CHAPTER-7

Conclusion, Suggestion and Recommendations
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After analyzing the information gathered and tabulated relevant information, we can conclude that: Impact of heavy R & D expenditure incurred in last 4 years by Indian Pharmaceutical companies is positive w.r.t. annual profit after tax. So Null Hypothesis statement is tested positive and hence finally accepted.

From a predominantly bulk drug manufacturer to pharmaceutical formulators and more recently into developing novel drug delivery systems and its foray into new chemical entities, the Indian Pharmaceutical Industry is carving a niche for itself in the global village. India has become so attractive as an R&D hub not just because of cost arbitrage but value arbitrage that India offers. Skill base, knowledge, innovative capacity, reduced timeliness & costs are only a few of the advantages.

The country has adequate resources in terms of manufacturing base, scientific manpower and facilities to manufacture as well as to undertake R&D on bulk drugs. When Pharma vision evolves circa 2020, all missions must be identified which will make drug production by India first in the world with a target of 20% in total value of production in the world and global sales of drugs with the multinational companies established in the world.

To build innovative pharma in India, we need to create a conducive environment for R&D, streamlining the regulatory process to make it simple, transparent and accountable. Having a huge and rich bank of human capital is going to be critical in enabling this. Encouraging research in universities and Medical colleges, upgrading training & technical facilities, creating world-class toxicological laboratories etc can trigger economic, technological & intellectual growth. It is therefore imperative to network Government, Industry & Academia and envisage necessary support to create centers of excellence.

Finally, it is essential to have an environment where creation and protection of intellectual property is encouraged. Today's world economy is held in Intellectual property. Wealth creation requires protection of IPR and adequate patent system. As India is ushering in product patent regime by January 2005 in compliance with the TRIPS agreement, increasing the R&D base becomes one of the key options for Indian Players.
Following observations also corroborates the above findings. In a study carried out by the Confederation of Indian Industry (CII) in association with Department of Commerce, Govt. of India, it is found that pharmaceutical research will become more innovative if the industry follows a three-fold path of improving the science, improving the economics, and looking for new paradigms in research. This was stated by Dr. R. A. Mashelkar, Director General of the CSIR at the inaugural session of the conference and reiterated by Dr. Tachi Yamada, global head of research at GlaxoSmithKline, the world's second-largest pharma company.

According to Dr. Mashelkar, Conference Chairman of "Building Innovative Pharma 2004," it was being held close to January 1, 2005, when India's pharma industry will usher in a new patents regime and therefore needed to develop a new model of competitiveness based on research rather than merely competing on being the lowest cost producer.

Dr. Mashelkar said that in the pharma sector, the world's expectations from India to provide cheaper and better medicines was rising; and India had to live up to it. He proposed that for this the industry needs appropriate regulatory support, but it needs to be more confident in its capabilities to develop new molecules, to use India's advantages of trained people and lower costs in a smarter way and to cooperate with other countries like China, Brazil, Mexico, which along with India, Dr. Mashelkar classified as Innovative Developing Countries (IDCs).

However, he cautioned the industry that in addition to developing new drugs, they should ensure that these drugs are affordable and accessible to hundreds of millions of poor Indians, rather than only the rich. Dr. Mashelkar said that incorporating the knowledge of traditional medicines combined with "Intelligent Inquiry" into the vast amounts of data that the research generated would help the industry.

Ajay Piramal, Chairman of CII's Pharma Committee, said that Indian pharma companies had succeeded in building up their size, their market share, and their market capitalization in India. They now had to move to the next stage from manufacturing to R&D. He hoped that to succeed in this, the industry required that the government overhaul its regulatory environment, strengthen the office of the Drug Controller General
of India, give faster approval of clinical trials, and work with industry to improve the quality of education.

Earlier, Dr. Yamada said that the pharma industry was facing what he called the "Perfect Storm" coming from the simultaneous challenges of pricing pressures, regulatory stringency, parallel imports, and patent and patient litigation. The cost of bringing a new drug to market was expected to rise to US$1.7bn. In his presentation, Dr. Yamada outlined the way forward for the industry. He said that better science would come through using automation to speed up the preliminary search for potential new molecules; the mapping of the human genome would also faster progression from idea to therapy; using new technologies like imaging to make smaller dosage sizes.

Better economics would come through improvements in the way improving productivity of the in-house researchers, through outsourcing, and through electronic data capture to transmit data directly from patient to the analysts. A new paradigm in research was also needed—one that brought together flexible working of global R&D teams, through partnerships with pharma companies in other countries.

In this new era, Dr. Tachi Yamada forecast a bright future for India. He said that building an innovative pharma is only possible when it is done in partnership with India. This would happen as India made the transition from a low-cost competitor to a generic player to what he termed, "me-too" competitor, to an innovator and finally to global scale. However, for India to achieve its ambitions, India needed very strong protection of intellectual property rights so that it was seen as a good partner to do business with.

