Chapter No 9

Findings


9.0 Introduction

On the basis of collected information, some important findings regarding pharmaceutical industry and Amended patent Act, 2005 are included in the chapter. The analysis of data and its interpretation have made the task of making observations and arriving at conclusions easier. As a matter of convenience, the findings and observations made are grouped under three heads.

9.1 Findings for Pharmaceutical industry and Patent experts

The findings of the research is based on three factors, as

1. Pharmaceutical industry
2. Patent experts
3. Doctors.

Three different questionnaires were prepared for the collection the data. Information related to the company, patent Act and strategies were asked to the respondents.

The findings of the research work are as follows:-

For Pharmaceutical industry and Patent experts

1. Research & Development activity is the future of Indian pharmaceutical company. This is promising due to amended patent act 2005. The life expectancy and health all over the world are the result of a steadily increasing investment in research. There is huge possibility for collaborative R & D in India. As per the data collected the inference is that for pharmaceutical companies- The 100% of the total says Research and development
Activities in Indian pharmaceutical company have increased since 2005 patent Act. And for Legal Experts - The 100% of the total says Research and development Activities in Indian pharmaceutical company have increased since 2005 patent Act. The implication which comes out from the analysis is that these firms have realized the need of R&D in post TRIPS period and as such they have been increasing the R&D Activity.

2. Percentage increase in Research and development Activities of Indian pharmaceutical company according to the research for pharmaceutical companies- is 44% of the total says that Research and development Activity has been increased 2005 patent Act by 5-10%. And for Legal Experts- 80% of the total says that Research and development Activity has been increased since 2005 patent Act by 10-30%. Introducing a new drug into the market may cost a company anywhere between $300 million to $800 million along with all the associated risks (1). But now it does require increasing research and development activity to survive in the market. The finding which comes out from the analysis is that percentage wise research and development activity has been increased by around 10 to 15% due to amendment patent Act 2005.

3. The introduction of product patents has important implications for both Indian and international companies. After 2005, Indian companies will increasingly need to look beyond the domestic generics market to sustain their sales, as their traditional strategy of copying on-patent drugs will no longer be allowed. According to the research study it is noticed that 96% of the total says that research and development activity plays major role in survival of Indian pharmaceutical company in the market. The inference which comes out from the examination is that as increase in research and development activity will help pharmaceutical company to survive and improve Economic status of Indian pharmaceutical companies in global market.

4. Due to process patent research and development has always taken the back seat amongst Indian pharmaceutical companies. In order to stay competitive in the future, Indian companies will have to refocus and invest heavily in R&D. Percentage total turnover share for R & D Activity according to the research study concludes that 40% of the total says that 4-6% is the total turnover share for R & D Activity in Indian pharmaceutical company. The connotation which comes out from the study is that Indian pharmaceutical company is increasing their share for research and development activity.

5. The different strategies of Indian pharmaceutical company are using for research and development department which commonly includes own department is working actively, collaboration with other pharma company, government, NGO, WHO, educational institutes, outsourcing, risk sharing partnership, agreement with foreign companies, hived off of research and development activity into different entities, merger of research and development units and attract investment. According to the research study for pharmaceutical industry 60% of the total says that their own departments are working Actively, 52% says that collaboration with the other companies for research and development it’s not a good strategies, 84% of the total says that outsourcing is not a good strategies for R & D, 84% of the total says that risk sharing partnership is not a good strategies for R & D, 24% of the total says that agreement with foreign is a good strategies for R & D and 76% says that it is not beneficial for research and development, 68% of the total says that hived off research and development activity is not a good strategies for R & D, 80% of the total says that merger of research and development is not a good strategies for R & D, 84% of the total says that attracting investment is not a good for R & D. The implication which comes out from the analysis is that the present situation is challenging, but at the same time it throws up several new opportunities for Indian pharma companies. What worked in the past may not necessarily hold them in good path in the future. Companies which take advantage of the fundamental changes, that industry go through and re-jig their strategies accordingly will be able to successfully steer the future in Indian pharmaceutical company.

6. Pharmaceutical industry is constantly undergoing a change. In the past, pharmaceuticals industry had a different strategy, companies use to build all the products internally and confine access to information or resources to third parties (2).
But now scenario is changing, companies are looking for outsourcing to share research and development activity. It’s a great challenge to successfully manage the outsourcing relationship and generate value. To maintain continuous growth in outsourced work from pharmaceutical companies, outsourcing partners need to confidentially retain the proprietary knowledge and meet the regulatory compliance.

