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INDUSTRY ANALYTICS REPORT

ON

DRUGS AND PHARMACEUTICALS

INDUSTRY

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DECLARATION

This is to declare that the report entitled “Industry Analysis-Indian Drugs & Pharmaceuticals Industry” is made in the partial fulfilment of completion of the course Industrial Analytics in Term 3 of PGP (2008-10 Batch) by Group-1(Section C) under the supervision and guidance of Prof. Samik Shome. We confirm that this report truly represents our work and accomplishments undertaken as a part of our Industrial Analytics Program. This work is not a replication of work done previously by any other individual or group.

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CERTIFICATE

This is to certify that Group 1 (Section C) of the Post Graduate Program in Management (2008-10) at Alliance Business School, Bangalore, have successfully completed their Industrial Analytics Report during the Term 3 of the curriculum as a part of Industrial Analytics course.

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Executive Summary

India's pharmaceutical industry has been growing at record levels in recent years but now has unprecedented opportunities to expand in a number of fields. The domestic industry's long-established position as a world leader in the production of high-quality generic medicines is set to reap significant new benefits as the patents on a number of blockbuster drugs are scheduled to expire over the next few years. In addition, more and more governments worldwide are seeking to curb their soaring prescription drug costs through greater use of generics. These opportunities are presenting themselves not only in India's traditional wealthy client markets such as the U.S. and European Union nations but also in emerging economies with vast populations such as Africa, South America, Asia, Eastern and Central Europe.

The pharmaceutical companies in India scan for new growth opportunities over the next decade, they have realised that some of the most promising are to be found in the world's emerging economies like India. In recent times, the pharmaceuticals industry has shown high interest in India due to its sustained economic growth, healthcare reforms and patent- related legislation.

Following a series of reforms beginning in the early 1990s, India has enjoyed over a decade of strong growth and a rise in the spending power of its citizens. Real average household income in India has roughly doubled over the past two decades. In the meantime, disease patterns in India have undergone a shift. Increasingly stressful lifestyles have led to significant increases in the incidence of chronic diseases. While government interventions have brought some acute ailments under control, a sizeable part of population remains susceptible to a wide range of acute diseases. Thus pharmaceutical companies such as Ranbaxy, Cipla, Sun Pharmaceuticals have a strong presence in the pharmaceutical market national as well as international. We analyse Ten Indian Companies to show the strength of this sector as well as opportunities of business which can be harnessed in future. These opportunities are presenting themselves not only in India's traditional wealthy client markets such as the U.S. and European Union nations but also in emerging economies with vast populations such as Africa, South America, Asia, and Eastern and Central Europe.

India's pharmaceutical industry has been growing at record levels in recent years but now has unprecedented opportunities to expand in a number of fields. We have analysed the future

prospects of the industry based on the impact of five fundamental growth drivers: income demographics, medical infrastructure build-up, health insurance penetration, incidence of diseases and likely competitive intensity. The analysis shows that if the Indian Economy gains strength, the Indian pharmaceutical market will undergo a major transformation in the next decade and it will become one of the top ten markets in the world.

Introduction

The pharmaceutical industry is one of the many unique industries of the world wherein enterprises earn profits operating under several ethical constraints and legal considerations. It is the knowledge-driven business of healing and saving lives with a set of challenges and peculiarities not found in any other industry. Patents, state-created price controls, technological breakthroughs, patent expiries, counterfeits, ethical considerations, intense competition, etc., are a few of the industry-specific characteristics of this industry. However, as in every other industry, the aim of the players is to overcome or capitalize on these challenges/opportunities so as to achieve their profit goals.

The global pharmaceutical industry, of which India's share is less than 2 per cent, is transforming due to changing cost structures, growing importance of emerging markets, patent expiries on popular generic drugs, and other reasons. The industry in India is growing rapidly owing to a number of factors such as rising population, increased interest in research and development, growth of exports, increased availability of skilled labour, changing lifestyles of the Indian population, increased disposable income, and so on. The industry is classified into several segments such as generics, retail drugs, nutraceuticals, clinical trials, bulk drugs, and Contract Research and Manufacturing Services (CRAMS). Sales are classified into retail sales (pharmacies, chemists) and institutional sales (hospitals).

India ranks 4th largest producer of drugs in the world which accounts for 8% of world's production by volume and 1.5% by value. Indian pharma industry ranks 17th in terms of export value of bulk actives and dosage forms. Indian exports are exported to more than 200 countries around the globe including highly regulated markets of US, Europe, Japan and Australia. It is one of the few industries which is export-surplus i.e. exports of pharmaceutical products are higher in value than imports of pharmaceutical products. Also, it is one of the few industries in India not greatly impacted by the current global economic slowdown.

Immense activity has taken place in the industry and continues to happen in the form of increases competition among large companies such as Cipla, Ranbaxy, GlaxosmithKline etc., mergers, acquisitions, new discoveries, international licenses for drugs, and so on. Owing to these and other factors, there is heightened interest in the drugs and pharmaceutical industry in India.

CHAPTER 2

LITERATURE REVIEW

Literature Review

Drug and Pharmaceutical industry is dynamic and we analyse the industry by doing a literature review on various aspects of this particular industry. We get experienced perspective of the various research papers published on this industry and thus helps us to understand the industry with new insights. We have mentioned all the articles and briefly stated the essence of all those articles.

Pharmaceuticals - Market and Opportunities 2007 Ernst & Young Indian Brand Equity Foundation reveals that India Brand Equity Foundation (IBEF) is a public-private partnership between the Ministry of Commerce & Industry, Government of India and the Confederation of Indian Industry. It aims to effectively present the India business perspective and leverage business partnerships in a globalising market-place. The report published by them on the pharmaceutical industry in India provides extensive information concerning the industry. It includes a market overview, the policy-setting mechanism, key trends, drivers, and opportunities, and a brief overview of the performance of key players such as Ranbaxy, Nicholas Piramal, and Cipla. Knowledge on opportunities for the industry such as contract manufacturing and research, pharmaceutical retail, bio-pharma, etc., along with the companies already engaged in capitalising on these sets the report apart from the rest. Despite data not being most recent, the report has useability value and is conclusive in nature.

Patent Expiry of Blockbuster Drugs and Push for Lower Healthcare Costs Drive Generic Pharmaceuticals Market, August 15, 2007 is based on a research report by Frost & Sullivan namely U.S. Generic Pharmaceuticals Market Outlook, this article provides a brief overview of the impact of patent expiries on the U.S. generic pharmaceuticals market. Statistical information such as the present and estimated market size of the generic pharmaceuticals in the U.S. support statements made by the author. Besides numerical evidence, qualitative reasons for the growing significance of generics in U.S. (such as demand for lower healthcare costs) are furnished by the author. The article also discusses the measures pharmaceutical companies are taking to counter the problem such as consolidation, manufacture of branded generics, and backward vertical integration. Lastly, the article advocates that low-cost manufacturing locations will play a pivotal role since pricing pressures would intensify as low-cost versions of blockbuster generics take centre stage in the pharmaceutical market.

Domestic drug makers immune to slowdown, Business Standard (March 13, 2009) PB

Jayakumar in his article views the pharmaceutical industry as one of the few industries that is 'recession proof.' Testifying to this, the author cites growth data provided by pharmaceutical industry researcher ORG-IMS. Growth has been witnessed in a number of segments of the industry such as anti-infectives, gynaecology, vitamins and minerals, and respiratory drugs, in the month of January in 2009. According to the article, the growth of the domestic drug sector, which was just 6.8 per cent in November 2008, improved to 13.2 per cent in December and to 14.4 per cent in January. Further, information regarding companies' ranks based on total market share as estimated by ORG-IMS forms a part of the article. The numerous reasons for the buoyancy of the pharmaceutical industry in recent times find mention in the article along with the sources of this information. The reasons attributed to the industry's growth are better health insurance coverage, increasing rural penetration, rising population, and so on. Lastly, Estimations of the growth rate of the industry by few institutions (KPMG, Yes Bank) are cited by the author.

Old is not gold? 2009 in Express Pharma Suja Nair says that among the most ignored segments of the pharmaceutical industry is the medicine for the elderly i.e. geriatric medicines. Exploring several reasons for the ignorance of this segment by the industry, the author provides an insight into the geriatrics market and the important place it will occupy in the future as today's young population grows old. The author states that there are a few companies such as Mumbai-based Elder Pharmaceuticals which cater to the medicinal needs of the elderly. However, geriatric medicines remain untouched to a large extent due to lack of clarity regarding the geriatrics market. The government has contributed to improving the situation by, among other things, formulating a national policy for aged under the Ministry of Social Justice and Empowerment. The author says that geriatric medicines need to be given more attention and this is possible through a strong pro-active government that starts and strengthens collaborations between the healthcare industry, insurance agencies and pharma companies.

India seeks pharmaceutical partnerships. Publication: Business Times (Malaysia)

Publication Date: 31-MAR-09. Rupa Damodaran in her article says that INDIA'S pharmaceutical industry is at the verge of an complete makeover, like it happened to Indian IT industry in 1990. According to an visiting Indian government official "INDIA'S pharmaceutical industry is looking to partner with Malaysian companies to expand

manufacturing of off-patented medicines. India is also at verge to have joint venture partnerships for production and export to third countries, towards building our Pharma its Vision 2020. (along with Indonesia and Thailand). The strong base of this sector is seen through the fact that even during slowdown; this sector contracted only 2%. Exports to countries like the US, European countries and even Asian countries like Malaysia has been very strong. Income from patent expiry is also very high (almost US\$70 billion by 2015). India will be soon an global hub of novel and innovative patented drugs. And India will float one out of every five innovative drug capturing 15-20 per cent of the world's research and development pipeline.

Government plans to make India, one of the top five pharmaceutical innovations hubs by 2020, will mobilize investment of two billion annually. Publication: PTI. Publication Date: 15-MAR-09, COPYRIGHT 2009 Asia Pulse Pty Ltd, By DEEPAK SHARMA in his article says that India is Aiming to become one of the top five pharmaceutical innovation hubs globally, the government plans to invest up to 2 billion dollars, or Rs 10,000 crore, annually till 2020. The entire amount would be spent on developing more effective medicines to cure diseases such as malaria and tuberculosis that hits millions every in India and other developing countries. The spread of diseases is more in countries with lower income levels, making research in these areas less remunerative. Rich multinational drug maker are not willing to participate in this because this drugs fetch less profits. Taking this into consideration department of pharmaceuticals proposed to offer incentives to domestic as well as multinational drug makers to encourage new drug discovery in the country. According to them the proposal has the potential to add \$20 billion to the GDP by 2020, along with creating lakh jobs. This proposal has already been sent to Prime Minister Manmohan Singh and are awaiting his approval. . Once they get the approval of the Cabinet, they will launch the programme within six months. According to them Africa, South Asia and Latin America are also huge markets for companies which would develop medicines for diseases such as malaria and tuberculosis. The government would invest in building infrastructure for R&D in the country and a significant amount from the proposed investment would be spent on upgrading human resources also. Besides this, the government is also working on framing regulations in such a way that it would promote R&D in the country.

Elder pharmaceuticals ltd published in 2008 - Care Research Report says that formulations and bulk drugs are its main product segments. CARE A+' (single A plus) rating

to the long-term & +' (PR one plus) rating to the short-term bank facilities of EP. EPL manufactures API and formulations across seven manufacturing plants in India possessing capability to manufacture various dosage forms like tablets, syrups, capsules, injectibles, topical creams and ointments. All its units are compliant with international standards and benchmarks.

The Indian Pharmaceutical Industry – Prescription for growth published in 2008 - Care Research Report says that the playing field for the domestic pharmaceutical companies changed completely with the advent of product patent regime from January 2005. The IPI is now exposed to a host of new opportunities and risks. This has led the domestic pharmaceutical companies to pursue various strategies on the business and R&D front with the aim of achieving long-term sustainable growth under the new regulatory regime. Besides changes in the patent laws, the issues with respect to drug pricing and the Union Pharmaceutical policy will shape the regulatory environment for the industry in future. CARE Research believes that the growth of the Indian pharmaceutical companies in the domestic market get restricted with the MNCs introducing newer patented drugs in the country. It also believes that the growth of the Indian pharmaceutical companies in the domestic market get restricted with the MNCs introducing newer patented drugs in the country. Under this scenario, the growth for the formulation companies is likely to come from the generics opportunity in the regulated markets and geographic expansion in the semi/non regulated markets. The investment in R&D is also on the rise as it has become important for Indian companies to start innovating new drugs in order to ensure long term sustainable growth and remain competitive at the global level.

Promoting Pharmaceutical Research under National Health Care Reform by Science, Technology, and Engineering Policy White Paper Competition 2008. Jacob Heller says the pharmaceutical industry is suffering a productivity crisis, brought on by soaring R&D costs and competition with generic manufacturers. Upcoming health care reforms in the US will curtail the remaining incentives for pharmaceutical research, but also provide us an opportunity for rebuilding a more efficient set of research incentives. Continued research into medical technologies is essential for improving the quality of life of Americans and eradicating diseases, and has historically proven exceptionally cost effective. To maintain robust incentives for medical research and to cure defects of the patent system, National Pharmaceutical Innovation Fund was introduced. The Fund will compensate innovators based

on market success and medical efficacy, measured by Quality-Adjusted Life Years (QALYs). By setting proper incentives, the Fund marshals private sector efficiencies, expertise, and resources to innovating improvements in medical treatments. Pharmaceutical products have tremendous returns in increased lifespan and quality of life, making continued support an important national priority.

Indian Pharmaceuticals and HealthCare Reports Q1 2009 article says that India holds an unchanged eighth position in BMI's Q109 regional Business Environment Rankings for Asia Pacific, remaining regarded as a moderately attractive proposition. India is fast-growing population representing one of the main drivers of pharmaceutical growth in the coming years, there are many barriers too like:

- low per capita consumption
- emphasis on generics (hampering the level of market development.)
- excessive amount of red tape
- underdeveloped infrastructure and
- The deficient legal framework.(although the government is striving to improve the regulatory environment)

In December 2008, India's drug price regulator decided to lower prices of 46 brands and to include 254 new medicine brands in the list of price-controlled drugs. Meanwhile generics industry continues to expand, both locally and abroad. Zydus Cadila - a unit of Cadila Healthcare - purchased Italy-based Etna Biotech from Dutch biotechnology firm Crucell, while Sun Pharma acquired 100% of the US-based narcotic producer and importer Chattem Chemicals. On the other hand, Lupin recently became the third drug maker to be accused of sub-standard manufacturing by the US Food and Drug Administration (FDA), which will attract greater scrutiny on the sector as a result. Other Indian companies facing similar problems in the past include Ranbaxy Laboratories, Sun's' US-based subsidiary, Caraco Pharmaceutical Laboratories, as well as Wockhardt and Granules India. Growth of India's pharmaceutical export sector is down by more than half, Key reasons being increased competition in the highly regulated markets of the US and Europe and the steady appreciation of the rupee. Even victory of Barack Obama and the Democratic Party in the US general election in November 2008 will increase generic substitution in the world's largest pharmaceutical market, while the 2011 patent cliff provides yet the greatest opportunity for

Indian generics exports. Nevertheless, generics are on winning position when domestic front is considered.

