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1.1 Introduction

Though the pharmaceutical industry remains one of the most profitable and stable industries, several macro-level variables are influencing fundamental changes in the industry structure. The chief variables are: the increasing role of substitutes-generic pharmaceuticals threat; the threat of new entrants-emergence of bio-pharmaceuticals and genome revolution; increasing buyer power-power of third party payers, government buyers, and health maintenance organizations, and increased health awareness amongst patients and changing suppliers-enhanced outsourcing in manufacturing and R&D. Additionally, changing world demographics (increasing graying of world population), stringent regulatory environment, declining R&D productivity, worldwide compliance of General Agreements on Tariffs and Trade (GATT) and Trade Related Intellectual Property Rights (TRIPS) and emergence of e-pharmaceuticals is likely to reshape the industry.

The value of the global pharmaceutical market is expected to grow 4 to 6 percent in 2010, exceeding $825 billion, led by stronger near-term growth in the US market, according to a forecast by IMS Health. In addition, the company raised its expectations for five-year growth in the international prescription drug market by one percentage point in its latest forecast, to between 4 and 7 percent per year through
2013, "partly due to the stronger demand being experienced in 2009."\(^1\)

1.2 International Pharmaceutical Industry

The multinational pharmaceutical industry is unique in that it is largely organized and operated by privately owned companies, created to realize profits for its stockholders. The industry deals in life-and-death issues, and its products not only relieve illness, but can often improve the quality of life. In addition to the life-giving aspect, the composition of products usually consists of highly toxic chemicals, which, when mixed indiscriminately, can cause serious health problems and even death. Since public health is of concern to all governments, the pharmaceutical industry is heavily regulated on the national level worldwide. This regulation takes the form of prior approval in order to market a new product and in some countries the establishment of a price for the product.

At the global level, the pharmaceutical industry is divided into two kinds of firms, the Innovative firm and the generic firm (producer of generic drugs).

\(^1\) http://www.imshealth.com/portal/site/imshealth/menuitem,october 7,2009

The first, the innovative or patent-protected firms, rely heavily on patent protection. These firms believe that in order to carry out the intensive research required to produce new products, patent protection is essential. As a result of the extensive research and cost to produce a patent-protected drug, patent-protected firms tend to be located in highly developed and industrialized countries. Not all research efforts are successful. It is only a small fraction that reaches the market. It is through the period of exclusivity provided under the patent, generally twenty years from the date of filing, that the firm can recoup its research and development (R&D) costs to continue new and innovative research. Actually, the effective term of the patents is more like 14-15 years due to delays in the patent approval process and in obtaining rights to market the new drug. These firms are dependent on patent protection and are reluctant to introduce new products in countries that deny such protection. Because the patent grant provides a period of exclusivity, the patent owning firm can establish a higher price for the product since no competition is allowed. This is true when patent protection exists, even in countries where the government regulates the price of the product.

The second, the generic pharmaceutical firm, manufactures and markets pharmaceutical products that are not
subject to patent protection. In countries with patent protection, generic firms come into their own at the expiration of the patent. At such time, the technology is in the public domain (as referred in US) and anyone is free to manufacture the product. Generic products are subject to some government regulation before any sales can be made, (in the United States the manufacturer must demonstrate to the satisfaction of the Food & Drug Administration (FDA) that the generic version is the bio-chemical equivalent of the patented product).

Generally speaking, once the generic drug appears on the market, it will be available at a lower cost than the original patented version. Often, several generic products will appear on the market within the same timeframe, thus causing even larger price reductions. In countries lacking pharmaceutical patent protection, the entire industry could be said to be generic. In such countries, the profile of the industry will include firms that may manufacture, internationally used drugs, which are in the public domain in the country of origin. In such a case, the industry is similar to the generic firm in the United States. However, many firms in countries that do not recognize pharmaceutical product patents manufacture products that are still under patent protection in the country of origin, thus diluting the value of the patent. This practice is viewed negatively by the country providing patent protection and is often characterized as piracy or counterfeiting by the firm whose patent is not being
recognized. Yet it is perfectly legitimate and legal in the country where the drug is being manufactured and sold.

Both the patent-protected and generic industries are patent-driven. The former rely on strong, effective patent laws and extending patent protection as long as possible both at home and abroad. The generic industry (as in the United States) is eager to begin manufacturing the generic equivalent as quickly as possible so as to gain market access at the earliest time, and is obviously opposed to any form of patent term extension. Each, however, is convinced that it is providing unique service to the public: the patent-protected firm by introducing the newest, breakthrough product and the generic firm by offering quality products at lower costs.

