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Introduction of Pharmaceutical Industry
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Introduction of Pharmaceutical Industry

1.1 Introduction of Pharmacy

The first known drugstore was opened by Arabian pharmacists in Baghdad in 754, and many more soon began operating throughout the medieval and eventually medieval Europe. By the 19th century, many of the drugstores in Europe and North America had eventually developed into larger pharmaceutical companies. Most of today’s major pharmaceutical companies were founded in the late 19th and early 20th centuries. Key discoveries of the 1920s and 1930s, such as insulin and penicillin, became mass-manufactured and distributed. Switzerland, Germany and Italy had particularly strong industries, with the UK, US, Belgium and the Netherlands following suit. Legislation was enacted to test and approve drugs and to require appropriate labeling. Prescription and non-prescription drugs became legally distinguished from one another as the pharmaceutical industry matured. The industry got underway in earnest from the 1950s, due to the development of systematic scientific approaches, understanding of human biology (including DNA) and sophisticated manufacturing techniques. Numerous new drugs were developed during the 1950s and mass-produced and marketed through the 1960s. These included the first oral contraceptive, “The Pill”, Cortisone, blood-pressure drugs and other heart medicines. MAO inhibitors, chlopromazine (Thorazine), Haldol (Haloperidol) and the tranquilizers ushered in the age of psychiatric medication. Valium (diazepam), discovered in 1960, was marketed from 1963 and rapidly became the most prescribed drug in history, prior to
controversy over dependency and habituation. Attempts were made to increase regulation and to limit financial links between companies and prescribing physicians, including by the relatively new U.S. Food and Drug Administration (FDA). Such calls increased in the 1960s after the thalidomide tragedy came to light, in which the use of a new anti-emetic in pregnant women caused severe birth defects. In 1964, the World Medical Association issued its Declaration of Helsinki, which set standards for clinical research and demanded that subjects give their informed consent before enrolling in an experiment. Pharmaceutical companies became required to prove efficacy in clinical trials before marketing drugs. Cancer drugs were a feature of the 1970s. From 1978, India took over as the primary center of pharmaceutical production without patent protection. The industry remained relatively small scale until the 1970s when it began to expand to a greater rate. Legislation allowing for strong patents, to cover both the process of manufacture and the specific products came into force in most countries. By the mid-1980s, small biotechnology firms were struggling for survival, which led to the formation of mutually beneficial partnerships with large pharmaceutical companies and a host of corporate buyouts of the smaller firms. Pharmaceutical manufacturing became concentrated, with a few large companies holding a dominant position throughout the world and with a few companies producing medicines within each country. The pharmaceutical industry entered the 1980s pressured by economics and a host of new regulations, both safety and environmental, but also transformed by new DNA chemistries and new technologies for analysis and computation. Drugs for heart disease and for AIDS were a feature of the 1980s, involving challenges to regulatory bodies and a faster approval process. Managed care and Health maintenance organizations (HMOs)
spread during the 1980s as part of an effort to contain rising medical costs, and the development of preventative and maintenance medications became more important. A new business atmosphere became institutionalized in the 1990s, characterized by mergers and takeovers, and by a dramatic increase in the use of contract research organizations for clinical development and even for basic R&D. The pharmaceutical industry confronted a new business climate and new regulations, born in part from dealing with world market forces and protests by activists in developing countries. Animal Rights activism was also a challenge. Marketing changed dramatically in the 1990s. The Internet made possible the direct purchase of medicines by drug consumers and of raw materials by drug producers, transforming the nature of business. In the US, Direct-to-consumer advertising proliferated on radio and TV because of new FDA regulations in 1997 that liberalized requirements for the presentation of risks. The new antidepressants, the SSRIs, notably Fluoxetine (Prozac), rapidly became bestsellers and marketed for additional disorders. In the United States as of 2012, the industry spent about 1.3 percent of its revenue on research vs. about 25 percent on marketing. Drug development progressed from a hit-and-miss approach to rational drug discovery in both laboratory design and natural-product surveys. Demand for nutritional supplements and so-called alternative medicines created new opportunities and increased competition in the industry. Controversies emerged around adverse effects, notably regarding Vioxx in the US, and marketing tactics. Pharmaceutical companies became increasingly accused of disease mongering or over-medicalizing personal or social problems.
1.2 The History of the Pharmaceutical Industry

As a result of introduction and success of penicillin in the early forties and the relative success of other innovative drugs, research and development (R&D) became a major thrust area of the pharmaceutical industry. The industry expanded rapidly in the sixties, benefiting from new discoveries. In the 1960s attempts were made by the U.S. Food and Drug Administration (FDA) to increase regulation of pharmaceutical industries and to limit financial links between companies and prescribing physicians. In 1964, after the thalidomide tragedy (in which the use of a new tranquilizer in pregnant women caused severe birth defects in the new born child), the World Medical Association set standards for clinical research. Pharmaceutical companies were required to prove efficacy and safety of the drug in clinical trials before marketing them. Tighter regulatory controls were introduced in the seventies. The new regulations revoked permanent patents and established fixed periods on patent protection for branded products. As a result industries flourished by producing generic products and they started earning huge profits, because generic manufacturers do not incur the cost of drug discovery.

Global Scenario

Global pharmaceutical market is highly dynamic and is characterized by greater levels of R&D expenditure and extensive regulation of its products. Global pharmaceutical sales are estimated to be US$ 643 billion in 2006, a growth of 7% over the previous year. Sales have grown from US$ 334 billion in 1999 to US$ 643 billion in 2006, witnessing a CAGR of 10%. North America is the major pharmaceutical market accounting for around
48% of global pharmaceutical sales, followed by Europe (30%), Japan (9%). Leading therapy classes in world pharmaceutical market include lipid regulators (with a market share of 5.8%), oncologics (5.7%), respiratory agents (4%), acid pump inhibitors (4%), and anti-diabetics (3.5%) (Pradhan et al.)

FIGURE 1.1

(Source: Report of the Pharmaceutical Research and Development Committee (PRDC) November 1999.)
The Pharmaceutical industry in India is the world’s third-largest in terms of volume and stands 14th in terms of value. According to Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, the total turnover of India’s pharmaceuticals industry between 2008 and September 2009 was US$21.04 billion, while the domestic market was worth US$12.26 billion. Sale of all types of medicines in the country is expected to reach around US$19.22 billion by 2012. Exports of pharmaceuticals products from India increased from US$6.23 billion in 2006-07 to US$8.7 billion in 2008-09 a combined annual growth rate of 21.25%. According to PricewaterhouseCoopers (PWC) in 2010, India joined among the league of top 10 global pharmaceuticals markets in terms of sales by 2020 with value reaching US$50 billion. Some of the major pharmaceutical firms including Sun Pharmaceutical, Cadila Healthcare and Piramal Healthcare.

**Relationship between Pharmaceuticals and Biotechnology**

Unlike in other countries, the difference between biotechnology and pharmaceuticals remains fairly defined in India. Bio-tech there still plays the role of pharma’s little sister, but many outsiders have high expectations for the future. India accounted for 2% of the $41 billion global biotech market and in 2003 was ranked 3rd in the Asia-Pacific region and 11th in the world in number of biotechs. In 2004-5, the Indian biotech industry saw its revenues grow 37% to $1.1 billion. The Indian biotech market is dominated by biopharmaceuticals; 75% of 2004-5 revenues came from biopharmaceuticals, which saw 30% growth last year. Of the revenues from biopharmaceuticals, vaccines led the way, comprising 47% of sales. Biologics and large-molecule drugs tend to be more expensive than small-molecule drugs, and India hopes to sweep the market in biogenerics and contract manufacturing as drugs go off patent and Indian
companies upgrade their manufacturing capabilities. Most companies in the biotech sector are extremely small, with only two firms breaking 100 million dollars in revenues. At last count there were 265 firms registered in India, over 75% of which were incorporated in the last five years. The newness of the companies explains the industry’s high consolidation in both physical and financial terms. Almost 50% of all biotechs are in or around Bangalore, and the top ten companies capture 47% of the market. The top five companies were homegrown; Indian firms account for 62% of the biopharma sector and 52% of the industry as a whole. The Association of Biotechnology-Led Enterprises (ABLE) is aiming to grow the industry to $5 billion in revenues generated by 1 million employees by 2009, and data from the Confederation of Indian Industry (CII) seem to suggest that it is possible.

**Comparison with the U.S.**

The Indian biotech sector parallels that of the U.S. in many ways. Both are filled with small start-ups while the majority of the market is controlled by a few powerful companies. Both are dependent upon government grants and venture capitalists for funding because neither will be commercially viable for years. Pharmaceutical companies in both countries have recognized the potential effect that biotechnology could have on their pipelines and have responded by either investing in existing start-ups or venturing into the field themselves. In both India and the U.S., as well as in much of the globe, biotech is seen as a hot field with a lot of growth potential.

**Relationship with IT**

Many analysts have observed that the hype around the biotech sector mirrors that of the IT sector. Biotech colleges have been popping up around the country
eager to service the pools of students that want to take advantage of a growing industry. The International Finance Commission, the private investment arm of the World Bank, called India the “centerpiece of IFC’s global biotech strategy.” Of the $110 million invested in 14 biotech projects investment globally, the IFC has given $43 million to 4 projects in India. According to Dr. Manju Sharma, former director of the Department of Biotechnology, the biotech industry could become the “single largest sector for employment of skilled human resource in the years to come.” British Prime Minister Tony Blair was similarly impressed, citing the success of India’s biotech industry as the reason for his own country’s own biotech opportunities. Malaysia is also looking to India as an example for growing its own biotech industry.