Amelia Gentleman (August 7, 2007) in her article **Setback for Novartis in India Over Drug Patent** deals with a case that was filed by Novartis to get a patent for the improved version of their previous drug Gleevec. Indian High Court in Madras rejected their appeal saying that they were more concerned about the patients rather than patents. If patent would have granted, this would have raised the prices of the drugs. And most of the drugs from India are exported to developing countries and the poorer section of the developed countries; they wouldn't be able to afford it.

Uwe Perlitz(April 9,2009) in her research paper **India's Pharmaceutical Industry course for globalization** provides readers an insight into the Indian pharmaceutical industry, including topics such as its history, the segments within the industry, the change caused by the new patent regime since 2005, its key growth drivers, exports, Indian companies investments abroad and so on. Detailed research has been carried out which is apparent throughout the report. The information conveyed through the report is supported by substantial evidence which have been gathered from DB Research itself and a few external sources. The report outlines India's position in the world pharmaceutical market as well as its standing among Asian countries. Summarily, the paper mentions the changes needed to be made for the pharmaceutical industry to rise and flourish. Since the paper includes valuable information about the pharmaceutical industry, it would be of great aid in making the report.

Jacob Heller and Gabriel Rocklin (2008) in the article **Promoting Pharmaceutical Research under National Health Care Reform** brings to light the current problems and scope of improvement of the Drug and Pharmaceutical sector of United States of America. It puts forth the 'patent system' which hinders the future growth of this sector. There is a need to start focusing on preventive measures which could be only attained by channeling funds towards research and development in drugs and pharmaceutical sector. Complacency can be the reason for the doom of this sector. Thus innovative steps should be taken in time as an impetus to this sector. Especially during these troubled times. The future is positive for research and to make Medicare be preventive rather than just be used for curing.

Manjeet Kripalani (March 25, 2008) in her article **Indian Pharma: Hooked on the Hard Sell** talks about the unethical marketing practices being carried out by pharma companies in India. Some pharma companies tend to engage themselves in aggressive marketing tactics which include showering physicians, pharmacists, and wholesale distributors with expensive gifts. In return doctors may prescribe drugs based on company incentives rather than the needs of patients. Here the author emphasizes the need of a regulatory body to in India to take care of the patient's well being. To look after this concern the Organization of Pharmaceuticals Producers of India has published a voluntary "Code of Pharmaceutical Marketing Practices," that calls for maintaining strict ethical standards when conducting promotional activities. And soon this code would be converted into law. Hence it is clearly evident that though the Indian pharma industry has been growing enormously in the past few years and has been coming up with new high quality, competitively priced, generic drugs, but this success story is not as glamorous as its seem to be.

Uni Blake (8th March, 2009) in her article **Are Pro-biotics the Answer to Keeping Allergies at Bay** opines that most people look forward to spring but some fear it, as it brings in allergies and related hay fever. Hay fever is caused due to pollens and spores which is an irritant to the cell tissues causing itching eyes, nasal drainage, difficulty breathing and a hoarse voice. According to researchers, probiotics (Probiotics are dietary supplements of live bacteria or yeasts, probiotics strengthen the immune system to combat allergies) is a solution to reduce allergies caused due to pollens and the like leading to hay fever.

The results of using probiotics, have been mixed. However the best way to avoid allergy is by:

- Showering before bed to remove allergens from skin or hair
- Keeping track of the daily pollen count and avoiding to going out on high pollen days
- Taking anti-histamines or decongestants to help relieve symptoms

George Yeh in his article **When Borders Break Down** has stated that globalisation coupled with the many benefits presents new challenges to entrepreneurs across the world. Many industries like the IT industry have already faced the process and thrive successfully in international arena it is now the turn of the pharmaceutical industry. There are some many benefits that Asian countries have over US. One of the advantages is cost competitiveness

due to relatively low labour costs. The cost of conducting development and clinical trials in Asia is about 70 to 80 per cent cheaper than that of the US. Due to its large population, locating volunteers for clinical trials becomes faster and easier in Asia, resulting in shortened clinical trial time, and subsequent cost reduction. Asian countries also face some hurdles like inferior technology, and investment.

CHAPTER 3

THE GLOBAL PHARMACEUTICAL INDUSTRY

3.1 Introduction

The pharmaceutical industry is a very unique and spectacular industry, with an impressive evolution along the 20th and the beginning of the 21st centuries, as well as facing a challenging future. The situation in the industry at the global level has spectacularly changed in the past two decades, leading to new strategies and new portfolios, especially for the major pharmaceutical companies worldwide. The current pharmaceutical industry characterizes as a mature and stable industry that is constantly affected by mergers and acquisitions, as well as by new scientific discoveries. Therefore, it becomes very essential to understand the global scenario and the current trends in the pharmaceutical industry for the companies to operate in a single market and serve the mankind across the globe. In this chapter an overview of the global pharmaceutical industry has been given. Starting from the origins and evolution of the global pharmaceutical industry to the current market structure and the industry trends are being discussed. Also the challenges that are faced by the global pharmaceutical industry are mentioned. Finally the future outlook is being provided for the current year 2009 based on the predictions of IMS Global Pharmaceutical and Therapy Forecast 2009.

3.2 Origins and Evolution

The modern pharmaceutical industry is a highly competitive non-assembled¹ global industry. Its origins can be traced back to the nascent chemical industry of the late nineteenth century in the Upper Rhine Valley near Basel, Switzerland when dyestuffs were found to have antiseptic properties. A host of modern pharmaceutical companies all started out as Rhine-based family dyestuff and chemical companies e.g. Hoffman-La Roche, Sandoz, Ciba-Geigy (the product of a merger between Ciba and Geigy), and Novartis etc. Most are still going strong today.

Over time many of these chemical companies moved into the production of pharmaceuticals and other synthetic chemicals and they gradually evolved into global players. The introduction and success of penicillin in the early forties and the relative success of other innovative drugs, institutionalised research and development (R&D) efforts in the industry. The industry expanded rapidly in the sixties, benefiting from new discoveries and a lax regulatory environment. During this period healthcare spending boomed as global economies prospered. The industry witnessed major developments in the seventies with the introduction

of tighter regulatory controls, especially with the introduction of regulations governing the manufacture of ‘generics’. The new regulations revoked permanent patents and established fixed periods on patent protection for branded products, a result of which the market for ‘branded generics’ emerged.

Branded companies are the innovative companies that carry out the Research and Development (R&D) of new drugs (or contract this process). Initially, their products are protected by patents. The clinical test data, used for the approval of the drugs, is usually protected as well. **Generic companies** produce drugs that they have not developed themselves. Normally these drugs are not protected by patents anymore. However, many branded companies have divisions or subsidiaries that produce generics as well. With regard to the products of these companies, three categories of drugs are commonly distinguished.

- **Prescription drugs.** These have to be prescribed or administered by healthcare professionals.
- **Over the counter (OTC) drugs,** also called self-medication drugs. These can be purchased without a prescription.
- **Vaccines.** These are usually regarded as a separate category next to pharmaceuticals. In contrast to pharmaceuticals, vaccines are not based on chemical compounds but on live bacteria and viruses. The production process of vaccines is therefore quite different and far more complicated.

3.3 Current Industry Scenario

The global pharmaceutical industry in the year 2007 was estimated to be around USD712 billion. According to the Pricewaterhouse Coopers estimates, the value of Pharmaceutical Industry by the year 2020 would reach to 1.3 trillion. In the year 2005 the global pharmaceutical sales was USD 602 bn, which increase to USD 643 bn in 2006 and registered a modest 6.5% growth in 2007. But due to recent recession and economic crisis it has seen a little slump for the year 2008. In spite of difficult market conditions and patent expiry of several blockbuster drugs, the global pharmaceutical markets expanded to \$750 billion in 2008 biotechnology drugs/biologics accounted for \$87 billion and generics for \$80 billion of the global market.

The three top therapeutic categories were **CNS drugs** at \$118 billion, **cardiovascular drugs** at \$ 105 billion and Cancer drugs at \$70 billion of sales. In biologics the top three categories

were **monoclonal antibodies** at \$33 billion, **Vaccines** at \$25 billion and **TNF inhibitors** at \$18 billion sales in 2008. Lipitor still remains the world best selling drug with projected sales of \$13.3 billion as its 12% sales decline in the USA was offset by higher international revenues and weak dollar. It was followed by Plavix and Enbrel. It is the first time that a biologic product has taken the 3rd top selling medicinal brand. Four biologics made the top ten best selling list and seven biologics made the top twenty lists in 2008. Patent expiry resulted in loss of sales of last year best sellers like Risperdal, Fosamax, Prevacid, Protonix and Norvasc. Regulatory action by FDA (black box warning, restricted use and labelling changes) resulted in loss of sales for Avandia as well as Aranesp and other erythropoietin brands. Tamiflu loss of sales was due to lack of demand to renew the stockpile for future avian flu pandemic. Seven brands had sales greater than \$ 5 billion and fourteen drugs with sales more than \$ 4 billion in the year 2008. Analysis of blockbuster brands sales and marketing data provides a better evaluation of the R&D performance of companies concerned.

3.4 Current Market Structure

The current global pharmaceutical market is dominated by US as always. It accounts for about 45% of global sales followed by the EU accounting for roughly 20% and Japan that accounts for 10% of global pharmaceutical sales. The rest of the world including India constitutes only 21% of the global market in terms of sales.

As at March 2008

Better Health through Research and In

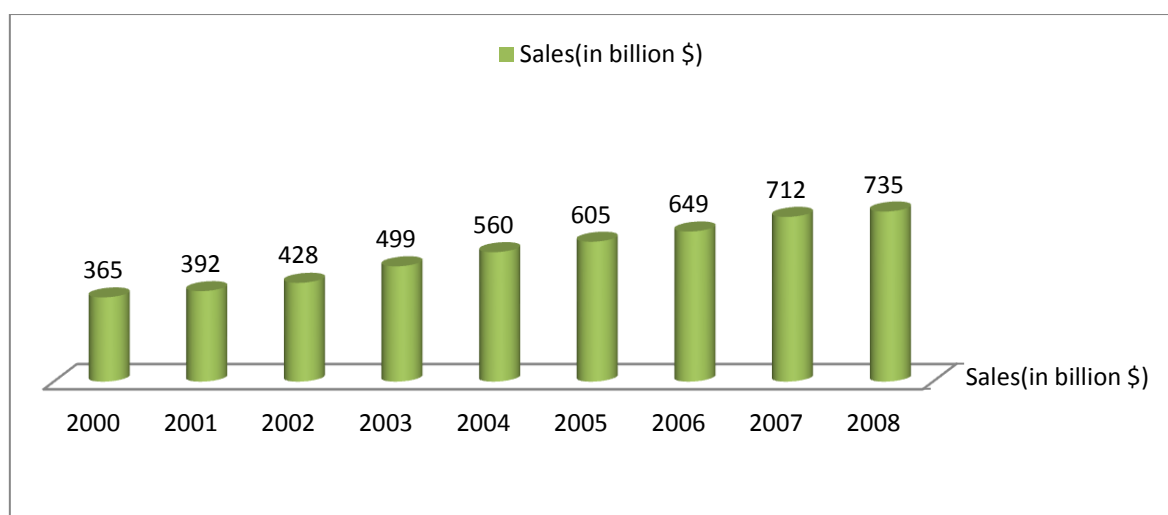


Source: IMS Health MIDAS, 2007.

Therefore it is very important for Indian pharma companies to establish their foothold in these biggest markets. In addition a lot of molecules are going off patent globally which provides a lot of opportunity for Indian generic manufacturers. In the year 2008, around 20bn USD worth drugs were expected to go off patent. Comparing these figures with the size of Indian pharma industry, the Indian pharma industry accounts a miniscule 1.5 to 1.8% of total global pharmaceutical market.

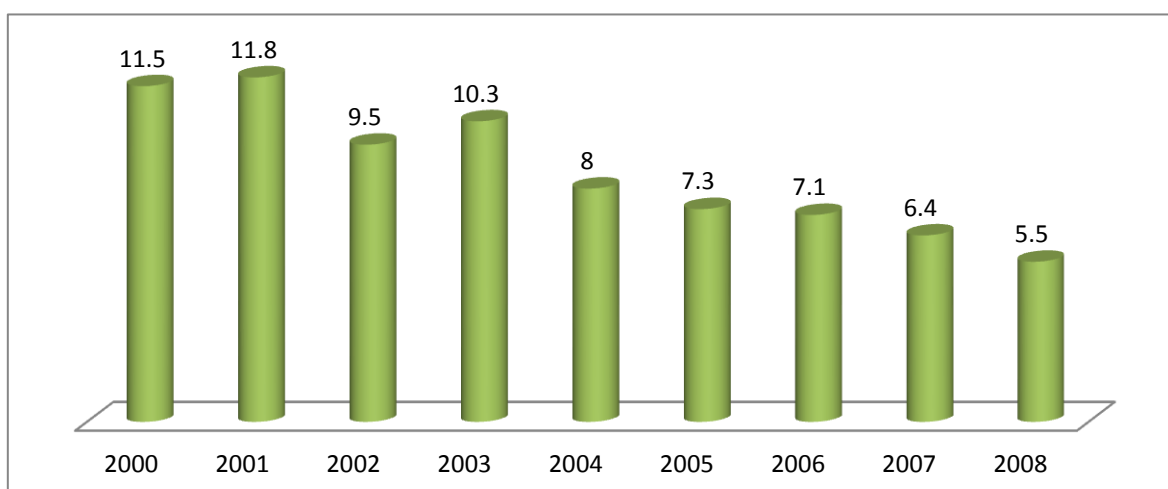
The global pharmaceutical sales have shown a rising trend since 2000. The sales figure has increased more than twice in the year 2008 as could be seen clearly from the chart given below.

Chart 3.1: Global pharmaceutical sales till 2008



Source: IMS Health Market Prognosis

Chart 3.2: Growth in Sales over previous year



Source: IMS Health Market Prognosis

Thus it can be concluded that the global pharma industry is growing at a tremendous pace but the growth percent over the previous years has been declining. In 2008 the growth percentage was only 5.5 over 2007 as compared to 2003 when it was 10.3%. This growth in the pharma sector can be attributed to the various structural and mainly the technological changes that have been taking place in the industry all this years.