The Pharmaceutical Research Manufacturers Association (PHRMA) located in Washington, DC, is a trade association representing the interests of the innovative or patent-protected manufacturers of pharmaceuticals. Its mission: is to help the research-based pharmaceutical industry successfully meet its goal of discovering, developing, and bringing to market medicines to improve human health, patient satisfaction, and the quality of life around the world, as well as to reduce the overall cost of health care. Currently, “PHRMA” membership consists of substantially all of the patent-protected pharmaceutical firms. A partial list of names and addresses of
PHRMA member firms is provided in Exhibit 1. High on PHRMA’s agenda is obtaining strong and effective patent protection in all countries where its members are active. In addition, PHRMA addresses such concerns as price control and generic competition, issues that could adversely affect the interests of its members domestically and abroad. On a global level, PHRMA keeps careful track of the availability and effectiveness of intellectual property protection throughout the world. Annually, it notifies the United States Trade Representative (USTR) of the outcome of its review and makes recommendations as to what action the United States government should take against countries believed to be deficient in meeting international standards.

For years, India had been a problem country and high on PHRMA’s list because of failure to grant pharmaceutical product patents. As a result of the intellectual property environment in India, PHRMA members tended to be low profile, and principally marketed drugs no longer protected by patent, as opposed to their premier, innovative products.

Global pharmaceutical firms watched developments in India closely after 1991. The situation in India may be changing. In 1995 India became a signatory of the Uruguay Round Agreement, Trade Related Aspects of Intellectual Property (TRIPS), and thereby showing willingness to accept one of its requirements, the issuance
of pharmaceutical product patents. India’s adherence to TRIPS would become effective in 2005 as a result of a provision of the Agreement granting developing countries an additional period if it is required “to extend patent protection to areas of technology not so protectable in its territory.” In an important first step towards full compliance, India acceded to the Paris Convention for Protection of Industrial Property (Paris Convention) and the Patent Co-operation Treaty (PCT). Adherence to the Paris Convention is required under the TRIPS, and membership in the PCT provided instant benefits to Indian firms seeking multiple country patent protection. As the year 2005 approached, the global pharmaceutical industry watched India with new interest and the Indian pharmaceutical industry positioned itself, for the first time, to face international competition.2

1.3 Indian Pharmaceutical Industry

“The Indian pharmaceutical industry is a success story providing employment for millions and ensuring that essential drugs at affordable prices are available to the vast population of this sub-continent.” - Richard Gerster

The **Indian Pharmaceutical Industry** today is in the front rank of India’s science-based industries with wide ranging

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capabilities in the complex field of drug manufacture and technology. It ranks very high in the third world, in terms of technology, quality and range of medicines manufactured. From simple headache pills to sophisticated antibiotics and complex cardiac compounds, almost every type of medicine is now made indigenously. Playing a key role in promoting and sustaining development in the vital field of medicines,

**Indian Pharma Industry** boasts of quality producers and many units approved by regulatory authorities in USA and UK. International companies associated with this sector have stimulated, assisted and spearheaded this dynamic development in the past 53 years and helped to put India on the pharmaceutical map of the world.

The evolution and growth of the Indian pharmaceutical industry has been largely driven by regulatory forces — the DPCO (Drug Price Control Order), which regulated the prices of bulk drugs and formulations, and the Indian Patent Act, which granted process patents but not product patents. Pharmaceutical Business came into existence in India in the year 1901 when Bengal Chemicals and Pharmaceutical Company started its production in Calcutta. Since then there is no looking back and today India has become one of the leading pharmaceutical products manufacturing nation. This fact would become evident by the current scenario of the industry, wherein it is not just meeting the increasing demand of the huge population of the country, but also exporting the products to
other developing and developed countries of the world including the USA. Starting from the humble beginning of repacking imported raw materials; the Indian pharmaceutical industry has graduated to become a net foreign exchange earner, making its presence felt in the global pharmaceutical arena. India is the fourth largest producer of bulk drugs and formulations in terms of volumes though not in terms of value. Indian drugs have the distinction of being the most competitive in terms of price causing much heartburn to the MNCs. In spite of the impressive statistics of the Indian pharmaceutical industry, our per capita consumption of drugs is one of the lowest in the world and only 30 per cent of the population mostly in the urban areas has access to modern drugs. The shortcomings of the Indian pharmaceutical industry are in the fields of R&D and new drug discovery.