Outsourcing solves the problems for the pharma companies and also allows them to exploit the potential of new drug discovery technologies. According to the current study if Indian pharmaceutical company outsourced their research and development activity then to whom they should outsource includes small scale, medium scale or large scale pharmaceutical company, the outcome is 16 % of the total says that if outsourcing option is used for R & D then it should be outsourced to medium scale industries and 72 % says think that outsourcing should not be done. The implication which comes out from the analysis is that most of the Indian pharmaceutical companies are not ready to outsource their research and development activity.

7. Due to the Patents Act, 2005, the Amendment to The Patents Act, 1970I Indian pharmaceutical company has taken a rise. Research study implicates about Indian intellectual property rights system usefulness to Indian pharmaceutical company, it has been noticed that for Indian pharmaceutical company- 96 % of the totals are in favor of IPR system to IPC. And for Legal experts- 100 % of the totals are in favor of IPR system to IPC. The implication which comes out from the analysis is that amended patent Act 2005 is useful to Indian pharmaceutical company.

8. The research finding about IPR system and growth of Pharma Companies that for pharmaceutical industry- 96 % of the total says that IPR system helped in growth of Indian pharmaceutical companies.
And for Legal experts - 100 % of the total says that IPR system helped in growth of Indian pharmaceutical companies. The inference which comes out from the examination is that intellectual property right system has helped Indian pharmaceutical companies in growth.

9. As per the research study about Indian intellectual property right system and its user friendliness, for Pharmaceutical industry- 96 % of the total says that IPR system is user friendly to Indian pharmaceutical companies. And for Legal experts- 80 % of the total
says that IPR system is user friendly to Indian pharmaceutical companies. The finding which comes out from the investigation is that Indian intellectual property right system is user friendly to Indian pharmaceutical company.

10. According to the research study about process of filling patent and user friendliness data are for Pharmaceutical industry- 96 % of the total says that process is excellent. And for Legal experts - 60 % of the total says that process is fine. The finding which comes out from the investigation is that process of filling patent to some extend is user friendly to Indian pharmaceutical company.

11. The lengthy time period between patent filing and placing a product on the market means that pharmaceutical manufacturers receive far shorter periods of patent exclusivity than is the case for other patent dependent industries. After doing study focusing on the period required registering to patent and actual required period difference, the inference which is noticed is that for pharmaceutical industry- 68 % of the total says that period required to register is more than required time. And for Legal experts- 40% of the total says that period required to register is more than required time. The implication which comes out from the analysis is that period required to register patent is averagely more than required time.

12. The filing of a patent application is the first step in securing a patent. If the application is submitted with the Patent Office, the officer then starts publication and examining the authenticity of invention. If everything is in order, the patent would be granted to the inventor. According to the research study about Problems faced by pharmaceutical companies while registering IPR commonly are Documentation work, financial support, Technology, Unavailability of Research and development center. The inference for Pharmaceutical industry- 60 % of the total says that documentation is a problem while registering IPR, 52 % of the total says that financial support is a problem while registering IPR, 52 % of the total says that technology is a problem while registering IPR and 24 % of the total says that unavailability of research and development is a problem while registering IPR. And for Legal experts 80 % of the total says that documentation is a problem while registering IPR, 60 % of the total says that financial support is a problem while registering IPR, 60 % of the total says that technology is a problem while registering IPR and 24 % of the total says that unavailability of research and
development is a problem while registering IPR. The implication which comes out from the analysis is that documentation, financial Support & technology these are the major problem areas respectively faced by pharmaceutical companies while registering IPR.

13. India signed the GATT on 15 April 1994, thereby making it mandatory to comply with the requirements of GATT, including the agreement on TRIPS (3). India’s patent legislation must now include provisions for availability of patents for both pharmaceutical products and processes inventions. According to the research study about ranking the problems in inventing patented molecule drug are commonly research and development facility, more time require for innovation, huge capital investment, lack of human resource, insufficient venture capital funding, paucity of trained person, different private equity market and early stage funding. The inference that comes out for pharmaceutical industry and for Legal experts data is research and development facility, more time requires for innovation and huge capital investment are the top 3 major problems in inventing patented molecule.