3.5 Major Players in the Market

The pharmaceutical industry is characterized by a high level of concentration of multinational companies dominating the industry. Table below contains information about the top 10 pharmaceutical companies across the globe that are sorted in the order of their 2008 revenues sales of pharmaceutical products in terms of US dollars.

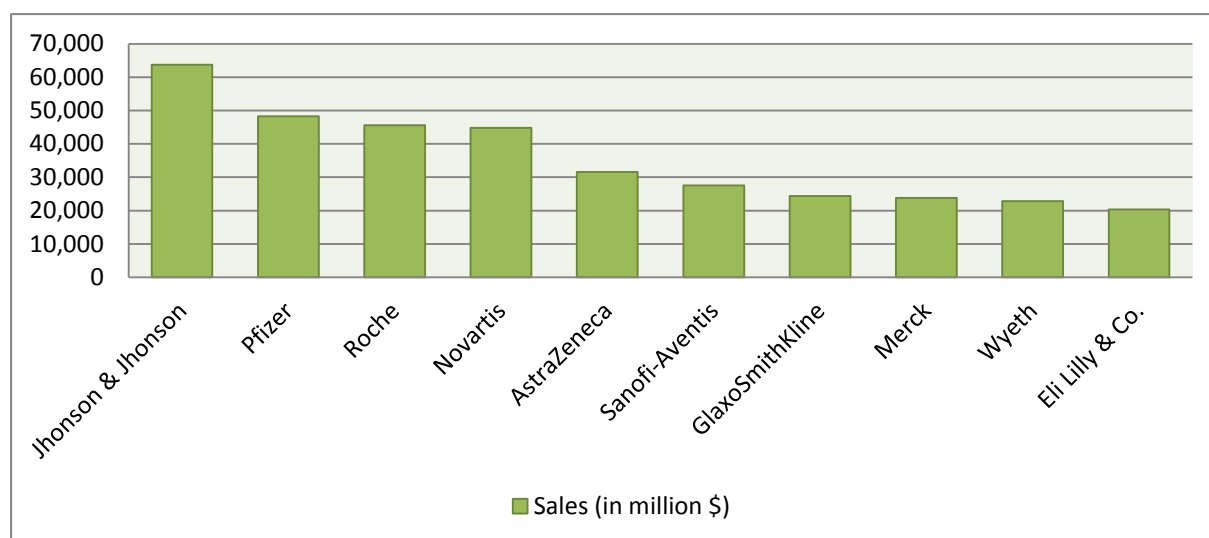
Table 3.1: Sales of top 10 global pharma companies

Sl.No.	Company Name	Sales(in million \$)
01	Johnson & Johnson	63,747
02	Pfizer	48,296
03	Roche	45,617
04	Novartis	44,821
05	AstraZeneca	31,601
06	Sanofi-Aventis	27,568
07	GlaxoSmithKline	24,352
08	Merck	23,850
09	Wyeth	22,834
10	Eli Lilly & Co.	20,378

Source: Wright Investor's Service

Geographical headquarters of major pharmaceutical companies are approximately evenly distributed between the U.S. and Western Europe with only one Asian company in the list.

Chart 3.3: Sales of top 10 global pharma companies



Source: Wright Investor's Service

From the chart it can be inferred that Johnson & Johnson was the leader in terms of sales in the global market in 2008 followed by Pfizer and Roche. Whereas w.r.t market share, Pfizer continues to lead with a market share of 6.2 percent. GSK comes in second with 5.4 percent, and Roche boasts a third-place with 4.3 percent. That's all going to change, though, as only two of today's top 10 are expected to post industry-beating growth: Roche and Novartis. The global pharma market is poised for compound annual growth of 5.5 percent over the next four years, to \$929 billion according to a report published by URCH. Roche is expected to rack up 6.2 percent and Novartis 6.1 percent. Johnson & Johnson and Merck are expected to generate only "stagnant growth" through 2012, URCH Publishing predicts.

According to a Ernst&Young, global pharmaceutical market, are counting on emerging markets to extend the life of mature products as well as to develop new markets for their ethical products. Current global financial conditions and the threat of a broad recession have accelerated the timetable for implementing change, as the industry confronts lower corporate stock prices and an increasingly cost-averse customer. The emergence of a middle class with growing disposable incomes in rapidly expanding countries with large populations, such as Brazil, Russia, India, China, Korea and Mexico, represents tens of millions of new customers who will demand improved healthcare.

3.6 Industry Trends

Structural changes

The pharmaceutical industry is currently undergoing a period of very significant transformation. The majority of “Big Pharma” companies are generating high returns which provide them with excess cash for further rapid growth – whether organic, or through mergers and acquisitions. In pharmaceutical industry size of the company on its own is a significant advantage. Besides economies of scale in manufacturing, clinical trials and marketing, bigger companies can get a competitive advantage by allowing investments in more research and development (R&D) projects which in turn diversify their future drugs portfolio and make them much more stable in the long term. As the result, top-companies in the industry were active participants of mergers and acquisitions (M&A).

Another form of structural change in the industry was establishing of new strategic alliances and joint ventures. So far as the research and development process for each drug take many years and requires significant investments, and the outcome of these investments of time and financial resources remains unclear until the final approval of the drug, “Big Pharma” companies are constantly looking for synergies that they can get from cooperation with their competitors. For example, cooperation of Sanofi-Aventis and Bristol-Myers Squibb resulted in production of Plavix, which is currently one of the top-selling products for each of these companies.

Yet another trend is selling off low-profitability or non-core businesses. “Big Pharma” companies in order to maintain strong sales growth and meet profitability expectations of their shareholders actively engage in these activities. For example, in 2003 Merck sold its low-profitability Medico Health Solutions that helped to increase its profitability margin. Massive sales of non-pharmaceutical businesses by Takeda also were compatible with its strategy to concentrate its financial resources on its core pharmaceutical business.

Major factors of future growth

The pharmaceutical industry showed high sales growth rates in the recent past, and a number of factors suggest that this trend will continue in the future. Some of these factors are:

- Due to numerous advancements in science and technology, including those in the health care industry, life expectancy in the developed countries has been steadily growing. As the result, growing proportion of elderly people promises further growth of demand for healthcare products.
- According to various studies, a significant portion of elderly population in the United States and other countries does not receive proper treatment. For example, only about one third of the U.S. population who requires medical therapy for high cholesterol is actually receiving adequate treatment. As it is expected, the Medicare Prescription Drug Improvement and Modernization Act starting from the beginning of 2006 will increase access of senior citizens to the prescription drug coverage, thus increasing pharmaceutical sales.
- Although developing countries at the moment have a small portion of world pharmaceutical sales, these countries also have a significant potential for the pharmaceutical industry in the future. Fast growing economies in Asia, South America and Central & Eastern Europe suggest an increasing solvency of population and make these markets more and more attractive for “Big Pharma” companies. Further reforms of legislation systems in the countries of these regions, especially regarding patent protection issues, will inevitably result in growing pharmaceutical sales.

Strong emphasis on R&D

One of the distinctive characteristics of the “Big Pharma” companies is a very high level of investments in research and development. On average, it takes about 10-15 years, and millions of dollars to develop a new medicine. According to industry statistics, only about one in ten thousand chemical compounds discovered by pharmaceutical industry researchers proves to be both medically effective and safe enough to become an approved medicine, and about half of all new medicines fail in the late stages of clinical trials. Not surprisingly, according to “Research and Development in Industry: 2001” report of the National Science Foundation, in 2001 the pharmaceutical industry had one of the highest R&D expenditures as percentage of net sales. More detailed information on this issue is provided in the second part of this paper.

3.7 Key Challenges

The main challenges for drug companies come from four areas. First, they must deal with competition from within and without. Second, they must manage within a world of price controls that dictate a wide range of prices from place to place. Third, companies must be constantly on guard for patent violations and seek legal protection in new and growing global markets. Finally, they must manage their product pipelines so that patent expirations do not leave them without protection for their investment.

➤ Competition

The pharmaceutical industry currently represents a highly competitive environment. One can distinguish three layers of competition for “Big Pharma” companies.

First, obviously, “Big Pharma” companies compete among themselves. Although not all leading pharmaceutical companies cover all segments of pharmaceutical market, almost all of them are active in R&D and production of drugs in the segments with the highest potential – such as treatment of infectious, cardiovascular, psychiatric or oncology diseases.

Secondly, “Big Pharma” companies experience significant profit losses due to competition from the generic drug manufacturers. Opposite to the research-oriented pharmaceutical companies, which invest significant financial resources and time to develop new medicines, generic drug manufacturers spend minimum resources on R&D, and start manufacturing already developed by other companies drugs after their patent expiration. Because generic drug manufacturers do not have to recoup high R&D costs, prices of their products are usually much lower than those of major pharmaceutical companies; as the result, after patent expiration, generic drugs manufacturers capture significant market share, dramatically decreasing revenues of the “Big Pharma” companies.

Finally, the whole pharmaceutical industry competes with other health care industries. In this case, pharmaceutical companies should not only demonstrate high efficiency of their products, but also provide obvious proof of cost advantages in comparison with other forms of care.

➤ Price control

Pharmaceutical companies have to operate in a highly regulated environment; the degree of regulation to a significant extent depends on the country and type of the product. One of the

most important aspects of government regulation for pharmaceutical companies is price regulation, and different countries have different policies on this issue. In the United States – the largest and the most attractive pharmaceutical market – currently there is no direct price control for non-government drug sales. At the same time, it is expected that Medicare Prescription Drug Improvement and Modernization Act will potentially increase downward price pressure. The majority of European countries control drug prices, and this downward pressure on prices has been increasing during last years. Japan has even stricter price controls than European countries; all prices are controlled by the government, and they are subject to a periodic price review. As the result of price control, prices of the same products can significantly differ in different countries.

➤ **Protection of patents**

Generic drugs manufacturers represent a significant threat to research-based pharmaceutical companies. For example, Schering-Plough's Claritin patent expired in 2002; as the result of generic drug competition, sales of Claritin by Schering-Plough declined from \$3.2 billion in 2001 to \$1.8 billion in 2002 and to \$0.37 billion in 2003. Moreover, generic drugs manufacturers sometimes start production of patent-protected drug analogues even before a patent expires. Although research-oriented companies in many cases are able to protect their patents, they do suffer from lost revenues.

Therefore, protection of patents is one of the key conditions necessary for further development of the pharmaceutical industry. At the same time, non-efficient legislation that does not provide the necessary level of patent protection is one of the factors that hamper expansion of "Big Pharma" companies to the developing countries.

➤ **Drugs portfolio management**

Drug portfolio management is one of the most important determinants of long-term prosperity of research-oriented pharmaceutical companies.

First, it takes an extremely long time to develop a new drug, and only a very small portion of all projects is successful. Projects that the company starts today will determine its financial performance 10-15 years later. Therefore, careful planning of R&D projects is very important for the long-term stability of the company.

Second, insofar as patents keep exclusivity of drugs only during a limited time, and soon after the expiration of the patent the sales of the drug sharply go down, the company has to carefully monitor its patent expiration dates, and insure that new products become available by that date. Otherwise, we are reminded of the case of Shering-Plough, when after expiration of its major drug patent the company did not have a new product of similar value and the company experienced losses in 2003 and 2004. Definitely, planning errors or rapidly changing demand in the industry can be corrected by acquisition of smaller research companies or patents from competitors, but in any of these cases the company will have to pay a premium price, thus reducing its profitability.

3.8 The Future

The global pharmaceutical market is expected to grow 4.5 - 5.5 percent next year, a pace similar to 2008, according to the IMS Global Pharmaceutical and Therapy Forecast(TM) released by IMS Health (NYSE: RX). The forecast, the leading annual industry indicator of market dynamics and therapy performance, predicts global pharmaceutical sales to surpass \$820 billion in 2009, reflecting sustained double-digit growth in key emerging countries tempered by a slower pace in more established markets. This includes the U.S., where growth is expected to be in the 1 - 2 percent range for both 2008 and 2009.

In its 2009 forecast, IMS identifies the following key market dynamics:

- **Slowing Growth in Mature Markets.** This year, the U.S. pharmaceutical market, the world's largest, is forecast to grow 1 - 2 percent to \$287 - \$297 billion, down from the 2 - 3 percent rate expected earlier this year. Contributing to the slower growth is less-than-expected demand for recently introduced products, as well as the economic climate, which appears to be having an impact on doctor visits and pharmaceutical sales.
- **Rapid Expansion of "Pharmerging" Markets.** The pharmerging markets of China, Brazil, India, South Korea, Mexico, Turkey and Russia are forecast to grow at a combined 14 - 15 percent pace to \$105 - \$115 billion. Along with the pharmaceutical industry's increased focus on these high-growth markets, these countries are benefiting from greater government spending on healthcare and broader public and

private healthcare funding - which is driving greater access to, and demand for, innovative medicines.

- **An Emphasis on Specialist-Driven Markets.** Products mainly prescribed by specialists are forecast to grow 8 - 9 percent in 2009 and are expected to contribute 67 percent of total market growth. Biologics are forecast to grow at an 11 – 12 percent pace, while oncology products will achieve 15 - 16 percent growth, and HIV therapies 13 - 14 percent growth. In contrast, products generally prescribed by primary care physicians are expected to grow 2 - 3 percent, due to the loss of patent exclusivity for several blockbusters and fewer significant product launches.
- **Fewer Products Winning Regulatory Approval.** New product approvals remain at historically low levels, with only 25 to 30 new chemical entities slated for launch in 2009. In addition, many of these are specialist-driven and niche products with relatively limited market potential. Expected launches for 2009 include four or five potential blockbusters for treating acute coronary syndrome, diabetes, rheumatoid arthritis and meningitis.
- **An Economic Slowdown, Most Pronounced in the U.S.** Economic conditions will be a complicating factor impacting the worldwide pharmaceutical market in 2009. In the U.S., the correlation between economic factors and pharmaceutical growth is stronger in the current slowdown than in previous downturns, given the continued shift of drug-related costs to patients. IMS estimates that in 2009, the downturn will effectively reduce growth in the U.S. by 2 - 3 percentage points. Other markets with large out-of-pocket spending requirements - including Brazil, India and Russia - also are likely to be affected by economic changes.
- **Generics Market Continues to Evolve.** An additional \$24 billion of branded products, including anti-epileptics, proton pump inhibitors and anti-virals, will lose their market exclusivity in the top eight markets in 2009. This will contribute to generics sales of more than \$68 billion next year, and a 5 – 7 percent growth rate - similar to 2008 and lower than the levels experienced in 2006 and 2007. The decline is being driven by growth slowdowns in the U.S. and U.K., where many competitors in large therapy areas are creating a fierce price war and cutting margins for generics manufacturers. Other countries are striving to increase the use of generics through various government efforts.
- **Intensified Involvement of Payers and Health Technology Assessors.** In 2009, growth across the leading European markets will be affected by payer actions, which include

increased rebating and contracting in Germany, expansion of regional formularies in Italy, a five percent decrease in branded prices in the U.K., a 10 percent price reduction on a number of brands in France, and the expansion of the reference pricing system in Spain. Meanwhile, the impact of Health Technology Assessors will be felt in Germany by reimbursement limitations for new drugs not determined to be cost effective. And in the U.K., the pharmaceutical market may be affected by any policy change that allows patients to buy additional treatments not offered by the National Health Service.