1.4 Strengths Of Indian Pharmaceutical Industry

During the current year 2009-10, Pharma was among the few sectors that managed to expand its revenues despite global recession and financial crises. Strong domestic demand, growing preference for generics worldwide and favourable rupee-dollar exchange rate helped the Indian Pharmaceutical sector. Aggregate income of the drugs and pharmaceuticals companies for the first two quarters of the current year grew by 13 per cent and 7.8 percent respectively as compared to previous year. As per Centre for
Monitoring Indian Economy (CMIE) the estimated growth in aggregate income for the next two quarters is 9.5 per cent and 10.2 percent respectively.\(^3\)

The Indian pharmaceuticals industry has grown from a mere US$ 0.32 billion turnover in 1980 to approximately US$ 21.26 billion in 2009-10. The country now ranks 3rd in terms of volume of production (10% of global share) and 14th largest by value.\(^4\)

### 1.1 Growth of Indian Pharmaceutical Industry from 2002-03 to 2008-09 are given in table below.\(^5\)

<table>
<thead>
<tr>
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<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Domestic Market</td>
<td>30365</td>
<td>32575</td>
<td>34128</td>
<td>39989</td>
<td>45367</td>
<td>50946</td>
<td>55454</td>
</tr>
<tr>
<td>Exports</td>
<td>12826</td>
<td>15213</td>
<td>17857</td>
<td>22216</td>
<td>24942</td>
<td>30760</td>
<td>38433</td>
</tr>
<tr>
<td>Imports</td>
<td>2865</td>
<td>2956</td>
<td>3139</td>
<td>4515</td>
<td>5867</td>
<td>6734</td>
<td>8552</td>
</tr>
<tr>
<td>Total Market Size</td>
<td>42326</td>
<td>47332</td>
<td>52029</td>
<td>62566</td>
<td>68442</td>
<td>78610</td>
<td>89335</td>
</tr>
</tbody>
</table>

**Exports**


\(^4\) Ibid;

\(^5\) Ibid;
India currently exports drug intermediates, Active Pharmaceutical Ingredients (APIs), Finished Dosage Formulations (FDFs), Bio-Pharmaceuticals, Clinical Services to various parts of the world.

1.2 Export of drugs and pharmaceuticals from 2002-03 to 2008-09 are given in table below:

<table>
<thead>
<tr>
<th>Year</th>
<th>Exports</th>
<th>Growth %</th>
</tr>
</thead>
<tbody>
<tr>
<td>2002-03</td>
<td>12826</td>
<td></td>
</tr>
<tr>
<td>2003-04</td>
<td>15213</td>
<td>18.61</td>
</tr>
<tr>
<td>2004-05</td>
<td>17857</td>
<td>17.38</td>
</tr>
<tr>
<td>2005-06</td>
<td>22216</td>
<td>24.41</td>
</tr>
<tr>
<td>2006-07</td>
<td>24942</td>
<td>12.27</td>
</tr>
<tr>
<td>2007-08</td>
<td>30760</td>
<td>23.33</td>
</tr>
<tr>
<td>2008-09</td>
<td>38433</td>
<td>24.94</td>
</tr>
</tbody>
</table>

The domestic Pharma Industry

The domestic Pharma Industry has recently achieved some historic milestones through a leadership position and global presence as a world class cost effective generic drugs' manufacturer of AIDS medicines. Many Indian companies are part of an agreement where major AIDS drugs based on Lamivudine, Stavudine, Zidovudine, Nevirapine will be supplied to Mozambique, Rwanda, South Africa and Tanzania which have about 33% of all people living with AIDS in Africa. Yet another US Scheme envisages

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sourcing Anti Retrovirals from some Indian companies whose products are already US FDA approved.

Many Indian companies maintain highest standards in Purity, Stability and International Safety, Health and Environmental (SHE) protection in production and supply of bulk drugs even to some innovator companies. This speaks of the high quality standards maintained by a large number of Indian Pharma companies as these bulk actives are used by the buyer companies in manufacture of dosage forms which are again subjected to stringent assessment by various regulatory authorities in the importing countries. More of Indian companies are now seeking regulatory approvals in USA in specialized segments like Anti-infectives, Cardiovasculars, CNS group. Along with Brazil & PR China, India has carved a niche for itself by being a top generic Pharma player.

