Chapter-8

Conclusion
Chapter VIII: Conclusion

Several conclusions emerge from the primary as well as secondary research on the strategic impact of the intellectual property rights on pharmaceutical business and public health in developing countries with special reference to India. These are presented here along with proposed business model for a pharmaceutical company incorporating the strategic ingredients required to cope up with the ever changing environment specially after implementation of new product patent regime. There has also been suggested some of the policy majors which should be taken by the government in order to mitigate the likely adverse impact of new product patent regime on the access to medicine.

8.1 FINDINGS OF THE STUDY AND SUGGESTIONS/RECOMMENDATIONS

After the exhaustive analysis of the secondary as well as the primary data collected, following is the summary of the points in light of the hypothesis to be tested:

❖ In the Pre-2005 era there was a complete ignorance for the Intellectual Property Management as a strategic tool. Strategies for major Indian Pharmaceutical companies were solely marketing driven which included the production of copy cat drugs by the process even patented in other countries. Respect for other intellectual property was comparatively less in the early scenario. Most of the strategies were marketing driven particularly focusing the domestic markets. The domestic industry was not efficient enough to
compete globally because of the prevailing strong intellectual protection in developing world.

- The awareness level for the creation and management of Intellectual Property was very low in the Pre-2005 era. It has increased gradually as India has chosen the path of becoming TRIPs compliant and introducing the product patent regime on 1st January 2005. Post 2005 the awareness level has increased particularly in the large pharma companies like Ranbaxy, Lupin, Zydus, Dr. Reddy's.....etc. These companies have created a separate IPR cell to cater the strategic needs to fulfill the IP requirements not only by Indian patent Act but also patent laws of developing countries.

- In the beginning of Product Patent Regime (after January 2005) most of the companies have realized the strategic importance of Intellectual Property Management and started investing in Research and Development with a sole purpose of creating and managing Intellectual Property.

- There was a paradigm shift in the strategy formulation as the focus has shifted from marketing to research in the Post-2005 era. Major pharmaceutical companies have started investing significantly in Research and development for synthesizing new molecules and novel process targeting the developed market such as US, Europe, Canada...etc.
Number of Patent filing by Indian Companies increased drastically in Post-2005 era which supports the fact that Indian Pharmaceutical companies formulated IPM driven strategies targeting the developed world. Therefore, Indian Phama industry has witnessed a strategic change from copying to innovation which has not only increase the competence level of industry globally but also improved the brand image of the country in light of the WTO/TRIPs implementation.

There is indeed a change in dimension in the business strategy of the Indian Pharmaceutical Industry which is now giving due importance to Intellectual Property.

In the current era Intellectual property is not only utilize as revenue generating tool but also an important strategic component in shareholder’s wealth maximinization.

Government’s role was and remains to be crucial in not only implementing the minimum standards required by WTO/TRIPs requirement without compromising public health concern but also protecting the interest of domestic industry and encouraging Indian Phama Industry to invest in Research and development for création and management of IP.
Most of the medical professionals (more than 80%) have the perception that the product patent regime would result in increase in drug prices and affordability in the long term.

Medical fraternity perceives that government should recognize the likely negative impact of the strong IPR regime on the access to medicine particularly the poor section of India and take necessary protective steps to minimize this.

Intellectual property right creates a monopolistic situation for a particular drug and therefore there is a strong overall perception that it may have negative impact on public health if appropriate steps are not being taken by the government in the long term.

Although Indian government has utilize the flexibility provided by in certain provisions in WTO/TRIPs requirement such as compulsory licensing, definition of patentability...etc. in protecting the public health concern and access to medicine, but there is still an ample scope and government should take necessary steps to minimize the adverse impact of the product patent regime.

The research has suggested some of the essential features of the government policy framework for minimizing anticipated adverse impact on public health.
without compromising the importance, providing incentive to innovation and help building competence of the domestic industry in global market by means of enforcing intellectual property rights

- The government should take measures to ensure greater transparency of investment flows and financing in basic research in development of new molecules through creation and management of intellectual property management.