3.9 Patent system

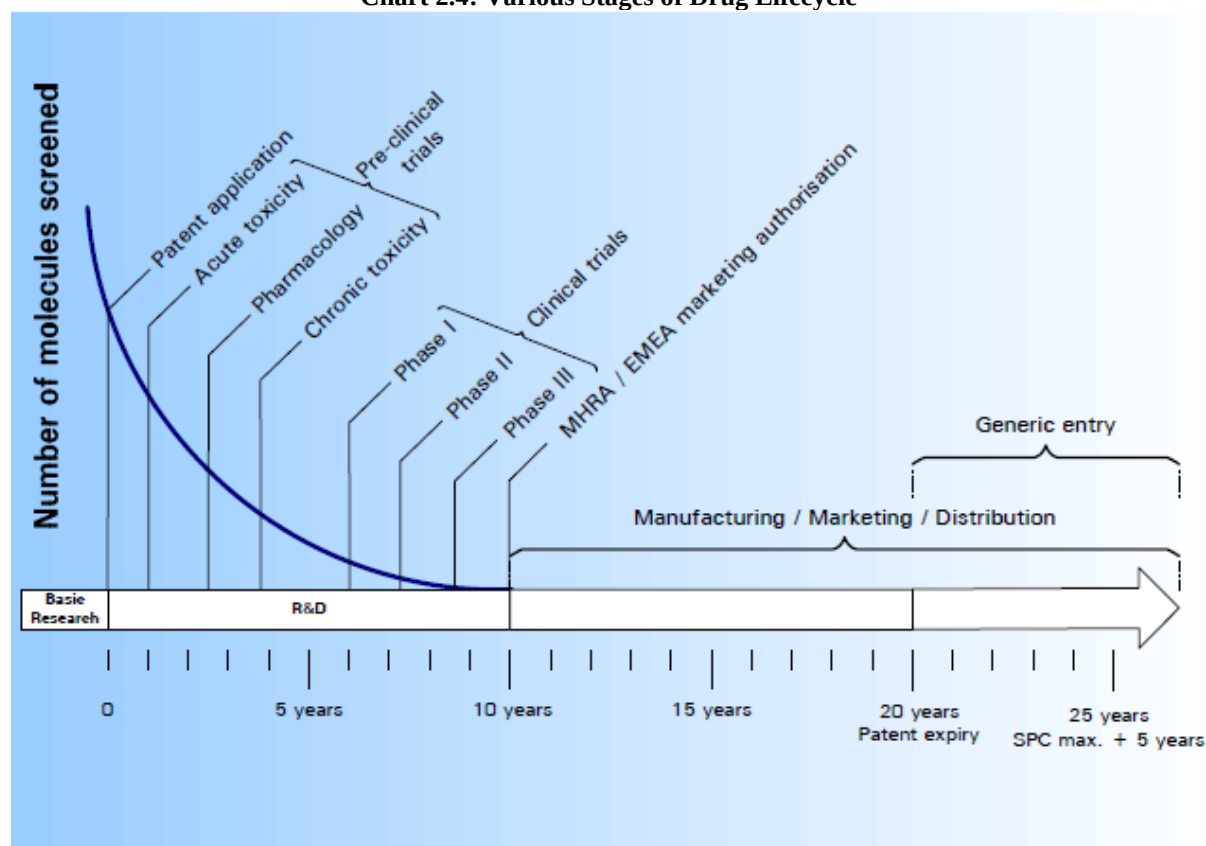
The patent system plays a crucial role in the pharmaceutical industry because of the importance of product innovation and the substantial R&D costs involved in developing a new drug. Patents give their owners the legal right to exclude others for a time from making, using or selling a product or process arising from an invention, and are typically granted for a period of 20 years. In the pharmaceuticals sector, companies can acquire patent protection once basic research has led to the identification of a promising NCE. A patent is then filed and may be granted, but the drug might typically be halfway through its patent period by the time it has progressed through the various stages of research and development and is ready to be launched onto the market.

Patent protection may allow a firm to exercise market power to some degree in pricing a drug. The profits that can potentially be earned during the patent period are crucial in providing incentives for pharmaceutical firms to undertake R&D, given the large amount of expenditure and the long lead times involved in new drug development.

2.10 Drug lifecycle

The diagram below shows the typical length of time that it takes for a new drug to go through the various stages of its life cycle.

Chart 2.4: Various Stages of Drug Lifecycle



Source: Office of Fair Trade

It is possible in the diagram to distinguish between components of the production process that can be considered 'international' (namely can be located anywhere in the world for supply to any given country) and those that are 'national' (that is need to be located in the country in question). As the diagram moves from left to right and becomes lighter, so the activities become increasingly 'national' in scope.

More formally, the term 'international' is used to denote those stages of a drug's lifecycle for which:

- The activity can be located anywhere in the world where a suitable environment exists
- Once the costs of that activity have been incurred somewhere in the world, they do not have to be incurred again in order to make the product available in other countries.

R&D is an 'international' activity in this sense of the term, as it can be located wherever a suitable research environment exists, and once a drug has been developed the R&D cost does not need to be incurred again to make the drug available in other countries. In addition, some

of the costs of global manufacturing facilities may also represent an 'international' cost element.

The different stages shown in the chart above normally follow the patent application and are described in the next few paragraphs. Even before patent application a considerable amount of time and money may have been spent on basic research to identify suitable entities for investigation, although much basic research is carried out in universities and publicly-funded institutes.

Pre-clinical trials precede any testing on humans, and involve rigorous testing of selected NCEs in laboratories and animals. There are very high attrition rates⁸ at this stage of development: less than one per cent of compounds successfully make the transition from pre-clinical trials to clinical studies in humans.

Clinical trials are carried out in humans. Three stages are carried out before drugs receive marketing authorisation, namely:

- **Phase I:** trials in 20-100 healthy adults to test the drug's safety. 70 per cent of investigational new drugs (INDs) proceed successfully through Phase I.
- **Phase II:** trials in 100-300 patient volunteers to determine the safety and efficacy of the drug. A third of INDs make it through both Phase I and II, and
- **Phase III:** trials on larger groups of patients (typically 1,000–3,000), to gain further data on safety and efficacy. Around 25 per cent of INDs progress through all three phases to a regulatory review.

Marketing authorization must then be obtained before drugs can be launched onto the market. Even after the preclinical stage, with its high attrition rate, only a small proportion of drugs proceed successfully to marketing approval.

After the drug reaches the market, Phase IV **pharmacovigilance trials** begin. These seek to identify any adverse drug reactions and continue throughout the lifetime of the drug.

As discussed earlier, generic manufacturers are able to enter the market and sell **generic copies** of the drug after a drug's patent (and any supplementary protection certificate) has expired.

In general it is clear that only a small fraction of drug entities will on average achieve a stage where commercialisation is valuable. For each new successful drug, there are many which prove unsuccessful.

3.10 Conclusion

Given the changing trends in the industry's global value chain and gradual shifts in international trade patterns, if the former pioneers (US, UK, Switzerland, and Germany) wish to remain competitive, they need to expand the development of new drugs. Otherwise, they will face a continuing of the intensified competition from developing nations that has appeared over the last decade as outsourcing investment in drug discovery and product development has grown. Also, as major patents expire and generic companies in countries like Israel and India enter these markets, this will be put added pressure from emerging economies on the former pioneer nations.

The political determinants that govern the pharmaceutical industry are all regulated by the Food and Drug Administration. The government established this organization to protect the health and safety of all customers by ensuring the quality of all drugs produced. As a result the regulations are extremely strict and few drugs are actually passed and reach the open market. Entering the field takes an immense amount of capital, due to the time needed to research, test and produce the drugs. Also drugs that have already been created are protected under WTO patents. But, once a successful drug is marketed, the industry can be very lucrative. The demand for pharmaceuticals is relatively stable even if other markets decrease in an economic slump, so with constant research and production of new drugs, a company can benefit largely. This therefore would ensure global competitiveness and success for a corporation; that is if the drugs also passed the other nations regulations.

Over the past 50 years, the pharmaceutical industry has experienced tremendous growth and change. Along with this growth has come a series of pressures to unite the industry under international standards and regulations. These international regulatory guidelines have increased the barriers to entry in the international market and have driven top firms to create

voluntary corporate standards. Also, the idea of "corporate social responsibility" has recently emerged as companies attempt to avoid liability issues and decrease their impact on the environment. In addition, environmental certification issues are a becoming driving force for change in the pharmaceutical industry. In the future, if pharmaceutical companies are able avoid liability issues by adjusting social and environmental regulations; they will be very competitive in the international marketplace.

CHAPTER 4

THE INDIAN PHARMACEUTICAL INDUSTRY

4.1 Introduction

The Indian Pharmaceuticals sector has come a long way, being almost non-existing during 1970, to a prominent provider of health care products, meeting almost 95% of country's pharmaceutical needs. Indian pharmaceutical sector is one of the fastest growing sectors. Initially India had to wait for imports of bulk drugs from global majors for re-processing and now it has become an industry which is driving product development and breaking new ground in medicine research worldwide.

The Indian pharmaceutical industry has gained significant traction in the last few years. It is currently on a high growth trajectory and rapidly integrating with the global industry. This integration is opening up tremendous new opportunities for Indian Pharmaceutical sector across all segments including generics, research and development of New Chemical Entities (NCE) and Contract Research and Manufacturing Services (CRAMS). Indian companies are now well positioned to explore these opportunities as they adopt effective and efficient business models that are spread across one or more of each of these segments.

India is getting recognition as a strong, and fast growing economy. Thus the industry is attracting many global entrants. Increasing purchasing power of the growing middle class population, high orientation towards health consciousness, quality and price driven mindset have reshaped the market structure of pharmaceutical business. The behaviour and bargaining power of different interest groups like patients, healthcare providers and regulatory authorities are expected to reinforce sectoral growth and scope.

Indian pharmaceutical industry is undergoing fast paced changes. The Indian Generics market is witnessing rapid growth opening up immense opportunities for firms. This is further triggered by the fact that generics worth over \$40 billion are going off patent in the coming few years which is close to 15% of the total prescription market of the US. The Indian pharmaceutical companies have been doing extremely well in developed markets such as US and Europe, notable among these being Ranbaxy, Dr. Reddy's Labs, Wockhard, Cipla, Nicholas Piramal and Lupin. The companies have their strategies in place to leverage opportunities and appropriate values existing in formulations, bulk drugs, generics, Novel Drug Delivery Systems, New Chemical Entities, and Biotechnology etc. The industry ranks

fourth globally in terms of volume and in terms of value, it is ranked thirteenth. The industry has thrived so far on reverse engineering skills exploiting the lack of process patent in the country. This has resulted in the Indian pharmaceutical players offering their products at some of the lowest prices in the world. The quality of the products is reflected in the fact that India has the highest number of manufacturing plants approved by US FDA, which is next only to that in the US. Multinational companies have traditionally dominated the industry, which is another trend seeing a reversal. Currently, it is the Indian companies which are dominating the marketplace with the local players dominating a number of key therapeutic segments. The market is also very fragmented with about 30,000 entities and the organized sector consisting of about 300 entities. Consolidation is increasing in the industry with many local players building a global outlook and also growing inorganically through mergers and acquisitions.

4.2 History

The pharmaceutical industry in India has evolved through three phases over the past 50 years. The first was the period prior to 1970, when the industry was relatively small in terms of production capacities. The second phase spanned the late 1970s to the early 1990s, a period during which the industry experienced policy-induced growth. In its third phase, during the 1990s, much of the regulatory structure that the Government had imposed during the previous two decades was dismantled.

Even as late as the mid-1970s, India had a relatively small pharmaceutical industry, with a total production of just over US\$ 600 million. During the subsequent four years, the total output of the industry more than doubled, the major contribution being made by formulations, which accounted for 85 per cent of total production. Table 5.2.1 shows the production figures for the two broad segments of the industry: bulk drugs and formulations.

Table 4.1: Production figures of bulk drugs and formulations in 1970s (US\$ million)

Years	Bulk Drugs	Formulations	Total
1974/75	111.1	493.7	604.8
1975/76	155.2	668.6	823.8
1976/77	167.4	781.3	948.7
1977/78	187.7	1029.9	1217.6

Source: Based On GOI, Ministry of Chemicals & Fertilizers, Annual Report (various years)

The table shows an overwhelmingly large share of installed capacity of the Indian industry was in the small-scale sector. In the 70's 43 were affiliates of foreign firms in which the parent firms' share in equity holdings exceeded 40 per cent. These foreign affiliates were deemed to be “foreign-controlled” firms, in accordance with the guidelines stated by the Foreign Exchange Regulation Act of 1973 (commonly known as FERA). This indicates that foreign industry had a disproportionately high share in total production in the mid-1970s. They produced 42 per cent of bulk drugs and formulations put together and about 38 per cent of the bulk drugs produced by the Indian industry.

Major changes that contributed in the growth of this sector are enumerated below:

4.2.1 The policy regime since the 1970s

Three critical policy initiatives taken by the Government marked a turnaround in Indian Pharmaceutical Industry:

- The Drugs Price Control Order (DPCO), which was adopted in 1970.
- Adoption of the new Patents Act, which became effective in 1972
- Adoption of a new drug policy in 1978.

The above-mentioned policy initiatives were taken with two broad objectives in view: (i) to develop a strategy for the expansion of the domestic pharmaceutical industry by relying essentially on Indian enterprises, and (ii) to establish a structure for keeping the prices of drugs within affordable limits.