Increasing number of Indian pharmaceutical companies have been getting international regulatory approvals for their plants from agencies like USFDA (USA), MHRA (UK), TGA (Australia), MCC (South Africa), Health Canada etc. India has the largest number of USFDA - approved plants for generic manufacture. Considering that the pharmaceutical industry involves sophisticated technology and stringent "Good Manufacturing Practice (GMP) requirements, major share of Indian Pharma exports going to highly developed western countries bears testimony to not only the excellent quality of Indian pharmaceuticals but also its price competitiveness.
More than 50% share of exports is by way of dosage forms. Indian companies are now seeking more Abbreviated New Drug Approvals (ANDAs) in USA in specialized segments like anti-infective, cardiovascular and central nervous system groups.

**Exports**

The Domestic pharma sector has been expanding and has is estimated at US$ 11.72 billion (Rs 55454 crore) in 2008-09 from US$ 6.88 billion (Rs 32575 crore) in 2003-04. Indian exports are destined to various countries around the globe including highly regulated markets of USA, Europe, Japan and Australia.\(^7\)

**1.3 Export of domestic drugs and pharmaceuticals from 2003-04 to 2008-09 are given in table below:**\(^8\)

<table>
<thead>
<tr>
<th>S.No.</th>
<th>Domestic Indian market (figure in Rs crore)</th>
<th>Growth Rate (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2003-04</td>
<td>32575</td>
<td>7.28</td>
</tr>
<tr>
<td>2004-05</td>
<td>34128</td>
<td>4.77</td>
</tr>
<tr>
<td>2005-06</td>
<td>39989</td>
<td>17.17</td>
</tr>
<tr>
<td>2006-07</td>
<td>45367</td>
<td>13.45</td>
</tr>
<tr>
<td>2007-08</td>
<td>50946</td>
<td>12.30</td>
</tr>
</tbody>
</table>

\(^7\) “Annual report”; Department of pharmaceuticals, Govt. of India; New Delhi; 2009-10 http://www.indiainbusiness.nic.in/industry-infrastructure/industrial-sectors/drug-pharma.htm Accessed : 26 July 2011 3:21 P.m.

\(^8\) Ibid;
1.5 Achievements of Indian Pharmaceutical Industry

The Department had played a pivotal role in the formation of Pharmexcil consequent to the recommendation from 9th Five Year Annual Plan Working Group Report on Drugs and Pharmaceuticals. In the light of this, the Department constantly interacts with Pharmexcil in their work areas. The role of Pharmexcil is for facilitation of exports of Drugs, Pharmaceuticals, Biotechnology products, Herbal medicines and Diagnostics, to name a few. It is authorized to issue Registration-cum-Membership Certificate (RCMC) which is one of the requirements for the importers and exporters of commodities. In addition to this, Pharmexcil is concerned with giving export thrust to the various products through visits of delegations to various markets abroad, organizing of seminars, workshops and exhibitions. As a major area of work, Pharmexcil also holds Buyers/Sellers meets and compiles detailed data base on pharma exports and problems in exporting pharma group products of Pharmaceuticals.

Key Factors of Pharma Sector

- Low cost of innovation/Manufacturing/Capex
costs/expenditure to run a CGMP compliance facility.

- Low cost scientific pool on shop floor leading to high quality documentation.
- Proven track record in design of high tech manufacturing facilities.
- Excellent regulatory compliance capabilities for operating these assets.
- Recent success track record in circumventing API/formulation patents.
- About 95% of the domestic requirement being met through domestic production.
- India is regarded as a high-quality and skilled producer in the world.
- It is not only an API and formulation manufacturing base, but also as an emerging hub for: Contract research Bio-technology Clinical trials and Clinical data management.
- The country has the distinction of providing quality healthcare at affordable prices.

