CHAPTER 7

SUMMARY AND CONCLUSIONS

1.1 SUMMARY & CONCLUSION

India has the highest population density in the world. A large majority of its people are poor, living in close proximity with unsanitary living conditions which is considered to be the breeding ground for many diseases in the country. They are financially weak and inaccessible to medicine and quality healthcare. Though the right to health and access to medicine is guaranteed under the constitution of India, the ability to deliver those promises has been a constant challenge to the Indian government, that too when the nation is under TRIPS-induced strong intellectual property right protection. Introduction of TRIPS agreement has replaced the Indian patent law from ‘process patent protection’ to ‘product patent protection’ for pharmaceutical inventions, which restricted Indian pharmaceutical companies to manufacture and market cost effective generic version of patented drugs by using reverse chemical process engineering method.

India may have achieved remarkable success with regards to economic growth, infrastructure development, science and technology. India has one of the sophisticated pharmaceutical industries in the world, capable of producing complex medications. Indian pharmaceutical industry with its quality and affordable drugs meets the country’s domestic demand for pharmaceuticals and protects the public health of the nation. India also exports generic drugs to more than 200 countries in the world. Despite the incredible success, the country is yet to discover a drug molecule of marketable grade in its century-old history of pharmaceuticals.

Post-2005 TRIPS agreement has changed the outlook of pharmaceutical industry in India. TRIPS regulation debarred pharmaceutical companies to produce copy-cat version of patented drugs. This has forced Indian pharmaceutical companies to realign their business strategy giving importance to research and development, particularly in the area of new drug molecule discovery to survive and grow in the industry. Alternatively, companies have to pay heavy royalty for the
license to manufacture or import patented drugs at an extremely prohibitive cost. Both of which are not considered to be viable when people are weak economically and they hold no public health insurance cover, therefore, they cannot afford to bear huge medicine cost for treatment on their own. Hence the investment in R & D and development of new drug molecules is critical to Indian pharmaceutical industry not only to resolve the issue of affordable drugs but to survive and grow in the pharmaceutical business.

It is in this context, the researcher has decided to investigate the reason for poor R & D investment and the absolute lack of new drug discovery in the country. For this study, the researcher has chosen pharmaceutical/biotech and clinical research organizations in the country to get their opinion as they are the prime mover of pharmaceutical inventions around the world including India.

The present study, therefore, makes a moderate attempt to explore and evaluate the pharmaceutical research and development in the post-2005 product patent scenario in the country with emphasize on new drug discovery and development. The study gave an attempt to identify various issues faced by the industry in their efforts towards drug discovery. The study further aimed to find out the area where government can support and cooperate to promote drug discovery in the country.

In this study, the researcher has tried to focus the objectives throughout the enquiry and the purpose has been fulfilled. The techniques used in this study, such as questionnaire and interview guide for data collection, have been found extremely useful and relevant to the point where hypotheses could be proved correct. The questionnaire helped the researcher in getting required response from industry segments like pharmaceuticals, biotech and contract research organizations across India, and interview guide has helped in getting in-depth opinions from R & D heads and clinical research investigators involved in conducting drug trials in the country. Various parameters like the nature of the organization, annual turnover have been properly presented in the samples. Other factors such as designation, education, number of years in the industry, number of years in the company and number of years in the present position have been taken into consideration for the present research to meet the objectives of the study.
The main purpose of the study was to find out as to why there was a significant lack of R & D investment from Indian pharmaceutical companies to promote new drug molecule research despite the implementation of strong product patent in the country ever since India signed the TRIPS agreement in 1995. The idea was to get input about the key parameters involved in decision making patterns of pharmaceutical research and development, thus helping the pharmaceutical companies as well as the government of India to frame appropriate strategies to promote new molecule research in the country.

The researcher, on the basis of detailed analysis, has arrived at a set of conclusion and recommendation, which are stated below.

1. The study had found that India has all required ingredients to undertake new molecule research in the country such as **finance** (GDP of over 2.2 trillion); **infrastructure** (10,563 pharmaceutical companies, 350 biotech companies, over 100 clinical research organizations, 14 research institutions, 250 dedicated R & D centres, 409 universities, 1,162 pharmacy colleges, 200 medical colleges, 191 master degree in pharmaceuticals and PhD offering colleges, 15,622 hospitals, 1,63,181 health centres, 14,000 diagnostic labs and a well-developed communication network with information technology capabilities); **humanresource** (1,55,000 researchers, 6,00,000 practising physicians, 7,37,000 nurses); **market** (a market of 1.21 billion people with a healthcare potential of US$ 68.4 billion and pharmaceutical market of US$ 13 billion excluding export). The above factors clearly indicate that India has well-developed R & D environment conducive enough to carry out successful drug discovery and development program on its own in the country.

