TRADE RELATED INTELLECTUAL PROPERTY RIGHTS – IMPACT OF PHARMA INDUSTRY

RESEARCH METHODOLOGY

CHAPTER - II
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1. Introduction:

Research is an academic activity and the term is issued in a technical sense. It compresses of defining and re defining problems, formulating hypothesis, suggesting solutions, collecting, organizing, evaluating data, making deductions, reaching conclusions and carefully testing the conclusions to determine whether they fit the formulating hypothesis. Research is a part and parcel of any systematic knowledge. The human urge for new areas of knowledge has developed a faculty for research which has become an integral part not only of academic pursuits, but also of all the area of human activity.

Research Methodology is the way to systematically solve the research problem. Methodology includes the collection of theories, concepts or ideas, comparative study of different approaches, etc. In a Methodology is the study of the methods and practices in research investigation the gathering of evidences in the process of knowledge and theory formulation. This chapter is included with the purposes of making clear the steps taken for the systematic completion of research.

2. Statement of the Problem:


The generic pharmaceutical industry in India that thrived on process patent and reverse engineering was no longer allowed to do so. On what had the implementation of TRIPS put restrictions on the Indian pharmaceutical industry in terms of producing generic drugs, on the
other hand, it opened up opportunities for the industry in terms of investment in Research and Development R&D. Many Indian Pharmaceutical companies viewed patents system with a positive attitude and started gearing up for the same. In the above background, the research work finds it interesting to see how the Indian pharmaceutical companies sustain their momentum of growth and develop new competencies to overcome the challenges posed by the patent regime.

3. Need for the Study:

The earlier research work and review of related literature in this topic Implement Trade Related Rights (TRIPS) and its impact on pharmaceutical Industry has not been a complete work accommodating all the issues relating to the topic. The final and growth of the pharmaceutical industry in the pre colonial, colonial and post colonial period has brought about various impacts in the global markets. The under stands and research on these lines are very essential for the growth of this sector and for the overall development of the country. The patents are demand to provide the necessary incentives for research and technology development. The research study is essential to understand the Health Friendly patents for providing good Health care system to the public.

4. Scope of the Study:

The study on IPR is of immense importance and will through light on various issues relating to the development of the economy and pharmaceutical sector. The present study intends to examine the trends in patent registration, to the impact of patents on prices of drugs, accessibility, availability, flexibility, innovation, Technology transfer etc.

This type of study will be many useful for policy formulation by the government to promote IPR in India and among the pharmaceutical sector.

- It would encourage innovation, Technology transfer, FDI Etc., required for Economic development of India and pharmaceutical sector.
- Providing adequate protection to IPR becomes an important issue in international negotiations on trade and other related matters.
5. Objective of the Study:

(A).
   i. To study the trends in Patents registered and Patents field in Pharmaceutical Industries (Secondary source of Data)
   ii. To Understand the impact of TRIPS on Pharmaceutical sector with reference to the following:
       1. Prices of Drugs.
       2. Accessibility of drugs
       3. Research and Development
       4. Technology Transfer
       5. Foreign Direct Investment
       6. Growth Competency
       7. Profitability Vs Values
       8. Flexibilities available.
       9. Data Exclusivity
       10. Economic Development

(B). To examine the knowledge level of selected personals in the pharmaceutical Companies regarding IPR and Patents in pharma sector.
   - To Document IPR “Legal Cases” in pharmaceutical Industries.
   - To study the Government and Non Government Institutions supporters IPR
   - To develop training modules on IPR for organizing Training Programmes for selected executives of Pharmaceutical Companies in Tamilnadu.
   - To understand the Indian Laws pertaining to IPR & Patents its amendments
   - To provide Suggestions for promoting patents among pharmaceutical sector.

