CHAPTER - I
INTRODUCTION AND DESIGN OF THE STUDY

INTRODUCTION

In the age of information technology people are spreading their wings to every aspect of the society. While exchange of one’s information such as ideas, techniques, process, and product to a target group, the one does not come to know this thing that someone is also targeting his information. It is much prone to unintentionally leakage of one’s precious ideas as his information passes through different portals.

It is the human tendency to share their innovative thoughts with their near and dear ones but that proves fatal, in most of the cases, in respect of the original creation or one’s property i.e. intellectual property (IP). Most of the people act indiscreetly and ignorantly which results in jeopardizing the chance of saving their intellectual property i.e. novelty of ideas as they come under public domain and lose their chance to be protected by the Intellectual Property Rights.

Intellectual property literally means some academic or scholar by work. Intellectual property (IP) pertains to any scholar or any original creation of the human intellect; that work can be artistic, literary, technical or scientific creation.

Intellectual property rights mean those rights, which are given by the State to the inventor or creator to protect one’s invention or creation for a certain period of time.
SUNRISE OF KNOWLEDGE

17th Century --- Scientific Revolution
18th Century --- Political Revolution
19th Century --- Industrial Revolution
20th Century --- Information Revolution
21st Century --- Knowledge Revolution

Revolutions have occurred through human history and vary widely in terms of methods, duration, and motivating ideology. Their results include major changes in culture, economy, and socio-political institutions. A drastic and far-reaching change in ways of thinking and behaving leads to many kinds of revolution. Scientific revolution took place in the 17th Century; Political revolution in the 18th Century; Industrial revolution in the 19th Century; Information revolution in the 20th Century; and in the 21st Century, it is knowledge revolution. Lester C Thurow has stated that, “For more than a Century, the world’s wealthiest human being has been associated with oil. Now it is associated with the knowledge worker”.

NEED FOR INTELLECTUAL PROPERTY RIGHTS

For individual it helps to protect investment of time, money, effort and such other resources of the inventor or creator. For public it provides a pool of information to the general public since all forms of IP are published in journals and magazines except in the case of trade secrets. For a country it provides a mechanism of handling infringement, piracy and unauthorized use and it encourages industrial development and technological
advancement, which leads to the overall economic development of the
country.

**BENEFITS OF NEW PATENT REGIME**

- It will force the Indian pharmaceutical sector into greater efforts in
  research and development. Many of the pharmaceutical majors in
  India have already made large outlays in this area and have applied
  for patents.

- Outsourcing of laboratory research and clinical trials to India will
  increase, thereby facilitating the domestic processes for the approval
  of the marketing of a new drug. Even more importantly, outsourcing
  to India will lower research costs, thereby reducing the costs, which
  will have to be recovered through pricing mechanisms. Finally, even
  bulk drug manufacture may be outsourced to India, which would
  further reduce the costs of the marketed product.

- Small companies, many of which manufacture and market generic
  drugs of doubtful quality, will fold up.

- Competition will eventually change from brand Vs brand to drug Vs
  drug.

**PROTECTION AND REGISTRATION OF IPRS**

Intellectual Property Rights (IPRs) should also be protected properly.

Table 1.1 shows various IPRs and their duration of protection and its
registration.
TABLE 1.1

IPRS DURATION OF PROTECTION AND REGISTRATION

<table>
<thead>
<tr>
<th>IPRs</th>
<th>Duration of Protection</th>
<th>Registration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patent</td>
<td>20 years</td>
<td>Compulsory</td>
</tr>
<tr>
<td>Copyright</td>
<td>Life &amp; 60 years</td>
<td>Optional</td>
</tr>
<tr>
<td>Trade mark</td>
<td>10 years &amp; renewable</td>
<td>Optional</td>
</tr>
<tr>
<td>Plant</td>
<td>18 years</td>
<td>Compulsory</td>
</tr>
<tr>
<td>Design</td>
<td>10 years &amp; 5 years renewable</td>
<td>Compulsory</td>
</tr>
<tr>
<td>Trade secrets</td>
<td>As long as kept</td>
<td>No registration</td>
</tr>
<tr>
<td>Integrated Circuits</td>
<td>10 years</td>
<td>Compulsory</td>
</tr>
<tr>
<td>Geographical Indications</td>
<td>10 years &amp; renewable</td>
<td>Compulsory</td>
</tr>
</tbody>
</table>


The TRIPS agreement is a minimum standard agreement, which allows members to provide more extensive protection of intellectual property if they so wish. Members are left free to determine the appropriate method of implementing the provisions of the agreement within their own legal system and practice.