14. A generic drug is a prescription drug which is not manufactured by the originator of the product. The molecule is off patent and available from multiple sources, and the product is known by the chemical name, not a trade name. A generic drug should possess the same active ingredients in the same dosage form and strength as the original brand drug (4). The development of generic drug does not involve lengthy and costly clinical trials because generic manufacturers only need to prove bioequivalence (5). On an average, the development of generic drugs takes only 3 years, in contrast to the six to seven years of development time spent on branded products (6). After doing investigative work on generic products and usefulness to the pharmaceutical industry which commonly includes generic drugs are useful for company for- increase market share, profitability, wide market coverage, lower manufacturing & capital cost, smart gain, striking a balance and lowering and leveling price of medicine.

4-Unpublished thesis by Monika Khanna thesis, University of Pune
5-Unpublished thesis by Monika Khanna thesis, University of Pune
6-Unpublished thesis by Monika Khanna thesis, University of Pune
The investigation study findings for pharmaceutical industry- 56% of the total says that generic products are useful to increase market share, 60% of the total says that generic products are useful for profitability, 48% of the total says that generic products are useful for wide market coverage, 52% of the total says that generic products are useful for manufacturing and capital cost, Only 20% of the total says that generic products are useful for smart gain, 32% of the total says that generic products are useful for striking a balance, and Only 28% of the total says that generic products are useful for lowering and leveling price of medicine.

The implication which comes out from the analysis is that generic products are used mostly to increase market share, to enhance profitability and to widen market coverage these are the three major advantages.

15. The analysis of the post-TRIPS period from 1994-95 to 2007-08, the patenting scenario of the pharmaceutical industry of India shows that the patents in drugs and pharmaceutical industry have grown at a higher rate (7). As per the research examination patenting helps pharmaceutical industry commonly for direct marketing, earning through loyalty, licensing, first mover advantages, for long term presence, monopoly market, to grow profitability and Inducement for capital investment. As per the research findings 16% of the total says that patents helps in direct marketing, 60% of the total says that patents helps in earning through loyalty percent, 60% of the total says that patents helps in licensing, 52% of the total says that patents helps as a prime advantage, 28% of the total says that patents helps for long term presence, 20% of the total says that patents helps in monopoly market, 60% of the total says that patent helps to grow profitability, and 36% of the total says that patents helps in inducement for capital investment. The implication which comes out from the analysis is that patents majorly help pharma companies to earn through loyalty, licensing and to grow profitability of pharmaceutical company.

16. The patentee gets the well protected exclusive right under Amended patent Act 2005 to use his invention. In the pharmaceutical industry patented drugs are commonly useful to company for brand building, goodwill generation, market penetration, profitability, maximize global profit, royalties, justify Indian prices, tax advantage and sale by considering Indian population. According to the research inferences for pharmaceutical industry- 36% of the total says that patent drugs are useful to a company for brand building, 32% of the total says that patent drugs are useful to a company for goodwill generation, 68% of the total says that patented drugs are useful to a company for market penetration, 84% of the total says that patented drugs are useful to a company for profitability, 48% of the total says that patented drugs are useful to a company for maximizing global profit, 28% of the total says that patented drugs are useful to a company for royalties, 20% of the total says that patented drugs are useful to a company for justifying Indian prices, 16% of the total says that patented drugs give the tax advantage and 20% of the total says that patented drugs are useful to a company for sale by considering Indian population. And for Legal experts- 60% of the total says that patent drugs are useful to a company for brand building, 60% of the total says that patent drugs are useful to a company for goodwill generation, 40% of the total says that patented drugs are useful to a company for market penetration, 60% of the total says that patented drugs are useful to a company for profitability, 20% of the total says that patented drugs are useful to a company for maximizing global profit, 40% of the total says that patented drugs are useful to a company for royalties, 100% of the total says that patented drugs are not useful to a company for justifying Indian prices, 40% of the total says that patented drugs give the tax advantage and 20% of the total says that patented drugs are useful to a company for sale by considering Indian population. The implication which comes out from the investigation is that patented drugs are useful to pharmaceutical company for market penetration, to increase profitability and maximize global profit respectively which in turn will improve economic status of IPC.

