Chapter No 1

Introduction to Research

Topic
Introduction

1.0 Indian pharmaceutical company – Current scenario

Indian pharmaceutical company is in the obverse position of India’s science based industries with wide ranging capabilities in the complex field of drug manufacturing and technologies. From simple headache pills to sophisticated antibiotics and complex cardiac compounds, almost every type of medicine is now made indigenously. The Indian pharmaceutical company has been built from an industry that copies patent drugs and manufactures them inexpensively. Now it is counted amongst the industries that are fueling India’s economic growth and holds enormous potential. Indian-based pharmaceutical companies are also predicted to gain considerable market share in the world by the end of the decade. It ranks third world wide, in terms of technology, quality and range of medicines manufactured. The industry is estimated to have generated revenue worth US$13.1 billion in FY 2011(1).

Indian pharmaceutical company fulfills around 70 percent of the country’s demand for bulk drugs, drug intermediates, pharmaceutical formulations, chemicals, tablets, capsules, orals and injectibles. (2) Currently, it’s estimated to be worth US$4.5 billion, and is growing at nearly 8 to 9 percent annually. (3)

Indian pharmaceutical company is not only catering to the domestic market and fulfilling the country’s demands, but also exporting to around 220 countries.(4) They are exporting high quality, low cost drugs to countries such as U.S, Kenya, Malaysia, Nigeria, Russia, Singapore, South Africa, Ukraine, Vietnam, and many more.

1- Report India’s pharmaceutical industry

2- A brief Report pharmaceutical company in Indian, 2012

3- Business and Technology report

4- Report India’s pharmaceutical industry
The exports are expected to increase by 20 percent in coming year, taking the overall value to £6.73 billion. (5) Currently, the U.S is the biggest customer and accounts for 22 percent of the sector’s exports, while Africa accounts for 16 percent and the Commonwealth of Independent States (CIS) places around 8 percent of the orders. (6) Earlier the year in February, India and Japan signed a Free Trade Agreement (FTA), which is expected to increase the export of pharmaceutical products to Japan. (7)

1.1 Background of Patent Regime in India

Because of amended patent Act 2005, Indian pharmaceutical company has taken a huge lead. Before the amendment in Patent act 2005, Section 5 of the Indian Patents Act, 1970 expressly permitted only process patent and prohibited product patents. After the implementation of TRIPS, the Patents amendment Act, 2005 repealed it and therefore gave way to product patents as well. Product patent is a much strict restriction than process patent. The difference between process patent and product patent is that under a process patent, medicine or drugs which have been patented can be manufactured by another manufacturer but by using a different process. However, in a product patent drugs which have been patented cannot be manufactured by any process. In consequence of India signing the TRIPS Agreement and WTO India accepted the product patent from 1-1-2005 in accordance with the obligation under Article 27(1) of the TRIPS.

The Patent Act of 1970 saw the mass departure of the multinational companies (MNCs) as it recognized only process patents. Indian companies had the freedom to replicate drugs manufactured by patent holding companies without paying any kind of fee. They were protected by the patent act to legally reverse engineer internationally patented drugs and sell it within India and also in those markets that did not conform to drug patents.

5- Business and Technology report

6- Research and Market report, “Indian Pharma Sector Forecast 2014.”

7- Business and Technology report
Post independence, 1947 to mid 50s, the country’s laws recognized both process and product patent. It was expected that the multinational MNCs will bring in their innovation, technology, and finance to benefit Indian customers.

In 1970, the Government passed the Drug Price Control Order (DPCO) to slow down the control of MNCs and cut down their supremacy of the Indian market. The order provided process patents for 5 to 7 years and was seen as a move to make the domestic market self-reliant. For the MNCs, India ceased to be a profitable market and they slowly left the country and Indian companies grabbed the chance and stepped in. As a result, the country became independent in the manufacturing of basic drugs. From the 1970s to 2005, many manufacturing units were established and researches were done to develop new processes for several drugs. Also, the DPCO put a limit on the prices of essential, lifesaving drugs, resulting in their availability in the domestic market at affordable prices.

The amendment act of 2005 changed the practice of manufacturing drugs without conforming to the patent laws of other countries. The act expelled the companies from producing patent products without paying patent royalty. In 1994 India had to amend its patent act as India had signed the General Agreement on Trade and Tariffs (GATT) and the Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement and joined GATT’s successor World Trade Organization (WTO). The amendment act opened the doors for MNCs. The time around, they have shed their reluctance to invest in India and are also collaborating with domestic players. Most of these companies are outsourcing their manufacturing to the country. A process patent system is benefiting Indian companies in the changed scenario as Indian companies with more than two decades of experience in manufacturing drugs. The MNCs are also bringing in their skill and research and development (R&D) to India.

Additionally, the government of India is also providing incentives to encourage investment in pharmaceutical sector and helping domestic players. The government has permitted 100 percent foreign direct investment (FDI) under the automatic route in the drugs and pharmaceuticals sector including the companies using recombinant technology. The Indian government plans to set-up a US$639.56 million venture capital (VC) fund. (8) The fund is expected to encourage, the discovery of new drugs and also help strengthen the pharma infrastructure.

The key to the future of Indian pharmaceutical company is Research & Development. The pharmaceutical advances for significant improvement in life expectancy and health all over the
world are the result of a steadily increasing investment in research. There is considerable scope
for collaborative R & D in India. India can offer several strengths to the international R & D
community. These strengths relate to availability of excellent scientific talents who can develop
combinatorial chemistry, new synthetic molecules and plant derived candidate drugs. R & D
groups can carry out limited primary screening to identify lead molecules or even candidate
drugs for further in vivo screening, pre-clinical pharmacology, toxicology, animal and human
pharmacokinetics and metabolic studies before taking them up for human trials. In such
collaborations, harmonized standards of screening can be assured following established good
laboratory practices.

