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CONCLUSION

7.1. CONCLUSION AND POLICY SUGGESTIONS

This study analyses Indian pharmaceutical industry and tries to compare it with world pharmaceutical industry. In the process it hopes to increase awareness of the general public – investors, policy makers, managers, employees of the companies – about its current developments. Its main aim is to analyze the current situation, major challenges and the prospects of the pharmaceutical industry. Unlike many other studies it tries to make a comparative analysis of their business practices and financial results. This study has also tried to find out India’s relative position of pharmaceutical companies in the global pharmaceutical industry, as well as to reveal opportunities for further strengthening of their positions. While making detailed analysis on various factors related to pharmaceutical industry necessary data regarding marketing, export import values were obtained which were available in articles and publications. Exact figures from individual industry were mostly not available, as they would divulge their policies and future strategies.

This study clearly states the evolution of Indian Pharmaceutical industry (Chapter 2) which has been classified into three periods: The first period is prior to 1970s; the second one from 1970 to 1995; and the third period is since 1995 onwards. It can be concluded that the increase in production was more pronounced in case of formulations due to large-scale production of generics by domestic firms. Technologies for the production of several bulk drugs including antibiotics like Ampicillin, Amoxycilin, Erythromycin; anti TB drugs; anti cancer drugs were
indigenously developed. (According to table 2.2) This approach will help the country to attain self-sufficiency in case of drugs production, and enabled the country to make available essential drugs at affordable prices. Many drugs like Chloramphenicol, Metronidazole, and Ibuprofen were available in India at less than half of the then prevailing prices. Low cost and high volume production has helped the Indian drugs manufacturers in opening export channels to explore many developed as well as developing countries, which is analyzed with the help of Stuart price differentiation model. (chapter 4) Exports showed substantial growth, especially for formulations from the beginning of 1990. Since then, India has been maintaining a positive trade balance in pharmaceutical trade. (According to table 2.8)

Further this study highlights that India now has a growing and increasingly sophisticated pharma industry of its own. It is quite apparent from the growth indicators (chapter 2) Table 2.7. that it is likely to become a competitor of global pharma in some key areas, and a potential partner in others. It has considerable contract manufacturing expertise. Indian companies are among the world leaders in the production of generics and vaccines. It can be also concluded (chapter 4) the expiration of patents through 2010 is expected to fuel the growth of this sector. Also the Indian Government has made the provision of healthcare one of its key priorities.

The macro economic factors affecting the demand (chapter 3) for drugs and medicines shows that Indian pharmaceutical sector has come a long way. There has been increasing demand for quality pharmaceuticals and new medicines. My study also states the global pharma market research has been done by many companies and almost all the market reports indicates a significant growth of pharma market by
The study also concludes Indian pharmaceutical industry, with its reverse engineering skills and relatively low cost structure, is ideally placed to tap the generics market. Indian companies are climbing the value chain by moving to developed markets and from bulk drugs to formulation exports. Indian Companies are targeting opportunities arising in the regulated and unregulated markets (Table: 3.4) My study also reaffirmed the report of Prof N. Lalitha by stating that large volume of production capacities is one of the basic advantages of the Indian industry contributed by the big and small producers, resulting in close competition and relatively low prices of the drugs compared to other countries, much due to the Patent Act of 1970. Though a sizeable percentage is engaged in the production of formulations, yet the production capabilities in the research intensive bulk drugs are also increasing.

This study is concerned with identifying the key structural features of pharma industry that determines the strength of competitive forces and industry profitability. (chapter 2) It can be concluded the price regulation has restricted profitability; weak patent laws have facilitated growth in the industry. In fact, the industry has been competing on its capability of reverse-engineering patented products that are produced by foreign companies and then selling them at lower prices. The structural analysis in the (chapter 3) formulates competitive strategy. This has identified a large number of factors that can potentially have an impact on industry competition. It has a scope for further research on framework which can be used to identify rapidly what are the crucial structural features determining nature of competition in pharma industry. Augmentation of the product is very essential in branding, especially in
Indian pharma industry. In the Indian pharmaceutical industry product augmentation is a must for survival and growth of brands which has been explained (chapter 3) by pharmaceutical market (9 Ps).

Improvement in public health has remained one of the foremost policy objectives for the government of India. It is see Indian Government has been playing a proactive role in promoting the pharmaceutical sector. (Chapter 4) Price reduces after the entry of competition. Besides the competition, the relatively lower prices of cost of production, materials and skilled labour compared to other countries have resulted in the lower prices of the drugs, which is an obvious advantage for the Indian firms. With the help of Stuart’s model it has been emphasized that the there is differences in the drug prices due to income elasticity. It is concluded that the costs of R and D investment determine the total cost which with profit goals determines price. Prices determine quantity demanded and ultimately profit. Prices are set according to cost.