4.2.1.1 DPCO, 1970

On 16 May 1970, a comprehensive order was promulgated under Section 3 of the Essential Commodities Act and in super session of all the earlier orders on the subject. This order was called the Drugs (Prices Control) Order, 1970. In its introductory form, DPCO was a direct control on the profitability of a pharmaceutical business, and an indirect control on the prices of pharmaceuticals. The government stipulated that a company's pre-tax profit from its pharmaceutical business should not exceed 15% of its pharmaceutical sales (net of excise duty and sales tax). In case profits exceeded this sum, the surplus was deposited with the government. So, a pharmaceutical company had the freedom to decide the prices of its products. Product-wise margins were also flexible, so long as the overall margin did not exceed the stipulated norm. Since individual product prices did not require approval from the government, bureaucratic hurdles were low. At that time, the Indian pharmaceutical industry was largely dominated by MNC affiliates and subsidiaries. These MNCs were hardly affected by the relatively mild form of DPCO and continued operating in the domestic market. However, FERA (Foreign Exchange Regulations Act) which came in mid 70s did curb the operations of MNCs. Overall, the Indian pharma industry prospered from 1970 to the next DPCO in 1979.

The first step towards evolving a comprehensive policy regime for the Indian pharmaceutical industry was taken by the setting up of the **Hathi Committee** in 1974. The Committee had an exhaustive mandate that aimed at the realization of the two broad objectives mentioned above. The Hathi Committee presented its recommendations in 1975.

4.2.1.2 The Hathi Committee, 1974

The Hathi committee report which, under chapter –IV stated -

“The committee believes that health care has a direct relationship with socio economic growth of the country and a welfare state should treat production, procurement and distribution of essential drugs, as a social responsibility just as import as ensuring supply of food and shelter. With a view to tackling the problem of large scale production of a Statutory Body which may be called the National Drug

Authority of India (NDA)”.

The report had mentioned several functions for NDA. The Government of India, however, did not accept this recommendation and no action was taken for creating NDA. Thus the drug policy formulated by Government of India for the first time in 1978 did not include the concept of NDA.

4.2.2 The new drug policy of 1978

The new drug policy announced by the Government in 1978 had the following five broad objectives: (i) to develop a strong Indian sector with the public sector playing a leading role; (ii) to channel the activities of the foreign firms in accordance with the national priorities and objectives; (iii) to deepen the production base of the domestic industry by ensuring that the production of drugs took place from as basic a stage as possible; (iv) to encourage research and development and improve the technological sinews of the industry; and (v) to provide drugs to consumers at reasonable prices.

4.2.3 Post-Liberalisation

As an integral part of economic reforms, the industrial, trade and technology policy framework that had evolved from 1950s to late 1980s was considerably changed in the 1990s. The New Industrial Policy (NIP) announced on 24th July 1991 and subsequent amendments brought far reaching changes in the policy regime evolved thus far. The liberalisation of the economy in 1991 had a major impact on the two vital policies (Drug Policy and Price Controls) related to the pharmaceutical industry which are discussed below.

i. Drug Policy

In September 1994, government announced a revision of the Drug Policy, 1986 making major modifications. The modifications included: abolishing licensing policy for all bulk drugs except those reserved exclusively for the public sector units and other using new technologies, removing limitations on the use of imported bulk drugs, allowing foreign holdings up to 51 percent, and automatic approval for foreign technology agreements in the

case of almost all drugs. Later on, the pharmaceutical industry was included in the list for automatic approval up to 74 per cent in March 2000 and to 100 per cent in December 2001.

ii. Price Controls

Another aspect of the reforms has been substantial dilution of the price controls. The Drug Policy, 1994 liberalized the criteria for selecting drugs for price controls. Inline with the changes in drug policy a new DPCO was notified in January 1995 bringing down the number of drugs under the ambit of price controls to 74 from 166 (as was under DPCO, 1987). These 74 drugs accounted for only about 40 percent of the total market thus setting the bulk of the pharmaceuticals market out of price controls. The exemption period for new drugs, produced through indigenous R&D was also increased from 5 years to 10 years. Although, the piecemeal reforms have been criticized for slow industrial progress gradual liberalization of the policy regime from overbearing governmental control to subtle emergence of ‘open market’ principles gave time and opportunity to firms and the local administration to adapt to the changing scenarios.

Table4.2: Depicting the changing trend in the pharmaceutical industry
Bulk Drugs under price control (1970 to 1995)

Year of introduction of the Drug Price Control Order	Number of drugs under price control
1970	347
1979	163
1987	145
1995	74

Source: Indian Credit Rating Agency (ICRA), 1999

The policy regime adopted for the pharmaceutical industry in India thus changed from one in which the industry was subjected to government controls in the 1970s to one that was almost completely guided by market forces two decades later. This changed scenario can be best understood by looking at the sharply declining number of bulk drugs under price control since 1970, the year in which the first DPCO was introduced in the country in Table 2.2.

4.3 Government initiatives

The government of India has taken various steps towards developing the pharmaceutical sector of India. They have taken steps by introducing various policies mentioned as under and investing in Research and Development to make Indian drug industry competent world wide. One of the major initiatives was the amendment of the drug patent system of India. Following are the various policies enumerated with brief descriptions which are major reasons of impact on this industry.

4.3.1 WTO, GATT and TRIPS agreement

The establishment of the world trade organization has led to a tremendous paradigm shift in world trade. The agreement on Trade Related Intellectual Property Rights was negotiated during the Uruguay round trade negotiations of the General Agreements on Trade and Tariffs and “one of the primary reason for incorporating intellectual property issues into the GATT framework was the pharmaceutical industry”. India signed the GATT on 15 April 1994, thereby making it mandatory to comply with requirement of GATT, including the agreements on TRIPS.

The WTO’s TRIPS Agreement is an attempt to narrow the gaps in the way these rights are protected around the world, and to bring them under common international rules. It establishes minimum levels of protection that each government has to give to the intellectual property of fellow WTO members. In doing so, It strikes a balance between the long term benefits and possible short term cost to the society. Society benefits in the long term when intellectual property protection encourages inventions, especially when the period of protection expires and the creation and invention enter the public domain. Governments are allowed to reduce any short-term costs through various exceptions, for example to tackle public health problem. And, when there are trade disputes over intellectual property rights, the WTO’s dispute settlement system is now available.

The agreement covers five broad issues:

1. How basic principles of the trading system and other international intellectual property agreements should be applied.

2. How to give adequate protection to intellectual property rights.
3. How countries should enforce those rights adequately in their own territories.
4. How to settle disputes on intellectual property between members of the WTO.
5. Special transitional arrangements during the period when the new system is being introduced.

Scenario Post-TRIPS

The most important amendment which had to be introduced by the amendment of 2005 in order to make the existing patent regime in India TRIPS compliant was the introduction of pharmaceutical product patents. The amendment of 2005 extends full TRIPS coverage to food, drugs and medicines. It requires patents to be provided to products as well, while the patent regime provided by the act of 1970 required patents only to be granted for chemical processes which resulted in the production of a particular drug. The other implications for the pharmaceutical sector under the new act are as follows:

- (i) The term of a patent protection has been extended to twenty years compared to the seven years which was provided by the act of 1970. This was made applicable to all the member countries and hence rules out all the differences with respect to patent protection which prevailed in different countries;
- (ii) If the law of the country provides so, then the use of the subject matter of the patent shall be permitted without the authorization of the patent holder, including use by the government or any other third party authorized by the government. However such use shall be permitted only if prior to such use, the user has made efforts to obtain the authorization of the patent holder and such efforts have not been successful within a reasonable period of time. This requirement can be waived in case of a national emergency after notifying the patent holder; and
- (iii) The burden of proof with respect to infringement matters have been reversed under the new act. The onus of proving on a legal complaint that the process used by one enterprise is totally different from that which has been used by another would lie on the defendant. Prior to the amendment the responsibility was on the patent holder to establish patent infringement.

The new amendment was not to affect the drugs which were in the market prior to 1995. As far as those drugs which were produced between 1995 and 2005, they will have the right to continue to produce them in return for the payment of a fixed royalty to the patent holder. The main problem arises for those drugs which are now being manufactured and patented. The only way by which such drugs can be manufactured in India is by way of compulsory licenses. Such compulsory licenses are granted by the government on grounds such as non availability, high prices, public interest etc

4.3.2 Pharmaceutical Policy 2002

There were several objectives to this policy when it was first implemented in 2002. It intended to ensure availability of good quality pharmaceuticals at reasonable prices for mass consumption and intended on encouraging pharmaceutical research and development which is compatible with India's needs. The *Pharmaceutical Policy 2002* also has the objective to strengthen the original capability for cost effective quality production and export of pharmaceuticals by reducing trade barriers in the pharmaceutical sector. Finally, one last objective of this policy is to encourage new investment in the pharmaceutical industry by means of introducing new technologies and new drugs.

4.3.3 National Drug Policy

A national drug policy (NDP) is a guide for action, containing the goals set by the government for the pharmaceutical sector and the main strategies and approaches for attaining them. It provides a framework to coordinate activities of pharmaceutical sector participants: the public and private sectors, nongovernmental organizations (NGO, donors, and other interested parties. A country's drug policy, although similar in many ways to that of other countries, may differ in its objectives, strategies , and approaches. National governments are the principal agency in the formulation and implementation of drug policies, leading a partnership among the government, drug prescribers, drug dispensers, drug consumers, and those who make, market, distribute, and sell drugs

4.3.4 Patents Amendment Act (2005)

The Patent Amendment Act 2005 passed by the Parliament in its budget session of 2005 brings the Indian Patent Act in full conformity with the intellectual property system in all

respects. This replaced an ordinance promulgated on December 2004 to meet WTO obligations. Some of the major amendments have been introduced in Sections 2 and 3 which are as follows:

Section 2 of the Patent Act is the definition clause:

According to Section 2(j) invention means a new product or process involving an inventive step and capable of industrial applications.

(j.a) inventive step means a feature of an invention that involves technical advance as compared to existing knowledge or having economic significance or both and that makes the invention not obvious to a person skilled in art.

Thus an invention in order to be patentable, should:

- (i) involve an inventive step capable of industrial application;
- (ii) which should involve technical advances as compared to the existing knowledge or having economic significance or both; and
- (iii) be not obvious to a person skilled in art.

Section 3 outlines various situations where an invention (properly so called) can yet be not patentable. Section 3(d) of the Patents Act 1970 has been amended under the new Act to prescribe a class of discovery which cannot be subject matter of patent; it reads as follows:

(d) mere discovery of a new form of known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least employs one new reactant.

Product Patents have been extended to fields of technology such as drugs, food and chemicals but granting of patents are subject to restrictions as mentioned above (Section 3(d)). This section prevents frivolous inventions from being patented.

The amendments introduced in the Patents Act exhibit the essence of patentability in the pharmaceuticals and chemicals is inventive ingenuity, novelty and existence of industrial application or economic significance of the new product or process.

4.4 Patent System of India

4.4.1A rigid patent regime

The bedrock of patent protection in India was the India Patents Act 1970, which only allowed 7 years for process patents. The act explicitly ruled out product patents for “substances intended for use, or capable of being used, as food or as medicine or drug.”

This situation greatly undermined patent protection in India while encouraging the generics sector. It allowed Indian companies, in partnership with the Council of Scientific and Industrial Research (CSIR) laboratories, to innovate drug processes that were under patents in the global market. Such legislation was also responsible for discouraging the participation of foreign firms, restricting the import of finished formulations and supporting the imposition of high tariff rates. In addition, there was no provision for an extension of the patent term. The patent reform of 2005, however, promises to bring about fundamental changes: the term of patents has been extended to 20 years.

4.4.2 Patent Reform for Indian Pharmaceutical

The pharmaceutical industry, with its rich scientific talent and research capabilities, supported by Intellectual Property Protection regime, is well set to take a great leap forward. As regards product patents for drugs, an amendment to the Indian Patents Act has been carried out through the Patent (Amendments) Ordinance, 2004 on December 26, 2004. The Ordinance amends the Indian Patents Act, 1970 for the third time with a view to introducing product patents for drugs, food and chemicals. Apart from manufacture of drugs, the product patent regime will help the pharmaceutical industry to tap outsourcing of clinical research. By participating in the international system of IPR protection, India, with its vast pool of scientific and technical personnel, and well-established expertise in medical treatment and health care, has unlocked vast opportunities in both exports and outsourcing and has the potential to become a global hub in the area of R&D based clinical research. The Patent

Ordinance also provides adequate safeguards to protect the interest of the domestic industry, and the citizen from any increase in prices of drugs.

4.4.3 Impact of product patent on Indian Pharmaceutical Industry

With a regulatory system focused only on process patents, helped to establish the foundation of a strong and highly competitive domestic pharmaceutical industry which in the grip of a rigid price control framework transformed into a world supplier of bulk drugs and medicines at affordable prices to common man in India and the developing world. Introduction of product patents will, however, mark the end of a golden age for IPI (Indian Pharmaceutical Industry). The new regulations will reshape the landscape of IPI forcing significant changes and divide within the industry.

A look into organization of pharmaceutical producers of India (OPPI) directory shows only 300 units out of 10,000 registered companies are in the organized sector. While process patent helped to flourish IPI into a world-class generics industry, product patent regime will filter the best from the pack and would be favourable to players with built-in scientific and technical resources. The impact of the new regulations will not deter the Indian pharma majors as they are already doing roaring business in the very countries where these patent laws are strictly in force.

Research & Development (R&D) is a key to the strength of pharmaceutical industry especially in the product patent period. The global pharmaceutical industry spent \$30.4 billion (2001) on R&D. The R&D expenditure (as a percentage of turn-over) by the IPI is low (1.9%) when compared global giants (1016%). With transition into the new regime many Indian companies are mobilizing their resources war chest with an increase in their R&D budget. Government of India (GOI) encouraged the R&D in pharmaceutical companies by extending 10 year tax holiday to this sector. Besides, planning commission has earmarked \$34 million towards drug industry R&D promotion fund for the tenth plan.

The focus under the R&D effort is to encourage development of new molecules. A provision of Rs. 150 crore has been made under the Pharmaceutical Research & Development Support Fund. A Drug Development Promotion Board under the Department of Science & Technology has also been set up for the utilisation of this fund. Feasibility of setting up a Mega Chemical Industrial Estate in the country with world class infrastructure facilities is

also being studied. For the first time in many years, the international pharmaceutical industry is finding great opportunities in India. The process of consolidation, which has become a generalised phenomenon in the world pharmaceutical industry, has started taking place in India.

4.5 Regulatory Bodies and Regulations

The Department of Chemicals & Petrochemicals (C&PC) under the Ministry of Chemicals & Fertilizers is responsible for planning, development and control of the Pharmaceutical industry along with ensuring availability and pricing of drugs and formulations. Apart from the Department of Chemicals & Petrochemicals, the Ministry of Health & Family Welfare has responsibility of approval of new drugs, import permission, quality control and clinical trials under the Drugs & Cosmetics Act, 1940. Besides, State Drug Controllers have responsibility for licensing, inspection and enforcement under the Drugs & Cosmetics Act, 1940.

