare, published by the Indian Pharmacopeia Commission (IPC) in the year 2014. IPC is playing an imperative role to improve the poor quality of medicines that would support the community wellbeing and speed up the development and enlargement of pharmaceutical sector.

The India Government going ahead Pharma Vision 2020. The main goal of this vision is to make India an international head in medicine development, therefore Indian pharma sector need to more investment to boost industry. Government of India introduced, Drugs Price Control and National Pharmaceutical Pricing Authority, as mechanism to tackle the difficulty of affordability and accessibility of remedy.

Except this, some other major policy formed by Government of India to improve the growth rate of Indian pharmaceutical industry are

1. The government has considered setting up 500 crore project capital support to enhance domestic pharmaceutical industry and availability of cheaper loans to launch and upgrading the manufacturing services.
2. Government of India launch, “Cluster Development Programme” for pharmaceutical sector, six pharmaceutical parks will be permitted, which will have adequate infrastructure facilities for innovation of drugs, testing of drug and also for training to industry professionals (Mr. Ananth Kumar 2014, Minister of fertilizer & Chemicals).

2. Review of Literature

The review of related literature has been categorized as follows.

1. Pharmaceutical Industry Related Study
2. IPR Related Study

2.1 Pharmaceutical Industry Related Study

Balasubramanian J. et al (2015) analyzed that product life cycle management creates a managers accompanies product - related intellectual capital starting from an idea to its final retreat. In pharmaceutical industry it benefits through enhancing the life span of patent and pricing strategies. The Agile product lifecycle manage platform to address business issues including speeding time to market, reducing operating and product cost. **PhRMA (2015)** Revealed that middle income countries markets are under seized but comprise a significant and growing source of revenue through pharmaceutical sector. The Pharmaceutical Research and Manufacturers of America (PhRMA) that as only 1 per cent of their market in Africa including South Africa, 7 per cent in South Asia and China 7.5 per cent in Latin America. **Nair GopaKumar G. (2014)** acknowledged the need for substantial refinement in other pharma related laws such as Drugs and Cosmetics Acts, Biodiversities etc. Need for more uniform and stringent enforcement of quality including up gradation of regulatory agencies is also called for. **EUROSTAT Data (2013)** revealed that European pharmaceutical industry is the soaring technological knowledge base and with the highest employment provider industry, which is significantly higher than the any other manufacturing industries. The pharmaceutical industry has too highest proportion of R&D investment to network trade. According to the EU Industrial R&D Investment 2013 scoreboard of the pharmaceuticals sector and bio technology sector has 18.1 per cent of total business. **Akhtar Gulshan (2013)** examined in their article that Indian's total pharmaceutical manufactured exports has revealed fluctuating tendency during 1991 to 2008. At present this industry has 4.7 per cent shares in world pharmaceutical export. In the coming years pharma sector made noteworthy development in infrastructure, scientific ability

production of bulk drugs. Indian pharmaceutical industry has technically skilled manpower. It has provides employment to 29 million people and this sector has 12 Per cent share in manufacturing sector GDP and it also contribution to India's GDP that is 2 per cent. **Mathew Jeo C. (2013)** discussed that India's manufacturing clout has made it a massive threat to established generics firms. Now a day Indian pharmaceutical industry is producing approximately more than 20 per cent of the world's generics drugs, around US\$70 billion value of the drugs are usually go to off patent more the next three years in USA. India has extensive share of the resulting innovative generics marketplace. **Mahajan Dinesh (2013)** discussed that India known as one of the fundamental target for Foreign Direct Investment (FDI). Pharmaceutical sector in Indian has been the chief supplier to the FDI inflows and exports of Indian pharmaceutical sector have greater than before in the current year. This is possible due to powerful centre, large market size and accessibility of low-cost labour force. Pharmaceutical sector is generally subjugated by U.S.A, United Kingdom, Mauritius and Singapore.

Couzin (2011) stated that Pharmaceutical companies need to massive investment that is recognize by researcher in the area of biotechnology firms which would time consuming. Large equivalent partnerships with biotechnology aggressively protected their privacy has began with pharmaceutical firm. **Pfundner Hagen P (2010)** revealed in the study (Germany), the company's extensive practice are available to highly trained labour force a safe and sound legal structure vocation provide by them. They proven documentation in biopharmaceutical manufactured goods were shaping cause for the site development. **Andrade Maria A. (2009)** examined that Pharmaceutical industry is a very complex on its process and requires qualified personnel to achieve its goals. Competency models have been developed in the United States, which describe the required soft and hard skills that a manager must have in order to be the successful in the execution of general as well as strategic projects at the pharmaceutical industry in Puerto Rico. **Abdul Noorbasha and Tulasidas V (2006)** analyzed that the US, EU and Japan together capture 90 per cent share in the world market. The world's top 10 drugs companies spend only 18-19 percent of their sale on R&D; most Indian drugs firms' still average mere 2

per cent of their total turnover. Some time the big firm's profit margins range between 20-30 per cent besides these pharmaceutical monopolists have enjoyed lot of tax benefits and foundation funds from the Government agencies.