1.4 Top 20 destinations of Indian Pharma products during 2008-09⁹

<table>
<thead>
<tr>
<th>S. No.</th>
<th>Importing country</th>
<th>2008-09 (figure in Rs Crore)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>USA</td>
<td>7103.27</td>
</tr>
<tr>
<td>2</td>
<td>Russia</td>
<td>1519.20</td>
</tr>
<tr>
<td>3</td>
<td>Germany</td>
<td>1441.87</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Country</th>
<th>R&amp;D Spending</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Austria</td>
<td>1417.15</td>
</tr>
<tr>
<td>2</td>
<td>UK</td>
<td>1233.09</td>
</tr>
<tr>
<td>3</td>
<td>South Africa</td>
<td>1126.75</td>
</tr>
<tr>
<td>4</td>
<td>Canada</td>
<td>1090.43</td>
</tr>
<tr>
<td>5</td>
<td>Brazil</td>
<td>1018.89</td>
</tr>
<tr>
<td>6</td>
<td>Nigeria</td>
<td>1001.74</td>
</tr>
<tr>
<td>7</td>
<td>Ukraine</td>
<td>687.22</td>
</tr>
<tr>
<td>8</td>
<td>Israel</td>
<td>686.22</td>
</tr>
<tr>
<td>9</td>
<td>Netherlands</td>
<td>669.98</td>
</tr>
<tr>
<td>10</td>
<td>Spain</td>
<td>620.02</td>
</tr>
<tr>
<td>11</td>
<td>Turkey</td>
<td>614.20</td>
</tr>
<tr>
<td>12</td>
<td>China</td>
<td>561.53</td>
</tr>
<tr>
<td>13</td>
<td>Kenya</td>
<td>543.86</td>
</tr>
<tr>
<td>14</td>
<td>Vietnam</td>
<td>536.62</td>
</tr>
<tr>
<td>15</td>
<td>Belgium</td>
<td>520.90</td>
</tr>
<tr>
<td>16</td>
<td>Italy</td>
<td>57.85</td>
</tr>
<tr>
<td>17</td>
<td>Mexico</td>
<td>501.54</td>
</tr>
</tbody>
</table>

**Research and Development**

In no other Industry segment innovative R&D is as critical as in Pharma industry. Here, the New Drug Discovery Research (NDDR) has to keep pace with the emerging pattern of diseases as well as responses in managing existing diseases where target organisms are becoming resistant to existing drugs. The NDDR is also an expensive activity. It is encouraging to observe that at least 10 Indian companies are into new drug discovery in the areas of infections, metabolic disorders like diabetes, inflammation, respiratory, obesity & cancer. Most of these companies have increased their R&D spending to over 5% of their respective sales.
turnovers. There is notable success from some Indian companies in out licensing new molecules in the asthma and diabetes segments to foreign companies. Introduction of Product Patent for Pharmaceuticals is an important feature for Indian Pharma R&D scenario. This has boosted the confidence of MNC Pharma companies in India where a number of western Pharma companies have already R&D collaborations with Indian Pharma companies in the field of NDDR. Some Indian companies have also got US-FDA approvals for their new molecules as Innovative New Drugs (IND).

Western Pharma companies have recognized the attractiveness of India as a R&D outsourcing destination due to low cost scientific manpower, excellent infrastructure, top quality with capability to conduct modern research under GLP, GCP guidelines. Many of them have set up independent R&D centres in India.

Clinical Trials to establish safety and efficacy of drugs constitute nearly 70% of R&D costs. Considering the low cost of Research and Development in India, several MNC Pharma companies as well as global Clinical Research Organizations are increasingly making India a clinical research hub. In conclusion new drug discovery in India has made a promising start wherein at least five to six potential candidates in the areas of Malaria, Obesity, Cancer, Diabetes and Infections are likely to reach Phase II clinical trials.

**Contract Manufacturing**
Many global pharmaceutical majors are looking to outsource manufacturing from Indian companies, which enjoy much lower costs (both capital and recurring) than their western counterparts. Many Indian companies have made their plants cGMP compliant and India is also having the largest number of USFDA-approved plants outside USA.

Indian companies are proving to be better at developing Active Pharmaceutical Ingredients (APIs) than their competitors from target markets and that too with non-infringing processes. Indian drugs are either entering in to strategic alliances with large generic companies in the world of off-patent molecules or entering in to contract manufacturing agreements with innovator companies for supplying complex under-patent molecules.

Some of the companies like Dishman Pharma, Divis Labs and Matrix Labs have been undertaking contract jobs for MNCs in the US and Europe. Even Shasun Chemicals, Strides Arcolabs, Jubilant Organosys, Orchid Pharmaceuticals and many other large Indian companies started undertaking contract manufacturing of APIs as part of their additional revenue stream. Top MNCs like Pfizer, Merck, GSK, Sanofi Aventis, Novartis, Teva etc. are largely depending on Indian companies for many of their APIs and intermediates.