Innovation

Several studies on the economics of technological change and technology gap approach to international trade (e.g., Fegerberg 1987, Verspagen 1991) have brought out that growth performance and competitive advantages of countries go together with their activities of technological innovation and imitation. They have shown that technological development measured by patent and R&D expenditures have significant impact on the trade performance of the countries. The pharmaceutical industry being one of the most technology intensive industries, the extent and nature of innovation is crucial for countries to prolong their productivity growth and competitiveness in the long run. In broad terms the process of technological change can occur through improvements in the products, production process, raw material and intermediate inputs, and through enhancements in the efficiency of the management system (Stoneman, 1983). Indian domestic pharmaceutical companies are known for their innovative cost
effective processes, discovery in novel drugs delivery system, self reliance in producing quality raw materials and production led by quality management. However, these technological strengths are confined to a few large Indian pharmaceutical companies. As the Indian industry is dominated by a large number of companies, both medium and small sized, the research activities in the sector are quite limited and inadequately focused on development of new drugs. Majority of the Indian companies suffered from limitation of financial, technical and skill resources to undertake any kind of R&D activities. A recent study found that in a sample of 223 firms, about 62.3 per cent of firms are not engaged in innovative activities and another 21.1 per cent firms undertake R&D, which is even less than 1 per cent of their sales in the year 1999–2000 (Pradhan, 2002b). Using R&D as an indicator of technological activities, Table 5 presents the growth rates of pharmaceutical R&D in selected countries. It can be seen that India had consistently pushed up its pharmaceutical R&D expenses since 1987. The Indian pharmaceutical R&D has grown by 17 per cent during the period 1987–91. The growth rate has gone up to 26 and 83 per cent over the periods 1992–96 and 1997–2001 respectively. This high growth rate of India in pharmaceutical R&D seems to be due to the low base of pharmaceutical R&D in the base years. In the period 1997–2001, India turned out to be second highest R&D growing pharmaceutical sector among the selected countries. Moreover, India’s R&D relative to the US is also observed to be increasing. For each PPP $100 worth of R&D expenditure incurred by the US pharmaceutical sector in 1990, Indian pharmaceutical sector had incurred just PPP $2 and 40 cents. The relative R&D spending of India in terms of the US spending has gone up to PPP $4 and 80 cents in 2000. Although, there is a vast gap in the amount of pharmaceutical R&D expenses undertaken by the US and India, the relative gap in R&D spending is falling modestly over the years. The growing trends of R&D expenses may be a good sign but not a sufficient condition to ensure a rising competitiveness for
Indian pharmaceutical sector. Unless the sector sets aside an increasing proportion of its value added for the R&D activities over time and across countries, expanding global position would be difficult. The R&D intensities, the percentage of the value added devoted for the R&D activities, for a group of countries is furnished in Table 6. Two important points can be deduced from it. First, Indian pharmaceutical industry as compared to global peers incurs a very small fraction of its value added for research and innovative activities. In 1990, its R&D spending is not even one per cent of the value added and is the lowest in the cross country comparison. Second, Indian pharmaceutical industry has significantly improved its R&D intensity in the 1990s. Between 1990 and 2000, its R&D intensity has increased by more than ninetimes from 0.91 per cent to 8.7 per cent. In 2000, the R&D intensity of India is higher than that of Korea, Italy and matches that of Spain.

**Challenges**

All of these changes are ultimately good for the Indian pharmaceutical industry, which suffered in the past from inadequate regulation and large quantities of spurious drugs. They force the industry to reach a level necessary for global competitiveness. However, they have also exposed some of the inadequacies in the industry today. Its main weakness is an underdeveloped new molecule discovery program. Even after the increased investment, market leaders such as Ranbaxy and Dr. Reddy’s Laboratories spent only 5-10% of their revenues on R&D, lagging behind Western pharmaceuticals like Pfizer, whose research budget last year was greater than the combined revenues of the entire Indian pharmaceutical industry. This disparity is too great to be explained by cost differentials, and it comes when advances in genomics have made research equipment more expensive than ever. The drug discovery process is further
hindered by a dearth of qualified molecular biologists. Due to the disconnect between curriculum and industry, pharmas in India also lack the academic collaboration that is crucial to drug development in the West.

1.3 Pharmaceutical Industry in India

Evolution of industry

In India, modern system of medicine is a 20th century phenomena, though the traditional system of medicine has been in practice for many centuries. Therefore, in discussing the evolution of the IPI, three points of time are very relevant. These are: 1900-1970, 1970-1990 and the decade of 1990s. The period 1900-1970 signifies the dominance of the multinationals in this field that were basically importing bulk drugs and formulations from abroad. Most domestic manufacturers were engaged in repacking the formulations produced by the multinationals and production was concentrated in the hands of the multinationals. Production of modern medicine by indigenous units started with the setting up of Bengal Chemical and Pharmaceutical works in 1892, which was followed by the establishment of Alembic Chemical, works in 1907 and Bengal Immunity in 1919. At this point in time, the Patents Act of 1911 was in practice, which facilitated patenting all the known and possible processes of manufacturing of the said drug besides patenting the drug itself. Hence, the indigenous firms were legally prevented from manufacturing most of the new drugs during the life of the patent secured by the latter, i.e., for 16 years, which could be extended to a maximum of another 10 years if the working of the patent had not been sufficiently remunerative to the patentee. This gave them the monopoly power initially. The domestic firms were also forbidden from processing a patented drug into...
formulations or importing it. However, the Second World War and the introduction of sulpha drugs and penicillin gave on impetus to the pharmaceutical industry. The policy instruments of independent India emphasized on creating a strong public sector unit. In the pharmaceutical front, specific areas of production were defined for the public, private and the domestic sector. The setting up of the public sector units and the technical institutes meant for creating technical skills in the country contributed to the growth of the domestic industry. By 1952, a few drugs like tetanus anti-toxin, AS and Indocblorhydroxyquinoline were produced in India from their basic stages. However, the import content of the basic drugs was high due to which the prices of the pharmaceutical products of India were the highest in the world. The second period of 1970-1990 is very significant for the IPI since, a few important changes that had implications on the growth of the IPI took place during this time. The Patent Act of 1911 was amended in 1970, which came into force in 1972. The 1970 Patent Act provides protection for the processes of manufacturing the drug for seven years from the date of filing the application or five years from the date of the grant of the patent. Under this Act only one process that was used in the actual manufacturing could be patented. This change brought a renaissance to the pharmaceutical industry of India. More units larger in size and capacity set up in the 1970s and 1980s started producing drugs, which were primarily imported till then. The technical institutes that were set up in the early 1950s and 1960s resulted in creating technical and engineering skills, which could easily adapt the technology developed elsewhere, proved to be very advantageous for the industry. By 1972, over 100 essential drugs covering a wide spectrum of therapeutic groups like antibiotics, sulpha drugs,
antileprotic drugs, analgesics, antipyretics, vitamins, tranquillizers, pho
tochemical and various other pharmaceutical chemicals were produced
in India from basic stages. A significant increase in the production of
bulk drugs and formulations is observed before and after the 1970s. In the
early 1970s, the government introduced the MRTP Act the FERA, which
aimed at reducing the concentration of economic power with few units
and controlling the flight of foreign exchange from the country. Basically
units, which were not bringing in any new technology, were asked to
reduce their foreign equity and renewal of their licence was also subject
to their bringing in new technology. This resulted in the dilution of the
foreign equity, which is reported in the Table. As a strategy to protect the
domestic industry from competition, the FERA companies were also not
permitted to produce a list of drugs, which were delicensed during the
1980s. The Indian pharmaceutical industry is one of the developing world’s
largest and most developed, ranking 4th in the world in terms of production
volume and 13th in domestic consumption value. 2 India’s industry, valued
at $5.3 billion in 2005, represents less than one percent of the global
pharmaceutical industry ($550 billion). 3 Over the last 30 years, India’s
pharmaceutical industry has evolved from almost nonexistent to a world
leader in the production of high quality generic drugs. India has garnered
a worldwide reputation for producing high quality, low cost generic drugs.
The industry currently meets India’s demand for bulk drugs and nearly
all its demand for formulations, with the remainder supplied by foreign
multinational corporations (MNCs). India’s pharmaceutical industry is
one of the fastest growing segments of the Indian economy with an average
annual growth rate of 14 percent during 2002-2005. Overall, the Indian
market for pharmaceuticals is projected to grow at an average annual rate
of between 15 and 20 percent during 2005 - 2010. The surge in production has been driven by legislative reforms, the growth in contract manufacturing and outsourcing, value added foreign acquisitions and joint ventures, India’s mastery of reverse engineering of patented drug molecules, and India’s efforts to comply with its World Trade Organization (WTO) Trade Related Intellectual Property Agreement (TRIPs) obligations. When India joined the WTO in 1995, its pharmaceutical exports were valued at less than $600 million. By 2005, its exports had grown to $3.7 billion and accounted for more than 61 percent of industry turnover. Currently, Indian pharmaceutical companies produce between 20 and 22 percent of the world’s generic drugs (in value terms) and offer 60,000 finished medicines and nearly 400 bulk drugs used in formulations. With changes in India’s patent laws in the early 1970s, Indian drug producers became experts in ‘reverse engineering’ and increased its supply of less expensive copies of the world’s best-selling patent protected drugs. India’s pharmaceutical industry grew and prospered in a highly regulated environment with government price controls on a significant number of formulations and bulk drugs. In January 2005, India amended its patent laws governing pharmaceuticals, bringing them into conformance with the WTO TRIPs agreement. Under the new patent law, Indian drug markers can no longer manufacture and market reverse-engineered versions of drugs patented by foreign drug producers. To replace sales lost to TRIPs compliance, many of India’s leading pharmaceutical producers have increased their exports of generic drugs to the United States and Western
Europe and entered into research and development agreements, mergers and acquisitions, and other alliances with foreign pharmaceutical firms.

**State of the Economy**

Economic growth decelerated in 2008-09 to 6.7 per cent. This represented a decline of 2.1 per cent from the average growth rate of 8.8 per cent in the previous five years (2003-04 to 2007-08). The five years of high growth has raised the expectations of the people. Few remember that during slowdown from the average growth of 7.3 per cent per annum during the previous five years, it is the preceding five-year period from 1998-99 to 2002-03 average growth was only 5.4 per cent, while the highest growth rate achieved during the period was 6.7 per cent (in 1998-99). Per capita GDP growth, a proxy for per capita income, which broadly reflects the improvement in the income of the average person, grew by an estimated 4.6 per cent in 2008-09. Though this represents a substantial still significantly higher than the average 3.3 per cent per annum income growth during 1998-99 to 2002-03.