The primary knowledge received for the study resets or the subjective perceptions, intents, experiences and reflections of a member intimately involved in the pharmaceutical industry in Tamil Nadu, India.
6. Research Methodology:

a) Research Design:
   
   A good research design ensures that research work is conducted efficiently and effectively. The research design used in this work is an exploratory research. The research design was based on a consultative process with the pharmaceutical industry experts.

b) Sources of Data:
   
   Data sources are an important tool to identify the source of information. The study is based on both primary and secondary sources of information. Primary sources included information collected through Questionnaire, interviews, focus group discussion from the experts in the field of Intellectual Property pharma sector.

c) The Secondary Sources of information:
   
   Most of the references are drawn from the secondary sources for analysis. The secondary sources of information includes, reference books, professional journals, magazines, business newspapers, patent office, published reports on IPR, Government office, Published & unpublished thesis, Trade journals, white papers, Industry portable, Trade associations, Monitoring Industry news and developments, access to number of data base websites etc.,

d) Questionnaire Design:
   
   The objective of using a questionnaire was to access decision makers in various pharmaceutical companies selected on the basis of different geographical locations. The questionnaire was framed to collect information regarding the knowledge of IPR acquired by the executives in the pharmaceutical sector with respect to access, availability, affordability and prices of medicine, R&D, Technology Transfer, FDI, Data Exclusivity and issues relating to profitability and values etc.,

d1) Sampling Unit & Area of Study:
   
   Sampling unit included the managers, experts, R&D officers, Drug manufacturer in the pharmaceutical units in Tamil Nadu, India.

d2) Sampling Method and Sample Selection (Sample Size)
   
   Since the study is an exploratory study, the sampling method used was non, probability, convenience sampling method. The study was strengthened by reflections of the various experts from the pharmaceutical sector. There were a total of nearly 180 registered units in Tamil Nadu (The Pharmaceutical Manufacture’s Association of TamilNadu. A sample of 100 units were
selected for collecting information from the pharmaceutical units. Out of these 100 units, all the units in Madurai (5), Nagercoil (1), Trichy (1), and Salem(1) were selected. In Chennai about 90 units were selected on the basis of convenience sampling for analysis.

7) Limitations of the Study:
The following limitations has been observed while conducting the present study

- The study is based on primary and secondary sources of data with a limited size of sample and in limited time period
- The results could not be generalized
- The study is restricted to only pharmaceutical Industry in Tamil Nadu.
- This can be considered as a indicative study.
- The study confines to IPR (Patents) in Pharma Sector alone & only in the District of Tamil Nadu. The information was drawn through Questionnaires & oral discussion which imply that the result cannot be applied to all situations at all places.

Chapterization:
The present research works is organized in the following manner. The first chapter ‘Introduction’ deals with the introduction of IPR, TRIPS, Agreement, Patents and Pharmaceutical Sector. The second chapter deals with ‘Research Methodology’ which includes the need, scope, significance objectives, methodology, sample selection, data collection, analysis, geographical area period of the study, limitation of the study. The Third chapter namely ‘Review of Literature’ includes the reviews, ideas and thoughts of various researches on IPR and impact on Pharmaceutical Sector. The Fourth chapter deals with the ‘Profile of the Pharmaceutical Industry’ and the Patents registered in this sector in India. The Fifth Chapter ‘Analysis and Discussion’ deals with the various aspects of the study which includes the Trends in the patents registration with Special reference to the Patents registered in the Pharma sector through Secondary Sources, the other issues in analysis include the understanding of the knowledge of executives in the pharmaceutical sector, and the results are analyzed from the data collected through various secondary sources with respect to the Impact of Patent on price, accessibility of drugs, R&D, Technology transfer, Foreign Direct Investment, etc., The Sixth Chapter deals with the ‘Documentation of IPR Legal Cases in Pharmaceutical Industries’ and the seventh chapter highlights the Institutions Promoting IPR, The Indian Laws
Pertaining to IPR are addressed in Chapter Eight. The Ninth Chapter deals with Findings and Challenges and the Tenth chapter includes Impact and Suggestions.