It can be also concluded India and other developing countries will restrict their access to the new inventions. One expected outcome, which has been vociferously pointed out in Regulatory framework (chapter 4) of the product patents in the pharma industry is the price of the medicines. In the absence of the health cover for majority of the population, prices of the drugs in the WTO regime is an issue of concern.

After understanding this differences across the countries Indian policy and regulation is studied and analysis on range of price increase is shown in the Table 4.1. We can see Indian pharmaceutical industry has witnessed tremendous growth due to favorable policy environment has been discussed (chapter 4). Increasing R&D investment has
been showing positive results in the pharmaceutical industry. The patents filed by and granted to Indian pharmaceutical companies have been increasing significantly. Indian companies have made large numbers of Drug Master Files and Abbreviated New Drug Application (ANDA) filing with US-FDA. Indian firms have comparative advantage in patent filings due to the prevalence of high intellectual base and low cost R&D. According to the Global Competitiveness Report, 2006-07 and Lalitha’s report, India got high score for the parameter on capacity for innovation. This is due to the high quality of scientific research and number of scientists and engineers available in the country.

It is determined (Appendix 2) Pharmaceutical industry is knowledge intensive and R&D investment plays a crucial role in the growth of the industry. R&D in pharmaceutical industry include directional search for solutions to existing medical problems and unmet medical requirements. In addition, pharmaceutical R&D may also be aimed at improving the existing solutions to improve the efficiency or safety of medicines. Thus, the pharmaceutical R&D may be concentrated in New Chemical Entities (NCEs), Novel Drug Delivery Systems (NDDS) or in generic products. After studying various annual reports of many companies it can be stated that research in Indian pharmaceutical firms was concentrated mainly on process engineering of bulk drugs and development of NDDS for formulations. Though research in the area of discovery of NCE has taken place, due to heavy investment required in the clinical trial phase, many companies have either licensed the molecules to players abroad or collaborated with the overseas players to conduct clinical research. However, the post-WTO patent regime introduced new challenges for the Indian pharmaceutical industry. Now the pharmaceutical companies are increasingly becoming innovative
rather than imitative. The industry is changing their R&D strategy from ‘reverse engineering’ to ‘patent driven’ research. Drug development process has been shown with the help of diagram (Fig 5.1) Chapter 5. The R and D status of Indian Pharma Industry can be seen as follows:

Fig: 6.2

![R&D Status of Indian Pharmaceutical Industry]

SOURCE: Indian Pharmaceutical Industry, ICRA, 2004

The current research programs at discovery research of the company are focused towards developing promising drug candidates in key therapeutic areas (chapter 3) such as metabolic disorder and cardiovascular indications. Other companies like Nicholas Piramal, Wockhardt, Sun Pharmaceuticals and IPCA Laboratories have also set up fully dedicated R&D centers at different places to meet the new R&D challenges. (Table 5.5) There is a increasing trend in R and D activities. Analysis shows though there was sudden fall in 2001 which again picked up in 2003-04.

In India, prior to the ‘90s, the government R&D was much higher than the private R&D (Bowander, 1998). But due to poor linkages between research laboratories and industry, utilisations of such research and research infrastructure facilities have remained at low level. The huge cost involved in patenting and subsequent fees to
make the patent protection effective during the protection term and the huge fees involved in PCT even after the subsidy provided for developing country members also may subdue the firms' enthusiasm to file patents and rather make it advantageous to sell the invention to other firms for further development. Lack of popularity of the contract research organizations is one of the reasons for the low R&D in India. In India, though a small number of firms are specifically undertaking research on contract basis, the concept of contract research organization has not yet become popular due to (a) the fear of the competitor gaining knowledge about the strategies of the said firm and (b) lack of funds from sources other than the parent firm to support new ideas in research.

The arrival of global patent regime and widespread liberalization measures at the individual country, bilateral, regional and multi-lateral levels, the issue of competitiveness is critical for understanding the strengths and weaknesses of a country in the global marketplace. The discussion in the chapter four provides strong support for the view that strategic government policies can have a long-term impact on the growth and structure of an industry.