1. Department of Pharmaceuticals (Ministry of Chemicals & Fertilizers)

The Department of Pharmaceuticals is formed recently and is a part of Ministry of Chemicals and Fertilizers. The Department is entrusted with the responsibility of policy, planning, development and regulation of Pharmaceuticals Industries. The some of the important functions of the Dept. are as follows:

- Drugs and Pharmaceuticals, excluding those specifically allotted to other departments.
- Promotion and co-ordination of basic, applied and other research in areas related to the pharmaceutical sector.
- Development of infrastructure, manpower and skills for the pharmaceuticals sector and management related information.
- Education and training including high end research and grant of fellowships in India and abroad, exchange of information and technical guidance on all matters relating to pharmaceutical sector.
- Promotion of public - private-partnership in pharmaceutical related areas.
- International co-operation in pharmaceutical research, including work related to international conferences in related areas in India and abroad.

- Inter-sectoral coordination including coordination between organizations and institutes under the Central and State Governments in areas related to the subjects entrusted to the Department.
- Technical support for dealing with national hazards in pharmaceutical sector.
- All matters relating to National Pharmaceutical Pricing Authority including related functions of price control/monitoring.
- All matters relating to National Institutes for Pharmacy Education and Research.
- Planning, development and control of, and assistance to, all industries dealt with by the Department.
- Bengal Chemicals and Pharmaceuticals Ltd. and other Pharmaceuticals PSUs.

2. Observer Research Foundation

Observer Research Foundation (ORF) is a not-for-profit, multidisciplinary public policy think tank based in New Delhi with chapters in Mumbai, Chennai and Kolkata. ORF is engaged in developing and discussing policy alternatives on a wide range of issues of national and international significance.

Some of ORF's key areas of research include international relations, security affairs, politics & governance, and economy & development. The objective of ORF is to influence formulation of policies for building a strong and prosperous India in a globalised world.

ORF pursues this goal by providing informed and productive inputs, in-depth research and stimulating discussions. Set up in the early Nineties during the troubled period of India's transition from a protected economy to a new engagement with the international economic order, ORF examines critical problems facing the country and helps develop coherent policy responses in a rapidly changing global environment.

As an internationally well-known independent think tank, ORF develops and publishes informed and viable inputs for policymakers in the Government and for the political and business leadership of the country. It maintains a range of informal relationships with politicians, policymakers, policy influencers, civil servants and the media in India and abroad.

With the objective of Building Partnerships for a Global India, ORF has been associated with reputed international think tanks and research institutions like the Brookings Institution, USA; Pacific Council on International Policy, USA; Rosa Luxemburg Foundation, Germany; Polity Foundation, Russia; Institute of World Economics and Policy, Kazakhstan; and Bangladesh Enterprise Institute. ORF also has a partnership with the Federation of Indian Chambers of Commerce and Industry (FICCI).

3. The Central Drug Standard Control Organization (CDSCO)

In the Ministry of Health is responsible for regulating pharmaceuticals in India. CDCSO's main functions include:

- Establish the drug standards and regulations, and administer the Drugs and Cosmetics Act
- Co-ordinate with the Drug Controllers in the states and union territories
- Approve import/manufacturing/sale of new drugs in India
- Check and control the quality of imported and manufactured pharmaceuticals
- It is the Central License Approving Authority with respect to blood and blood products, intravenous fluids, sera and vaccines.

Besides the CDSCO, there are other organizations under the Ministry of Health as well. There is the Central Drugs Laboratory in Kolkata, which is responsible for testing samples of imported drugs. There is also the Central Indian Pharmacopoeia Laboratory in Ghaziabad, which undertakes experimental work related to standards for drugs and functions as a government analyst for several Indian states. The Central License Approving Authority is an organization that examines applications for licenses with respect to blood banks, and vaccines. And, finally, there is the Drugs Consultative Committee, which is a statutory advisory body under the Drugs and Cosmetics Act. This organization issues licenses to import biological and other unique products.

4. Organisation of Pharmaceutical Producers of India (OPPI)

Organization of Pharmaceutical Producers of India (OPPI) established in 1965, is a premier association of research based international and large pharmaceutical companies in India and is also a scientific and professional body. It caters to the needs of Research based Pharmaceutical Industry thereby creating and sustaining an environment conducive to innovation and growth, simultaneously, facilitating industry and stakeholders partnership

through various advisory and consultative processes to achieve the Healthcare objectives of the Nation.

- OPPI Members Follow:
 - Good Manufacturing Practices (GMP)
 - International Code of Pharmaceutical Marketing Practices
 - OPPI's position on Intellectual Property Rights (IPR)

I. OPPI functions mainly on the following areas:

1. Continuous dialogue with the stakeholders
2. Actively engage in knowledge creation & knowledge sharing with value addition
3. Engage in 'Corporate Academia' Interaction

- OPPI identifies itself with the country's national healthcare objectives and encourages its members to make substantial contributions to social concerns and actively promotes Corporate Social Responsibility (CSR).
- OPPI is an active member of International Federation of Pharmaceutical Manufacturers Associations (IFPMA), Geneva and the World Self-Medication Industry (WSMI), France.

The organization aspires to be an Active Partner with Government, Non-Governmental Organizations (NGOs) and other healthcare providers in improving the health and quality of life of our people through reduced morbidity and mortality by discovering, developing and making available safe, cost-effective and quality medicines. In particular, to play an important role in improving the access to medicines of people in rural areas and those living at or below the poverty line. To build on India's existing strengths in manufacturing and Distribution and substantially enhance the beginnings made in R&D in order to become one of the leading players in the global pharmaceuticals market.

To develop a realization that the degree of success that the Industry attains in these areas will be a direct function of the emphasis given to the development of a sound system of Intellectual Property Rights, Biological Sciences Research (particularly genomics and proteomics), Clinical Research & Development and Innovative Process Chemistry. To

make India a global sourcing base of high quality pharmaceuticals to international consumers. To be one of the major creators of intellectual capital and wealth for the economy.

5. National Pharmaceutical Pricing Authority (NPPA)-

- NPPA is an organization of the Government of India which was established, to fix/revise the prices of controlled bulk drugs and formulations and to enforce prices and availability of the medicines in the country, under the Drugs (Prices Control) Order, 1995.
- The organization is also entrusted with the task of recovering amounts overcharged by manufacturers for the controlled drugs from the consumers.
- It also monitors the prices of decontrolled drugs in order to keep them at reasonable levels.

4.6 TYPES OF DRUG SYSTEM IN INDIA

Ancient civilization allowed India to develop various kinds of medical and pharmaceutical systems. In addition to the allopathic system, which is prevalent in the United States, Japan and Europe, the following types of medical and pharmaceutical systems are used by the Indian people:

- **Ayurveda:** Ayurveda translates as the “science of life”. It encompasses fundamentals and philosophies about the world and life, diseases and medicines. The knowledge of Ayurveda is compiled in Charak Samhita and Sushruta Samhita. The curative treatment lies in drugs, diet and general mode of life.
- **Siddha:** The Siddha system is one of the oldest Indian systems of medicine. Siddha means “achievement”. Siddhas were saintly figures who achieved healing through the practice of yoga. The Siddha system does not look merely at a disease but takes into account a patient’s age, sex, race, habits, environment, diet , physiological constitution and so forth. Siddha medicines have been effective in curing some diseases, and further work is needed to truly understand why this system works.
- **Unani:** The Unani system originated in Greece and progressed to India during the medieval period. It involves promotion of positive health and prevention of disease.

The system is based on the humoral theory i.e. the presence of blood, phlegm, yellow bile and black bile. A person's temperament is accordingly expressed as sanguine, phlegmatic, choleric or melancholic. Drugs derived from plant, metal, mineral and animal origins are used in this system.

- **Homeopathy:** Homoeopathy is a branch of therapeutics that treats the patient on the principle of “**SIMILIA SIMILIBUS CURENTUR**” which simply means “**Let likes be cured by likes**”. Homeopathy seeks to stimulate the body's defense mechanisms and processes so as to prevent or treat illness. Treatment involves giving very small doses of substances called remedies that, according to homeopathy, would produce the same or similar symptoms of illness in healthy people if they were given in larger doses. Treatment in homeopathy is individualized (tailored to each person). Homeopathic practitioners select remedies according to a total picture of the patient, including not only symptoms but lifestyle, emotional and mental states, and other factors.
- **Yoga and Naturopathy:** Yoga and Naturopathy are ways of life. In naturopathy one applies simple laws of nature. It advocates proper attention to eating and living habits. It also involves hydrotherapy, mud packs, baths, massage and so forth. Yoga consists of eight components: restraint, observance of austerity, physical postures, breathing exercises, restraining of the sense organs, contemplation, meditation and Samadhi. Increasing interest exists in revisiting these ancient drug systems.

4.7 Market structure

During the last two decades, the Indian pharmaceutical industry has grown considerably and presently it manufactures drugs and other products valued at about Rs. 65,000 crore annually. Apart from meeting indigenous requirements, the export of drugs and pharmaceuticals were Rs. 16,681 crore as against import of Rs. 2,956 crore during the year 2006-07.

India accounts for 8% of world's production by volume (4th rank) and 1.5% by value (13th). Of the total market, pharmaceutical formulations account for 78 percent and bulk drugs for the balance 22 percent. A study by the Indian Commission for Health in India indicates that 56 percent of the Indian health expenditure is on drugs equivalent to around \$17.9 billion in 2004 but most of this is on traditional medicines rather than allopathic drugs.

Table 4.3: Indian Pharmaceutical market

Market size	\$8,790 million
As a percent of GDP	1.3
Growth rate in percent	7-8

Source: Espicom Business Intelligence report dated February 2005

The Indian pharmaceutical industry has 200 medium and large size researches and development (R&D) based pharmaceutical companies including multinationals, government owned and Indian private companies. In addition to these large companies, it is estimated that there are 10,000 smaller licensed generic manufacturers but only around 3,000 of these companies are operational.

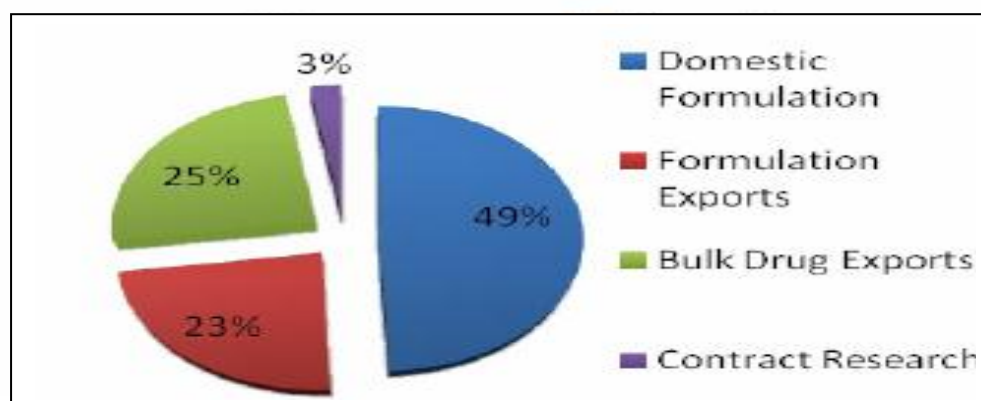
This highly fragmented industry has resulted in with no players controlling more than 7 percent of the retail formulation market. However, similar to the global trends, mergers and acquisitions in the Indian pharmaceutical industry has resulted in the 10 top formulation firms accounting for 37 percent of the retail formulation market.

Pharmaceutical companies in India both Indian and foreign, manufacture bulk drugs in several therapeutic categories and the industry has facilities to manufacture various types of dosage namely capsule, tablets, injectable, orals, and liquids. Of the 400 bulk drugs in the Indian market, it is estimated that 300 are domestically produced. In the past few years, under-production of some bulk drugs has led to rising imports.

Indian pharmaceutical industry can be widely classified into bulk drugs, formulations and contract research. Bulk drugs are the Indian name for Active Pharmaceuticals Ingredients (API). Formulations cover both branded products and generics. Indian pharmaceutical sector is self sufficient in meeting domestic demand and exports successfully to various markets globally. The existence of process patents in India till January 2005 fuelled the growth of domestic pharmaceutical companies and developed them in areas like organic synthesis and process engineering, as a result of which, Indian pharmaceuticals sector is able to meet almost 95 percent of the country's pharmaceutical needs. India is globally recognized as a low cost, high quality bulk drugs and formulations manufacturer and supplier. Contract Research, a nascent industry in India has witnessed commendable growth in the last few years. As per Yes Bank /OPPI report (2007-08), formulation segment (including domestic

formulation and formulation exports) constituted 72% of the total pharmaceutical industry (in terms of sales) while bulk drugs and contract research constituted 25% and 3% of pharmaceutical industry respectively.

Chart 4.1: Segment-wise Sales



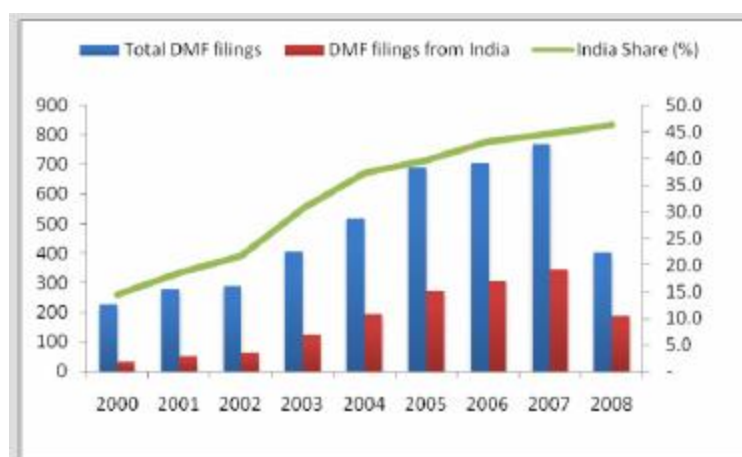
Source: OPPID report

4.7.1 BULK DRUGS

Bulk drug industry is the backbone of the Indian pharmaceutical industry. Growth of Indian bulk drug industry in the last five decades has been impressive and highest among developing countries. From a mere processing industry, Indian bulk drug industry has evolved into sophisticated industry today, meeting global standards in production, technology and quality control. Today, India stands among the top five producers of bulk drugs in the world. The market is fragmented with far too many players. About 300 organised companies are involved in the production of bulk drugs in India. Over 70 percent of India's bulk drug production is exported to more than 50 countries and the balance is sold locally to other formulators. Indian bulk drug industry is mainly concentrated in the following regional belts - Mumbai to Ankleshwar, Hyderabad to Madras and Chandigarh. Around, 18000 bulk drug manufacturers exist in India. Some major producers of bulk drugs in Indian pharmaceutical industry are Ranbaxy Laboratories, Sun Pharma, Cadila, Wockhardt, Aurobindo Pharma, Cipla, Dr. Reddy's Laboratories, Orchid Pharmaceuticals & Chemicals, Nicholas Piramal, Lupin, Aristo Pharmaceuticals, etc. Most are involved in bulk as well as formulations while a few are solely into bulk drugs.