17. The scope of patent protection is continuously widening. Companies have to spend enormous amount on researching innovations which will circumvent of patents. The invention cost of the medicines includes R&D costs, production costs, marketing costs and profits. The research-based pharmaceutical industry is distinguished from others by relatively high R&D costs, marketing costs and profit margins. Risks are high even
though patents support high margins for new, innovative drugs. Consequently, R&D expenditures have to be recovered from the relatively few commercially successful products. 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. As per the study when data collected for IPR Act 2005 and effect on price of medicines for common man ratio are commonly as there is increase in price of medicines by 0-25%, 25-50%, 50-75%, 75-100% and above 100%. After doing investigation, it came to know that 60% of the total says that due to IPR Act 2005 prices of medicines has increased between 25-30%. The implication which comes out from the analysis is that due to product patent, there in an increase in cost of the medicines.

18. The development of the Indian pharmaceutical company would create new jobs; mainly it would provide access both to modern technology in the field of medicines and to medicines developed indigenously. As a result, it will be able to provide new drug formulations and improved healthcare treatments to Indian patients. But it may be possible due to amended patent Act 2005 there are an adverse effect on availability of medicines for the common man. As per the study on amended patent Act 2005 and ease of use of medicines to common man there are commonly adverse effects in the form of high, moderate or low way. Research indicates 60% of the total says that there is moderate percentage of patent’s adverse effect on availability for common man. The implication which comes out from this analysis is that patent Act has adverse effect on availability of medicines to common man.

19. An innovative industry in India can get competitive advantage in the market if it develops the necessary expertise and skills in developing and manufacturing new products, which are patented. For example, the advantage of a three year excise duty exemption or exemption from Drugs Price Control Order may translate into reserves income which may offset the cost towards R&D (8). In order to promote R&D and innovation in Indian industries, Government of India provides a number of fiscal incentives and support measures to industries.

8-R Saha, 2010, Management of Intellectual Property Rights in India, Adviser, Department of Science and Technology and Director, Patent Facilitating Centre, Technology Information, Forecasting and Assessment Council, New Delhi.
As per the research, for suggesting ways or strategies to make patented drug affordable to common man includes Government subsidy, NGO support, tax exemption or CSR activity of the company. As per the data collected for pharmaceutical industry- 84 % of the total thinks that government subsidy is a way or strategy to make patented drug affordable to common man, 52 % of the total thinks that NGO support is a way or strategy to make patented drug affordable to common man, 40 % of the total thinks that CSR Activity of the company is a way or strategy to make patented drug affordable to common man, Only 12 % of the total thinks that tax exemption is a way or strategy to make patented drug affordable to common man. And for Legal experts- 20 % of the total thinks that government subsidy is a way or strategy to make patented drug affordable to common man, 60 % of the total thinks that NGO support is a way or strategy to make patented drug affordable to common man, 60 % of the total thinks that CSR Activity of the company is a way or strategy to make patented drug affordable to common man, Only 40 % of the total thinks that tax exemption is a way or strategy to make patented drug affordable to common man. The implication which comes out from this analysis is that government subsidy, NGO support and CSR Activity are three different strategies respectively to make patented drug affordable to common man.

20. There is a debate on reduction in patented life of product will result in the economic treatment of the poor population. As per the research data collected for pharmaceutical industry- 84 % of the total says that reduction of patented life of product result in economic treatment. And for Legal experts- 60 % of the total says that reduction of patented life of product result in economic treatment. The implication which comes out from this analysis is reduction in patented life of product will result in the economic treatment of the poor population.

21. Patents provide the patent owner with the legal means to prevent others from making, using or selling, importing or offering for sale the new, patented drug for a limited period of time. The TRIPS-compatible 20-year term of a patent runs from the time of filing of the application. In the case of pharmaceutical products, which are subjected to lengthy procedures that verify safety and efficacy, the effective patent life may only be an average of 11 or 12 years (9). In the pharmaceutical sector it is patents that are especially crucial in appropriating the returns to R&D. This is because once the originator, breakthrough drug is produced through lengthy and relatively expensive R&D processes,
the time, capital and effort involved in copying it is often minimal. As per the data collected for suggesting expected patent life of the product, from given options 0-5 yrs, 5-10yrs, 10-15yrs or 15-19yrs. The data for pharmaceutical industry- 48 % of the total suggested expected life of the product is 5-10 years. And for Legal experts - 80 % of the total suggested expected life of the product is 5-15 years. The implication which comes out from the analysis is that deduction in patented life of product will result in the economic treatment of the poor population.

22. From the exhibit no 12- Select cases of MNC Acquisitions in Indian pharmaceutical sector and exhibit no 13 -Mergers and Acquisitions by Indian companies from exhibit, there in increase in number of merger and acquisition in Indian pharmaceutical sector.