Once it is known where a country lacked in competitiveness, then the concerned government can take facilitating policy measures to address the inadequacy. In what follows, an assessment of the competitiveness of Indian pharmaceutical industry is presented. (Table 3.3.) The inference drawn from my data is reinforcing the findings of Pradhan Jaya Prakash, 2006. The result of the consistently higher growth performance in the last two decades; the size of Indian pharmaceutical industry has
increased impressively with significant gains in the share of world pharmaceutical value-added. India's share of value-added nearly doubled between 1980 and 2000, from 3.79 per cent to become 7.11 per cent.

As in the study (chapter 4) we have emphasized that the Indian government is encouraging private and public sectors as well as foreign investors to increase investments in pharmaceutical R&D. Some positive steps taken by the Indian government in recent years include:

- Recognition of the pharmaceutical industry as a knowledge-based industry
- Reduction in interest rates for export financing
- Additional tax deductions for R&D expenses
- Reduction in the price control of pharmaceuticals

The Indian Pharma Industry (IPI), seeking to take full advantage of benefits offered by the government, has been allocating money to R&D. Its focal points are drug discovery, development of drug delivery systems, biotechnology, and bioinformatics. Companies are reevaluating their strengths and emphasizing product segments that are profitable to the company. Pharmaceutical marketing is also changing rapidly, and pharmaceutical companies are making elaborate marketing efforts. It is also stated that the IPI’s tremendous potential to produce bulk drugs will be a major asset in future drug discovery programs.

The development of the IPI would create new jobs, but 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. The development of the
pharmaceutical industry would help the Indian economy produce more national wealth. Foreign investment would increase, and Indian companies would have the opportunity to collaborate with many companies from around the world. Indirectly, developing the pharmaceutical industry would also help other industries. The study can further link with economics Walt Rostow; five stages of economic development exist. The first two stages are traditional society and the preconditions for takeoff. The third stage is economic takeoff, which then matures in the fourth stage. The fifth stage is high mass consumption. It is seen the Indian economy is most likely in the second or third stage, according to Rostow’s model, and is expected to take off. Many Indian pharmaceutical companies have taken advantage of the lucrative global generics market. India especially is well positioned in this industry with their product development skills through advance chemistry capabilities and low-cost manufacturing. With large intellectual capabilities and existing cost advantage at all levels, India has become the outsourcing capital to the U.S. and European companies in many different industries. (Chapter 6)

As in the study we concluded, generics pharmaceutical market is an attractive market for many pharmaceutical companies, especially for the Indian pharmaceutical companies who have two main competitive advantages; highly talented pool of chemists and low costs. However, with fierce competition already in place, the Indian pharmaceutical companies have to carefully select their market position within the industry and further define their specialties. With some of the larger Indian pharmaceutical companies already successful in the marketplace, the smaller company should also take advantage of their competitive advantage and enter the market. With disciplined approach to the market, and ability to plan longer term,
many smaller Indian pharmaceutical can find their niche to succeed in this lucrative market.

7.2. LIMITATIONS OF THE STUDY

Substantial data had to be collected through secondary sources only because of high degree of secrecy maintained by management of drug companies. Hence large proportion of analysis is based on data collected from secondary published sources and this has imposed several limitations on the study. In the present study we have analyzed the policies of the sample companies on the basis of certain qualitative analysis or quantitative indicators. For instance, the entire area of financial policies has been analyzed on the basis of relevant financial ratios. By following this approach what we have been able to analyze is the design of policy after its implementation and not as it was actually planned. At times there may be significant differences in the planned policy and policy as indicated by certain broad indicators of performance.

Similarly the planned objectives relating to growth and profitability may be quite different from the actual growth and profitability calculated on the basis of sale and profit figures given in the annual reports of the companies. Because of our dependence on secondary sources of data, at many places we have not been able to reflect on a particular policy area in respect of all companies. In terms of the policies that have been analyzed, it was not possible to include the research and development policy, social policy and personnel policy. Although in case of some companies the research and development expenditures were indicated in the annual reports but this information alone was not adequate to comment on this aspect of behavior.
Another limitation of this study is that it does not discuss about the influence of the parent company on the policies pursued by its subsidiary. This influence in terms of transfer of managerial skills and technical know-how could be of vital importance in case of many companies. At times, state wise or region wise study and collection of appropriate data was not possible. With given information and data we have tried to study the topic. The study is divided into seven chapters as mentioned below.

7.3. SCOPE FOR FURTHER RESEARCH

It has been seen that over the years Indian industry has grown tremendously in generic production but to retain its competitiveness research and development have to be strongly followed. Leading companies are slowly but firmly advancing in this destination since availability of funds for this activity is limited the main leanings will necessarily be on generics. Further research is required to look into various areas to know the correct trend to be followed in future.