CHAPTER 6

CONCLUSION

6.1 SUMMARY

The pharmaceutical industry is an important source of health care for billions
of population globally and in India. Hence it is a highly regulated sector. The
pharmaceutical industry is influenced by a host of practices which may primarily
relate to price regulations, insurance and reimbursements, drug procurement by
government agencies, patent laws, innovation polices, biotechnology and safety
policies, drug regulation, data protection, trademarks and use of international non-
proprietary names, drug promotion regulation, drug advertising regulation etc...
Hence competition law has to work in tandem with all such diverse set of laws,
polices and regulation governing the pharmaceutical sector.

The main focus of the present study is the analysis of the role of market
structure variables on a firm’s decision to participate in innovative activity and its
depth. The study also attempts to determine whether the same set of firm-specific,
industry-specific and product-specific factors affects the probability of undertaking
innovative activity and its intensity for the two industries.

In order to arrive at an analytical framework on the market
structure/innovative activity relationship, the available empirical literature is
examined both in the context of both developed countries and India. During this
review, it is obvious that no consensus on the results exists. An attempt is made to
explain this in terms of the innovation concept used in the studies as well as
diverging empirical procedures.
The present study is based on firm-level data, prepared by the Capitaline Database. The selection of this database is guided by its comprehensive nature and easy accessibility as compared to official data sources for the post-liberalization period. For analysing the relationship between market structure variables, the period of analysis (2009-2011) is extended to account for the dynamic policy changes taking place after liberalization.

The results of the study indicate several conclusions. Firstly, the most important critical success factors in the pharmaceutical branch are customer orientation and social responsibility. The relevance of process orientation, innovation, scale effects, and the ability to adapt to changes seems to be gaining more and more importance in the future, since the participants evaluated the importance of these success factors significantly higher for the future. Secondly, a specific set of three critical success factors can be identified for each enterprise segment by examining the “best-in-class”-companies. Thirdly, companies that focus on less critical success factors are more successful. Different combinations that fit best to different company segments are identified. Finally, for each company segment strategic directions of impact are derived from the study results.

The study has examined issues concerning working of pharmaceutical sector both from a horizontal and vertical point of view. It should not be lost sight of the fact that the pharmaceutical sector in India has grown out of policy patronage adopted since 1970s. The most important policies decisions were to limit the grant of patent only to process and not to products and the drug policy of 1970. Subsequent to this pharmaceutical prices came to be regulated through the Drug Price Control Orders which have been amended from time to time. The pharmaceutical industry is currently divided in to a three tier structure. Large MNCs operate as originator drug companies and generic companies along with large Indian generic companies. Medium and small scale industries are also engaged in production of branded generics and contract manufacturing related activities. Much of the units in small scale sector are engaged in production of generic-generic
medicines. India is the 4th largest manufacturer of pharmaceutical products and it ranks 14th in terms of value. Indian generic export have shown a steady increase since 1990’s and are a major supplier of generic drugs to both developed and developing countries. At the same time generic price competition offered by Indian companies has been globally recognised.

The study has examined market shares of top companies based on sales. It is noted that sales are largely driven by nature, operation and brand of the firm. While there is primafacie no evidence for such market shares having been gained through direct exercise of market power, it is evident that in the pharmaceutical industry passive market power and information asymmetries can lead to higher market shares.

6.2 Validation of Results

The questionnaire study as part of the research project had the target, to create an overview of the market structure pharmaceutical companies. Based on the results of the descriptive analysis it can be noted first that the target group has been addressed so that the participating companies constitute a representative group that allows drawing conclusions on the pharmaceutical companies. Accordingly, some significant differences between the meanings and levels of skills for different types of companies can be identified. Particularly interesting appears the fact that innovation could be determined as the competence with the strongest importance which will increase in the future.

The study of critical success factors as coverage of enterprise-type-specific relevance and the company-specific strength is of particular relevance for the research project. Very interesting is the fact that the theoretically justifiable context,
whereas focused companies are more successful, could also be demonstrated empirically for the sample.

6.3 LIMITATIONS

The present study has a few limitations, which need to be acknowledged.

1. The wide-scope of the variables studied meant that the level of detail in the analysis of each one of them had to be sacrificed for time and data-collection efficiency reasons.

2. The sample of firms covered in the survey analysis was 181. Larger samples would have led to greater predictive power of the study.

3. There was a sample bias in the sense that the companies that responded to the survey were significantly larger and more international than the sample of surveyed companies, though there appears to be no response bias in terms of size effect on the extent of organizational transformation in the responding companies.

4. The survey responses were based on self-reporting’s, which introduces its own bias. While objective measures for many of the organizational variables were unavailable to the present study, future researchers could try to overcome this shortcoming.
6.4 **CHALLENGES**

1. **Failure of the new patent system:** Prerequisites associated with Sec 3(d) of the Patent (Amendment) Act 2005 restrict the copyright of an existing drug. Moreover, mandatory licensing permits Indian companies to keep producing generics of copyright products for overseas selling to underdeveloped nations.

2. **Lack of proper infrastructure:** Issues associated with regular power cuts and lack of suitable transport infrastructure will decelerate the expansion of the sector.

3. **Inadequate funds:** Restricted funding from FIs, venture capitalists and the government may decelerate the expansion of the biotechnology sector in India.

4. **Regulatory impediments:** Rising due to meticulousness and conformity with product standards leads to high costs and interruption in the launch of new products.

5. **Severe competition:** Low margins and restricted capital to assist R&D is the result of intense pricing competition among local producers. This rivalry will further deepen from the joining in of the big drug companies in the Indian market to control the cost benefit and large reserve sources.

6.5 **RECOMMENDATIONS**

Policy recommendations for action at the Indian level that follow from the analysis are as listed below:

1. The Indian government needs to invest extensively in strengthening existing institutions such as local competition enforcement agencies, patent examiners, an informed judiciary which is more attuned to the public health
and local industry needs in a country like India, and price control mechanisms in order to promote access to medicines in the local market and other LDCs.

2. The patent regime incorporates several major TRIPS flexibilities. But it also contains several provisions that are open to different sets of interpretations and therefore whether all the flexibilities that are permissible under the TRIPS Agreement will be used by India in day-to-day practice or not, is still much in the open.

3. Other rules affecting the industry, such as those on data exclusivity should be enacted only after taking into consideration the interests of the generics industry and the scope of its impact. If the generic industry in India is curbed further, a large amount of cheap supply of medicines at very competitive prices will be seriously affected.

4. The government should apart from providing an expedient administrative procedure for the implementation of Section 92(A) of the Act, create a higher level of awareness amongst the local industry on the option of compulsory licensing to supply to other least developed countries. This could result in a more conducive attitude amongst the firms to deal with requests from other least developed countries in future.

5. The government should, in a concerted effort with the industry, plan ways in which to reduce bottlenecks to pharmaceutical R&D in the local Indian context. These will be very helpful to aid the industry to devise and implement strategies for survival.

6. The government should strengthen its activities in terms of identifying key areas where there is potential (for example, clinical research) and invest in development of these facilities systematically.
7. Promotion of R&D into diseases of the developing world, as the survey goes on to show, will remain a public good problem, irrespective of the capacities in the pharmaceutical sectors in developing countries. The government of India (either singularly or in collaboration with other governments in developing countries) should initiate more public R&D programmes that utilize the strengths of the Indian industry to find cures for neglected diseases. There are already several such programmes in which the Government of India is involved. This recommendation is to augment these efforts further.
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