Chapter No 5

Review of Literature
5.0 Introduction

The Indian pharmaceutical company is expected to undergo phenomenal change after 1st January, 2005, when international patent laws were implemented. India’s domestic pharmaceutical companies have experienced a significant increase in R&D spending to be competitive in the world market. (1) After the signing of the General Agreement on Tariffs and Trade (GATT) Uruguay Round Trade Agreement in Marrakech, Morocco, in April 1994, WTO was created. WTO is an institution rather than an agreement such as GATT. It sets rules governing trade between its 132 member countries. It has allowed member countries until 1st January, 2005 to make necessary adjustments before they are required to abide by WTO rules. (2)

The subject is related to the impact of amended intellectual property rights act 2005 on Indian pharmaceutical company. Because of the amended intellectual property act 2005, research and development scenario of Indian pharmaceutical company is changing. (3)

For all the disciplines as research and development activity in pharmaceutical industry, patent act and Indian pharmaceutical company there are number of books, periodicals available for reading both from overseas authors as well as Indian authors. Number of articles are also being published which deal with the various aspects of the subject.

The researchers have had, the opportunity to read a lot of material on these disciplines and have reviewed the following books and periodicals to appraise him so as to what has been so far published which can have direct or indirect bearing on the research study.

1- “Analysis of the Indian pharmaceutical company with Emphasis on Opportunities in 2005” by Hemant N. Joshi, Pharmaceutical Technology, January 2003
2- www.patentpill.com
3- Research and Development, Exports and Patenting in the Indian pharmaceutical company: a Post TRIPS Analysis by Ravi Kiran, Sunita Mistra
5.1 Review Article

The article by Dr. A. Selvaraj (4) focuses on compatibility of Indian pharmaceutical company. Production wise, Indian manufactured drugs are at quite economic rate. The reasons are like infrastructure cost, labor cost, clinical trial cost, etc. but India is lacking in patented drug manufacturing. As compare to western countries, research and development activities of pharmaceutical industries are not up to the expectation. This can be because of process patent agreement.

There are various steps government is taking to increase research and development activity as mention in the article. But what is the success rate of these steps to increase research and development activities in Indian not only by domestic pharmaceutical companies but also from multinational companies is need to study.

The article by R Saha (5) talks about the innovation and need of innovation. India has signed TRIPS agreement in which the protection of intellectual property rights are obligatory in chemical, food and drug industry. Consequently to accept the changed scenario, not only Indian pharmaceutical companies but also government needs to adopt new strategies or policies to increase or motivate research and development activities in India. In amended patent act 2005, government has come up with different policies like tax exemption, funding, collaboration with academic, public and private sector etc to increase research and development activities. Indian pharmaceutical companies have adopted new strategies like collaboration, merger and acquisition, outsourcing etc to increase research and development activities.

Accordingly what is result of these strategies and policies on Indian pharmaceutical companies need to study.

The article by Gautam Arti and Kharia Anil (6) focuses on government initiatives that are taken for rising research and development activities in Indian pharmaceutical company. Not only Indian pharmaceutical company but also government understood the significance of research and development activity, accordingly as to motivate research and development activity which needs huge investment, time, skilled people etc. government is giving special consideration by various ways like tax concession, export, import duty concessions, etc. so as Indian pharmaceutical companies will get encouraged for research and development activity.

As per the editorials Ravi Kiran, Sunita Mistra (7) which focus on the changed scenario due to Amended Patent act 2005. India as a signatory member signed TRIPs for protecting product patent, preliminary India refused for the change. This can be because of n number of reasons like if product patent becomes compulsory licensing may get affected, price of medicine may increase etc. patented product is like an asset to the company. It increases profitability of respective company and future competition or turnover won’t be on sale of product but it will be on the number of patent a company is holding. Indian domestic as well as international company understood the need of research activity to survive in market and nowadays most of them are changing from imitation to innovation by increasing R and D activity to sustain in market.

The article by Daara B Patel (8) discusses about the opportunities of Indian pharmaceutical company from outsourcing point of view.

6- Current Scenario of Pharmaceutical Industries in India by Gautam Arti and Kharia Anil
8- Indian pharmaceutical company overview: Challenges and Opportunities, Daara B Patel, Product patents & drug price controls, 2nd June 2011, Goa
Cost of some of the Indian manufactured medicines is quite cheap as compared to the world. This may be because labor costs are cheaper than in the West. Infrastructure costs are lower and fixed cost is less that in the United States and Western Europe. Consequently, India can produce bulk drugs that cost 60% less that in the West and can open a production plant in India 40% cheaper than in developed countries. India has signed TRIPS agreement which secure product patent. As a result India has an opportunity or future in doing outsourcing work in research and development for many domestic as well as international companies which will increase its research and development ability.