23. with reference to E-Table 5: Patenting scenario in the post-TRIPS period, Patents granted to the selected leading pharmaceutical companies by USPTO in post-TRIPS period, E-Table 14: Patent applications filed in the last five years in India patent office and E-Table 15: Patents granted in the last five years in India patent office from exhibit, there is increase in number of patented product granted in India.

24. Time required for filling to approval is comparatively large in India. With the help of following table.

**Comparison of Drug approval process**

<table>
<thead>
<tr>
<th>Country</th>
<th>Time for Regulatory Approval of CTA/IND Application</th>
<th>Time for Evaluation of MAA</th>
<th>MAA Fee</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td>120 day</td>
<td>50 days</td>
<td>$192,400</td>
</tr>
<tr>
<td>China</td>
<td>50 days</td>
<td>180 days</td>
<td>DNA</td>
</tr>
<tr>
<td>India</td>
<td>16-18 weeks</td>
<td>8-12 weeks</td>
<td>50,000 INR</td>
</tr>
<tr>
<td>UK*</td>
<td>35 days</td>
<td>210 days</td>
<td>£254,100</td>
</tr>
<tr>
<td>USA</td>
<td>30 days</td>
<td>180 days</td>
<td>$217,787</td>
</tr>
</tbody>
</table>

By Centralized Procedure; MAA-Marketing Authorization Application, IND-Investigational New Drug, CTA-Clinical Trial Authorization, DNA-Data Not Available
25. IP scenario of Indian Pharmaceutical Industry has changed significantly since 1st January 2005. The innovation capability of the domestic pharmaceutical industry has witnessed an increase in both, research and patenting. The number of patent applications filed in the Indian Patent Office has consistently increased with annual growth averaging 9% per annum from 2005-2010. Over the entire period a total of 16459 applications in Drugs have been filed. The leading players in the Indian pharmaceutical market comprise both India-based and MNCs. Top 10 Assignees who have been granted maximum number of product patent by Indian Patent Office during 2005-2010 includes Aventis Pharmaceuticals (190 Patents) followed by Roche (146 Patents) and Novartis (136 Patents). India's leading pharmaceutical companies are competing not only in the domestic market, but also in the global market for both generic drugs and original products. India's top five pharmaceutical companies, who have been granted majority of product patents from 2005-2010 are Glaxo, CSIR, Dr. Reddy's, Cipla and Cadila. These companies manufacture a wide range of generic drugs (branded and non-branded), intermediates, and active pharmaceutical ingredients (APIs). So there is positive impact of amended patent act 2005 in India.

(Source: Patenting in the Indian Pharmaceutical Industry, http://EzineArticles.com)
9.2 Finding for doctors

To check out improvement in quality, affordability and availability in Indian medicines, the data was collected from 30 different specialty doctors. Again to compare imported medicines and indigenous medicine, doctor’s views were collected. The findings made on the base of collected data are as follows,

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 innovations, technology, and finance to benefit Indian customers (10). When the data was collected to study use of imported medicines to slow down the control of MNCs and cut down their supremacy of the Indian market. The finding is 40% of the total says that they are using imported medicine & 60% says that they are not using imported medicine. That means some Indian doctors use imported medicines.

The growth of the Indian pharmaceutical company would create new work opportunities; mainly it would provide way in both to modern technology in the field of medicines and to medicines developed indigenously. As a result, it will be able to provide new drug formulations and improved healthcare treatments to Indian patients. Due to globalization, few of the medicines are now available in Indian market. When ask to doctors about their preference over imported medicines. 57 % of the total says that they prefer imported medicines. The implication which comes out from the analysis is that doctors prefer imported medicines to some extent.

Making medicines affordable to all Indian citizens is a noble goal, but one must strive for a fair distribution of low-priced medicines to the masses and high priced modern medicines to wealthier people. Reasons behind using Indian medicines could be their quality, availability or affordability. As per the data 60 % of the total population says quality is the reason, availability and affordability carries 20 % each. The implication which comes out from the analysis is that quality is the major factor which is affecting the use of Indian medicines. Hence there is improvement in quality of medicines.

As per the research when data was collected about the preference of imported medicines over locally available parallel brands only for quality reason. It is seen that use of imported medicines over locally available medicines of the parallel brands for the quality factor is nearly giving mixed result that is 43 % of total says that quality is a factor for using those medicines and rest says quality is not an issue. The implication which comes out from the analysis is that quality is still a problem with Indian pharmaceutical company.