- The government should expect to meet or exceed norms regarding aggregate funding of R&D. The funding could be supported through a variety of means, including purchase of commercial products from innovators, direct public funding, research mandates, or other mechanisms.

- The government should bring in policies which encourage public-private partnership particularly in basic research for developing new molecules.

- The government should interpret compulsory licensing provision to protect the access to medicine for poor section of the society.

Finally, a business model for pharmaceutical industry incorporating intellectual property as an important strategic tool which helps in profit as well as shareholders wealth maximization in the long term is described herein below via a schematic diagram.
The above diagram depicts the IP centric proposed pharma business model for an Indian company in new product patent regime. It shows how a company should invest in R & D to build IP which can not only utilized in revenue generation but also wealth maximization through selling or licensing the created IP.

Further it shows there are four different strategic dimensions which the industry would like to incorporate in the future business model to face the challenges of post-2005 era. These dimensions are investment in Basic Research in developing new molecules, creating strong IP portfolio before entering in developed market, understanding the IP scenario of respective target market before entering, creating the wealth by selling or licensing Intellectual Property created by the company, Wealth
maximization of creating and valuating intellectual property. Out of these above elements understanding the IP scenario of respective target market before entering is extremely important.

8.2 Hypothesis testing

Following is the list of hypothesis which were laid down in the beginning of the study:

1. There will be a significant impact of Intellectual Property Rights enforcement on Indian Pharmaceutical Industry.

2. The business strategy of the Indian Pharmaceutical Industry has changed in dimension by giving due importance to Intellectual Property.

3. Intellectual Property Rights enforcement in line with TRIPs agreement will have an significant impact on public health and Indian Pharmaceutical business.

4. Intellectual Property rights enforcement will have a negative impact on public health.

The forgoing in depth research study and the study finding through primary and secondary means it clearly evolves following hypothesis test results of the hypothesis listed above respectively:
1. Our hypothesis was correct that there will be a significant impact of Intellectual Property Rights enforcement on Indian Pharmaceutical Industry.

2. Our hypothesis was indeed correct that the business strategy of the Indian Pharmaceutical Industry has changed in dimension by giving due importance to Intellectual Property. Intellectual Property management has gained a lot of significance in the product patent era and there has been a strategic shift in giving importance has been witnessed wherein the IP comes ahead of business.

3. Our hypothesis was partly true for Intellectual Property Rights enforcement in line with TRIPs agreement will have a significant impact on public health and Indian Pharmaceutical business. Although pharma business was significantly impacted, the impact on public health can only be seen in the long term because in short term since the availability of off-patent molecule would be there for at least another five to seven years.

4. Our hypothesis was correct since there is a general perception that Intellectual Property rights enforcement will have a negative impact on public health. However this negative impact can be mitigated by sound policy consideration by the government and utilization of the flexibility provided in the interpretation of TRIPs requirement in such a way that enforce complete or required access to medicine specially by the poor section of the society.
8.3 Scope for future research

There are several areas related to the similar field which are untapped and there exists a tremendous scope for future research particularly the small scale pharmaceutical companies tactics for surviving in the product patent regime. A study of SME from the early 1970 wherein copying the patents was allowed and lots of SMEs have survived on that. However, in order to cope up with the changing environment and in the era where you have to respect others IP, contract manufacturing could be an important way for future growth for SMEs. Further, one can also compare and study the measures taken by the government of India Vs other developing countries e.g. Brazil for mitigating the adverse impact of new IPR regime. This study could also provide some more realistic suggestive measures to the government as well as the industry since it would be based on the case study of one country versus another and examining its experience from the Industry professionals.

Further, a yet another area of research could be the booming retail pharmaceutical segment which has gain lot of attention. The retail segment wherein the pharmaceutical companies invest in retail pharmacy has also been an important strategic element which could form an important part of strategic management in the Indian pharmaceutical business.