**Background Analysis**

The Indian Pharmaceutical Industry has come a long way from being almost non-existent in the 1970’s to being one of the largest and most advanced Pharmaceutical industries in the world. The domestic Pharmaceutical output has increased at a CAGR of 13.4. Currently the Indian Pharmaceutical Industry is valued at $ 8 billion (approx). Globally the industry ranks 4th in terms of volume and 13th in terms of value. It provides employment to millions and ensures that essential drugs are available to the vast population of India at affordable prices. Indian Pharmaceutical Industry has attained wide ranging capabilities in the complex field of drug manufacture and technology developed through a range of
governmental incentives and the industry has been declared a knowledge based industry. This Industry is a highly organized sector and is extremely fragmented with severe price competitions and governmental price control. The major players in the Industry are Ranbaxy, Dr. Reddy’s Laboratories, Cipla, Sun Pharmaceutical Industries, LupinLab, Glaxo SmithKline Pharmaceutical, Cadila Healthcare, Aventis etc. (Department of Chemicals and Petrochemicals, Ministry of Chemicals and Fertilizers, Annual Report 1999-2000; Government of India, New Delhi)

Relevance for Growth

India has the highest number of manufacturing plants approved by US FDA, which is next only to that in the US. More than 85% of the formulations produced in the country are sold in the domestic market. Over 60% of India’s bulk drug production is exported. India holds the lion’s share of the world’s contract research business as activity in the Pharmaceutical market continues to explode, over 15 prominent contract research organizations (CROs) are now operating in India attracted by her ability to offer efficient R&D on a low cost basis. Thirty five percent of business is in the field of new drug discovery and the rest 65 percent of business is in the clinical trials arena. India offers a huge cost advantage in the clinical trials domain compared to Western countries. India got a major boost with the signing of Trade Related Intellectual Property Rights (TRIPS) under the General Agreement on Tariffs and Trade (GATT) in January 2005 with which it began recognizing global patents.

1.4 Export Profile

Exports constitute a substantial part of the total production of Pharmaceutical in India. The formulations contribute nearly 55% of the total exports and the rest 45% comes from bulk drugs. Pharmaceutical
exports clocked $7.2 billion in 2007-08, accounting for six per cent of the country’s total exports. Indian companies export drugs to over 200 countries, but the top 25 markets, which includes the US, Germany, Russia, China and few European and African countries, account for about half of the total. Indian drug makers exported medicines worth Rs 31,608 crore during April 2008-January 2009 and exports shot up 30.7% as compared to last year due to a weak Indian currency and increased demand for low-cost generic medicines. US is the Largest importer of drugs followed by Russia and Germany.

1.5 Foreign Participation

Drugs and Pharmaceuticals ranks 8th in India’s top 10 FDI-attracting sectors. The government of India has allowed foreign direct investment up to 100% through the automatic route in the drugs and Pharmaceuticals industry of the country, on the condition, that the activity should not fall into the categories that require licensing. Pharmaceutical industry accounts for about 2.91% of total FDI into the country. The FDI in Pharmaceutical sector is estimated to have touched US$172 million, thereby showing a compounded annual growth rate of about 62. The Industry has received almost Rs 2141 crore investment from 36 countries through FDI between April 2007 to April 2009 with most of the fund infusion directed to healthcare and biotech ventures. Out of the total investment, almost 82 per cent of the FDI in Pharmaceutical sector was from five countries- Mauritius, Singapore, USA, UAE and Canada. The increase in FDI Inflows to Drugs and Pharmaceuticals industry in India has helped in the expansion, growth, and development of the industry. This in turn has led to the improvement in the quality of the products from the drugs and
Pharmaceuticals. Technologically strong and totally self-reliant, the Pharmaceutical industry in India has low costs of production, low R&D costs, innovative scientific manpower, strength of national laboratories and an increasing balance of trade. The Pharmaceutical Industry, with its rich scientific talents and research capabilities, supported by Intellectual Property Protection regime is well set to take on the international market as a global leader.

### 1.6 Research and Development (R & D)

Both the Indian central and state governments have recognized R&D as an important driver in the growth of their pharma businesses and conferred tax deductions for expenses related to research and development. They have granted other concessions as well, such as reduced interest rates for export financing and a cut in the number of drugs under price control. Government support is not the only thing in Indian pharma’s favor, though; companies also have access to a highly developed IT industry that can partner with them in new molecule discovery in R&D. With the reintroduction of product patents, leading Indian pharmaceutical majors are altering their business strategies by placing greater focus on R&D and the discovery of new chemical entities. Traditionally, the vast majority of India’s pharmaceutical R&D spending was concentrated on reverse engineering and the adaptation of patented foreign drugs to the Indian market. Most of the industry’s funding went to research rather than to new drug discovery and development. Low levels of industry productivity and the relatively small size of India’s pharmaceutical companies limited
funding for R&D as they dedicated only less than 2 percent of their annual turnover to R&D compared with between 15 percent and 20 percent allocated by Western innovator companies. After 2005, India’s leading drug companies recognized that they could not survive as global players without significant R&D capabilities. Since 1995, total industry R&D spending has grown from nearly $30 million to more than $495.3 million in 2005-06 (table 8).46 The vast majority of the industry’s R&D spending is conducted by 15 companies whose R&D spending rose to $192.3 million in 2005 from $131 million in FY2004, representing an increase of 47 percent. R&D expenditures are expected to gradually rise to between 9 percent and 10 percent of total industry spending by the end of 2007.47 Likewise, the vast majority of the industry’s R&D expenditures on new drug discovery and development is conducted by a limited number of companies, with Dr. Reddy’s and Ranbaxy at the forefront. In 2005, Dr. Reddy’s committed 14 percent of its annual sales to R&D, whereas, Ranbaxy

The Role of Indian Generic Drugs in the U.S. Market

The United States is the world’s largest single market for pharmaceutical products accounting for nearly 50 percent of the value of the total world market. According to the Generic Pharmaceutical Association, U.S. retail drug sales for 2006 totaled $221 billion and generic pharmaceutical sales totaled $54.1 billion.61 U.S. pharmaceutical sales grew by 73 percent from $128.1 billion in 2006. France is next spending $457 per capita 62 followed by Japan at $339. Economist Intelligence Unit. “Express Scripts Study Shows Substantial Savings Opportunity for Consumers,
states, Health Care Purchasers with Generics, says GPhA,” Generic Pharmaceutical Association, Press release, Aug. 16, 2005.2006 Chain Pharmacy Industry Profile, The National Association of Chain Drug Stores. Pharmaceuticals in the United States, Industry Profile, India’s greatest strengths lie in its people. India also boasts of well-educated, English-speaking labor force that is the base of its competitive advantage. Although molecular biologists are in short supply, there are a number of talented chemists who are equally as important in the discovery process. In addition, there has been a reverse brain drain effect in which scientists are returning from abroad to accept positions at lower salaries at Indian companies. Once there, these foreign-trained scientists can transfer the benefits of their knowledge and experience to all of those who work with them. India’s wealth of people extends benefits to another part of the drug commercialization process as well. With one of the largest and most genetically diverse populations in any single country, India can recruit for clinical trials more quickly and perform them more cheaply than countries in the West. Indian firms have just recently started to leverage.
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<td>1.13</td>
<td>1.28</td>
<td>1.78</td>
<td>1.74</td>
</tr>
<tr>
<td>Canada</td>
<td>496</td>
<td>1055</td>
<td>174</td>
<td>343</td>
<td>2338</td>
<td>2017</td>
<td>1.36</td>
<td>1.95</td>
<td>2.15</td>
<td>1.56</td>
</tr>
<tr>
<td>Denmark</td>
<td>329</td>
<td>381</td>
<td>366</td>
<td>787</td>
<td>1611</td>
<td>0.44</td>
<td>0.58</td>
<td>0.61</td>
<td>0.63</td>
<td>0.75</td>
</tr>
<tr>
<td>Ireland</td>
<td>411</td>
<td>189</td>
<td>194</td>
<td>711</td>
<td>719</td>
<td>0.44</td>
<td>0.42</td>
<td>0.78</td>
<td>0.78</td>
<td>0.71</td>
</tr>
<tr>
<td>France</td>
<td>2180</td>
<td>3400</td>
<td>5388</td>
<td>7199</td>
<td>9079</td>
<td>7.24</td>
<td>6.89</td>
<td>6.11</td>
<td>5.97</td>
<td>5.98</td>
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<tr>
<td>Germany</td>
<td>3618</td>
<td>5213</td>
<td>6081</td>
<td>7408</td>
<td>9541</td>
<td>5.40</td>
<td>4.58</td>
<td>4.12</td>
<td>7.05</td>
<td>6.97</td>
</tr>
<tr>
<td>India</td>
<td>1136</td>
<td>1381</td>
<td>1381</td>
<td>6240</td>
<td>11481</td>
<td>3.59</td>
<td>3.61</td>
<td>3.99</td>
<td>4.18</td>
<td>5.82</td>
</tr>
<tr>
<td>Italy</td>
<td>2777</td>
<td>4121</td>
<td>6191</td>
<td>6073</td>
<td>6057</td>
<td>9.19</td>
<td>8.39</td>
<td>7.77</td>
<td>6.80</td>
<td>5.21</td>
</tr>
<tr>
<td>Japan</td>
<td>6718</td>
<td>10311</td>
<td>15612</td>
<td>16166</td>
<td>19236</td>
<td>22.10</td>
<td>20.89</td>
<td>19.83</td>
<td>18.09</td>
<td>16.51</td>
</tr>
<tr>
<td>Korea</td>
<td>799</td>
<td>1492</td>
<td>2775</td>
<td>3030</td>
<td>4520</td>
<td>2.06</td>
<td>3.02</td>
<td>3.53</td>
<td>3.39</td>
<td>3.89</td>
</tr>
<tr>
<td>Mexico</td>
<td>790</td>
<td>1203</td>
<td>2102</td>
<td>2159</td>
<td>3430</td>
<td>2.66</td>
<td>2.59</td>
<td>2.77</td>
<td>2.42</td>
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<tr>
<td>Netherlands</td>
<td>319</td>
<td>733</td>
<td>585</td>
<td>705</td>
<td>1304</td>
<td>1.06</td>
<td>1.98</td>
<td>0.74</td>
<td>0.79</td>
<td>1.12</td>
</tr>
</tbody>
</table>

(Source: Pharmaceutical employment and value added in local currency for India and other countries have been obtained from the Central Statistical Organization, Annual Surveys of Industries, various years and OECD, STAN Database 2004 respectively.)
Table: 1.2

