Chapter No 6

Research Design and Methodology
6.0 Introduction

The chapter is included with the purpose of making clear the steps taken for the systematic completion of the research. The steps taken are the common steps for doing research in the faculty of management and the topic selected is ‘research in social sciences’.

The Indian pharmaceutical sector has come a long way, being almost non-existent before 1970 to a prominent provider of healthcare products. (1) Indian-based companies fulfill around 70% of the country’s demand for bulk drugs, drug intermediates, pharmaceutical formulations, chemicals, tablets, capsules, orals and injectibles. (2) Currently the Indian pharmaceutical company is valued at approximately $ 8.0 billion. (3) The Indian pharmaceutical company in recent years has grown in stature from an industry that copies patent drugs and manufactures them cheaply. It’s now counted among the industries that are fueling India’s economic growth and holds vast potential. (4) The industry is estimated to have generated revenue worth US$13.1 billion in FY 2011, according to a new Research and Market’s report, “Indian Pharma Sector Forecast 2014.” India is a member/signatory to –TRIPS (1995), Paris Convention (1998), Convention on Bio-diversity (1994), Budapest Treaty (2001), Berne Convention, Universal Convention for Copyright (1952) and many others.
India fulfilled the WTO Commitment and our Patent’s (Amendment) Act 2005 has become TRIPS Compliant since 1st Jan 2005. India thus joined the countries having industrialized free market economies.

6.1 Origin of Research Problem

Our pool of knowledge is protected by patents for monopoly rights. As per the patent act 1970, product patent was not sanctioned. Consequently, Indian pharmaceutical companies were in reverse engineering. Indian pharmaceutical company is specialized in generic drugs. (5)

But as per amended patent act 2005, product patent is allowed. As a result what will be the impact of the change on Indian pharmaceutical company. Again how Indian pharmaceutical companies are coping up with change from imitation to innovation.

The trend of patent filing in our country has tremendously increased, economic times of Jan 7th, 2009 has reported that “a total of 35,218 patent applications were filed, 6040 from domestic and 29,178 from foreign applicants in the last fiscal”. Though innovations and strengthening of the Patent System is important for Industrial Growth, it is equally important to take necessary steps to safeguard the sanctity of our Patent System and prevent filing and grant of frivolous un-patentable subject matters. All this has generated an interest in Indian Industry and market and India is now becoming inundated with interest from multinational companies looking to invest in its burgeoning pharmaceutical industry, considering the advantages of the Indian market viz. solid legal framework & strong financial markets; committed to free market economy & globalization; large middle-class market with huge growth potential and huge cost advantage. (6)

5- IBEF- www.ibef.org
The new patent regime has led many multinational pharmaceutical companies to look at India as an attractive destination not only for R&D but also for contract manufacturing, conduct of clinical trials, generic drug research and co-marketing alliances.

The focus of the Indian Pharmaceutical Companies is also shifting from process improvisation to drug discovery and R&D. (7) Indian companies are setting up their own R&D setups and are also collaborating with the research laboratories like CDRI, IICT etc. Mergers, acquisitions and alliances have been taking place on an unprecedented scale, most notably with companies in the U.S, Europe and Japan. (8)

These transactions provide Indian companies with access to foreign markets and facilitate the process of seeking regulatory approval for new products. Money generated can be pumped back into drug discovery and clinical research to make Indian Companies self sufficient.

Moreover, if the industry is able to transfer a part of their improved performance due to consolidation to the consumers in the form of a price reduction and a better quality of drugs, it would be a welcome sign and on the other hand if it leads to increased market power and consequent price rise, then it would deserves special attention.

7- IBEF- www.ibef.org

6.2 Research questions

The research questions are:

1. What various R & D and business strategies have been adopted by Indian pharmaceutical company 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. Status & impact of government policies which are offered for innovation & creation.
5. What are the problems faced by pharmaceutical companies in converting imitation to innovation?

6.3 Aims and Objectives of the Study

The aims and objectives are:

1) To study the problems faced by innovating from conception idea to pilot product manufacturing before filing patents at national and international level.
2) To study the impact of intellectual property rights on financial gains through innovation in pharmaceutical drug manufacturing companies.
3) To study the impact of amended intellectual property rights act, on pharmaceutical companies and on its marketing.
4) To study the scope and importance of intellectual property rights in converting Indian pharmaceutical company from imitation to innovation.
5) To give suggestion for effective implication of intellectual property rights policies to pharmaceutical companies.