Signing of Trade Related Intellectual Property Subjects (TRIPS) is considered to be a landmark step towards development of intellectual property rights in the international law sphere. It sets down minimum standards for many forms of Intellectual Property regulation. Compliance with TRIPS mandates all the WTO member countries to amend their national legislations and bring it in conformity with its provisions. It is the developing countries and the least developed countries, which are required to make the most extensive changes. All the WTO members were given one
year, i.e. upto January 1996 to ensure that their national laws were TRIPS compliant. The developing countries were given an additional four years i.e. up to January 2000, and the least developed countries ten years i.e. up to 2006, to do so. A further period of five years up to 2005, were given to the developing countries to introduce product patents in the fields of technology which had so far been excluded from their national patent laws.

India is a member of various international treaties on patents and intellectual property rights. As per the TRIPS agreement under the WTO regime, India amended the 1970 Patents Act in 1999. India being a developing country was given a grace period of 5 years to change its Patent Laws under agreement on TRIPS. At the same time a grace period of 10 years was also granted for technologies previously unprotected in market. During this interim period of ten years all patent applications were put in a black box. Pharmaceutical companies applied for an Exclusive Marketing Right (EMR) for their products for 5 years only even before the patent regime fully transformed that is to product patent.

The TRIPS agreement requires member countries to make patents available for any inventions, whether products or processes, in all fields of technology without discrimination, subject to the normal tests of novelty, inventiveness and industrial applicability. It is also required that patents be available and patent rights enjoyable without discrimination as to the place of invention and whether products are imported or locally produced (Article 27.1).
WTO AND ITS MEMBERSHIP

Anil Kumar Kanungo⁠¹ in his lead article stated that the World Trade Organisation (WTO) is a rule based on multilateral trading system that seeks to provide transparency, stability and predictability in international trade in terms of market access and other trading issues. Countries view WTO membership as a means to integrate themselves into the global economy and maximize the benefits of international trade. The WTO has two types of members: the original members who were members of the General Agreement on Tariffs and Trade (GATT) by virtue of which they are the founding members of WTO; and the new members who joined the WTO through accession negotiations. Among the 153 Members of the WTO, 123 are original members, while others joined through the accession process, which is shown in Annexure – I. Most of the recent members in the WTO belong to the Least Developed Countries (LDCs) category and it is shown in Annexure – II. There are no WTO definitions of “developed” or “developing” countries. Developing countries in the WTO are designated on the basis of self-selection although this is not necessarily automatically accepted in all WTO bodies.

SCENARIO OF INDIAN PHARMACEUTICAL INDUSTRY

The pharmaceutical industry in India is among the most highly organized sectors. This industry plays an important role in promoting and sustaining development in the field of global medicine. Due to the presence

⁠¹ Anil Kumar Kanungo, editor, Indian Institute of Foreign Trade, New Delhi
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of low cost manufacturing facilities, educated and skilled manpower and cheap labor force among others, the industry is set to scale new heights in the fields of production, development, manufacturing and research.

Table 1.2 shows the number of applications filed from Residents and Non Residents through various routes for 10 years. In the year 2005-2006 the number of applications filed is 24505 and in the year 2007-2008 it is 35218 which has considerably increased by 10713