Alfred (2005) stated that European and American firms enjoyed an intractable advantage. Chandler claimed that Japanese consumer electronics firm were able to penetrate global market but Japanese pharmaceuticals firms are not able to fight with American firms. The large portion of the pharmaceutical market occupied through the European and American pharmaceutical companies. **Sood Neeraj (2005)** stated that the pharmaceutical regulatory surroundings in 19 developed countries described and examines the changes in regulatory policies and its impact on pharmaceutical revenues we find that most countries that adopted new regulations and had some regulations position for controlling cost, that introducing new regulations in a largely unregulated market, US shrinks pharmaceutical revenue. **Lichtenberg F.R (2002)** examined the force of latest drugs endorsement on longevity of Americans. In the year 1960 to 1997 life expectancy at birth improved 10 per cent from 69.7 years to 76.5 years. The period in which life expectancy increased most rapidly 5 years in the year 1973 this was the period of dismal macro economic performance. Lichtenberg found the highly statistically the integer of fresh or new molecular entities approved by FDA.

Lanjouw and Cockburn (2001) evaluate the impact of pharmaceutical manufactured goods patent in Indian economy. The most important result is that, there is inappropriate IPR regime. The advancement of new treatment for traditional diseases and that by way of TRIPS incentives' to spend money in this area of research.

Chandler Haksar (1995) identified that the larger return to Research and Development on Indian pharmaceutical industry was due to the extremely unbeaten Research and Development attempt of Indian pharma firms concentrating at growth of alternative processes of identified drugs made likely through the nonattendance of pharmaceutical products patent.

2.2 IPRs Related Study

DIPP (2015) revealed that Aim is to develop an I.P regime to encourage inventiveness and to build up the culture of admiration for innovation and originality. An innovative tool showing the stock and flow of patents and trademarks applications at every stage of its processing has ushered in transparency. **Smetacek Ranjana (2015)** evaluated in his study that Three-fourth of the pharma products (48 patented drugs launched in India) is under threat. Five patents have been revoked and more than 11 are under challenge by way of infringement. Patent on an additional seven products are involved in pending opposition proceedings, while one patent is under compulsory licensing. A dozen others are under review.

Higgins Wm Brain and Lessler P Jay (2014) stated in his article that the Food and Drug Administration (FDA) has strict requirement for generic drugs. These needs possible avoid a generic company from varying medicine products to avoid patent contradiction. Generic manufacture required to employ an original method for eminence rule. These type of circumstances is known as `FDA trouble. **Hamied Y.K. (2012)** revealed in the article that we are gathering to the WTO. If any country has an issue (with Indian's IPR laws) then they should raise it at the WTO. We need to change; we can have bilateral talks with any country on trade but not on IPR laws related to pharmaceuticals. **Battelle (2011)** discussed in their study the pharmaceutical industry help to hold up scientific and economics ecosystem to the U.S economy and competitiveness in global market of country. Biopharmaceutical companies put downwards roots to helping for generate jobs in whole sector, from manufacturer to retail services. **Balasegaram Manica (2010)** revealed that the US is pushing India to play by its rules on intellectual property, which we known will lead to medicines being priced beyond the reach of millions of people. **Croix Sumner LA and LU Ming (2008)** investigate the U formed association among GDP per capita and country exclusive rights protection for the pharmaceutical industry using the Pharmaceutical Intellectual Property Protection (PIPP) Index. However, confirmation for a U shaped association in yearly section scatter plots and Tobit regression lines. Researchers find confirmation for both an increasing relationship between

GDP and PIPP. **Nair Gopakumar G. (2008)** concluded in his study that Indian patent laws are being modelled or being considered by about 30 to 40 developing countries to ensure rights of developing countries to ensure rights of their patents and this is one reason for the pressure to change our laws. **Chandler Alfred (2005)** concluded in the study of (European and America) firms enjoyed an insurmountable advantage. Chandler claimed that Japanese consumer electronics firm were able to penetrate global market but Japanese pharmaceuticals firms are not able to fight with American firms. The large portion of the pharmaceutical market occupied through the European and American pharmaceutical companies. **Kumar and Siddarthan (1997)** stated that in his study the strong IPR system is effectively contributes on the basis of principal that it will lead to increase in R&D expenditure, which is very low in India as compare to the developed countries like the USA and UK. But it may be argued that officially permitted safety provided by the patent regime for 20 years is probable to wear down the danger of competition between the industry, for this reason the there is need for sustainable improvement control and tiny R&D on humid area diseases. **Scherer and Weiburst (1995)** analyzed the Patent protection impacted the strengthening of pharmaceutical in Italy since 1978. Conclusion of the study was that the patent regime had little change and they not impacted the trend of price rises and adjusted expenditure on R&D. Moreover the MNCs research aims are resolute by the price.