The R & D expenditure of Indian pharmaceutical company is around 1.9% of the industry’s
turnover. (9) This is very low when compared to the investment on R & D by foreign research
based pharma companies, as they spend 10 - 16% of the turnover on R & D. (10)

However, now that India is entering into the Patent protection area, many companies are
spending relatively more on R & D. When it comes to clinical evaluation at the time of multi-
center trials, India would provide a strong base considering the real availability of clinical
materials in diverse therapeutic areas.

Such active collaboration will be mutually beneficial to both partners. According to a survey by
the Pharmaceutical Outsourcing Management Association and Bio/Pharmaceutical Outsourcing
Report, pharmaceutical companies are utilizing substantially the services of Contract Research
Organizations (CROs). Indian pharmaceutical company, with its rich scientific talents, provides
cost-effective clinical trial research.
It has an excellent record of development of improved, cost-beneficial chemical syntheses for various drug molecules. Some MNCs are already sourcing these services from their Indian affiliates.

The implementation of the TRIPS Agreement will give rise to factors that can put access to medicines out of reach for millions of people in the developing world. The TRIPS Agreement obliges WTO Members to adopt and enforce high standards of intellectual property rights protection, which were derived from the standards used in developed countries.

Implementation of the TRIPS Agreement may lead to high drug prices, low access to medicines and a weakening of pharmaceutical industries in the developing countries. It is feared that patent protection for pharmaceutical products and processes will effect on reeducation or elimination of competition from generic production of medicines.

TRIPS effectively allows a pharmaceutical company, a monopoly over production, marketing and pricing of patent protected medicines for a minimum term of 20 year patent protection and thereafter, further periods of 20 years each could be applied for products covered by patented processes. This may keep the price of the drug high during the protection period, free from competition. Due to TRIPS protection, no generic equivalent can come into the market until expiry of the 20 years, denying patients cheaper alternatives. Domestic manufacturing of pharmaceutical products in developing countries will come to a standstill.

Developing country’s pharmaceutical producers will find themselves pushed out of the market, having to compete with the large MNCs. For the smaller producers in the developing world, which specialize and depend on manufacturing cheaper generic alternatives, this would no longer be possible at least, until the expiry of the 20 year period.

Regardless whether the products are imported or locally produced, the TRIPS Agreement requires patents to be granted. Patent holders can merely import their product, without having to work the patent in the country granting the right. This will mean that a MNC can supply global markets under the patent monopoly, exporting the finished product instead of transferring technology or making foreign direct investment. This is contradictory of the argument of TRIPS proponents that strict patent regimes will increase the flow of technology and investment into developing countries. The TRIPS Agreement, in its present form, contains certain provisions that can be used to limit patent rights. These limitations or exceptions are to be effected through
national legislation, in order to control abuses of intellectual property rights and anti-competitive practices, and generally, to offset the negative impact of patent monopolies. Two of the most important measures include the right of government to grant compulsory licenses and the application of the principle of exhaustion of intellectual property rights, which allows for parallel importation of patented products.

1.2 Previous study

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 we are exporting good numbers and fulfilling domestic demand sufficiently. Indian pharmaceutical companies are lacking in patented drugs which need to be imported 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 they are equally concentrating on foreign market with domestic market. That means TRIPS agreement is bringing a 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 in 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. Indian companies have 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 $ 800 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 pharma 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.

1.3 Problem identified

The research questions for the study are as follow:

1) What various R & D and business strategies have been adopted by Indian pharma industry to sustain business after the issuance of patent ordinance in 2005?
2) What was the effect of merger & acquisition before & after 2005?
3) Status of generic market in India after 2005 & the strategies of Indian generic players?
4) Impact of new patent regime on controlled prices of drug?
5) Status & impact of government policies which are offered for innovation & creation.
6) What are the problems faced by pharma companies in converting imitation to innovation?
1.4 Contribution to research work

- Systematic study of pharma industries with reference to intellectual property rights-
  International policies toward protecting intellectual property rights (IPRs) have seen profound
  changes over the past two decades. Rules on how to protect patents, copyrights, trademarks, and
  other forms of IPRs have become a standard component of international trade agreements. Indian
  companies need product patent protection to encourage research in developing inexpensive
  drugs that suit the Indian disease profile. The learning will allow for systematic study of changes
  in Indian pharmaceutical company with reference to Intellectual property rights.

- Impact of amended intellectual property rights act, on pharmaceutical industry-
  After amended Patent act 2005, the Indian firms are increasing their total R&D expenditure as a
  percentage of sales and they are beginning to move in the direction of new molecule discovery
  rather than concentrating solely on development research. So this will allow studying the impact
  of amended intellectual property act 2005 with respect to strategies to survive on pharmaceutical
  companies.

- Study of intellectual property rights management and Indian pharma industry with a
  business management prospective –Due to amended patent act 2005, which demands increase in
  research and development activities of Indian pharmaceutical company which business policies
  company are adopting, is very interesting e.g. companies are going for alliances to reduce R and
  D cost, risk or they are increasing their own R and D activities etc. the research allow to study
  business policies company are adopting.

- This research work will focus on various R & D activity and business strategies adopted
  by Indian pharma industry to sustain business after the issuance of patent ordinance in
  2005.

- The research work will give the status of merger & acquisition before & after 2005.

- The research emphasis on the status of generic market in India after 2005 & gives
  thought about the different strategies of Indian generic players.

- The work will give the status & impact of government policies which are offered to
  pharmaceutical industry for innovation activity.

- The research will focus on the problems faced by pharma companies in converting
  imitation to innovation.

- Base for the further studies- The research will help future researcher for further study in
  same area or related area.