<table>
<thead>
<tr>
<th>Country</th>
<th>Growth of Pharmaceutical R&amp;D (%</th>
<th>Relative R&amp;D Expenditure (USA=100)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td>19 48 24 1.4 1.3 1.9 1.9</td>
<td></td>
</tr>
<tr>
<td>Belgium</td>
<td>42 36 4.5 3.6 5.6</td>
<td></td>
</tr>
<tr>
<td>Canada</td>
<td>76 41 23 2.0 3.1 3.6 4.2</td>
<td></td>
</tr>
<tr>
<td>Czech Republic</td>
<td>49 74 0.2 0.3</td>
<td></td>
</tr>
<tr>
<td>Denmark</td>
<td>51 41 1.9 2.1 2.5</td>
<td></td>
</tr>
<tr>
<td>Finland</td>
<td>17 25 94 0.8 0.7 0.7 1.2</td>
<td></td>
</tr>
<tr>
<td>France</td>
<td>31 18 13 18.3 16.9 19.8 19.7</td>
<td></td>
</tr>
<tr>
<td>Germany</td>
<td>17                                  11.9 17.7</td>
<td></td>
</tr>
<tr>
<td>India</td>
<td>17 26 83 3.2 2.4 2.9 4.8</td>
<td></td>
</tr>
<tr>
<td>Ireland</td>
<td>107 30 0.3 0.4 0.9</td>
<td></td>
</tr>
<tr>
<td>Italy</td>
<td>-15 13 5.6 4.9</td>
<td></td>
</tr>
<tr>
<td>Japan</td>
<td>35 10 20 44.2 42.0 37.0 37.1</td>
<td></td>
</tr>
<tr>
<td>Korea</td>
<td>70                                  1.3 1.5</td>
<td></td>
</tr>
<tr>
<td>Netherlands</td>
<td>15 26 23 3.7 3.3 2.3 3.3</td>
<td></td>
</tr>
<tr>
<td>Norway</td>
<td>48 -7 0.6 0.7 0.5</td>
<td></td>
</tr>
<tr>
<td>Poland</td>
<td>22                                  0.3 0.3</td>
<td></td>
</tr>
<tr>
<td>Spain</td>
<td>47 16 16 2.7 2.9 2.5 2.4</td>
<td></td>
</tr>
<tr>
<td>Sweden</td>
<td>48 41 38 4.7 5.4 6.3 9.2</td>
<td></td>
</tr>
<tr>
<td>UK</td>
<td>32 11 23 29.4 31.8 27.1 34.1</td>
<td></td>
</tr>
<tr>
<td>USA</td>
<td>36 13 5 100 100 100 100</td>
<td></td>
</tr>
</tbody>
</table>

(Source: Central Statistical Organization, ASI, various years)

1.7 Patents

As it expands its core business, the industry is being forced to adapt its business model to recent changes in the operating environment. The first and most significant change was the January 1, 2005 enactment of an amendment to India’s patent law that reinstated product patents for the first time since 1972. The legislation took effect on the deadline set by
the WTO’s Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement, which mandated patent protection on both products and processes for a period of 20 years. Under this new law, India will be forced to recognize not only new patents but also any patents filed after January 1, 1995. Indian companies achieved their status in the domestic market by breaking these product patents, and it is estimated that within the next few years, they will lose $650 million of the local generics market to patent-holders.

In the domestic market, this new patent legislation has resulted in fairly clear segmentation. The multinationals narrowed their focus onto high-end patients who make up only 12% of the market, taking advantage of their newly bestowed patent protection. Meanwhile, Indian firms have chosen to take their existing product portfolios and target semi-urban and rural populations. (Slater et al.)

1.8 Product Development:

Indian companies are also starting to adapt their product development processes to the new environment. For years, firms have made their ways into the global market by researching generic competitors to patented drugs and following up with litigation to challenge the patent. This approach remains untouched by the new patent regime and looks to increase in the future. However, those that can afford it have set their sights on an even higher goal: new molecule discovery. Although the initial investment is huge, companies are lured by the promise of hefty profit margins and thus a legitimate competitor in the global industry.
Local firms have slowly been investing more money into their R&D programs or have formed alliances to tap into these opportunities.

1.9 Role of Government

The Indian government has been very supportive. It established the Department of Biotechnology in 1986 under the Ministry of Science and Technology. Since then, there have been a number of dispensations offered by both the central government and various states to encourage the growth of the industry. India’s science minister launched a program that provides tax incentives and grants for biotech start-ups and firms seeking to expand and establishes the Biotechnology Parks Society of India to support ten biotech parks by 2010. Previously limited to rodents, animal testing was expanded to include large animals as part of the minister’s initiative. States have started to vie with one another for biotech business, and they are offering such goodies as exemption from VAT and other fees, financial assistance with patents and subsidies on everything ranging from investment to land to utilities.

1.10 Pharmaceutical Industry Today

The number of purely Indian pharma companies is fairly low. Indian pharma industry is mainly operated as well as controlled by dominant foreign companies having subsidiaries in India due to availability of cheap labour in India at lowest cost. In 2002, over 20,000 registered drug manufacturers in India sold $9 billion worth of formulations and bulk drugs. 85% of these formulations were sold in India while over 60% of the bulk drugs were exported, mostly to the United States and Russia. Most of the players in the market are small-to-medium enterprises; 250
of the largest companies control 70% of the Indian market. Thanks to the 1970 Patent Act, multinationals represent only 35% of the market, down from 70% thirty years ago.

Most pharma companies operating in India, even the multinationals, employ Indians almost exclusively from the lowest ranks to high level management. Mirroring the social structure, firms are very hierarchical. Homegrown pharmaceuticals, like many other businesses in India, are often a mix of public and private enterprise. Although many of these companies are publicly owned, leadership passes from father to son and the founding family holds a majority share.

In terms of the global market, India currently holds a modest 1-2% share, but it has been growing at approximately 10% per year. India gained its foothold on the global scene with its innovatively engineered generic drugs and active pharmaceutical ingredients (API), and it is now seeking to become a major player in outsourced clinical research as well as contract manufacturing and research. There are 74 U.S. FDA-approved manufacturing facilities in India, more than in any other country outside the U.S, and in 2005, almost 20% of all Abbreviated New Drug Applications (ANDA) to the FDA are expected to be filed by Indian companies. Growth in other fields notwithstanding, generics are still a large part of the picture. London research company Global Insight estimates that India’s share of the global generics market will have risen from 4% to 33% by 2007. The Indian pharmaceutical industry has become the third largest producer in the world and is poised to grow into an industry of $ 20 billion in 2015 from the current turnover of $ 12 billion.
### Biotechnology Statistics:

#### Table: 1.3

Top Biopharmaceutical & Biotechnology Companies in India, as of 2011:

<table>
<thead>
<tr>
<th>Rank</th>
<th>Company</th>
<th>Revenue 2011 (Rs crore)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Biocon</td>
<td>1483</td>
</tr>
<tr>
<td>2</td>
<td>Serum Institute of India</td>
<td>1041</td>
</tr>
<tr>
<td>3</td>
<td>Panacea Biotech</td>
<td>928.41</td>
</tr>
<tr>
<td>4</td>
<td>Nuziveedu Seeds Private Limited</td>
<td>610</td>
</tr>
<tr>
<td>5</td>
<td>Reliance Life Sciences</td>
<td>490</td>
</tr>
<tr>
<td>6</td>
<td>Quintiles</td>
<td>476.25</td>
</tr>
<tr>
<td>7</td>
<td>Novo Nordisk</td>
<td>462</td>
</tr>
<tr>
<td>8</td>
<td>Rasi Seeds</td>
<td>371.88</td>
</tr>
<tr>
<td>9</td>
<td>Mahyco</td>
<td>364.9</td>
</tr>
<tr>
<td>10</td>
<td>Trans Asia</td>
<td>350</td>
</tr>
<tr>
<td>11</td>
<td>Ankur Seeds</td>
<td>325</td>
</tr>
<tr>
<td>12</td>
<td>Syngene International</td>
<td>318</td>
</tr>
<tr>
<td>13</td>
<td>Bharat Biotech International</td>
<td>298.34</td>
</tr>
<tr>
<td>14</td>
<td>Indian Immunologicals Limited</td>
<td>283</td>
</tr>
<tr>
<td>15</td>
<td>Krishidhan Seeds</td>
<td>276.13</td>
</tr>
</tbody>
</table>

(Source: Annual Report of Biocon)
The Indian Pharmaceutical industry has grown from a mere Rs. 1,500 crore turnover in 1980 to over Rs. 78,000 crore in 2008 with about 10 per cent of share volume of global production. High growth has been achieved through; the creation of required infrastructure, capacity building in complex manufacturing technologies of active production ingredients (APIs) and formulations, entering into drug discovery through original and contract research and manufacturing (CRAM) and clinical trials and product specific strategies of acquisition and mergers. The domestic sector had a production turnover of Rs. 47,241 crore from about 10,000 small-scale and 300 large and medium manufacturing units in 2008.

**India’s Pharmaceutical Industry in 2005**

Ø Share of global sales: Value 1%, Volume 8%

Ø Global ranking: 4th in volume, 13th in value

Ø Domestic market: $5.3 billion

Ø Exports: $3.7 billion

Ø Imports: $985 million

Ø Bulk drug production: $2.1 billion

Ø Employment: 5 million direct, 24 million indirect.

Ø Capital investment: $1.2 billion

Ø Production costs: Among the lowest in the

Ø World, estimated to be 70% less than the West.
India’s Pharmaceutical Industry: Independence to 2005

At the time of independence in 1947, India’s pharmaceutical market was dominated by Western MNCs that controlled between 80 and 90 percent of the market primarily through importation. Approximately 99 percent of all pharmaceutical products under patent in India at the time were held by foreign companies and domestic Indian drug prices were among the highest in the world. The Indian pharmaceutical market remained import-dependent through the 1960s until the government initiated policies stressing self-reliance through local production. At that time, 8 of India’s top 10 pharmaceutical firms, based on sales, were subsidiaries of MNCs. To facilitate an independent supply of pharmaceutical products in the domestic market, the government of India founded 5 state-owned pharmaceutical companies. Today, India is the world’s fifth largest producer of bulk drugs. Government policy culminated in various actions including: the abolition of product patents on food, chemicals, and drugs; the institution of process patents; the limitation of multinational equity share in India pharmaceutical companies, and the imposition of price controls on certain formulations and bulk drugs. Subsequently, most foreign pharmaceutical manufacturers abandoned the Indian market due to the absence of legal mechanisms to protect their patented products. Accordingly, the share of the domestic Indian market held by foreign drug manufacturers declined to less than 20 percent in 2005. As the MNCs abandoned the Indian market, local firms rushed in to fill the void, and by 1990, India was self-sufficient in the production of formulations and nearly self-sufficient in the production of bulk drugs.
Table: 1.4