**TABLE 1.2**

<table>
<thead>
<tr>
<th></th>
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<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Residents</td>
<td>2247</td>
<td>2206</td>
<td>2179</td>
<td>2371</td>
<td>2693</td>
<td>3218</td>
<td>3630</td>
<td>4521</td>
<td>5314</td>
<td>6040</td>
</tr>
<tr>
<td>Non Residents</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ordinary</td>
<td>6707</td>
<td>2349</td>
<td>2160</td>
<td>1870</td>
<td>1723</td>
<td>1678</td>
<td>3165</td>
<td>1008</td>
<td>693</td>
<td>834</td>
</tr>
<tr>
<td>Convention</td>
<td>--</td>
<td>--</td>
<td>--</td>
<td>--</td>
<td>--</td>
<td>--</td>
<td>--</td>
<td>3509</td>
<td>3969</td>
<td>4453</td>
</tr>
<tr>
<td>National phase application under PCT</td>
<td>--</td>
<td>269</td>
<td>4164</td>
<td>6351</td>
<td>7049</td>
<td>7717</td>
<td>10671</td>
<td>15467</td>
<td>19768</td>
<td>23891</td>
</tr>
<tr>
<td>Grand Total</td>
<td>8954</td>
<td>4824</td>
<td>8503</td>
<td>10592</td>
<td>11466</td>
<td>12613</td>
<td>17466</td>
<td>24505</td>
<td>28940</td>
<td>35218</td>
</tr>
</tbody>
</table>

*Source: CGPDTM Annual Report 2007-2008*

Table 1.3 depicts the number of applications filed, examined and granted during the period 2003 to 2008. The number of patent applications filed in 2003-2004 is 12613. Filing of patent application gradually increased year after year and it was 35218 in the year 2007-2008.
TABLE 1.3
TRENDS IN PATENT APPLICATIONS

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Filed</td>
<td>12613</td>
<td>17466</td>
<td>24505</td>
<td>28940</td>
<td>35218</td>
</tr>
<tr>
<td>Examined</td>
<td>10709</td>
<td>14813</td>
<td>11569</td>
<td>14119</td>
<td>11751</td>
</tr>
<tr>
<td>Granted</td>
<td>2469</td>
<td>1911</td>
<td>4320</td>
<td>7539</td>
<td>15261</td>
</tr>
</tbody>
</table>


Table 1.4 exhibits the number of patents, designs, trademarks and geographical indications granted from the year 2003-2004 to 2007-2008. The number of patents granted has considerably increased from 2469 (2003-2004) to 15261(2007-2008).

TABLE 1.4
COMPARATIVE TRENDS OF IPRS GRANTED/REGISTERED

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Patents</td>
<td>2469</td>
<td>1911</td>
<td>4320</td>
<td>7539</td>
<td>15261</td>
</tr>
<tr>
<td>Designs</td>
<td>2547</td>
<td>3728</td>
<td>4175</td>
<td>4250</td>
<td>4928</td>
</tr>
<tr>
<td>Trade Marks</td>
<td>39762</td>
<td>45015</td>
<td>184325</td>
<td>109361</td>
<td>100857</td>
</tr>
<tr>
<td>G.I</td>
<td>-</td>
<td>11</td>
<td>19</td>
<td>3</td>
<td>61</td>
</tr>
</tbody>
</table>


Table 1.5 brings out the number of patents granted during 2003-2004 to 2007-2008 under various fields of inventions. With respect to Drug the number of patents granted in the year 2006-2007 is 798 and it is 1469 in the year 2007-2008.
**TABLE 1.5**

**NUMBER OF PATENTS GRANTED**

<table>
<thead>
<tr>
<th>Year</th>
<th>Chemical</th>
<th>Drug</th>
<th>Food</th>
<th>Electrical</th>
<th>Mechanical</th>
<th>Computer /Electronics</th>
<th>Bio technology</th>
<th>Other fields *</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>2003-2004</td>
<td>609</td>
<td>419</td>
<td>110</td>
<td>396</td>
<td>539</td>
<td>--</td>
<td>--</td>
<td>401</td>
<td>2469</td>
</tr>
<tr>
<td>2004-2005</td>
<td>573</td>
<td>192</td>
<td>67</td>
<td>245</td>
<td>414</td>
<td>71</td>
<td>71</td>
<td>278</td>
<td>1911</td>
</tr>
<tr>
<td>2005-2006</td>
<td>1140</td>
<td>457</td>
<td>140</td>
<td>451</td>
<td>1448</td>
<td>136</td>
<td>51</td>
<td>497</td>
<td>4320</td>
</tr>
<tr>
<td>2006-2007</td>
<td>1989</td>
<td>798</td>
<td>244</td>
<td>787</td>
<td>2526</td>
<td>237</td>
<td>89</td>
<td>869</td>
<td>7539</td>
</tr>
<tr>
<td>2007-2008</td>
<td>4071</td>
<td>1469</td>
<td>88</td>
<td>1078</td>
<td>3230</td>
<td>2052</td>
<td>314</td>
<td>2959</td>
<td>15261</td>
</tr>
</tbody>
</table>