2. The study had found that India has a sophisticated pharmaceutical industry with more than 250 companies having dedicated R & D set-up. It has world-class manufacturing facilities with 160 USFDA approved pharma manufacturing plants, the highest outside USA. The industry is capable of producing complex medication, caters almost entire domestic demand for drugs. The pharmaceutical R & D is very active in India as it accounts almost one third of total drug master files (DMFs) and highest number of abbreviated new drug applications
(ANDAs) filed in the US. India exports quality generic drugs to more than 200 countries in the world including stringent market like US, UK and Europe. India is reputed in the world for quality drug producer at affordable cost. These parameters strongly suggest that pharmaceutical industry in India is quite capable of undertaking new drug research and development program in the country.

3. The study had found that India with its rich scientific talent and cost efficient operation can reduce the time and cost of developing new drug molecules in the world. India offers a significant cost advantage of roughly 40-60% lower than in developed countries and around 10-20% lower than emerging economies. It can employ more scientists and investigators at low cost to speed up the time taken to discover a new drug molecule. This may be one of the strong reasons that many multinational pharmaceutical companies are outsourcing their clinical trials to India. The same has been proved when researcher collected the data through questionnaire in which a whopping 100 (90.1%) out of total 111 respondents have agreed or strongly agreed to the said statement. The above factors clearly endorse the view that India has a superior advantage over the rest of the nation when it comes to discovery of new drugs in the world.

The researcher on the basis of further investigation has arrived at the following points that despite India having superior advantage, no new drug molecule invention from the lab of Indian pharmaceutical companies till date. India should put every effort to capitalize its strength and create a strong research oriented pharmaceutical industry to deliver successful drug molecules on a regular basis.

4. The study had found that none of the Indian pharmaceutical companies are financially big enough players to contribute significantly for the new drug discovery and development in the country as it shows that the average annual sales turnover of twelve leading Indian pharmaceutical companies for nine consecutive years from 2005 to 2013 is in the range between Rs. 1108 to 5094 crores, which is absolutely inadequate to develop even a single drug molecule. This indicates, in India, virtually no pharmaceutical companies are financially strong enough to invest in R & D on a sustained basis to discover new drugs.
5. The study had found that the average net profit between 2005 and 2013 for twelve leading Indian pharmaceutical companies stood at Rs. 358 crores. These figures suggest that none of the pharmaceutical companies are earning substantial profit to invest for the discovery of new drug molecules. For instance, the combined earnings of all these companies are still insufficient to discover a new drug molecule. This suggests companies in India are not financially capable to invest large sums into new drug discovery and development in the country.

6. The study had found that the combined average R & D spending between 2005 and 2013 of twelve leading Indian pharmaceutical companies stood at 8.66% (roughly US$ 3.66 billion over nine years) of their sales turnover as compared to MNCs who spends anything between 15 – 20%. For instance, Merck, USA had spent US$ 11 billion in just one year on R & D during 2010 as compared to India’s US$ 3.66 billion (8.66%) spread over a period of nine years. This suggests that Indian pharmaceutical companies although interested, are highly constrained to invest in R & D due to lower revenue and profitability.

The above observations tallied when researcher analysed the questionnaire received from 111 respondents, in which a massive 86 (77.5%) of the respondent ‘agreed’ or ‘strongly agreed’ to the statement that pharmaceutical companies in India lack adequate finance to invest large sums in to new drug research and development. To another question, 61 (84.7%) respondents out of 72 pharmaceutical companies have said that it is due to small size and operation affecting companies’ revenue and profitability resulting into low investments in new drug molecule research. Thus, it is established that there is no significant investment in R & D from Indian pharmaceutical companies to promote new drug research in the country. They have to really reach size, operation and financial volume before they think of entering to drug discovery process.

The study had also revealed certain other important factors that had direct impact on pharmaceutical research in the country as detailed below.
7. The research had found that India, for more than three decades, had followed only process patent protection, which enabled its pharmaceutical industry to master the skills of process chemistry at the expense of biology and medicinal chemistry skills required to study and undertake discovery-led drug research. This had led to poor technology and research skills in the country for basic drug research program. An overwhelming 48 (66.7%) out of 72 respondents from pharmaceutical industry has endorsed this view.