Top 20 Publicly Listed Life Science companies in India, as

<table>
<thead>
<tr>
<th>Rank</th>
<th>Company</th>
<th>Revenue 2011 (USD millions)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Cipla</td>
<td>1348.51</td>
</tr>
<tr>
<td>2</td>
<td>Ranbaxy</td>
<td>1327.56</td>
</tr>
<tr>
<td>3</td>
<td>Dr. Reddy's Laboratories</td>
<td>1178</td>
</tr>
<tr>
<td>4</td>
<td>Lupin Ltd</td>
<td>929.84</td>
</tr>
<tr>
<td>5</td>
<td>Aurobindo Pharma</td>
<td>855.19</td>
</tr>
<tr>
<td>6</td>
<td>Dabur</td>
<td>700.3</td>
</tr>
<tr>
<td>7</td>
<td>Sun Pharmaceutical</td>
<td>673.99</td>
</tr>
<tr>
<td>8</td>
<td>Cadila Healthcare</td>
<td>629.45</td>
</tr>
<tr>
<td>9</td>
<td>Jubilant Lifesciences</td>
<td>561.03</td>
</tr>
<tr>
<td>10</td>
<td>Piramal Healthcare</td>
<td>480.26</td>
</tr>
<tr>
<td>11</td>
<td>GlaxoSmithKline Pharmaceuticals Ltd</td>
<td>475.8</td>
</tr>
<tr>
<td>12</td>
<td>Ipca Laboratories</td>
<td>390</td>
</tr>
<tr>
<td>13</td>
<td>Wockhardt</td>
<td>381.23</td>
</tr>
<tr>
<td>14</td>
<td>Torrent Pharmaceuticals</td>
<td>380.2</td>
</tr>
<tr>
<td>15</td>
<td>Sterling Bio</td>
<td>358.1</td>
</tr>
<tr>
<td>16</td>
<td>Biocon</td>
<td>340.38</td>
</tr>
<tr>
<td>17</td>
<td>Orchid Chemicals &amp; Pharmaceuticals Ltd</td>
<td>320.62</td>
</tr>
<tr>
<td>18</td>
<td>Alembic</td>
<td>270.62</td>
</tr>
<tr>
<td>19</td>
<td>Aventis Pharma</td>
<td>253.75</td>
</tr>
<tr>
<td>20</td>
<td>Glenmark Pharmaceuticals</td>
<td>260.14</td>
</tr>
</tbody>
</table>
1.11 Challenges

The biotech sector faces some major challenges in its quest for growth. Chief among them is a lack of funding, particularly for firms that are just starting out. The most likely sources of funds are government grants and venture capital, which is a relatively young industry in India. Government grants are difficult to secure, and due to the expensive and uncertain nature of biotech research, venture capitalists are reluctant to invest in firms that have not yet developed a commercially viable product. As previously mentioned, India hopes to solve its funding problem by attracting overseas investors and partners. Before these potential saviors will invest significant sums in the industry, however, there needs to be better scientific and financial accountability. India is slowly working towards these goals, but it will be a while before they are up to the standards of Western investors.

India’s biotech firms share another problem with their pharmaceutical cousins: a lack of qualified employees. Biotech has the additional disadvantage of competing against IT for ambitious, science-minded students but not being able to guarantee the same compensation. An aspiring researcher in India needs 7–10 years of education covering a range of specialties in order to qualify to work in biotech. Even if a student does choose to go on the biotech path, the ineffectual curriculum at many universities makes it doubtful as to whether he will be qualified to work in the field once finished. One estimate shows that 10% of upper-echelon biotech recruits have come from foreign countries. While this is not a problem, per se, it drives up cost in a country whose competitive advantage is based on cheap, high-quality labor. Far from ending with scientists, there is also a shortage of people with knowledge of biotechnology in related fields: doctors, lawyers, programmers, marketing personnel and
others. While little has been done about the latter half of the employee crunch, the government has addressed the problem of educated but unqualified candidates in its Draft National Biotech Development Strategy. This plan included a proposal to create a National Task Force that would work with the biotech industry to revise the curriculum for undergraduate and graduate study in life sciences and biotechnology. The government’s strategy also stated intentions to increase the number of PhD Fellowships awarded by the Department of Biotechnology to 200 per year. These human resources will be further leveraged with a “Bio-Edu-Grid” that will knit together the resources of the academic and scientific industrial communities, much as they are in the

1.12 Regulatory Environment

The Patent Act, 1970

The Act’s stated objective was to foster the development of an indigenous Indian pharmaceutical industry and to guarantee that the Indian public had access to low-cost drugs. The Act replaced intellectual property rights laws left over from the British colonial era and ended India’s recognition of Western-style “product” patent protection for pharmaceuticals, agricultural products, and atomic energy. Product-specific patents were disregarded in favor of manufacturing “process” patents that allowed Indian companies’ to reverse engineer or copy foreign patented drugs without paying a licensing fee. (William et al.)

Drug Price Control Order, 1970 (DPCO)
The order was introduced when most of India’s drugs were under strict price controls. Since its introduction, the number of bulk drugs under price controls gradually declined from 347 in 1987 to 163 in 1994 to 74 in 1995. In 2005, the government capped prices on 74 bulk drugs and 260 formulations that account for approximately 25 percent of India’s retail pharmaceutical market (attachment). Trade margins for these drugs were capped at 8 percent for retailers and 16 percent for wholesalers. The National Pharmaceutical Pricing Authority, founded in 1997, is responsible for monitoring prices using the DPCO to fix ceiling prices on drugs and ensure that no Indian company in a monopoly position takes advantages of its monopolistic position by profiteering. In June 2006, the National Pharmaceutical Policy 2006 (Part A) proposed to add price controls on 354 specific drugs listed as essential medicines. The new policy will cap margins on generic drugs at 15 percent for wholesalers and 35 percent for retailers. It will also enforce a 5 percent price cut on more than 75 commonly-used medicines resulting from import duty reductions of 5 to 7.5 percent on certain active pharmaceutical ingredients (APIs). The NPPA controls ceiling prices for controlled bulk drugs in all intra-industry transactions as well as the retail ceiling prices for controlled formulations.

1.13 Industry Production

Thirty-five years of protection has enabled the Indian pharmaceutical industry to perfect its scientific and manufacturing capabilities, allowing many of its leading companies to move up the value added chain. India’s pharmaceutical industry consists of large, medium, and small companies and is one of the world’s most price competitive. It is also highly fragmented with more than 20,000 domestic production units. Because of low barriers to entry and low capital requirements, the number of domestic pharmaceutical firms engaged in the formal and informal sectors
expanded dramatically from 2,257 in 1970 to more than 20,000 in 2005 (table 1). Because many of these companies focus on producing similar generic drugs, with possibly hundreds of companies producing the same drug, the industry is characterized by fierce competition and high volumes, razor-thin profit margins, overcapacity, and declining prices. According to FICCI, there are only 6,000 firms participating in the formal sector that have received drug manufacturing licenses from the Indian government. India’s pharmaceutical firms can be differentiated by size, annual sales, function, export markets, and R&D capabilities.

1.14 Grouping Number of Firms Description

Group 1 100 Largest firms, includes both wholly-owned Indian firms and subsidiaries of MNCs have annual revenues of at least $650,000; have brand recognition and are engaged in developing R&D capabilities; responsible for recent wave of cross-border acquisitions and alliances; export to regulated, semi-regulated, and unregulated markets. Group 2 200 Mid-size firms with annual revenues between $210,410 and $650,000; they have limited investment capabilities and primarily serve the domestic market. They are generic drug producers that subsist mainly on reverse engineering of patented and off-patent drugs (primarily bulk drugs and APIs) also includes niche players specializing in contract research (CRAMS) and contract clinical trials in segments of the market where they have a competitive advantage; export to semi-regulated and unregulated markets. Group 3 5,700 Smallest firms with annual revenues of less than $210,410; primarily perform contract manufacturing services for MNCs or domestic firms. Many have been adversely affected and have been forced to close their doors due to revised Good Manufacturing
Practices set by Schedule M of India’s Drug and Cosmetic Act, 1940 that came into effect from July 1, 2005. Those affected cannot meet production standards of regulated market regulators and their production will be limited to the domestic, semi-regulated, and unregulated markets. (Source: Padmashree Gehl Sampath, Indian Pharma Within Global Reach?, United Nations University, 2006-031. Sasikant Misra, CRAMS (Contract Research and 17 Manufacturing services), Confederation of Indian Industry (CII).)

The vast majority of India’s pharmaceutical firms are small by global standards with annual revenues of less than $5 million. The Confederation of India Industries (CII) estimates that approximately 80 percent of them are engaging in some type of contract manufacturing or outsourcing. 17 The largest 250 companies control nearly 70 percent of the domestic market with the top 10 controlling approximately 40 percent. The domestic Indian pharmaceutical industry consists of both domestic companies and subsidiaries of MNCs. In the 1970s, the vast majority of foreign pharmaceutical companies abandoned the Indian market during the “process” patent era due to inadequate product protection, government price controls, growing domestic competition, and declining prices and profitability. Consequently, the share of India’s market controlled by multinationals dropped to less than 20 percent by 2005. 18 In the absence of government protection, India’s leading drug producers are moving toward new drug discovery rather continuing to rely solely on copying patented foreign drugs. Industry experts project that by 2010, Indian firms will produce 6 of the top 10 drugs scheduled to lose their patent protection in developing countries. 19 Indian pharmaceutical companies now supply
nearly all the country’s demand for formulations and nearly 70 percent of its demand for bulk drugs. Indian firms produce nearly 60,000 generic brands in 60 therapeutic categories and between 350 and 400 bulk drugs. Approximately 80 percent of domestic production consists of formulations, and more than 85 percent of those formulations are sold in the domestic market, whereas at least 60 percent of bulk drug production is exported. Nearly 97 percent of India’s drug market consists of second- and third-generation drugs no longer subject to patent protection in the developed world. Some under-patent, lifesaving drugs continue to be imported, primarily from developed countries, especially the United States, Germany, the United Kingdom, and France. India has the world’s third-largest API manufacturing industry valued at nearly $2 billion in 2005. Currently, India’s drug industry produces more than 400 different APIs and is among the world’s top 5 API producers accounting for approximately 6.5 percent of the world’s API production. Italy’s Chemical Pharmaceutical Generic Association (CPA) projects that India’s share of the world API market will grow to 10.5 percent by 2010 as patented blockbuster drugs lose their patent protection. The CPA also expects that the domestic Indian market for APIs, both generic and branded, will rise from $755 million in 2005 to $1.9 billion in 2010.20 According to the Assocham, the leading APIs were antiinfectives, and gastrointestinal, cardiovascular, and respiratory drugs (table 2). In terms of volume of sales, the gastrointestinal and cardiac segments saw the highest rates of growth and accounted for the largest number of new drug launches
1.15 Industry Structure:

Mergers, Acquisitions, and Other Alliances:

The last 3 years have seen a significant rise in the number of consolidations, mergers & acquisitions, and other types of alliances and tie-ins in the Indian pharmaceutical industry. Most of the acquisitions involve Indian companies searching for ways to penetrate overseas markets and widen their global footprint, diversify and enhance their product portfolios, offer their customers a ‘nearshore-offshore’ option, improve their custom manufacturing, packing, and R&D capabilities, acquire existing brands, and gain access to the highly regulated markets.