3. Need of the study

Although many efforts have been made by the policy makers and Government, even execution of the operations could not be provide up to the satisfactory level, one can observe the following problems in pharmaceutical industry.

1. Intellectual property rights (IPRs) in the pharma sphere have been a contentious issue globally. Previously, the IPRs debates were typically between the branded pharma companies and generic pharma companies. India was no exception to this IPRs tussle and in view of the large poor population in need of basic healthcare; the Indian authorities were initially not keen on granting substantial IPRs protection.
2. All the instrument of IPRs, patent is the most contentious issue which is deliberated in several international forums. Patents are mostly debated for their role in pharmaceutical field. In the US, India's alleged violation of IPRs best practices had become a big issue.
3. Though there was an overall improvement in patent protection in India, recent issues such as granting of compulsory licenses have been contentious. Under Indian patent law compulsory licenses can be awarded if the reasonable requirement of the public with respect to the patented invention has not been satisfied. The patented invention is not available to the public at a reasonable price. The patented invention is not worked in the territory of India. In the pharma context, the conditions for grant of a compulsory licenses are aimed at preventing a situation where the public health is prejudiced by the exclusivity granted to the patented product.
4. Many international pharmaceutical companies wants to invest in India, although due to inappropriate patent system, cost rule and unyielding manual labour laws, they don't spend their money in R&D the firms tend to outsource of pharma products and services. The India Government wants to expand the Foreign Direct Investment (FDI) inflow with more liberalized policies regarding the pharmaceutical industry.
5. India is a major market for pharmaceutical companies with population of 1.2 billion yet the country and impressive export turnover of US\$ 10 billion spread over 200 countries.

Indian pharmaceutical products export increase day by day but still Indian pharmaceutical sector depends on China. India's imported APIs worth is \$ 3.9 billion in 2014-2015. The Indian government want to reduce dependence on China.

6. The drugs and pharma sector has attracted one of the highest FDI inflows in India. It has been a matter of debate whether such investments have indeed benefitted the Indian pharma industry or not. Recently, there have been demands from certain quarters of the government for banning brown field foreign investments altogether. In the pharma context such increased investments should be accompanied with technology sharing, increased production and increased employment generation.
7. The pharma sector in countries such as the USA Indian pharma market is a price controlled one. Pricing remain a contentious issue and more often than not, the pharma industry and the regulators lock horns on pricing issues.
8. Another serious problem in the pharmaceutical industry is the prioritization of research for common diseases and lack of research and development for rare diseases. This is simply explained by profit motive.
9. The Competition Commission of India (CCI) has passed various orders on prevalent working practice of the Indian pharma industry. The pharma market in India was dominated by a number of national and state level chemist and druggist associations. The CCI has closely examining these issues and in numerous orders held such practices as anti-competitive.
10. The privatisation and globalisation policy of the government of India provided incentives to R&D in the pharma sphere. Innovative products were given exemption from price control, a number of financial schemes were made available to firms given exemption from price control, a number of financial schemes were made available to firms for undertaking R&D technology collaborations were brought under the automatic approval route, and patent rights were granted for a period of 20 years for products as well as processes. India's cost of production is significantly lower than that of USA and almost half of that of Europe. It gives a competitive edge to over others.

Pharmaceutical industry is remedying the pain of unhealthy persons; it also works for wellbeing of human kind. Industry gives important contribution in the improvement of a country's economy by creating employment, supply chain and community development.

On the basis of reviews and views of the experts as have been given in above, it has become imperative to analyze the impact of the Intellectual Property Right (IPR) on Indian pharmaceutical industry. Therefore, the present study entitled, `` *Impact of pre and post Patent Regime on Indian Pharmaceutical Industry: An Analytical Study* '' has been undertaken.

The present research study will be beneficial for framing future policies, programmes, projects for the healthier growth of the Indian pharmaceutical industry and economic development.

4. Objectives of the Study

The study will be based on the following objectives.

1. To study the present status and trend of Indian pharmaceutical industry.
2. To study the impact of pre and post patent regime on Indian pharmaceutical industry.
3. To identify the problems of Indian pharmaceutical industry and suggest an effective action plan.