6.4 Hypothesis of the Study

The hypotheses for the research are as follows:

1) Indian 2005 amended patent act resulted in pharmaceutical companies to move from imitation to innovation.

Clustering:
- Patented product introduced
- Companies Research and development expenditure
- Companies Turnover
2) Imitation to innovation has resulted in improving Economic status and exports of Indian pharmaceutical companies.

Clustering:
- Number of patented product introduced
- Turnover

3) Government policies resulted from amended patent act 2005 have stimulated Indian pharmaceutical companies for more research and development investment.

4) Imitation to innovation has positive impact on quality of the pharmaceutical product.

### 6.5 Collection of data

Data collection- primary and secondary data

**Primary Data**
Primary data are the original observations collected by the researcher for the first time and used for investigation.

The sources of primary data include:

The source for primary data is structured personnel interview for legal experts of intellectual property rights (Lawyers) in Pune and medicine practitioners (Doctors with different specialization) and E-mail for pharmaceutical industry. (The list of respondents is attached.)

**Tool**

With a view to obtain data from the field, three different questionnaires designed, one for the pharmaceutical companies managers, second for patent experts and the other for doctors, have been prepared and are administered. The responses received have been tabulated and statistically analyzed.

**Source of secondary data**

Secondary data is information has already been obtained. Generally, the objective of any secondary data is to further refine the decision in some very specific way.
The sources of secondary data includes Research Journals, Economic Surveys (various issues of patent and pharmaceutical industry and other research materials), Magazines, Periodicals, newspapers, Website based trade data etc. and interaction with the number of lawyers, doctors as well as executives of various pharmaceutical companies from Mumbai and Pune Region.

**Data Analysis**

The field survey and personal interview technique adopted for data collection and collected data has been tabulated and presented with the help of graphs, tables and charts.

Both descriptive and inferential statistics were used in presenting and analyzing the data. Descriptive tools such as frequency counts, mean scores, percentages were calculated for the statements on the questionnaire in order to determine the impact and its related issues.

**Statistical Technique:**

**Chi square test**- Chi-square is a statistical test commonly used to compare observed data with expected data to obtain according to a specific hypothesis. The test allows research student to compare a collection of categorical data with some theoretical expected distribution.

**Research design:** Descriptive research design.

**Population:** Indian pharmaceutical company, lawyers and doctors

**Sampling Area:** Mumbai and Pune region

The term Mumbai and Pune Region used in this study refers to area carved out by the pharmaceutical industry for its high rate of development. Mumbai and Pune region as understood in the Pharmaceutical Marketing phraseology is quite a large area spread over. There are around 300 pharmaceutical companies which are catering to the population of this area. Hence it was possible only to obtain data from the representatively selected top 25 pharmaceutical companies based on purposive sampling, in Mumbai and Pune region, having major market share.

(Based on secondary data from thesis of Mahesh Keshav Karajgikar, TMV, Ph.D.Thesis 20-11-10)
Doctors with different specialization like radiologist, gynecologist, cardiologist etc and practicing since 8 years are considered from Pune city.

Patent experts practicing in private firms are contacted to collect information, whose experience is more than 10 years in Pune city.

**Sampling Technique:** Non-probability purposive sampling for pharmaceutical companies, stratified convenience sampling for lawyers and doctors

**Sample Size:** Total -60

Doctors – 30 with different specializations

Patent Experts – 5 practicing in private firms

R and D, Legal department etc of Indian pharmaceutical company – 25

**Research Instrument:** Personal Interview, structured Questionnaire

**E sources:** Internet, sites, journals, publications, articles, online research papers etc.

**6.6 Significance of Study**

Human beings are intelligent and creative. Human beings express their creativity through inventions in various fields like literature, drawings, paintings etc. That can be used for commercial purposes for making money. The creativity in any organization is stimulated by need to customer satisfaction, competitor pressure, quality pressure, and shareholder expectations. The human creativity works as a property for a creator. And fall under the title of Intellectual Property. These intellectual creations which result from intellectual exercise enrich our life. Intellectual property aims at motivating intelligent creators by rewarding them with monopoly rights and protects public interest by limiting the term of right in the form of period. These monopoly property rights provide profits in the form of financial incentive to the creator for the creation of intellectual property. And pay the creator associated research and development costs in the form of revenue.