India is the world's fifth largest producer of bulk drugs. The market size is expected to grow at higher percentages in future years with more and more international companies depending on India to meet their bulk-drug supply needs. Moreover, India is way ahead of competitors in the total number of Drug Master File (DMF) filings. Of the overall DMF filings to US FDA, the portion of filings by Indian players has jumped from around 14% in 2000 to 46% of total filings in 2008(January-June) This growth in proportion speaks volumes about the quality standards followed in Indian manufacturing facilities.

Chart 4.2: Increasing share of Indian companies in DMF filings (US FDA)

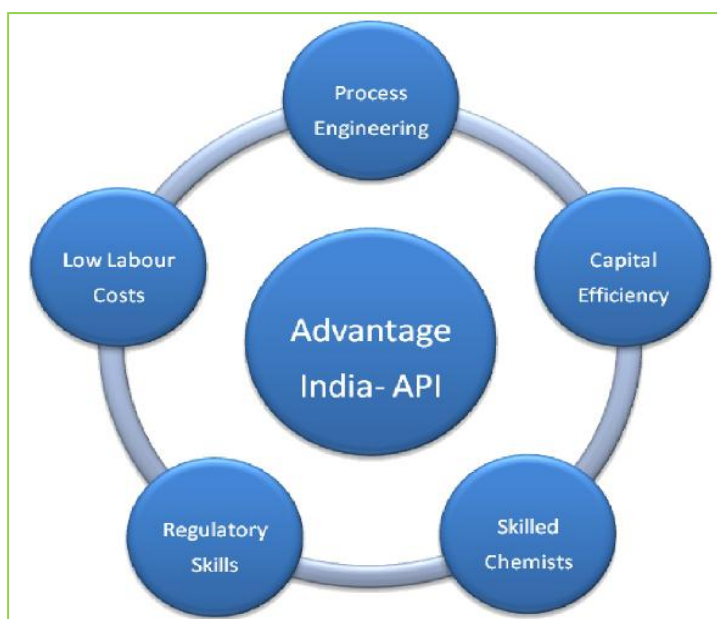


Source: CRISINFAC, Yes Bank/ OPPI

The growing number of DMF filings signifies the increase in number of contracts that Indian players have garnered. While India has recorded 1671 DMF filings, China shows a tally of 520, the second largest number of DMF filings after India. In 2008 (January-June), India's DMF filings were around 3.5 times that of China -187 from India vis-à-vis 51 from China.

The bulk drug segment is a low-margin and volume-driven business. The thrust is on manufacturing. In manufacturing operation, efficiency through better process skills to reduce both manufacturing time and cost is critical. Low cost manufacturing is a distinct advantage gained by Indian companies over a period of time with a steep learning curve. Bulk Drugs exports have grown significantly in the past on account of growth in generic industry, increasing share of Indian companies in DMF filings and contract manufacturing opportunity.

Chart 4.3: Advantage India-API

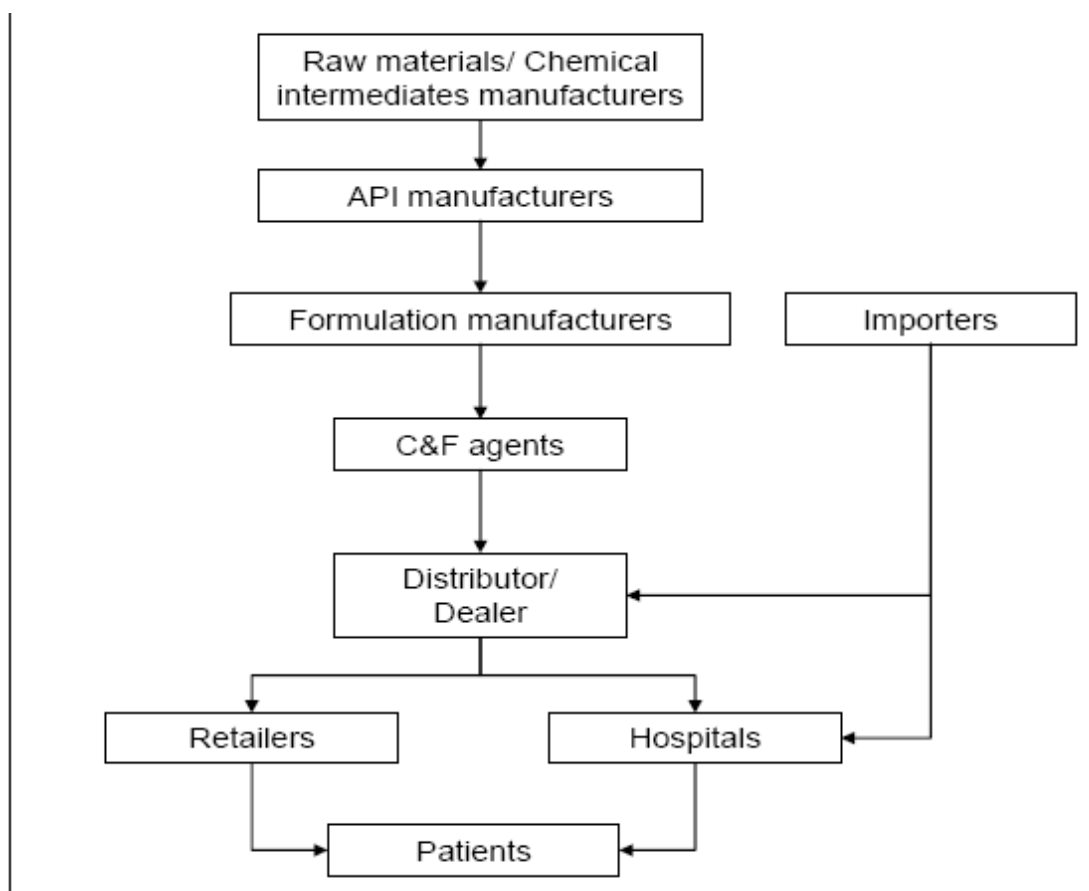


Source: CRISINFAC, Yes Bank/ OPPI

India has many local manufacturing equipment manufacturers. These equipments are of high quality and low cost, thus reducing the cost of capital. According to industry estimates, Indian companies are able to reduce the upfront capital cost of setting up a project by as much as 25-50% due to locally manufactured equipment and high quality technology/engineering skills. Competition in the India's domestic formulation market has made it inevitable for API suppliers to continuously develop alternative production methods to improve yield or reduce costs. This ensures that India has a significant cost advantage due to process engineering.

Apart from availability of a high number of skilled chemists, India also offers scientists with vast experience and unmatched skills. The scientific staff in India though equivalent or better qualified are also available at a fraction of the cost. This makes Indian research firms more competitive than many international firms while being cost competitive. Labour costs are also low in India, being almost 1/7th of that in many developed countries and offer an obvious cost advantage.

Chart 4.4: Distribution Structure of Indian Pharmaceutical Industry



The above illustration depicts the market structure of Indian market. It depicts how the structure is close knit and the system is well connected.

4.7.2 FORMULATIONS

Formulations are broadly categorized into patented drugs and generic drugs. A patented drug is an innovative formulation that is patented for a period of time (usually 20 years) from the date of its approval. A generic drug is a copy of an expired patented drug that is similar in dosage, safety, strength, method of consumption, performance and intended use.

Formulation Industry can be subdivided into two segments:

- Domestic Formulation Industry
- Indian Formulation Exports

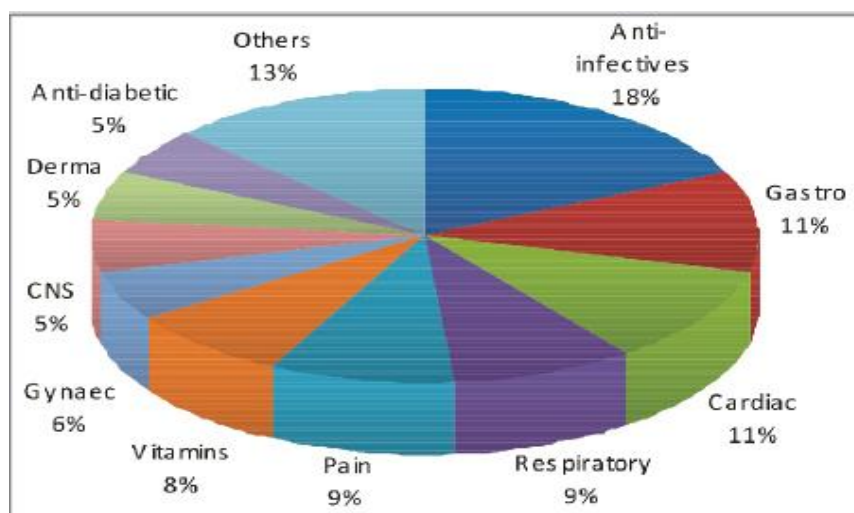
Domestic Formulation Industry

Between 2002 and 2007, the domestic formulation industry grew at a CAGR of 14% from around USD4.3 billion in 2002 to USD 8.4 billion in 2007. Demand in India is growing markedly due to rising population, increasing per capita income, increasing access to medicine, especially in the rural areas and an increasing population of over sixty years of age. Presently, the growth of a domestic pharmaceutical company is critically dependant on its therapeutic presence. In terms of end-use, the pharmaceutical industry is sub-divided into several therapeutic segments. These segments are broadly defined on the basis of therapeutic application. Some of these segments are low-volume, high margin segments, while the others are high-volume with relatively low margins. The new lifestyle categories like Cardiac, Respiratory and Vitamins are expanding at double-digit growing rates. The long term ailment, chronic therapies is now accounting 24% of the market. The only growth driver for acute therapies is the new product introduction under this segment. Today, anti-infective which used to be the single largest therapeutic segment in Indian pharmaceutical industry is increasing. Anti-infective segment is now 1st in terms of value contribution followed by Gastrointestinal and Cardiac.

The key therapeutic segments include:

- Anti-infective
- Cardio vascular
- Central nervous system drugs

Chart 4.5: Therapeutic wise distribution (ORGIMS)



Source: CRISINFAC, Yes Bank/ OPPI

Anti-infective is currently the largest therapeutic segment in India. It accounts for one-fifth of total market turnover. Next in line, and accounting for one-tenth each, are cardio-vascular preparations, cold remedies, pain killers and respiratory solutions.

4.7.3 CONTRACT RESEARCH AND MANUFACTURING:

Increasing costs of R&D, coupled with low productivity and poor bottom lines, have forced major pharmaceutical companies worldwide to outsource part of their research and manufacturing activities to low-cost countries, thereby saving costs and time in the process. The global pharmaceutical outsourcing market was worth USD57.2 billion in 2007. It is expected to grow at a CAGR of 10% to reach USD76 billion by 2010. Global market for Contract Research and Manufacturing Services (CRAMS) in 2007 is estimated to be USD55.48 billion. Out of the total global CRAMS market, contract research was USD16.58 billion, growing at a CAGR of 13.8% and contract manufacturing was USD38.89 billion accounting for the major share (approximately 68%) of the total global pharmaceutical outsourcing market.

India, with more than 80 US FDA-approved manufacturing facilities, is one of the most preferred locations for outsourcing manufacturing services in India by the multinationals and global pharmaceutical companies. The Indian pharmaceutical outsourcing market was valued at USD1.27m in 2007 and is expected to reach USD3.33 billion by 2010, growing at a CAGR of 37.6%. The Indian CRAMS market stood at USD1.21 billion in 2007, and is estimated to reach USD3.16 billion by 2010.

India holds the lion's share of the world's contract research business as activity in the pharmaceutical market continues to explode in this region. Over 15 prominent contract research organisations (CROs) are now operating in India attracted by her ability to offer efficient R&D on a low-cost basis. Thirty five per cent of business is in the field of new drug discovery and the rest 65 per cent of business is in the clinical trials arena. India offers a huge cost advantage in the clinical trials domain compared to Western countries. The cost of hiring a chemist in India is one-fifth of the cost of hiring a chemist in the West.

4.7.4 Rural Market

Driven by factors such as rising rural incomes and a strong distribution network, India's rural pharmaceuticals market is also experiencing strong growth. Estimates say that while small towns contribute 20 per cent to the country's pharmaceuticals market, rural areas account for 21 per cent. In 2006-07, the rural Indian pharmaceuticals market was estimated at around US\$ 1.4 billion, having grown at about 40 per cent in 2006-07 against 21 per cent in the previous year. With increased cell phone coverage and the spread of business in rural areas, rural markets will hold a significant growth opportunity for the pharmaceutical industry.

The Ministry of Chemicals and Fertilisers, which oversees the drug sector, has launched the country's first national level low-cost medicine bank scheme in a bid to help people buy drugs at affordable prices. The Jan Aushadhi medical stores, planned to be set up as a public-private partnership, is expected to provide commonly used medicines such as antibiotics, anti-diabetics, anti-hypertensive and anti-bacterial at half the market price.

4.7.5 Pharmaceutical Retail

India has 5.5 million chemists and druggists, and the organised retail market accounts for just 2 per cent of the industry but is posting a year-on-year growth of 30-40 per cent.

Soon organised pharmaceutical retail, presently dominated by the big names like Apollo and Subhiksha, will see a lot more happening at the regional level. Players like Hyderabad-based API firm Hetero Drugs and Chennai-based Regenix Drugs are to soon enter the segment in a big way.

The country's pharmaceutical retail market is expected to cross the US\$ 10 billion mark in 2010 and be worth an estimated US\$ 12 billion-13 billion in 2012.

4.7.6 Generics

There is a great opportunity for India as generic drugs manufactured in India are now being accepted worldwide, and leading companies like Ranbaxy, Cipla and Dr. Reddy's are making way for others.

According to a report by global pharmaceutical market intelligence company, IMS Health, the Indian generic manufacturers will grow to more than US\$ 70 billion as drugs worth approximately US\$ 20 billion in annual sales will face patent expiry in 2008. In fact, with nearly US\$ 80 billion worth of patent-protected drugs to go off patent (including 30 of the best selling US patent-protected drugs) by 2012, Indian generic manufacturers are positioning themselves to offer generic versions of these drugs.