8. The research had found that India signed the TRIPS agreement with the expectation that the introduction of strong intellectual property rights will encourage inflow of FDI, transfer of technology and research skills into India by multinational pharmaceutical companies for developing new as well as drugs specific to India. However, this has not happened as expected whereas India received only a limited FDI in R & D and virtually no transfer of technology and research skills because the bulk of foreign investments into India had been for phase III clinical studies, which required limited technology and basic drug research skills. This fact has been acknowledged by a majority of the respondents 78 (70.3%) out of 111 from both pharma/biotech and clinical research industries indicating lack of technology and research skills to undertake molecular level research in the country.

9. The study had found that neither there is drug research program nor there is any new molecule in the research pipeline of Indian pharmaceutical companies barring a few. Companies who are into new drug research is entirely concentrating on lifestyle diseases of the rich merely for the reason of better financial returns while neglecting primary care diseases (AIDS, TB, and Malaria etc.) affecting a large section of poor population. This is not phenomenon confined to India, but spread the world over. It suggests that apart from lifestyle drugs, India need to develop its own drugs to treat diseases specific to tropical regions like India and other developing and least developed nations in the world.

The study had further identified the following impediments in the new drug discovery process as stated below.
10. The study had found that pharmaceutical innovation is highly time consuming and very expensive, involve various research stages in the process of drug discovery and development. Despite investing huge amount of money on new drug research, there is no guarantee that the molecule will come out to be a successful medication. The very nature of drug discovery is so risky that it has every possibility to fail at any stage of its development journey. Therefore, the long, risky and expensive R & D investment with uncertain outcomes pause serious threat to Indian pharmaceutical companies who, with their limited finance, would always prefer to avoid such high-risk high-cost area of drug development.

11. The study had found that majority of the pharmaceutical houses in India are promoter lead organizations, so their natural appetite to risk taking is extremely calculative and highly restricted to those areas where investments and threats are low at the same time returns are high and quick. So, it’s quite natural for them to avoid high-cost, high-risk segment of new drug development. However, it is found that many leading companies had realized early the importance of R & D and started investing in new drug discovery which they felt is the only way out for long term survival and growth in pharmaceutical business. But, the R & D intensity steadily start declining as companies have experienced, for the first time, that new drug discovery is lengthy, expensive and risky proposition, which mandate sustained investments to succeed at NCE level. This lull phase later on gained increased momentum that led to further lack of risk-taking ability in Indian pharmaceutical companies.

12. The study had found that strong intellectual property regulation is neither serving the country nor the pharmaceutical industry. On the contrary, it is favouring MNCs to get strong control over the markets with its new product range as well as acquisition of large Indian pharmaceutical companies, which, in effect, is killing the generic drug competition leading to rising drug price in the country – a scenario which India had gone through before 1970 product patent era and may slip into the present product patent era as well if nation do not discover new drug molecules soon.

13. The study had found that strong intellectual property regime without discovery of new drug molecules will restrict the growth of pharmaceutical industry in India. Those companies who
finds it difficult to remain relevant to the new intellectual property regime may compel to sell their stakes to MNCs, who, in turn, will take control of the generic markets in the world causing large scale price rise of medicines in the world.

14. The study had shown tremendous confidence among respondents from pharma/biotech and clinical research industry that India will gradually overcome the tough intellectual property regime in the country and will eventually become one of the top discovery nations in the world. It suggests that companies are willing to invest in R & D, but certainly requires supports from all other stake holders.

15. While India cannot go back on its commitment to TRIPS, it has to strike a balancing act between nation’s healthcare and patent protection, for which there is no option but to invest in research and development of new drug discoveries.

The contribution of this study to research front has immense value. The study provides new insights into the issue of low R & D investments in the country. It will help to identify and offer solutions to the problems faced by the industry through strong R & D participation by the government of India as this not only save pharmaceutical industry but will make newest medicine available to general public at affordable cost. To prove the objectives of the research, due importance is given to all stake holders who directly or indirectly influence the R & D climate in the country.