This study gives a greater insight into the Pharma industry w.r.t post 2005 era. According to the distributors of pharmaceuticals, before the year 2000 there was a difference in the excise duty rate for branded and generic (un-branded) drugs; which was 16% and 8% respectively. But the current excise duty charges are 16% for both branded and generic (un-branded) drugs.

This has had an effect on the price of the drugs and the branded companies have a competitive advantage over the generic brands in terms of quality as well as economics of scale. According to the new schedule 'M' implications the manufacturers have to maintain new standards of quality of work in terms of lighting, hygienic conditions, healthy atmosphere, specified space, proper handling equipment and other standards.
To, match up to these standards there would be financial constraints as there would be a need for new equipment and other implementations. This would create a situation where extra investments will be required.

There are many large companies like Ranbaxy, Sarabhai, Rolcin, that have started manufacturing generic drugs like paracetamol at cheaper rates in bulk. This has become possible because now they and small generic manufacturers both have to pay the same excise duty. Also the big companies branded products are preferred by the doctors and medical practitioners as they hold a good reputation in the market.

7.2 SUGGESTIONS & RECOMMENDATIONS

7.2.1 Suggestions Strategy related to IPR

The Pharmaceutical industry is intensely knowledge driven. Its intellectual assets are the key determinants to its competitiveness. A higher level of innovation and IPR management, coupled with strategic manufacturing and aggressive marketing will determine Indian Pharma Industry’s future. The expectation can only be realized, when the rights of the innovators are not only protected but are seen to be protected through legislation and its effective enforcement. Thus strengthening the overall Indian IPR system, and not just merely amending the IPR laws is needed in which various stakeholders such as industry, government, legislators and judiciary have to play crucial role.

7.2.2 INDUSTRY WOULD NEED TO

- Need to improve the potentials of skills required to understand, analyze and manage IPR as a means for corporate strategy.
- Explore and degenerate alliances with sources of IPR for market positioning.
- Conceptualize and treat the applications of IPRs as any other tangible property.
- Superfluous formation of a National Association of Inventors to foster inventiveness and to provide a forum for inventors to meet together and recapitalize the resources available.
7.2.3 GOVERNMENT WOULD NEED TO

Restructuring the patent offices by
- Innovating modern tools and equipments within the premises which would lead to efficient flow of internal and external information that would enhance the processing and assessing systems and office management.
- The development initiated would become the cynosure that will attract talented, qualified, trained and motivated personnel to work in these office.
- Entrusting the employees in the patent offices with apt responsibility to motivate and raise their level of confidence and
  - Enabling quick and timely grant of IPR.
  - Provide attractive fiscal incentives and strategies to develop and encourage patenting of inventions overseas.
  - Initiate massive programme for the creation of digital support systems to develop a sound foundation for knowledge management mechanisms.
  - Amend IPR laws keeping in mind the nation's well-being while fulfilling international obligations.

7.2.4 JUDICIARY AND LEGAL SYSTEM WOULD NEED TO

- Build policies and mechanisms for quick and effective clearance of legal cases.
- Structure a committee for maintaining high professional standards and provide for registration of Legal Patent Representatives.

7.2.5 S&T SYSTEM WOULD NEED TO

- Publicize the need and importance of IPR protection.
- Motivate the employees to formulate better and to the best of their potentials.
- Enhance capabilities to understand, analyse and utilize the information provided in the patents.
- Develop skills to manage and exploit IPR.
- Improve accessibility to international IPR and information databases.
- Identify and reward creativity in employees.

7.2.6 EDUCATIONAL SYSTEM WOULD NEED TO

- Formulate suitable courses on the subject of IPR and introduce these as part of curriculum at graduate and postgraduate levels.
- Develop capable Human Resource to delve into the contents of IPRs.
- Enable training to prospective IPR professionals.
- Perform regular research on IPR for its updated utilization.

7.2.7 FUTURE STRATEGIES TO FACE NEW CHALLENGES

Now that the GATT is a reality and will come into force within agreed timeframe, the Indian companies are visualising the best possible means to encounter the situation.

A two-fold strategy is being recommended to face new challenges:

(1) To strengthen R&D capabilities during the 10 year transitional period.

(2) To enter into strategic alliance with research-based companies abroad for setting up joint ventures in India or licensing in patented new Drugs.

Both the Government policy of granting automatic approval for joint ventures in which foreign investment is up to 51 percent (which is applicable to the Drug industry) and the new incentives being considered for total R&D should go a long way to encourage indigenous companies to adopt the future strategy.

The prescription for Indian Pharma industry would be that while frontline pharma companies would move up the research chain from generics to new drug delivery research and to specialty pharma space, the risk averse companies, both big and medium size, can focus on supplying APIs to global pharma companies. On the other hand, medium and smaller firms can focus on in-licensing, contract manufacturing, contract research and niche therapy focus. With the global pie significantly higher, appropriate business model and right business alliances with global and domestic pharma majors is the key for a concerted growth of domestic pharma industry.