Contract Research and Manufacturing, Outsourcing, and Other Services:

The passage of the Patents (Amendment) Act 2005 has significant implications for both Indian and multinational companies competing in the Indian market. Leading Indian companies are moving away from a reliance on the domestic market to the development new drugs, exports to regulated markets, and cooperative agreements with MNCs. Facing lagging sales of patented drugs by MNCs in their home markets, declining R&D revenues, and rising costs, many MNCs have turned to contract manufacturing and research services (CRAMS), co-marketing alliances, outsourcing of research and clinical trials to reduce costs, increase development capacity, and trim the ‘time to market’ for new drugs. These strategies permit MNCs to focus on their core profit making activities (competencies), such as drug discoveries and marketing, rather than on manufacturing. India has emerged as the principal destination for global
pharmaceutical companies across the pharmaceutical value chain. Indian pharmaceutical companies have two basic options: compete with MNCs for vanilla generics and new chemical entities (new drugs) or co-operate. Subcontracting in India has gradually moved up the value-added chain from intermediates and APIs to new drug discovery, clinical trials, marketing, and sales. According to India’s Federation of Indian Chambers of Commerce and Industry (FICCI), many Indian companies, especially those without the resources for R&D, are embracing custom manufacturing, contract research, and marketing alliances to remain profitable. Others are planning to manufacture and export vanilla generics to regulated markets before eventually producing either more difficult to manufacture generics or new chemical entities.

1.16 Evolution of Pharmaceutical Industry in Gujarat

There is no stopping the pharmaceutical and biotechnology industry in Gujarat, which from its glorious past is racing ahead by meeting the needs of era of outsourcing that has of late infused new life into the pharma and biotech industry world over. The pharma industry in Gujarat, which took off in 1907 with Alembic setting up its facility, is now a major contract research and manufacturing services (CRAMS) provider in India contributing significantly (more than $400 million as per various industry analysts) to the country’s US $1.21 billion CRAMS market in 2007. The latest distinction as the favorites locale for outsourcing follows its stint as the major exporter of pharmaceuticals and producer of active pharmaceutical ingredients (APIs) in the country.
From the days that saw pharma and biotech industry making its path in the country, Gujarat has used its available resources to the best of its ability to propel the industry and in course of time came to be known as the pharma capital of India. In the process, Gujarat, the jewel of the West, became the first state in India to manufacture active pharmaceutical ingredients (APIs), finished dosage forms and pharmaceutical machineries. Also, as pharma and biotech industry slowly gained ground in the country, this jewel of the West earned the distinction of becoming the first state in the country to embark on preclinical safety and toxicology studies.
When contacted industry sources, they pointed out that like many other segments of pharma business, in outsourcing to the state has got certain milestones to boast of. “The Gujarat pharmaceutical industry has carved out a special place for itself over a period of time. In fact, one of the early deals in the area of global contract manufacturing, the recent buzzword in the pharma industry, was accomplished in Gujarat way back in 1996. Hence, Gujarat is emerging a pioneer in this area too,” said a leading pharma and biotech player in the state requesting anonymity due to certain technical reasons.

1.17 Comparison With Other States:

“Gujarat is home to approximately 40 per cent of contract research organizations (CROs) in the country. The state has witnessed action on
outsourcing of clinical research activities and drug discovery related services. Globally, contract research is a high growth segment led by increasing outsourcing activities of multinational pharma companies. Gujarat is increasingly emerging as one of the most globally preferred outsourcing/off shoring destinations for pharma. This trend can be largely attributed to Gujarat’s inherent competencies in terms of low manufacturing cost, vast talent pool having excellent chemistry skills, strong support from ancillary industries and a favorable regulatory environment,” added by one of the prominent industry player. Agreeing that Gujarat has already emerged as an ideal pharma outsourcing destination, Hitesh Gajaria, sector head, pharmaceuticals, KPMG, said, “The state has a lot to offer in lines with the industry’s requirement that includes good manufacturing infrastructure, skilled workforce and cost competitive advantages, apart from the regulatory support. Also, the existence of various pharma manufacturing clusters like the ones in Ahmedabad, Vadodara, Bharuch, Ankleshwar and Vapi / Valsad would further fuel the state’s growth as an outsourcing destination.”
Figure: 1.4

Share of Export of Pharmaceutical Industry in Gujarat:

Of the state’s total exports, bulk drugs constituted for 40 percent, while formulations accounted for the remaining 60 percent.

Gujarat holds a dominant position in India’s pharma industry. The state has successfully captured a share of over 42 percent of India’s total turnover in 2005-06. This is a steep increase from the mere 10 percent market share in 2002-03.

(Source: Gujarat Pharma Industry striding in to the future KMPG IN INDIA)
He also indicated that Gujarat’s established academic and research institutes and pharma manufacturing, packaging and chemical industries, coupled with factors such as backward linkages, large number of CROs, and enhanced level of investment in R&D by local industry and IT capabilities would give it an edge as a preferred sourcing partner over other states in the country.

During its growth as a sourcing centre through CRAMS business, Gujarat has also developed its own strengths in different segments of pharma business. Referring to the competencies that Gujarat pharma industry hold in this outsourcing regime, I. A. Modi, chairman, Cadila Pharmaceuticals Ltd, said, “In the field of outsourcing, Gujarat has a great potentiality in tackling and development of problems in research and development (R&D). Gujarat can take up demand of new molecules either by manipulating the existing molecules or a total new molecule. In the case of therapeutic vaccines also, Gujarat can contribute needed potential adjuvant.” He also said that in Gujarat, fairly a good number of clinical research organizations have come into existence to meet the international standards and they have successfully trained required technical staff. “One can say that CROs have come to the top gear line in the state,” he added. There is no doubt that Gujarat has progressed extremely well on the CRAMS front. The existence of cost competitive research base, technically qualified and skilled workforce and globally harmonized regulations complement the world class manufacturing infrastructure that it has. All this has helped Gujarat to emerge as the manufacturing and research hub of Indian pharmaceutical industry. As far as contract manufacturing is concerned, Gujarat has WHO GMP
complaint and internationally accredited manufacturing facilities to meet global demand. It has around 3,245 manufacturing licensees. When it comes to contract research front, the state houses CRO players like Lambda Therapeutics, Synchron, Clinsearch, B.A. Research and Veeda Research. Also, several companies like Cadlia Healthcare, Dishman Pharma and Jubilant Pharma are likely to set up special economic zones that would further enhance Gujarat’s stand in the CRAMS space.

“Gujarat is definitely a fertile ground for CRAMS. A series of positive factors - world class infrastructure, skilled work force, low cost competitive advantage and GMP compliant manufacturing facilities and government support - makes Gujarat conducive for the contract manufacturing as well as contract research activities. Also Gujarat is having a well developed chemical and drug intermediates industry and hence various raw materials required for running CRAMS process trials are readily available. The existence of a strong alliance with the allied industries, especially the chemical industry makes the state more promising in the CRAMS arena,” noted Hitesh Gajaria of KPMG.

(www.clusterpulse.org, KPMG Analysis)
Figure: 1.5

SWOT ANALYSIS

Strengths
- Modern infrastructure facilities
- Backward linkages with raw material suppliers
- Established pharma industry
- Entrepreneurial mindset
- Well-developed allied industries
- Benign regulatory environment.

Weaknesses
- Low level of R&D spend
- Relatively inadequate technical manpower and skilled workforce
- Limited international exposure for most small to medium scale companies.

Opportunities
- SEZ-led significant export opportunities
- High growth segments such as CRAMS, R&D and generics.

Threats
- Announcement of tax holidays from governments of other Indian states
- Emergence of other alternative pharma destinations abroad
- Inadequate emission norms and waste disposal facilities may hinder growth.

(Source: KPMG Analysis)
1.18 Export & R&D

However, the strides that the Gujarat pharma industry, which was worth around US $4.4 billion in 2005-06, is making is not limited to contract research and manufacturing services. The state is still batting as a major exporter of pharmaceuticals in the country with recent expert estimates putting the state’s export growth rate at 20 to 25 per cent, at a time when the overall national export growth rate stands at 35 to 40 per cent. Available figures indicate that the state’s pharma export is worth Rs 5,000 crore, while its total production stands at between Rs 12,000 and Rs 14,000 crore. Gujarat manufactures and exports different dosage forms, including tablets, capsules, dry syrups, external application preparations, and cytotoxic drugs, hormones, vaccines, small and large volume parental, APIs and biopharma products. The pharma industry in Gujarat houses more than 3,000 registered manufacturers and the stringent implementation of current good manufacturing practices (cGMP) has enabled these players to meet the international parameters and the much needed fillip to the export business.

“The change in GMP is concerned to small and medium units and it has really helped the good units to come up, while poor units went into oblivion. As far as the larger units are concerned they are achieving much more than the recognized GMP norms laid by the drug authorities,” noted I A Modi when asked how far the implementation of GMP has changed the pharma manufacturing landscape in Gujarat. Besides, in the wake of appreciating rupee, there was a unanimous move by the pharma players in this state to embrace EURO to save export revenue. “Exporters from Gujarat and other part of the country prefer to deal in EURO wherever
possible. As far as import is concerned, the industry prefers transactions in dollars. Apart, several Gujarat-based companies have acquired fairly goon number of units in developing and developed countries, which has helped to bring more export business for pharmaceuticals,” he added. And when it comes to APIs and finished dosage forms, Gujarat pharma once again tops the chart in the country. In the words of I A Modi Gujarat has been the pharma hub of India since independence. “Today, 40 per cent of total pharmaceuticals production of the country is contributed by Gujarat. This ratio is even more in API segment.” In what can be considered as a testimonial to the state’s rich base of APIs, several multinational companies such as Wyeth, Sanofi-Aventis and Abbot have set up facilities in Gujarat to take advantage of the API edge it offers. Hinting that Gujarat would hold the leadership position in manufacturing APIs and finished dosage forms, I A Modi of Cadila Pharmaceuticals said: “The existing research and development strength in APIs and formulations and development strength in finished dosage form are Gujarat’s built up strengths and that has a lead over all the other competitors.” Endorsing a similar point of view, one of the industry players in the state said, “Gujarat has a 100 year legacy in the field of pharmaceuticals and it continues to be a leading contributor to the national output of drugs and pharmaceuticals. Successful vertical integration makes Gujarat-based pharma companies one of the competitive manufacturers in the world. It has adopted new technology and demonstrated capabilities in research, generic drugs and R&D and will leverage these strengths in the new patent era. All these would catapult Gujarat into a leader in APIs.”
Rich Opportunities

Though the pharmaceutical industry in this jewel of the West is faring well adopting to new and emerging business conditions and opportunities, all is not well with the industry. There are certain issues to be addressed. “The pharmaceutical industry has shown its strength in R&D at all levels, but unfortunately it is facing crisis for the enough funds for R&D activities due to redundant drug price control order (DPCO). In India, the market forces keep prices at the lowest and therefore I feel DPCO neither helps the consumer nor the industry. Hope the government becomes practical so that the funds are available for research activities,” said, I A Modi.