*Source: CGPDTM Annual Report 2007-2008*
Number of patents granted during 2007-2008 under various other fields of inventions is shown in Table 1.6. The maximum number of patents granted during 2007-2008 is in the field of Biochemistry, which is 1149. The total number of patents granted during the same period is 2959.

**TABLE 1.6**

**NUMBER OF PATENTS GRANTED UNDER VARIOUS OTHER FIELDS**

<table>
<thead>
<tr>
<th>Field</th>
<th>Number</th>
<th>Field</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biomedical</td>
<td>138</td>
<td>Metallurgy/ Material science</td>
<td>228</td>
</tr>
<tr>
<td>Biochemistry</td>
<td>1149</td>
<td>Agriculture</td>
<td>53</td>
</tr>
<tr>
<td>Microbiology</td>
<td>25</td>
<td>Polymer science</td>
<td>286</td>
</tr>
<tr>
<td>Physics</td>
<td>328</td>
<td>Veterinary</td>
<td>14</td>
</tr>
<tr>
<td>Civil</td>
<td>287</td>
<td>Communication/ Agrochemical</td>
<td>158 / 44</td>
</tr>
<tr>
<td>Textiles</td>
<td>249</td>
<td>Total</td>
<td>2959</td>
</tr>
</tbody>
</table>

*Source: CGPDTM Annual Report 2007-2008*

It is clear from Table 1.7 that as on 2007-2008 the number of Indian patents in force is 7966 and Foreign patents in force is 21722. Further it also shows the application filed details, number of requests made for examination, number of patents granted and the number of patent in force from 1998 to 2008. It also shows the miscellaneous information relating to Patent during the period from 1998 to 2008.
TABLE 1.7
NUMBER OF PATENTS IN FORCE

<table>
<thead>
<tr>
<th>Year</th>
<th>No. of applications filed</th>
<th>No. of requests for examination</th>
<th>Number of patents granted</th>
<th>Number of patents in force</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Indian</td>
<td>Foreign</td>
</tr>
<tr>
<td>1998-1999</td>
<td>8954</td>
<td>--</td>
<td>645</td>
<td>115</td>
</tr>
<tr>
<td>1999-2000</td>
<td>4824</td>
<td>--</td>
<td>557</td>
<td>1324</td>
</tr>
<tr>
<td>2000-2001</td>
<td>8503</td>
<td>--</td>
<td>399</td>
<td>919</td>
</tr>
<tr>
<td>2001-2002</td>
<td>10592</td>
<td>--</td>
<td>654</td>
<td>937</td>
</tr>
<tr>
<td>2002-2003</td>
<td>11466</td>
<td>--</td>
<td>494</td>
<td>885</td>
</tr>
<tr>
<td>2003-2004</td>
<td>12613</td>
<td>12362</td>
<td>945</td>
<td>1524</td>
</tr>
<tr>
<td>2004-2005</td>
<td>17466</td>
<td>19001</td>
<td>764</td>
<td>1147</td>
</tr>
<tr>
<td>2005-2006</td>
<td>24505</td>
<td>21926</td>
<td>1396</td>
<td>2924</td>
</tr>
<tr>
<td>2006-2007</td>
<td>28940</td>
<td>20645</td>
<td>1907</td>
<td>5632</td>
</tr>
<tr>
<td>2007-2008</td>
<td>35218</td>
<td>22146</td>
<td>3173</td>
<td>12088</td>
</tr>
</tbody>
</table>


VITAL INFORMATION ON PHARMACEUTICAL COMPANIES IN INDIA

- In terms of volume - India's pharmaceutical industry is the third largest in the entire world.
- In terms of value - India's pharmaceutical industry ranks fourteenth
- By 2015 - It will be in the list of top 10 global pharmaceutical markets and it will touch US $ 20 billion.
- 2013 - Indian formulation market is expected to touch US$ 13.7 billion.