**International Co-operation/Export Promotion**
An important focus area for the Department of Pharmaceuticals is the promotion of Indian pharma exports. The Department participated in the following International Cooperation events during 2009-10:

- The fourth meeting of the India-EU Joint Working Group on Pharmaceuticals and Biotechnology was held in the month (September, 2009) at New Delhi under the Co-chairmanship of Shri Arun Jha, Joint Secretary (Pharma).
- Participation in the BIO 2009, held in May, 2009 in USA.
- Participation in the India-USA HTCG, held in May, 2009 on the margins of BIO 2009.
- Organization of Brand India-Indian Pharma Expo in Myanmar from 12-14 June, 2009.
- Participation in the 45th Annual Meeting of the DIA, held in June 2009 in San Diego, USA.
- Organization of India Pharma Summit 2009, on 30th September 2009 in Mumbai and celebration of India Day on 1st December, 2009 and CPhl 2009, held from 1st to 3rd December, 2009.
- Participation in the US-India Bio Pharma and Healthcare Summit which was held in Boston on 14-15 May, 2009.
- Visit of Nigerian delegation led by DG, National Agency for Food & Drug Administration & Control to India in connection with wrong labeling of generic drugs as being of Indian origin even while not being actually made in India.

- Department of Pharmaceuticals also provided financial assistance for following activities, for promotion and development of the sector:

  - Publishing of advertisement in Kazakh journal "Ghazab Hindustan" for promotion of Indian Pharma products in Kazakhstan.

  - Conducting of Pre-feasibility study for development of A Greenfield Project for Medical Devices Cluster in Gujarat and a Brownfield Project for Bulk Drugs Cluster in Andhra Pradesh.

  - Presentation of Patent Awards on the eve of Indo-Africa Pharma Business Meet.

  - Preparation of Film on Pharma Industry in India.

1.6 International Pharmaceutical Industry, CHINA and INDIA
China has got the largest population in the world, ranking second among the producers of pharmaceutical ingredients and first in the production of Penicillin, Cephalosporin, DoxycyclineHC1, Terramycin, and Vitamin C in the world.

The Chinese pharmaceutical market is currently the 7th largest in the world (worth $14 bn) and by the year 2010, it is estimated to be the 5th largest. Considering the Chinese economic boom and the pace with which the country is growing, it is surely a market which cannot be ignored. The high incidence of diseases in China on account of the consistently changing lifestyles and consumption patterns, and ultimately, the demands for drugs are also rising consistently.

The economical manufacturing and operational costs add to the attractiveness of the Chinese market. Globalization being the primary motive of Indian firms, China offers huge opportunities to tap other markets world over. The increasingly congenial trade ties between India and China have also fueled investments by Indian companies in China. The pharmaceutical industries play an important role in the economic development of both the countries. Thus the Indian pharmaceutical players are making the most of these opportunities and are entering China. However, the Chinese pharmaceutical market is unique in many ways and the Indian
players have to play their cards with utmost care to sustain their business in the long term.

1.7 Understanding the Chinese Pharmaceutical Market

A variety of factors make the Chinese pharmaceutical market an enticing option. The pharmaceutical industry in China is one of the fastest growing industries with an average annual growth of 17.7%. According to a survey by the Boston Consultancy Group (BCG), the Chinese pharmaceutical market is likely to emerge as the fifth largest market globally, with revenues over of over $24. Approximately, 70% of the Chinese market (6800 firms) is controlled by the domestic firms (in terms of value). There are about 1700 sino-foreign joint ventures, with an investment of around $2 bn, according to IMS Health, a global source for pharmaceutical market intelligence. These foreign companies include some of the world’s leading players. The subsidiaries set up by top players like GlaxoSmithKline, Novartis, Pfizer, and Roche, are among the top 10 marketing companies in China, in terms of sales.
Some of the important factors that make the Chinese market attractive are low labour costs and better infrastructure for manufacturing when compared to India. According to DFID Health Systems Resources Center, with the acceleration of patent expiries, about $60 bn worth of blockbusters will open up to legitimate generic competition in the regulated markets. It will lead to a gradual global migration of manufacturing companies to China, which has the expertise and infrastructure for low-cost generic manufacturing. As Chenthir K, CEO, Plutus Pharma Network Pvt. Ltd. Opinies, “Indian pharma companies are searching for a destination where cost of manufacturing base in China would help Indian companies to compete in generics business in regulated markets and fulfil their dreams in export of Active Pharmaceutical Ingredients (APIs) with non-infringing processes.”

Though India is becoming an R&D hub in itself, China also provides excellent opportunities for research activities. And with both the countries becoming TRIPS compliant, R&D is the key to develop new formulations for drugs. Neeraj Bharadwaj, CEO, RocSearch Ltd., a global research support service company, says, “Beyond pharma sales, China is also an attractive for clinical research services and contract manufacturing. As a low cost R&D base, with a huge pool of PhDs and scientists, and dedicated infrastructure, Indian pharma companies may also explore China
for outsourcing research and development.”