As stated in the first hypothesis, it is statistically proved that Indian pharmaceutical companies lacks tremendously in terms of financial resources to invest in new drug research initiatives. Although, companies are aware that R & D is the backbone of their industry, but they are unable to invest in new drug research because of scarce financial resources due to lower operational revenue and profitability. Companies have to increase their revenue, and earn more profit in order to have substantial fund allocation to meet financial requirements for research at NCE level.
The second hypothesis, it has been proved that small size and operation is limiting companies earning potentials resulting in fewer fund allocation for companies R & D activities. Hence, companies have to grow larger in size and operation to increase their business volume and cash flows for sustained funding with respect to new drug discovery. This has been adequately supported with various sub-hypothesis, each of which has been tested properly.

The third hypothesis revealed that there is no quality foreign direct investment despite implementation of strong patent rights in the country. Although it was projected that strong patent protection will bring more foreign funds to pharmaceutical R & D in India, but it has not happened as expected. This has been tested statistically on the basis of sub-hypothesis and each has been minutely studied with reference to answers received from respondents.

The fourth hypothesis, it is proved that introduction of TRIPS agreement has not encouraged pharma multinationals to move their R & D centres to India thereby acquiring the rare technology and research skills by Indians is thoroughly tested which shows there is no positive correlation between introduction of TRIPS and transfer of technology and skills as envisaged while signing the agreement.

Based on the specific hypotheses, the main hypothesis that “There is no significant R & D investment to promote new molecule research in India after 20 years into signing TRIPS agreement” has been statistically proved and justified.
1.2 RECOMMENDATIONS

India has been able to manage its medicines requirement so far with indigenous production of generic drugs whether a drug is under the patent or off the patent. Manufacturing latest drugs to treat deadly viruses affecting the population were possible in India just because it had followed only the process patent protection for pharmaceutical inventions ever since the introduction of Indian patent act 1970. This has kept the medicine price and accessibility issues under check in the country fairly a long time. The process patent act has made easy and less expensive for Indian pharmaceutical manufactures to produce the generic version of patented drugs which, in no doubt, has facilitated the nation to cater for its demand of medicine in the country.

However, the process patent act has not given any incentive for pharmaceutical companies in India to engage NCE level research to discover new drug molecules. In this process, pharmaceutical companies were left behind in the crucial area of research technology and medicinal chemistry skills required to initiate basic drug research. So, India has never ventured truly to the discovery and development of new drug molecules of commercial success. It has always been depended on drugs discovered elsewhere in the world, being copied in India by using reverse chemical process engineering methods to produce generic version of patented drugs.

In 1995, with the introduction of strong product patent protection for pharmaceutical inventions in India, pharmaceutical companies have left with only one option that to increase the level of investment in research and development and discover new drug molecules to survive and grow in the industry. The government of India has no alternative but to encourage and support its pharmaceutical industry to engage in the process of new drug discoveries. This way Indian government can ensure availability of latest drugs at affordable cost to its citizen. However, research has revealed that so far there is no significant investment and dedication to research and development to promote new drug molecules in the country after 20 years into signing TRIPS agreement by India.

Drug research and development is an expensive and lengthy process. It required huge financial investments on a sustained basis to bring out new molecules to be a successful medication in the
market. Indian pharmaceutical companies, in this context, are small in size, operation, revenue and profitability, which are real impediments for private sector companies to finance for new drug research and development program in the country.

Study discovers that Indian pharmaceutical companies, with its limited income, are unable to fund large scale investments in R & D. Therefore, it obliges government’s intervention to support investment in the field of pharmaceutical research and development to promote drug discoveries in the country.

Whatever may be the situation, government can’t afford to neglect the critical area of drug development as it severely affects the health of millions of people in the country. Keeping these in view, the following recommendations are made to help India develop a research oriented pharmaceutical industry with strong R & D culture and discovery of new drug molecules in the country.

1) Government must involve and invest to promote massive drug discovery and development in the country as healthcare is a social responsibility of the government.

2) Government should revive public sector pharmaceutical units and invests heavily in R & D to take up aggressive drug research programs in the country as the private sector invests only where there is low risk and high returns.

3) Government should take advantage of its massive infrastructure, financial power, quality human skills, and large market size and low cost of drug development to promote drug research programs through public and private sector establishments.

4) Government should encourage established universities and research institutions across the country to undertake active drug research programs to harness the essential technology and research skills in biology and medicinal chemistry critical to the development of new drugs at molecular level.
5) Government should encourage and support private sector industry by providing incentives/exemptions to undertake aggressive drug research program in the country.

6) Government should encourage and help to collaborate with reputed multinational companies within and outside India to undertake new drug research program to minimise the risk of drug failures as new drug research is a high cost – high risk process.