As per the article by Anshu Shrivastava (9) which focus on domestic and multinational company’s strategies before and after patent act. Before amended Patent act 2005, where only process patent was allowed, Indian companies had liberty to reproduces drugs manufactured by patent holding companies without paying any sort of fee and used to make profit. So innovation was missing. At the same time, multinational companies instead of bringing technology, innovation and finance in India brought import of bulk drugs which increased price of medicine to Indian customers. But now due to the Amended Patent Act 2005, scenario is changing.

As per Dr. A. Selvaraj (10) article, as Indian has signed WTO (World Trade organization) agreement, so it is now not only the process patent but also product patent is also permitted by the amended Patent act 2005. As India is more in generic products, to sustain in market and also from MNC, Indian pharmaceutical companies need to come up with product patent.

At the same time, Government should aid Indian pharmaceutical companies to increase their research and development activity.

9- Report on India’s Pharmaceutical Industry by Anshu Shrivastava on Wednesday, October 5, 2011
And if multinational pharmaceutical company take over the Indian pharmaceutical company then multinational companies may keep price of medicines higher and common man will not able to afford that high price.

The research article by Hemant N. Joshi (11) discusses on the problem which Indian pharmaceutical companies are facing. Research and development activity demands huge capital investment, skilled people, technology etc (around $300 million to $ 600 million of investment) where success rate is even very little. Indian pharmaceutical companies have skilled people, strong IT back up, technology but is deficient in capital investment. Even Due to Amended patent act 2005, which globally harmonized patent system that prohibit the replication or reverse engineering of patent protected new drugs, patent holding companies are enjoying monopoly. This is affecting availability and affordability of patented drugs to common Indian customers.

The research article by Ravi Kiran, Sunita Mistra (12) discuss about the research and development activity, exports and patenting activity of Indian pharmaceutical companies post TRIPS period. The present study like a number of earlier studies reports an increase in R&D and R&D intensity in the post TRIPS period. The study by Gupta (2000) highlights that after the establishment of WTO; there is a greater effort by the Indian R&D organizations to obtain patents in USA. Kubo (2004) opines that R&D intensity and patent to R&D ratio has increased in India after 1995 for large pharmaceutical firms. Grace (2004) is of the opinion that most successful firms investing an increasing amount in R&D including in partnership with MNCs, and with increasingly positive results. Dhar and Gopakumar (2006) also accept that there has been an increase in the R&D spending of some of the leading firms, in particular, Ranbaxy and Dr Reddy’s. As a result, R&D intensities of the firms have improved.

---

11- “Analysis of the Indian pharmaceutical company with Emphasis on Opportunities in 2005” by Hemant N. Joshi, Pharmaceutical Technology, January 2003

Indian pharmaceutical companies are taking efforts to increase research and development activity so the result of this Indian pharmaceutical company are filling more patent post TRIPS. At the same time they are equally concentrating on foreign market with domestic market. That means TRIPS agreement is bringing positive impact on Indian pharmaceutical company.

The research report of Corporate Catalyst India (13) focuses on emerging trends due to post TRIPS, current scenario about domestic market, import and export of Indian pharmaceutical company.

The Indian pharmaceutical company is doing fine globally as growth rate of Indian pharmaceutical company (10%) is more than global rate (7 %). At the same time, companies are exporting in good number and fulfilling domestic demand sufficiently. Only Indian pharmaceutical company are lacking in patented drugs which need to import from multinational companies and market it in India. Indian pharmaceutical companies are concentrating not only in research and development activity but also in contract manufacturing, clinical research, outsourcing, etc. which will improve efficiency of Indian pharmaceutical company at all the stages.

CBO Study (14) discusses about research and development cost, time and risk. Research and development requires huge capital investment at the same time, the risk is high in research and development activity in the form of success which means the cost of successes and failures alike. Even time require is long as 11.8 years to come up with patented product. According to the pharmaceutical company have various strategy like instead of going for mew molecule they modify existing molecule. The strategy depends on company policy of profitability.


The article by Richard E. Rowberg (15) talks about the cost allocation of the research and development department.

As discussed above the research and development department demands huge capital investment. Cost allocation plays very important role in research and development activity which depends on company strategy.

The research article by KPMG International (16) discusses about the strategies that Indian pharmaceutical companies are using to explore their market in overseas. From above paper it is clear that, to get advantages from overseas companies Indian pharmaceutical companies are forming merger, acquisition, collaboration etc which will open doors for Indian pharmaceutical companies in overseas market.

Even Indian pharmaceutical companies are doing well in generic manufacturing in western countries.

Report of the Task Force (17) put focus on the current scenario of Indian pharmaceutical company. In India not only public but even private sector shares pharmaceutical companies in large amount which have competitive advantages of various resources. Even Indian pharmaceutical companies are increasing their export percentage which includes near about all type drug formulations. India is among top 20 pharmaceutical exporters worldwide. At the same time, in patent application India is growing. In patent challenges, India ranks next to USA with as share of 21%. Definitely India is a rising leader in pharmaceuticals.