2 Pre-budget 2010 economic survey
Pre-budget 2010 economic survey said that the Indian Pharmaceutical industry has become the third largest in the world in terms of volume, which will be US$20 billion by 2015. Mergers and acquisitions are the part of this growth. The compounded annual growth rate of pharma in India is 12-15% and the global figures are 4-7% for the period 2008-2013. With such a profound growth of pharmaceutical companies in India, numerous pharmaceutical jobs can be seen. It ranks 14th in terms of value at over Rs1 lakh crore (Rs1 trillion). The Indian pharmaceutical industry has grown from a humble Rs1,500-crore (Rs15-billion) turnover in 1980 to approximately Rs1,00,611 crore (Rs1006.11 billion) in 2009-10. The growth of the Indian pharmaceutical industry has been fuelled by exports, which increased 25 per cent in 2008-09. Exports of pharmaceuticals have consistently outstripped imports.

Angel Broking has done a research on the growth of pharmaceutical industry and found that by 2015 the pharmaceutical industry in India will be in the top 10 markets. Yet another finding of FICCI-Ernst & Young study reveals that the population of high-income group in India is rising which will give rise to more influx of MNCs and expensive drugs. Pharmaceutical companies along with native companies are also competing with the top MNCs. Such a profound growth is because of the heavy population figures and with the increasing number of middle class people and their income to access the drugs and medicines. But still the low-priced generics are popular in Indian pharmaceutical industry.
INITIATIVES BY GOVERNMENT

- Tax breaks are offered to pharma industry.
- New procedure for the development of drugs.
- Proper clinical procedures.
- New Millennium Indian Technology Leadership Initiative and the Drugs and Pharmaceuticals Research Programme - schemes launched by the government.

STATEMENT OF THE PROBLEM

The Patent Act 1970 was amended thrice during the years 1999, 2002 and in 2005. Patent Act now in force is The Patent (Amendment) Act 2005. This Act was brought into force with many salient features. Among them are;

The new Act repealed the controversial section 5 of the Indian Patents Act 1970. For over three decades only processes were patentable in respect of inventions relating to food, drug and medicines and ‘substances produced by chemical processes’. From 1st January 2005, only product patents were granted for all the above categories of inventions. The other features are deletion of the provisions relating to Exclusive Marketing Rights (EMRs), introduction of a provision for enabling grant of compulsory license for export of medicines to countries which have insufficient or no manufacturing capacity to meet emergent public health situations, modification in the provisions relating to opposition procedures with a view to streamlining the system by having both pre-grant and post grant
opposition in the Patent Office, strengthening the provisions relating to national security to guard against patenting abroad of dual use technologies, rationalisation of provisions relating to time-lines with a view to introducing flexibility and reducing the processing time for patent application.

Once the pharmaceutical company gets its product patented, it has all the rights to produce, market and use or sell their products. The term of patent is for 20 years. During this period, if any one has infringed, then the remedy available for the patented company are (i) it can prevent the other company to stop producing, marketing, using and selling the products. (ii) get adequate compensation for the period they have used and (iii) can insist for both the above mentioned two remedies.

If the Indian pharmaceutical companies get their products patented, then with respect to the impact of product patent, there are difference of opinions in respect to price of the medicines, survival and growth of pharmaceutical industries, quality of the drugs and circulation of fake products. The present study seeks to examine the impact of product patents in India with reference to the selected companies in Tamil Nadu. The investigator also wishes to bring to limelight the opinion with regard to The Patent (Amendment) Act 2005.

In the new patent regime, the investigator has attempted to find out (1) What will be the position of the selected pharmaceutical companies in Tamil Nadu in the wake of new patent regime coming into force from 01/01/2005? (2) What strategies will the pharmaceutical companies adopt
for their survival and growth? (3) What will be impact of product patent? and (4) Will the product patent benefit pharmaceutical companies?