The demographic and socio-economic factors of China make its pharmaceutical market a unique proposition in itself. China is the world’s most populous country with around 1.33 billion population, which is ageing at an estimated rate of 3% per annum. The country has more than 88.1 million people aged 65 or over, more than in any other country in the world. It ranks second among the largest producers of pharmaceutical ingredients in the world and ranks first in the world in the production of important medicines like penicillin, cephalosporin, vitamin c, etc. These factors are adding attractiveness of doing business in China’s pharmaceutical market.

One of the factors typical in Chinese Pharmaceuticals is that hitherto, there have been no private clinics; doctors were available only at hospitals. Therefore, companies have to sell their products primarily through hospitals. In India, drugs are sold mainly through doctors’ recommendation and 4,00,000 medical stores. While as in China, interestingly, 85% of the drugs are sold through hospitals and for this to happen, the firms have to first register their products with concerned medical authorities in each province. This is lengthy and tiring processes for the firms. Therefore, it requires great levels of patience and commitment on part
of the venturing companies. However, this scenario is also gradually changing with the onset of economic reforms. Some private clinics and hospitals have been established in the last 3-4 years, though they are very costly for the consumers.

China is becoming a major competitor to India, especially in exports of Active Pharmaceutical Ingredients (APIs). China’s Pharmaceutical Industry ranks 7th in the world and is expected to become world’s 5th largest by 2010. China’s domestic drug sales have been estimated at about US $8 billion in 2003 and the exports are growing at 20% per annum.\(^\text{10}\)

The reasons for Chinese competitive advantage are:

The electricity costs are lower in China as compared to India. The power costs range from Rs.1.50 to 2.50 per KWH as against Indian cost of Rs.4.5 to 6.0 per KWH. Labour charges are 40% lower in China than India. More favourable labour policies like policy of hire and fire in China On the whole China is more cost competitive in manufacturing sector. China has already implemented clear intellectual property laws and data exclusivity rules that take it one step ahead of India in attracting

\(^{10}\) Kanwar K.C.; “Pharmaceutical Industry in India”; Science reporter; August 1997 p.147
foreign players. In 1992, a pact was signed with US, which heralded the Product patent regime coming in force in China.

China has established a large number of profit oriented research and development institutions, which are today independent of government funding in contrast to institutions in India, which are mostly dependant on government funding. The Chinese government provides an income tax holiday of 100 per cent for the first two winning years (profit making years) and 50 per cent for the next three years.

The companies are also allowed duty free import of capital equipment. Lower turnaround time for ships at Chinese ports make it conducive as a base for exports.

1.8 Indian Ventures in China

A lot of Indian pharmaceutical companies have ventures into China and most of them exist as joint ventures with Chinese Pharmaceutical companies. The joint ventures are necessary considering the complex and fast changing nature of the market. Indian companies are leveraging china as an effective platform to make their exports activities more efficient. Initially companies enter china and gain market share, then companies make it as home base and finally, as manufacturing base to export globally.
Dr. Reddy’s Laboratories entered the Chinese market in the year 2000 as a joint venture between Dr. Reddy’s (51%), Canada Rotam Enterprise (47.41%), and Kunshan Double Crane Pharma Co. (1.59%). The partnership venture is known as Kunshan Rotam Reddy Pharmaceutical Co. Ltd. (KRRP), is involved in producing and repackaging bulk formulations, tablets, ointments, gels, etc. KRRP currently supplies its products to more than 100 distributors across 18 provinces. The firm registered a turnover of $9 mn during 2004-05, and now it is targeting a turnover of $12 mn and gradually $15 mn, which would then create profits for the firm.

Globalization is the primary motive of Dr. Reddy’s as C V Narayan Rao, Chief Representative, KRRP said, “We want to be a global company and we can’t claim to be one without being in China.” Dr. Reddy’s has its manufacturing facilities only in India and China, though it has its subsidiaries in other countries as well.