Notwithstanding the factors working against the interests of the industry’s growth, it offers a myriad of business opportunities to both the foreign and domestic pharma players. “Gujarat’s growth story has been a phenomenal one, moving swiftly from its avatar as the pharma capital of the country, contributing over 40 per cent of the national output of pharmaceuticals, to global pharma hub,” according to sources within the industry. “Gujarat has a lot to offer to the pharma companies in India exploring newer avenues for growth such as the global generics market and contract manufacturing for international pharma companies. Always, Gujarat-based pharma companies have been quick to seize the advantage and encash these opportunities. The pharma companies in the state with their integrated capabilities, from concept to production, in API and finished dosage formulations and high skills in chemical synthesis and process engineering, all at competitive costs, are attractively placed to lead the way,” the sources added.

In times to come, Gujarat-based pharma companies are expected to leverage some of the inherent advantages to create new growth avenues.
The ability to deliver high quality products at low costs, meet the stringent compliance requirements of various regulatory agencies, abundant talent and skilled workforce would give it a distinct advantage, as pharma companies forge ahead with CRAMS.

“With companies investing in new chemical entities research, biopharmaceuticals, process research, proteomics, genomics, stem cell research and transgenic research, Gujarat is poised for further growth. Opportunities will abound in the areas of contract research and we would also see several alliances and tie-ups with global pharma majors for out licensing molecules,” said an industry player. (Grooming bio-industry)

Backed by the proactive government policies, the biotech industry is expected to attain new heights in Gujarat. According to Hitesh Gajaria of KPMG, Gujarat with its rich bio-resource, strong reservoir of medical and marine resources, strong pharma and health care base is also well poised to grow in the biotechnology front. “Biotech industry in Gujarat today consists of more than 50 biotech companies and 66 support organisations. The present annual turnover in biotechnology in the state has been around US $150 to $175 million,” he noted. The thrust areas of Gujarat biotech industry include healthcare, pharmaceuticals, agriculture biotechnology, industrial enzymes, bioinformatics, contract research and marine and environmental biotechnology. The Gujarat government has proposed the development of various biotech zones that would act as enablers for the growth of this industry in Gujarat. Gujarat is again a recombinant deoxyribonucleic acid (rDNA) hub with the presence of world class centres in companies like Zydus Cadila, Intas Biopharmaceuticals, Sun Pharma and Torrent Pharmaceuticals. Of late,
Gujarat has taken strong initiatives to develop bio-clusters based on intrinsic academic and entrepreneurial strengths. Key features of these clusters are - biotech parks, biotech policies, fiscal incentives like tax holidays, capital subsidies and energy concessions, centres of biotech excellence, specific biotech development funds and incubators. Gujarat is already providing funding support to biotech research. The state has developed a dedicated action plan for promoting biotech research wherein it has identified sector-specific facilities, and institution-specific facilities, which would be developed alone or through collaborative funding. Explaining what went into the success of biotechnology in the state, Mani Iyer, Executive Director, Intas Biopharmaceuticals Ltd, said, “The government’s response to regulatory and intellectual property rights issues, development of skilled resources as well as increased allocation of funds - with an emphasis on R&D in recent years - has made an important contribution towards strengthening the biotechnology sector.”

1.19 Gujarat - A Leader in Pharma Machines:

According to industry estimates, a great chunk —almost 40 per cent— of machinery used in the pharmaceutical manufacturing in India is produced in Gujarat. This creates a very good local and global opportunity for Gujarat in the manufacturing of pharmaceutical machinery, given its strong and well established engineering sector, points out a recent study titled Gujarat Pharma Industry-striding into the Future, KPMG, India. The strong growth prospects of the pharmaceutical exports segment and growing demand from the domestic market, will further fuel growth in the pharmaceutical machinery sector. However, Gujarat’s engineering sector is highly fragmented, especially the pharma machinery manufacturing.
segment. Due to the highly fragmented nature, there is a dearth of pricing power and critical scale. This in turn restricts the ability to produce the technology-driven products required for operating in global markets. The pharma machinery manufacturing industry in Gujarat needs to consolidate and synergise the skills and complementarities available in the broader engineering sector (like the CNC machine tools industry) to be able to create world-class players with the scale and resources required, to tap the global as well as local demand. Gujarat’s dominant position in India’s pharmaceutical sector is well known. The next logical step is to aspire for global leadership in the pharmaceutical industry. However, global dominance would require:

Continuance of current growth-oriented policies that have helped Gujarat achieve this mark, and Acquisition or development of capabilities required for operating in the global market place.

Many pharma companies in Gujarat have adopted the inorganic route to participate in the global markets. However, operating in the world markets is not just about acquiring global assets but also about having a global mindset. In order to benefit from the on-going integration of the world pharma markets, the pharma industry and companies have to change internal mindsets to think and compete globally, and create an environment of innovation. Companies would have to imbibe a culture that enhances its efficiency while responding to the global challenges in different geographies. Having a world-class management team, reflective of the diverse global markets in which they operate, would be a start in this direction. The enterprise-wide use of global IT solutions is another area that needs to be addressed. The proposed Pharma SEZs are expected to
further boost India’s pharmaceutical exports segment. And Gujarat, which is witnessing a vibrant growth in this segment, will be one of the major beneficiaries of this development. SEZs are instrumental in bringing in globalization at a faster pace, due to their inherent outward looking foreign trade focus by establishing close global contacts. SEZs, therefore, offer distinct advantages to export oriented pharma companies who are present in these zones. Currently, India represents a very small portion of the outsourcing market as compared to global peers like China, Singapore etc. Additionally, the size of projects handled by India are also small. SEZs- which have good infrastructure facilities and technology- can help these pharma companies develop a global mindset.

Gujarat is set to witness tremendous benefits from the development of SEZs, as it already has an established pharma ecosystem with excellent infrastructure facilities. Through these SEZs, pharma companies in Gujarat will further facilitate India’s integration in the global pharma industry.
Characteristics of Pharma Clusters in Gujarat:

<table>
<thead>
<tr>
<th>Location</th>
<th>Existing products</th>
<th>Export Potential</th>
<th>Market-based / Resource-based / Infrastructure-based</th>
<th>Degree of Competition with large units</th>
<th>Potential Future Products</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ahmedabad</td>
<td>APIs, Finished Dosages, Contract Manufacturing, Biological Manufacturing</td>
<td>High</td>
<td>Market and Infrastructure</td>
<td>High</td>
<td>Biological manufacturing, Medical Devices</td>
</tr>
<tr>
<td>Vadodara</td>
<td>Finished Dosages, Biogenetics</td>
<td>High</td>
<td>Market and Infrastructure</td>
<td>High</td>
<td>API, CRAMS, Biological Manufacturing</td>
</tr>
<tr>
<td>Ankleshwar</td>
<td>APIs, Formulations, Vaccines</td>
<td>Medium</td>
<td>Resource</td>
<td>Medium</td>
<td>APIs for global companies</td>
</tr>
<tr>
<td>Bharuch and Vapi/Valsad</td>
<td>APIs, Finished Dosages</td>
<td>Medium</td>
<td>Resource</td>
<td>Medium</td>
<td>Intermediate and Finished Dosages</td>
</tr>
</tbody>
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Source: www.clusterpulse.org, KPMG Analysis

1.20 Brief Idea About Top 5 Pharma Companies of Gujarat

Origin:

Sun Pharmaceuticals Ltd.

Sun Pharma began in 1983 with just 5 products to treat psychiatry ailments. Sales were initially limited to two states in Eastern India. Sales were rolled out nationwide in 1985. Products for cardiology were introduced in 1987, and Monotrate, one of the first products launched then, continues to be sold even today. Important products in Cardiology were later added; several of these introduced for the first time in India, and these brought patients the latest treatments at a sensible cost, a belief we’ve always lived by.
Realizing the fact that research is a critical growth driver, we established our first research center, SPARC, in 1993 and this created the base for strong product and process development that enabled growth in the subsequent years.

Sun Pharma was listed on the main stock exchanges in India in 1994; and the Rs. 55 crore issue of a Rs. 10 face value equity share offered at a premium of Rs. 140/-, was oversubscribed 55 times. The minimum 25% that was required under the regulations then for listing was offered to the public, the founder’s family continues to hold a majority stake in Sun Pharma. We used this money to build a greenfield site for API manufacture, as well as for acquisitions. For allowed acquisitions, typically companies or assets that allowed us entry into a new market or therapy area, assets that could be turned around and brought on track were identified.

Our first API manufacturing plant was built in Panoli in 1995, for access to high quality actives ahead of competition, and in order to tap the vast international opportunity for speciality APIs.

Another API plant, our Ahmednagar plant, was acquired from the multinational Knoll Pharmaceuticals in 1996, and expanded and substantially upgraded for regulated markets, with capacity addition over the years across differentiated API lines such as anticancers and peptides. This was the first several sensibly priced acquisitions, each of which would bring important parts to our long-term strategy.