7) Government should encourage and support public-private-partnership (PPP) model of investments to resolve the issue of fund availability in pharmaceutical R & D in order to promote new drug research and development in the country.

8) Government should promote venture capitalists to fund pharmaceutical inventions and act as a guarantor to the investment as innovative R & D is as critical to industry as well as the economy.

9) Government should incentivise pharmaceutical innovation whether it is private or public sector initiatives.

10) Government should limit the authority and power of the national drug price control organization on drugs, except the most essential drugs, to earn greater profitability by Indian pharmaceutical companies so that they can allocate more investments to new drug research.

11) Government should act as prime investor in pharmaceutical R & D to improve drug accessibility and affordability issues of the nation as private sector is inadequate to fund drug research.

12) Government should step in and support financially to those pharmaceutical units which are genuinely engaged in research and development of new drug molecules in the country.
13) Government should encourage pharmaceutical industry and engage innovator companies to improve access through collaborative research for pharmaceutical invention instead of relying on off-patent products or using provision of compulsory licensing.

14) Government should welcome mergers and acquisitions in private sector pharmaceutical industry to create large size companies for greater revenue and profitability to leverage investments in new drug research and development program.

15) Government should initiate educational programs through universities to impart skills in biology and medicinal chemistry to develop new drugs as MNCs are reluctant to transfer technology and research skills to the country.

16) Revisit the TRIPS agreement and stress the need of the transfer of technology and research skills in order to undertake molecular level research in the country.

17) Government should encourage and earmark corporate India’s CSR funds to support institutions and universities involved in new drug discovery particularly drugs which required treating primary care diseases specific to tropical region like India.

18) Government should provide insurance facilities to improve the public healthcare that will push revenue resulting better investment in R & D by private sector pharmaceutical industry.

19) Government should levy a health cess in line with that of education cess to create a corpus fund purely for pharmaceutical invention.

20) Indian pharmaceutical companies should pay more attention to leverage the low-cost advantage and scientific skills of the nation to develop new drugs in the country.

21) Companies should take advantage of government-run hospital with clinical research facilities to be used as a centre for clinical trials to reduce overhead costs.
22) Companies should leverage India’s biotechnology capabilities that can replace the chemical synthesis products, which seems to be the future of pharmaceutical industry.

23) Companies should play a crucial role in the development of a research oriented pharmaceutical industry to improve innovation and better accessibility and healthcare to millions of people.

24) Companies should enhance their industry-academia interaction particularly in the field of innovative drug research to increase speed and reduce cost of drug development.

1.3 LIMITATION OF THE STUDY
Research & Development in pharmaceutical is a highly sensitive area to undertake any serious study, because the information which they would want to share may be considered as extremely private and confidential. The researcher, in the process of this study, had run into the following limitations with regards to:

a) R & D is a highly sensitive area and companies particularly private sector consider the information mostly confidential.

b) Lack of sufficient literature specifically on new drug molecule research from Indian pharmaceutical sector to understand about the behaviour and the extent of involvement in active drug research of new molecules.

c) TRIPS agreement is fairly a new phenomenon, so many companies are yet come in terms with its regulations.

d) Identification of companies with active R & D of new drug molecule research is cumbersome barring a few well-known companies.

e) R & D, specifically new drug molecule research, is a new concept for many Indian pharmaceutical companies; hence they lacked expertise while responding to questionnaire.

f) Even though the research had aimed at collecting maximum responses but, the data confined to only 111 respondents.
g) Precise identification of companies with active new drug molecule research is always a difficult task as there is lack of information in the public domain.

h) Selection of the respondents is another big challenge.

1.4 SCOPE FOR FUTURE RESEARCH

The respondents were mainly from listed pharmaceutical companies across India. The findings can therefore be generalized only to public listed companies. Though private pharmaceutical companies may have similar views across the board, it would be inappropriate to extend it widely across the sector.

Study also investigated the important issue of R & D investments and new drug discoveries in the country. It would be valuable to extend the investigation exclusively to those companies who are with active new drug molecule research would entail precise information, which will help in understanding their commitment towards R & D and discovery of new drugs in the country. The study has further scope with respects to:

a) The present study has only 111 companies, while researcher feels it can extended many more companies with dedicated R & D with active molecule in the pipeline.

b) A study can be undertaken with top 25 Indian pharmaceutical companies who are into active development of new drug molecules which can reveal more about the practical problems of drug research in the country.

c) An exclusive research can be conducted for companies who are into biosimilars research which has greater prospects of finding new drugs.