15- A Description and Analysis of the Process, CRS Report for Congress, Received through the CRS Web, by Richard E. Rowberg, Senior Specialist in Science and Technology Resources, Science, and Industry Division, April 2, 2001, Order Code RL30913
The research article by Cheri Grace (18) is for the discussion about the competitive advantages of Indian pharmaceutical companies and their strategy.

The Indian pharmaceutical company has competitive advantages in various ways. Like India has good quality of chemist, engineers etc which can be taken into service for reengineer the manufacturing process or ion clinical development, another factor pulling MNCs is quality standards with Indian firms, the market size is another attraction etc. so Indian companies are entering collaboration, merger, acquisition with multinational companies for various areas.

The research article by Prabhuddha Ganguli (19) focuses on the competitive advantages with knowledge.

In the above research paper and as per previous discussion India has competitive advantages, the one who come up with innovation will enjoy.

The article by A.Sahay, and V. Sharma (20) discusses about the meaning about the invention, innovation and imitation and also about the patent pattern of Indian pharmaceutical company.

As invention is creation of new concept, innovation is like getting returns on invention and imitation is duplication of innovation. Our patent act pattern goes similarly, till 2005 imitation was there and now Amended Patent act demands innovation. The patent act 2005 has equal policies for domestic as well as international company.


The article by R.L. Varshney, K.L. Maheshwari (21) focuses on the relationship of innovation with profit. The innovation is directly proportional to profit where innovator enjoys monopoly.

As per the article by Peter F. Drucker (22), innovation is not the same as invention. Innovation is a process, which begins from the conception of an idea to the launching of a new product/process in the marketplace. As in the Indian pharmaceutical company, innovation is very important as the future income will not be on the sale but it will be on the innovation.

5.2 Summary

Indian pharmaceutical company is doing fine globally, as growth rate of Indian pharmaceutical company (10%) is more than global rate (7%). At the same time, Indian pharmaceutical company are exporting in good number and fulfilling domestic demand sufficiently. Indian pharmaceutical company are lacking in patented drugs which need to import with research and development activity. Indian pharmaceutical companies are taking efforts to increase their research and development activity so the result of this they are filling more patent post TRIPS.

At the same time Indian pharmaceutical company are equally concentrating on foreign market with domestic market. That means TRIPS agreement is bring positive impact on Indian pharmaceutical company. Indian pharmaceutical companies are also concentrating in contract manufacturing, clinical research, outsourcing etc which will improve efficiency of Indian pharmaceutical company at all the stages. As India is more in generic products, to sustain in market and also from MNC, Indian pharmaceutical companies need to come up with product patent. Even Due to Amended patent act 2005, which globally harmonized patent system that prohibit the replication or reverse engineering of patent protected new drugs, patent holding companies are enjoying monopoly. This is affecting availability and affordability of patented drugs to common Indian customers.

Before amended Patent act 2005, where only process patent was allowed, Indian companies had liberty to reproduces drugs manufactured by patent holding companies without paying any sort of fee and used to make profit. So innovation was missing. At the same time, multinational companies instead of bringing technology, innovation and finance in India brought import of bulk drugs which increased price of medicine to Indian customers. But now due to the Amended Patent Act 2005, scenario is changing.

Cost of some of the Indian manufactured medicines is quite cheap as compared to the world. As India has signed TRIPS agreement which secure product patent. So Indians/India has an opportunity or future in doing outsourcing work in research and development for many domestic as well as international companies which will increase its research and development ability. Not only Indian pharmaceutical company but also government understood the importance of research and development activity, so as to motivate research and development activity which needs huge investment, time and skilled people, etc. government is giving special consideration
by various ways like tax concession, export, import duty concessions, etc. so as Indian pharmaceutical companies will get encouraged for research and development activity and they will change from imitation to innovation to sustain in market. But what is the success rate of these steps to increase research and development activities is need to study.

Research and development activity demands huge capital investment, skilled people, technology etc (around $300 million to $ 600 million of investment) where success rate is even very little. Even time require is long as 11.8 years to come up with patented product. Indian pharmaceutical companies have skilled people, strong IT back up, technology but is deficient in capital investment.

Indian pharmaceutical companies have adopted new strategies like collaboration, merger and acquisition, outsourcing, etc. to increase research and development activities. So what is the result of these strategies and policies on Indian pharmaceutical companies need to study.

To get advantages from overseas companies Indian pharmaceutical companies are forming merger, acquisition, collaboration, etc. which will open doors for Indian pharmaceutical companies in overseas market. Definitely India is a rising leader in pharmaceuticals. The Indian pharmaceutical company has competitive advantages in various ways.