In 1997, our headquarters shifted to Mumbai, India’s commercial capital. We began the first of our international acquisitions with an initial $7.5
million investment in Caraco, Detroit. By 2000, we had completed 8 acquisitions, each such move adding new therapy areas or offering an entry to important international markets. A new research center was set up in Mumbai for generic product development for the US market. In India, as new therapy areas were entered into post acquisition; customer attention, product selection and focused marketing helped us gain a foothold in areas like orthopedics, gynecology, oncology, etc. From a ranking at 38th in 1994, by 2000 we were ranked 5th with a leadership in 8 of the 11 therapy areas that we are present in. The year 2000 was the year of turnaround at the US subsidiary, Caraco, as it began to receive approvals after successful inspection by the USFDA. In December 2004, a research center spread over 16 acres was inaugurated by the President of India, with special lab space for drug discovery and innovation. The post 2005 years have witnessed important acquisitions to strengthen our US business-the purchase of manufacturing assets for controlled substances in Cranbury, NJ; that of a site to make creams and lotions in Bryan, that of Alkaloida, a Hungary based API and dosage form manufacturer, and, Chattem Ltd., a Tennessee-based controlled substance API manufacturer.

Torrent Pharmaceuticals Ltd.

These words sum up the efforts of the Torrent group, which integrates people, processes and potential towards the betterment of mankind. It all began with the toil of one enterprising individual, Shri. U N Mehta, when he ventured on his own to create history in the Indian pharmaceutical industry by implementing successfully the concept of niche marketing. His journey, characterized by ups and downs, reached a milestone in 1970, with the launch of Trinicalm Plus, an effective tranquilizer in the niche
segment, central nervous system (CNS). The foundations for Torrent were laid when ‘Trinity Laboratories’ began operations under the able guidance of Shri Mehta whose efforts are worthy of emulation. ‘Trinity’ was renamed ‘Torrent’ and with this not only did the company get a new name, it also focused on establishing its own manufacturing facilities in the early 80s. Torrent augmented its efforts with the expansion of its manufacturing capacity, emphasis on marketing and creating business opportunities through focus on exports. Torrent Pharmaceuticals Limited recorded a quantum leap in the year 1994. It has also been rated India’s ninth best company among capital intensive companies in terms of ROCE in a study by ETIG-BCG in 2001. In recognition of the consistent performance Torrent Pharmaceuticals Limited has been receiving accolades from various quarters, such as the President’s award for highest pharmaceuticals exports of Rs. 1570 million in 1991-92. The Company that had a humble beginning has now grown to become one of the leading players in pharmaceuticals. It has ambitious plans for the years ahead. The emphasis is on Post-2005 opportunities with greater focus on the international market, in particular the lucrative North American market.

**Corporate Profile:**

The flagship company of Torrent group, Torrent Pharmaceuticals Limited, is a dominant player in the therapeutic areas of cardiovascular (CV) and central nervous system (CNS) and has achieved significant presence in gastro-intestinal, diabetology, anti-infective and pain management segments. To cater to new niche segments and sharpen its focus among customers, Torrent Pharma has six marketing divisions, each catering to defined therapeutic segment. A 2300 strong field force caters to around
2,00,000 doctors across the country, which makes it rank fifth in terms of market reach. Torrent Pharma’s competitive advantage as a manufacturer stems from its world-class manufacturing facilities. Its manufacturing facilities at Indrad, Gujarat, comply with WHO, cGMP, MHRA and TGA norms and have received ISO 9001, ISO 14001 and OHSAS 18001 (Occupational Health and Safety Management System) and ISO/IEC-17025 certifications. With a view to cater to its growth requirements, Torrent Pharma commissioned a new formulations manufacturing facility at Baddi, Himachal Pradesh, in November 2005. The facility has a capacity to manufacture 3600 million tablets, 400 million capsules and 18 million Oral Liquid bottles, per annum and would cater to the domestic formulations requirement. Torrent has a modern and well-equipped state-of-the-art R&D Centre, built with an investment of US $ 40 million. It is manned by more than 525 highly qualified scientists, with a combined experience of over 2500 scientific man-years in Drug Discovery and Development. Torrent Pharma has earmarked 9% of sales year-after-year for R&D advancement. In the International operations arena, Torrent Pharma exports to more than 50 countries around the world with over 1000 product registrations. The international business has been broadly divided into five zones- USA, Latin America, Russia and CIS, Western Europe and CEE and Rest of the World (ROW). For its export excellence in International Business, Torrent Pharma has won several prestigious export awards. Torrent Pharma is now gearing up to enter the advanced highly regulated international markets. Torrent Pharma has incorporated Zao Torrent Pharma in Russia, Torrent Do Brasil Ltda in Brazil, Torrent Pharma GmbH in Germany, Torrent Pharma Inc. in USA and Torrent Pharma Philippines Inc. in Philippines. These wholly owned subsidiaries (Source:www.dishmangroup.com)
will become a springboard for entry into several regulated and less regulated international markets. (www.torrentpharma.com)

**Dishman Pharmaceuticals and Chemicals Limited:**

Dishman is the global outsourcing partner for the pharmaceutical industry offering a portfolio of development, scale-up and manufacturing services. The products and services offered span customers’ needs from chemical development to commercial manufacture and supply of active pharmaceutical ingredients. Dishman has a relationship driven business model that improves its customers' businesses by providing a range of solutions at locations in Europe, China and India. Our offer delivers the best of both worlds: western expertise in speed, flexibility, innovation and rapid material provision new world expertise in process optimisation, robust large scale processes and secure economic commercial supply. Our commitment is to deliver cost-competitive technical excellence and to be a reliable partner to our customers, protecting their interests as if they were our own. Dishman is headquartered in Ahmedabad, India and is listed on the Bombay Stock Exchange (BSE). In 2008/09, Dishman had sales of over US$230m. (www.dishmangroup.com)
Zydus Cadila Healthcare Ltd.

An Integrated Global Healthcare Company

Zydus Cadila is an innovative global pharmaceutical company that discovers, develops, manufactures and markets a broad range of healthcare products. The group’s operations range from API to formulations, animal health products and cosmeceuticals. Headquartered in the city of Ahmedabad in India, the group has global operations in four continents spread across USA, Europe, Japan, Brazil, South Africa and 25 other emerging markets. In its mission to create healthier communities globally, Zydus Cadila delivers wide ranging healthcare solutions and value to its customers. With over 13,000 employees worldwide, a world-class research and development centre dedicated to discovery research and eight state-of-the-art manufacturing plants, the group is dedicated to improving people’s lives.
Formulations Business – India

With three multi-therapy divisions and eight specialty divisions, Zydus Cadila is one of the leading player in the Indian healthcare industry. It is the leading player in the cardiovascular, gastrointestinal and women’s healthcare segments. The group has strong presence in respiratory, pain management, CNS, anti-infectives, oncology, neurosciences, dermatology and nephrology segments. It has been able to maintain overall position and market share through faster growing chronic / lifestyle segments. With several new product introductions and pillar brands such as Aten, Ocid, Deriphyllin, Pantodac, Atorva, Nucoxia, Mifegest to name a few, Zydus Cadila is considered a tour-de-force in therapy management and brand management. one of the strongest distribution channels in the industry, the group reaches out to 1,00,000 chemists and serves 2,00,000 doctors including physicians, specialists and super specialists.

Zydus Wellness Ltd., one of the companies managed by zydus group, spearheads the group’s presence in the consumer and wellness segment. Zydus Wellness aims to promote ‘healthy living’ by anticipating the emerging and day-to-day needs in dietetic / health foods. Health and wellness have been identified as the emerging areas in consumer healthcare. The Company is focussed on empowering individuals who wish to adopt healthy eating habits and lifestyles. The Company is a pioneer, offering healthier dietary options to the consumers. The product range comprises Sugar Free Gold– India’s No.1 sweetener with a market share of over 70%, Sugar Free Natura– a zero calorie sucralose based sugar substitute, Sugar Free D’lite– a low calorie healthy drink and Nutralite– a premium cholesterol-free table spread. Nutralite has
emerged as the second largest brand in the category of butter and butter substitutes.

The Company also caters to the skincare segment with its Everyuth and Dermacare brands, which occupy a unique distinction of being a ‘skincare brand from a healthcare company’. Enriched with the power of natural ingredients, EverYuth has a strong presence in advanced skincare segments like soap-free, face washes, face masks, scrubs etc.

**Alembic Pharmaceuticals**

Established in 1907, Alembic Pharmaceuticals Limited is a leading pharmaceutical company in India. The Company is vertically integrated with the ability to develop, manufacture and market pharmaceutical products, pharmaceutical substances and Intermediates. Alembic is the market leader in the Macrolides segment of anti-infective drugs in India. Alembic’s manufacturing facilities are located in Vadodara and Baddi in Himachal Pradesh. The plant at Vadodara has the largest fermentation capacity in India. The Panelav facility houses the API and formulation manufacturing (both US FDA approved) plants. The plant at Baddi, Himachal Pradesh manufactures formulations for the domestic and non-regulated export market. The company has a state of the art Research Centre at Vadodara. Alembic Pharmaceuticals Limited understands that only making profit should not be the sole purpose of any enterprise. Therefore we are not only involved in manufacturing and making the medicines available to the masses but also making a difference to society.
at large and rural areas in particular through various initiatives. One such Initiative by the company is the Rural Development Center for the upliftment of rural population. Activities and programmes initiated by the Company consists of Health education, Health care & HIV/AIDS programmes, Vocational training, Self employment training, Industrial co-operatives, self help groups (Papad & Snack services, hosiery & garment making, carpentry, Acrylics etc), Yuvati Vikas Kendra i.e. Adolescent Girls center (for psycho social support, school support, Adolescent counseling) & youth development, Legal AID center, Farmer training programme & Agriculture development, Sanitation programme, Vikas Secondary high school for the village children to name a few. During weekends, some of Alembic employees also try to make a difference in the lives of rural people by delivering lectures and programs on health related areas. (http://www.alembic-india.com/)

References:

1. Barbhaiya RH. Research and Development in Indian Pharmaceutical Industry Evolution of Indian Pharmaceutical Companies. 2008;

2. Delhi N. The drugs and pharmaceutical clusters Sponsored by unido cdp New Delhi prepared under the aegis of the unido project/ : current status Drugs. 1999;

3. Ommission USINTRC, Greene W, Greene w. Office of economics working paper The Emergence of India’s Pharmaceutical Industry and
Implications for the U.S. Generic Drug Market: The Emergence of India’s Pharmaceutical Industry and Implications for the U.S. Generic Drug Market. Office. 2007;


8. Indian pharmaceutical industry/: 2007;(119). The globalization of the pharmaceutical industry. 2009;


14. Rashmi H. Barbhaiya, Advinus Therapeutics Pvt Ltd Bangalore, India
23. Karnani N.A project report on the pharmaceutical industry, 2005
24. www.sunpharma.com


27. www.zyduscadila.com

28. www.alembie-india.com