5. Hypothesis

The following null hypothesis has been taken by the researcher on the basis of objectives for this study.

H_0^1 –There is no significant difference of the impact of pre and post patent regime on Indian pharmaceutical Industry.

In addition to the above mentioned hypothesis the researcher would like to frame some more hypotheses during the course of study as per the requirement of the study.

6. Research Methodology

This research will be descriptive as well as exploratory in nature. The entire assessment is analyzing the Indian pharmaceutical Industry will be based on primary and secondary data. The impact will be measured through focused observations and discussions.

6.1 Variables

The variable for the study is divided in to two parts.

1. **Independent Variable:** Sales, Cost of Material, Cost of Manpower, Capital Cost, R&D Investment, Innovation M&A, FDI, Out Sourcing
2. **Dependent Variable:** Export, Productivity and Efficiency

In this study researcher will trying to analyze their relationship between dependent and independent variables. Variables are based on the literature review such as Tyagi Shilpi at al. (2014) `` *Innovation in Indian Drug and pharmaceutical Industry: Have they Impacted Export*'', Akhtar Gulshan (2013), `` *Indian Pharmaceutical Industry: Overview*'', Pannu H.S and Kumar Dinesh U (2007), `` *Indian Pharmaceutical Industry in Transitivity: A Study of Productivity, Efficiency and Innovation*''.

6.2 Sampling Design

The best source of measuring effectiveness of new Patent Act 2005 and its impact on pharmaceutical industry is the view of concerned persons.

1. **Population:** According to Directory of Pharmaceutical Manufacturing Units (2014), there are 10,563 manufacturing units of India in different states such as Maharashtra, Gujarat, West Bengal, Andhra Pradesh, Tamil Nadu and others.
2. **Sample Unit:** Top 10 pharmaceutical companies of India will be selected as the sample unit on the basis of Market Capitalization rated by Business Today January, 2016.

Top Ten Pharmaceutical Companies of India

Table- 0.2

Rank	Company	Market Capitalization (2016) In Crore (Rs.)
1	Sun Pharma	1,89139
2	Lupin	76,613
3	Dr. Reddy Laboratories	50,102
4	Cipla	48,788
5	Aurbindo Pharma Ltd.	47,578
6	Cadila Pharmaceutical Ltd.	31,541
7	Divi's Laboratories	28,609
8	Glaxosmithline	26,954
9	Glenmark	23,410
10	Torrent Pharma	22,392

Source: Business Today January, 2016

- 3. Sample Seize:** Sample seize will be 400 for the present study.

Table-0.3

<i>Categories of Respondent</i>	<i>Division of Sample</i>	<i>Size</i>
Finance Executives of the Companies	10 from each company (10x10)	100
Manufacturing Executives of the Company	10 from each company (10x10)	100
R&D Executives of the Company	10 from each company (10x10)	100
Marketing Executives of the Company	10 from each company (10x10)	100
Total		400

Source: Self Structured, 2016

The table 0.3 is tentative for research proposal. The division of sample (at what percentage), will be exactly decide on the basis of the field survey during the study.

- 4. Sampling Method:** Purposive sampling method is used for selecting companies and respondents in this study.

6.3 Data Source

For this study, data source will be divided in two parts for the sake of greater understanding.

1. **Primary Data:** The research will be prepared well designed questionnaire to conduct extensive field survey along with some unstructured interview of pharmaceutical companies' administrative for comparative study of Indian pharmaceutical industry.
2. **Secondary Data:** The secondary data will be collected from reliable secondary sources such as annul reports, companies websites, regulatory filings and data with industry association, regulatory bodies, reports of various concerned associations like Government websites and various newspaper articles, business magazines etc. to analyze the Indian pharmaceutical industry.

6.4 Statistical Tools

For analysing the findings and to draw the inferences, the statistical and mathematical tools have been used like Regression, Chi-Square Test, Z-Test, MANOVA and other appropriate tools. In addition to the above mentioned tools various other econometric tools such as OLS model and Semi Log, Cointegration, and Causality test can also be used as per the requirement of the study. E-views and SPSS software will be used for the data analysis.

The above mentioned tool can be changed or extra tools can be used according to the collected data and as per the requirement of the study.

7. Proposed Chapterization

The study will be divided into following chapters

Chapter I –Introduction

- a. Background
- b. Need of the Study
- c. Objectives of the Study
- d. Research Methodology

Chapter II- Review of Literature

Chapter III- Present Status of Indian Pharmaceutical Industry

Chapter VI- IPRs and Indian Pharmaceutical Industry

Chapter VI- Data Analysis and Interpretation

Chapter V- SWOT Analysis of Indian Pharmaceutical Industry

Chapter VI- Conclusion and Suggestions

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