Ranbaxy entered China in the year 1993; in fact, it is one of the earliest Indian Companies to enter China. It formed a joint venture with Guangzhou Qiaoguang Pharmaceutical co. and HK New Chemic, with an initial investment of $17 mn. It currently holds an 83% stake in the subsidiary (Ranbaxy
Guangzhou China Ltd. RGCL) and manufactures and unlimited number of capsules, tablets, infusion bottles, etc. Today Ranbaxy has become a brand to reckon with in China, with its drug cepodem (Cefpodoxime Proxetil) becoming the market leader in the first year of its launch. Cifran (Ciprofloxacin) has also emerged as the market leader in the country with a market share of 40% (app. In the year 2003). RGCL improved its ranking from 31 to 27 amongst the leading joint venture companies operating in China and achieved sales of $12.3 mn, showing a growth of 87% in the year 2003. The firm reaches out to 500 hospitals and more than 20,000 doctors in the country. RGCL has been consistently trying to expand its market reach by venturing into varied therapeutic segments and introducing new drugs.

Orchid Chemical and Pharmaceuticals is another Indian Pharma player that has ventured into the Chinese market. It started its operations in 2002 as a $25 mn manufacturing and marketing joint venture (50:50) with the leading Chinese Pharma Company North China Pharmaceutical Group Corporation (NCPC). The firm has a 30 million ton manufacturing capacity and offers a product range of six cephalosporin bulk actives. The business strategy followed by Orchid is to target more regulated markets like the US and Europe, having high value generics that are out of patent. The JV was able to add $20 mn to the top line in just one year and it is expected to increase to $30 mn by 2006.
It is not easy going for in fact every Indian Pharmaceutical Company. Aurobindo Pharma has invested a huge sum of $75 mn, one of the largest investments by an Indian company. It was already buying huge quantities of Penicillin G from china and thus, thought it was wiser to set up a branch in China itself. The company entered china in the year 2000 as a $10 mn 50:50 venture with the Chinese pharma company Shanxi Tongling Pharmaceutical to form Aurobindo Tongling Pharmaceutical. However in, 2002, Aurobindo acquired its partner’s stake and thus, formed a 100% owned subsidiary. Aurobindo Pharma has another entity in China, Aurobindo Bio-Pharma. The combined turnover of both entities is Rs. 270 cr, which is one of the highest. Aurobindo also employs one of the highest numbers of people. Though all this seems to give a rosy picture, the unfortunate part is that the subsidiary is not making profits. Aurobindo Bio-Pharma ran into a loss of Rs. 4.2 cr. on a turnover of Rs.123 cr. and Aurobindo Tongling made a loss of Rs. 8.4 cr on a turnover of Rs. 147.9 cr. Though the subsidiaries were making money a few years back, this sudden turn of events is due to the fact that Chinese drug market is very price sensitive.

A well defined market segmentation can be used to market different drugs (and prices) to different segments of the population. Price of Penicillin G, which can be called the flagship
drug of Aurobindo’s china operations, has taken a dip and, therefore the losses. The company has invested a huge sum of $75 mn. hence it can never think of packing its bags from china. Even the objective of every Indian company to venture in Dragon Land is to expand their operations globally and make their presence felt world over.

1.9 Reasons for Indian Pharmaceutical Companies venturing into Chinese Market

The Chinese pharmaceutical market is quickly evolving into a large market due to the rising incomes of a significant portion of the Chinese population. Even if one assumes that only 5% of the Chinese population has the purchasing power to acquire certain pharmaceuticals, this is still a huge market of 65 million consumers. This is a larger market than most European countries, and it is certainly growing a lot faster. One of the key reasons for Indian Pharmaceutical companies foraying into China is the huge Chinese domestic market, and the low operational costs. In addition, china is providing an excellent infrastructure and speedy implementation of new projects.
Exhibit 1: Partial list of PHRMA Member Firms

AMERICAN HOME PRODUCTS CORPORATION
Five Giralda Farms
Madison NJ 07940
(973) 660-5000

BAYER CORPORATION
One Mellon Center
500 Grant Street
Pittsburgh, PA 15219-2502
(421) 394-5500

BOEHRINGER INGELHEIM CORPORATION
900 Ridgesbury Road
P.O. Box 368
Ridgefield, CT 06877
(203) 798-9988

BRISTOL-MYERS SQUIBB COMPANY
345 Park Avenue
New York, NY 10154
(212) 546-4000

GLAXO WELLCOME, INC.
Five Moore Drive
Box 13408
Research Triangle Park, NC 27709
(919) 248-2100

HOECHST MARION ROUSSEL, INC
9300 Ward Parkway
P.O. Box 8480
Kansas City, MO 64114-0480
(816) 966-4000

HOFFMANN-LA ROCHE, INC.
340 Kingsland Street
Nutley, NJ 07110
(973) 235-5000