The major challenges of the sector are shortage of patent knowledge along with the challenges of procedure and policies. As after Amended Patent act 2005, not only Indian pharmaceutical
companies but multinational companies are focusing on research and development activity so as to get patent on the research. To study what is the changed scenario after Amended patent act 2005 in Indian pharmaceutical companies. It will help to know the business strategies (like merger, acquisition, outsourcing etc) Indian pharmaceutical companies are adopting to increase research and development activity. At the same time, it will help to understand the government policies and its impact on Indian pharmaceutical company. It will put focus on the generic market of Indian pharmaceutical company. It will also give guideline to government to understand the impact of amended patent act 2005 on Indian pharmaceutical company. It will put light on the changes in the drug quality of Indian pharmaceutical company that doctors are feeling. At the same it will put light on suggestions of lawyers (patent experts) on amended patent act 2005 with respect to pharmaceutical industry.

6.7 Scope of the study

- For data collection from pharmaceutical industry Mumbai and Pune region and for data collection from patent experts (lawyers) and medicine practitioners (doctors) Pune as understood in the Pharmaceutical Marketing phraseology is quite a large area. There are more than 300 pharmaceutical companies.
- Taking into consideration the varied nature of Mumbai and Pune Region’s geographical area under study, the findings are applicable in similar situation elsewhere in India.
- The Mumbai and Pune region has been selected because of its varied nature.
- The research period is from 2000 to 2008.

Limitations of the study

1. The study was restricted to pharmaceutical industry located around Mumbai and Pune region, lawyers and doctors located in Pune.
2. The study focused on pharmaceutical industry and Amended patent act 2005 only and hence results of the analysis are not applicable to any other type of industry.
3. This is an indicative study.
4. Quality of medicine being subjective but if it is quantified in terms of quality, subjectivity can be originated.
6.8 Research Work Contribution

1. Systematic study of pharmaceutical industries with special reference to amended patent act 2005-

International policies toward protecting intellectual property rights (IPRs) have seen profound changes. Rules on how to protect patents, copyrights, trademarks, and other forms of IPRs have become a standard component of international trade agreements. Indian companies needed 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 especially the patent Act 2005.

2. Impact of amended patent act 2005, on Indian pharmaceutical company.

After amendment of the 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 for pharmaceutical companies.

3. Study of intellectual property rights management and Indian pharmaceutical company with a business management prospective.

Amended patent act 2005 demands increase in research and development activities of Indian pharmaceutical company. For this, to study 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, or outsourcing etc. the research allow to study business policies company are adopting. Even study of the impact of amended patent act 2005 on reverse engineering.

4. 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.

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

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

7. The work will give the status & impact of government policies which are offered to pharmaceutical industry for innovation activity.
8. The research will focus on the problems faced by pharma companies in converting imitation to innovation.

9. Base for the further studies.

The research will help future researcher for further study in same area or related area.

6.9 Chapter Scheme

6.1 Chapter Scheme

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6.10 Summary

The chapter has outlined the purpose of research design in both descriptive and explanatory research. In explanatory research the purpose is to develop and evaluate causal theories. Research design is not related to any particular method of collecting data or any particular type of data. Any research design can, in principle, use any type of data collection method and can use either quantitative or qualitative data. Research design refers to the structure of an enquiry: it is a logical matter rather than a logistical one.

It has been argued that the central role of research design is to minimize the chance of drawing incorrect causal inferences from data. Design is a logical task undertaken to ensure that the evidence collected enables us to answer questions or to test theories as unambiguously as possible.

When designing research, it is essential to identify the type of evidence required to answer the research question in a convincing way. This means not simply collect evidence that is consistent with a particular theory or explanation. Research needs to be structured in such a way that the evidence also bears on alternative rival explanations and enables us to identify which of the competing explanations is most compelling empirically. It also means not simply look for evidence that supports our favorite theory; also look for evidence that has the potential to disprove our preferred explanations.