**NEED FOR THE STUDY**

The present study helps to understand the long-term orientation for survival and growth of the pharmaceutical companies in the wake of WTO accord and research and development initiatives. This industry boasts of huge fragmented players and the pharmaceutical companies who have followed the process patent and operating in all the therapeutic areas available in the market. With the product patent becoming imminent by 2005, companies with clear vision and understanding of the domestic and global markets will only be successful. In this context, the study was conceived to see such a focus from the players of the pharmaceutical industry.

**SCOPE OF THE STUDY**

The study focuses on the implications of TRIPS agreement for the pharmaceutical companies, the importance and the impact of product patents and the problems faced by the pharmaceutical companies. Besides these, the study also covers select cases in respect of patents with reference to pharmaceutical companies. The study covers on the selected pharmaceutical companies in Tamil Nadu, which are manufacturing allopathy medicines. It also dwells upon future prospects, survival, sustainable development and growth of pharmaceutical companies.
OBJECTIVES OF THE STUDY

1. To critically examine the applicability of provisions of New Patent Act in Pharmaceutical companies.

2. To analyse the TRIPS agreement and its implications for Pharmaceutical companies in India.

3. To ascertain the impact of product patents in pharmaceutical companies in India.

4. To identify the problems faced by small and large pharmaceutical companies on new patent regime.

5. To examine the importance of getting product patent for drugs manufactured.

6. To study select case laws in respect of patents with reference to Pharmaceutical companies.

7. To offer suggestions for the survival and growth of the small and large pharmaceutical companies in the product patent regime.

METHODOLOGY

The present study was conducted keeping in mind the top management professionals in the pharmaceutical industry, who can understand and provide information related to the product patent aspects concerning the industry. Chief executives and representatives of small-scale companies, General managers and professionals’ who have knowledge about patenting were contacted to get the information from the medium and large-scale companies.
Questionnaire method was adopted to collect the primary data. All the 168 members of Tamil Nadu Pharmaceutical Manufacturers Association represent the population of the study. Judgment sampling method was adopted for selection of sample pharmaceutical companies. 50 percent of the total population that is, 84 companies were selected for the study. A pilot study was also conducted in the beginning with the limited respondents and necessary modifications were made in the light of suggestions received.

DATA COLLECTION

Both primary data and secondary data were collected for the present study. Primary data were collected through the questionnaire and the secondary data were collected by referring various standard textbooks, professional journals, magazines, business newspapers and also through internet browsing.

LIMITATIONS OF THE STUDY

The study was mainly based on the primary data collected through questionnaire from the Pharmaceutical Manufacturers Association of Tamil Nadu members. Members present at any one level of office in Tamil Nadu were contacted to collect the data. The study mainly focused on human medicines and not on animal care or industrial equipment such as surgical device, syringes and so on. With regard to human medicines allopathy alone was considered, leaving other fields of medicines such as ayurvedic, siddha, naturopathy and homeopathy.
DATA ANALYSIS

Data collected were edited, coded, classified, tabulated and analyzed to derive meaningful interpretation. Statistical tools were used to interpret and analyze the primary data. Statistical tools such as chi-square test, percentage analysis, Kendall’s coefficient of concordance test, t-test and Discriminant Function Analysis were used for interpretation.

GEOGRAPHICAL AREA OF THE STUDY

Tamil Nadu Pharmaceutical Manufacturers Association members have any one or more level of offices in Tamil Nadu. The present study is confined to the major cities in Tamil Nadu.

PERIOD OF THE STUDY

WTO agreement became fully operational in the year 2005. So it is proposed to conduct the study for a period of 3 years (i.e.) from 2005 – 2008.

HYPOTHESES OF THE STUDY (CHI-SQUARE)

H₀₁: There is no significant relationship between age of the companies and companies, which patented their products.

H₀₂: There is no significant relationship between size of the companies and companies, which patented their products.

H₀₃: There is no significant relationship between nature of medicine and companies, which patented their products.

H₀₄: There is no significant relationship between total number of products manufactured and companies, which patented their products.
H₀₅: There is no significant relationship between initial capital invested and companies with patented products.

H₀₆: There is no significant relationship between annual turnover of the companies and companies with patented products.

H₀₇: There is no significant relationship between area of sales and companies with patented products.

H₀₈: There is no significant relationship between the application filed and companies with patented products.

H₀₉: There is no significant relationship between the existence of R&D and companies with patented products.

H₀₁₀: There is no significant relationship between the amounts allocated for research and companies with patented products.

H₀₁₁: There is no significant relationship between the opinions on cost of patent and companies, which patented their products.

H₀₁₂: There is no significant relationship between essentiality of patent and companies with patent rights.

H₀₁₃: There is no significant relationship between the strategic alliance and companies with patented products.

H₀₁₄: There is no significant relationship between business acquisition and companies with patent rights.
HYPOTHESES OF THE STUDY (T – TEST)

H₀₁: There is no significant difference in the average ratings given by patented and non-patented companies with regard to the opinion ‘procedure should be simplified’.

H₀₂: There is no significant difference in the average ratings given by patented and non-patented companies with regard to the opinion score on ‘separate cell for assistance should be opened’

H₀₃: There is no significant difference in the average ratings given by patented and non-patented companies with regard to the opinion score on ‘more number of patent offices should be opened’

H₀₄: There is no significant difference in the average ratings given by patented and non-patented companies with regard to the opinion score on ‘time for granting patent should be reduced’

H₀₅: There is no significant difference in the average ratings given by patented and non-patented companies with regard to the opinion score on ‘activities carried by the patent office is satisfactory’

H₀₆: There is no significant difference in the average ratings given by patented and non-patented companies with regard to the opinion score on ‘transparency benefits all’

H₀₇: There is no significant difference in the average ratings given by patented and non-patented companies with regard to the opinion score on ‘fake products are controlled’
H₀₈: There is no significant difference in the average ratings given by patented and non-patented companies with regard to overall opinion score on Patent Law.

H₀₉: There is no significant difference in the average ratings given by patented and non-patented companies with regard to the impact ‘increase in price’.

H₀₁₀: There is no significant difference in the average ratings given by patented and non-patented companies with regard to the impact ‘affects the domestic market’.

H₀₁₁: There is no significant difference in the average ratings given by patented and non-patented companies with regard to the impact ‘helps for survival in Global market’.

H₀₁₂: There is no significant difference in the average ratings given by patented and non-patented companies with regard to the impact ‘fake product loses its market’.

H₀₁₃: There is no significant difference in the average ratings given by patented and non-patented companies with regard to the impact ‘affects unorganized Industry’.

H₀₁₄: There is no significant difference in the average ratings given by patented and non-patented companies with regard to the impact ‘helps pharmaceutical Industry’.
H₀₁₅: There is no significant difference in the average ratings given by patented and non-patented companies with regard to the impact on ‘quality drugs alone available in the market’.

H₀₁₆: There is no significant difference in the average ratings given by patented and non-patented companies with regard to overall impact score on product patenting.

CHAPTER ARRANGEMENT

The present study is organized into seven chapters.

The first chapter deals with introduction, statement of the problem, need for the study, scope of the study, objectives, methodology, hypothesis, data collection and analysis, period of the study and limitations of the study.

In the second chapter namely ‘Review of Literature’, researches already carried out in pharmaceutical sector, ideas and thoughts of researchers are presented. Group of works already published by external authors through articles, journals, newspapers and books are given in this chapter. Further few important case laws relating to patents are also presented.

The third chapter deals with the ‘Patent Act – An Overview’ in which the rules and regulations of patentable and non-patentable inventions, rules for obtaining patent and its use, grant of compulsory license, remedies available for infringement, appeal provisions are discussed.
In the fourth chapter, provisions relating to Trade Related Intellectual Property Rights and information relating to Indian pharma industry are discussed. Its impact in India and the scenario pre-TRIPS and post-TRIPS are also analysed.

The fifth chapter namely ‘Patent Rights of study companies’ shows the profile of the companies, their patent rights, problems faced in patenting their products and about their research and development activity. In this chapter statistical tools are applied and the results thus obtained are also presented.

Sixth chapter deals with opinions, strategies and impact of patent rights and patent law. The data collected by the investigator have been analysed with the help of statistical tools and the same is interpreted and presented in this chapter.

In the last chapter, the major findings of the study are presented. On the basis of the findings few suggestions are also given for the survival and growth of the Indian pharmaceutical industry.