4.7.7 Nutraceuticals

With the growing awareness about healthcare, several pharmaceutical companies are introducing products in the nutraceuticals category which covers dietary supplements and vitamins among others, expecting a significant increase in their profits. The Indian healthcare sector is currently valued at US\$ 7 billion, with the nutraceutical segment estimated roughly at US\$ 400 million, which is expected to grow at approximately 20 per cent per year. The industry estimates global sales to reach US\$ 190 billion by 2010. In India, the dietary supplement market alone is estimated to reach US\$ 1.11 billion by 2010, and witness a rate of growth of 16 per cent, according to an analyst with Frost & Sullivan.

Major players in the nutraceuticals segment include Elder Pharmaceuticals Ltd, Wockhardt, Plethico, Glenmark and Troikaa Pharmaceuticals.

4.7.8 Diagnostics Outsourcing/ Clinical Trials

Many hospitals in the US and Europe are outsourcing laboratory and diagnostic tests to India to save costs without compromising on quality. The Indian diagnostics and pathology laboratory business is presently around US\$ 864 million and is growing at a rate of 20 per cent annually.

Moreover, the US\$ 200-million Indian clinical research outsourcing market will reach up to US\$ 600 million by 2010, according to a joint study done by research firm KPMG and the Confederation of Indian Industry (CII) in September 2008.

While the cost of clinical trials vary on the basis of complexity and disease segment, a simple trial in India can cost 15-20 per cent of the US price, while a more sophisticated trial—involving imaging systems—may cost about 50-60 per cent of the US price. Studies suggest that R&D expenditure is increasing by 15 per cent per year, making global biopharmaceutical

companies look for cheaper options. India scores high due to faster enrollments, speed of completion, large and diverse patient pool as well as increasing private healthcare network.

Inspite of global recession, large pharma customers such as AstraZeneca and Glaxo continue to send more work to India.

Moreover, US companies are also entering into tie ups to open clinical trial units in India. Recently, US-based Quintiles Transnational Corporation, a pharmaceutical services provider, has entered into a partnership with the Apollo Hospitals group to open a Phase I clinical trial unit in Hyderabad.

4.7.9 End Users

Nearly three quarters of the pharmaceuticals produced are for the retail market, while the rest are for direct sales to the hospitals and nursing homes. End users of pharmaceuticals are the government and private healthcare service providers as well as retailers.

Healthcare services in India are provided both by the government, public, and private sector. The size of the Indian healthcare delivery market is estimated at \$18.7 billion. The private sector provides for sixty-three percent of the healthcare market. With only fifteen percent of the population covered by insurance, a large proportion of the healthcare spending is out of pocket spending.

Table 4.4: Healthcare Data

Pharmacies	150,000 (urban) 150,000 (rural)
Number of Doctors	500,000
Number of Nurses	600,000
Number of Hospitals	15,000
Health Centers	180,000
Medical Colleges	171

Source: National Health Policy 2002, and Organization of Pharmaceutical Producer of Indian, and Espicom report

The government healthcare infrastructure includes primary health centers and sub centers in the villages that are the first point of contact that provide basic drugs for minor ailments. At the secondary level, the district hospitals and the community healthcare centers, and finally, at the tertiary level are the government owned hospitals and medical colleges. The private healthcare providers consist of private practitioners, for profit hospitals and nursing homes, and charitable hospitals. They are numerous and fragmented.

4.8 EXPORTS & IMPORTS

4.8.1 EXPORTS

Indian pharma industry is set to defy recession by registering a 25% growth in exports during the current fiscal. As per projections made by Centre for Monitoring Indian Economy (CMIE) pharma exports from India is expected to touch the figure of Rs36,471 crore in 2008-09 against the exports of Rs29,140 crore in the previous year. Depreciation in Indian rupee and cost advantage will help the industry to post such an exponential growth in overseas sales. The forecast seems quite optimistic, as the industry posted just 8% growth in export in 2007-08 compared to Rs26,895 crore recorded in 2006-07. However, depreciation in Indian currency is going to help them in a big way to achieve the growth. In the first half of the current fiscal, rupee depreciated by whopping 6.6% against the dollar and the trend is likely to continue till the end of the fiscal. India's export of drugs and pharmaceuticals accounts for almost 40% of the sectors' aggregate sales.

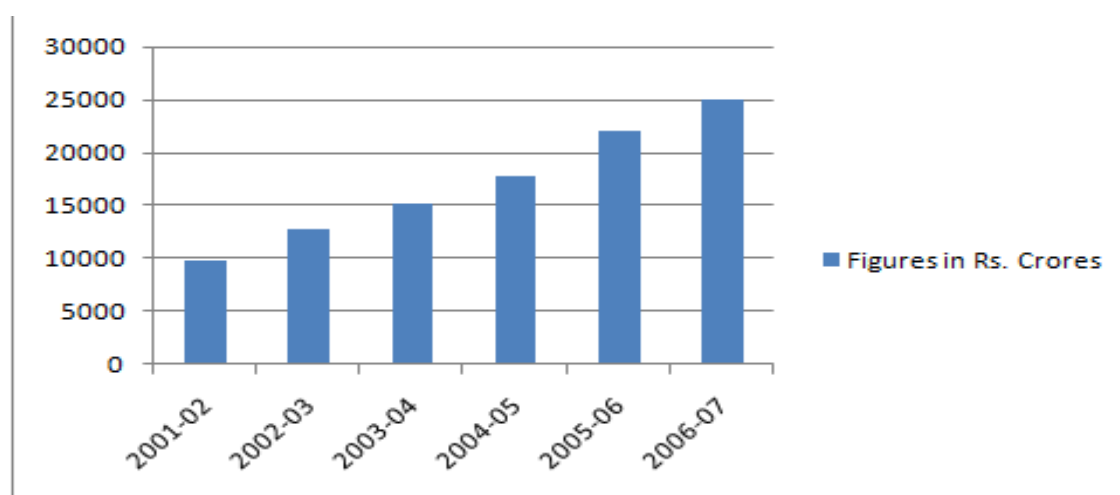
Global recession is not expected to impact Indian pharma sector due to its low cost manufacturing advantage. Indian companies are mostly into the manufacturing of generic drugs and offers drugs at a price much lower than the patent holder company. In fact, slowdown will prove to be a boon for Indian pharma companies, as foreign customers will look for cheaper products. However, growth of exports may slowdown in last two quarters. The first two quarters have been good for pharma sector and no significant impact of slowdown was visible. However, last two quarters may not be same and the sector may see some slowdown in export.

Those companies are feeling the pinch of slowdown that has exposure to the Latin American market. Majority of Indian pharma export goes to Europe. Of the total export in 2007-08,

25% went to European countries, 19% to Asia, 18.3% to North America, 13.5% to African countries, 8% to CIS countries and rest to other regions. India exported drugs and pharmaceuticals worth Rs1,872 crore to the US and Rs564 crore to Germany in 2007-08. This distribution is also likely to be same in current fiscal. Country wise US gets largest exports from India followed by Netherlands, UK and Germany.

Bucking the trend Pharma exports are expected to be around Rs36,471 crore this fiscal against Rs29,140 crore in the previous year. Export accounts for almost 40% of the aggregate sales of the industry. Indian pharma market is contributing 8% globally in terms of production, 2% in terms of value by producing drugs worth \$18 billion.

Chart 4.6: Pharmaceutical Exports in India till 2006-07



Source: E&Y Study

According to the E&Y Report India's exports should continue to show strong growth through 2010 as \$60 billion worth of patented drugs lose their patent protection in the United States and Western Europe. As seen from the graph, the exports have shown a steady growth through 2001-2007 and will continue to do so. Exports have grown to constitute a major revenue source for India's major pharmaceutical companies including Ranbaxy, Cipla, and Dr. Reddy's. Collectively, regulated markets accounted for more than 50 percent of their total annual revenues. In 2005-06, Ranbaxy derived nearly 80 percent of its sales revenues from exports, while exports and international acquisitions accounted for 66 percent of Dr. Reddy's sales and 50 percent of Cipla's. The successful penetration of the U.S. and EU markets has encouraged a growing number of Indian "copycat" companies to enter these markets.

India's exports to the regulated Western markets are expected to remain strong in the mid-term, even though Indian companies will be challenged by declining prices in the U.S. market, declining profit margins, growing competition from other low-cost countries, parallel launches of authorized generics by Western innovator companies, and the increasing power of large distributors in the U.S. and European markets. About \$60 billion in blockbuster drugs will open to generic competition between 2002 and 2010 and Indian companies are expected to vie for a significant percentage of that business.

Our leading exporters include Dr. Reddy's, Wockhardt, Sun Pharma, and Lupin Labs. The vast majority of India's exports, by value, are destined for the developed economies of the West, particularly the United States, Germany, the United Kingdom, and France. Exports to these countries consist primarily of bulk drugs that account for nearly 60 percent of India's pharmaceutical exports. The remainder, mostly formulations, is exported to the countries of the former Soviet Union (CIS) and developing countries (Southeast Asia, Africa, and Latin America). India continues to be a leading supplier of less expensive antibiotics, cancer therapy, and AIDs drugs to the developing world.

4.8.2 IMPORTS

India's consumption of imported pharmaceuticals accounts for only a minimal portion of the world's production. Its imports consist of mainly life-saving drugs and new generations of formulations that are under patent by innovator companies. These include anti-cancer, cardiovascular, and anti-hypertension drugs imported primarily by major global pharmaceutical companies for sale in the Indian market. Within these categories, leading imports consisted of penicillin (13 percent), antibiotics for combating stomach infections (9 percent), and other medicines for retail sales in dosage form (19 percent). Life saving drugs can be imported into India duty free, whereas all other pharmaceutical imports faced a base duty rate of 30 percent and an effective duty rate of 56.8 percent in 2002, compared with "zero" duty in the United States. India's imports of finished pharmaceutical drugs, intermediates, and APIs nearly tripled in value from \$516.1 million in 1999 to more than \$1.3 billion in 2005. India's top 7 import source countries accounted for approximately 32 percent of the total during 2005, down from 37 percent in 2004. India's leading import suppliers included Switzerland (8 percent), Germany (6 percent), the United States (7 percent), and France (3 percent). Although India's pharmaceutical market is relatively small, at least 45

MNC pharmaceutical companies are serving the market through subsidiaries, other tie-ins, and imports. India's imports from Switzerland, the United States, and Germany consisted primarily of other medicaments in dosage form for retail sales

4.9 Conclusion

There has never been a more important time for India's government and its drug producers, both multinational and domestic, to work together in partnership for the good of the industry and the nation. With its enormous advantages, including a large, well-educated, skilled and English-speaking workforce, low operational costs and improving regulatory infrastructure, India has the potential to become the region's hub for pharmaceutical and biotechnology discovery research, manufacturing, exporting and health care services within the next decade.

However, in order for this to happen, it is imperative that the regulatory environment continues to improve. Otherwise, India needs to look to the achievements of China, where the government's strong commitment pro-industry policies have produced a positive environment that not only offers drug manufacturers a product patent regime but also, and crucially, data protection. India's continuing failure to do so needs to be urgently rectified.

The goals set out in the Indian government's draft National Pharmaceuticals Policy for 2009 in terms of domestic market development are ambitious, and will require a positive pricing environment if the country's 1 billion people are to be able to access the life-saving and innovative medicines they need. Industry leaders are keen to work with government on issues of affordability and point out that price controls will do nothing to increase access to new and effective treatments. For foreign investors, collaborations with India present a huge opportunity both in terms of joint production for the global market and supply of the growing domestic market.

CHAPTER 5

INDUSTRY ANALYSIS

5.1 Introduction

The Indian Pharmaceuticals sector has come a long way, being almost non-existing during 1970, to a prominent provider of health care products, meeting almost 95% of country's pharmaceutical needs. The domestic pharmaceutical output has increased at a compound growth rate (CAGR) of 13.7% per annum. Currently the Indian pharma industry is valued at approximately \$ 8.0 billion. Globally, the Indian industry ranks 4th in terms of volume and 13th in terms of value. Indian pharmaceuticals industry has over 20,000 units. Around 260 constitute the organized sector, while others exist in the small scale sector.

Fast economic growth, increasing economic and political stability coupled with tremendous patient potential and increased Westernization of lifestyle present new opportunities for global pharmaceutical companies.

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

The Indian Pharmaceutical sector is highly fragmented with more than 20,000 registered units. It has expanded drastically in the last two decades. The leading 250 pharmaceutical companies control 70% of the market with market leader holding nearly 7% of the market share. It is an extremely fragmented market with severe price competition and government price control.

The exports constitute almost 40% of the total production of pharmaceuticals in India.

India's pharmaceutical exports are to the tune of \$3.5bn currently, of which formulations contribute nearly 55% and the rest 45% comes from bulk drugs. The export revenue now contributes almost half of the total revenue for the top 3 pharma majors: Dr Reddy's, Ranbaxy and Cipla. The other major exporters are Wockhardt, Limited, Sun Pharmaceutical Industries Ltd. and Lupin Laboratories. The formulations and exports are largely to

developing nations in CIS, South East Asia, Africa, and Latin America. In the last 3 years generic exports to developed countries have picked up.

5.2 QUALITATIVE ANALYSIS

5.2.1 SWOT ANALYSIS:

The Indian pharmaceutical industry is one of the fast growing sectors of the Indian economy and has made rapid strides over the years. From being an import dependent industry in the 1950s, the industry has achieved self-sufficiency and gained global recognition as a producer of low cost high quality bulk drugs and formulations. Leading Indian companies have developed infrastructure in over 60 countries including developed markets like US and Europe. In the recent past, several pharmaceutical companies have demonstrated that they possess the ability to engage in commercially viable research and development activities and become significant players in the international market. SWOT Analysis, is a strategic planning tool used to evaluate the Strengths, Weaknesses, Opportunities, and Threats involved in a project or in a business venture. It involves specifying the objective of the business venture or project and identifying the internal and external factors that are favorable and unfavorable to achieving that objective.

Strengths:

1. India with a population of over a billion is a largely untapped market. In fact the penetration of modern medicine is less than 30% in India. To put things in perspective, per capita expenditure on health care in India is US\$ 93 while the same for countries like Brazil is US\$ 453 and Malaysia US\$189.
2. The growth of middle class in the country has resulted in fast changing lifestyles in urban and to some extent rural centres. This opens a huge market for lifestyle drugs, which has a very low contribution in the Indian markets.
3. Indian manufacturers are one of the lowest cost producers of drugs in the world. With a scalable labour force, Indian manufactures can produce drugs at 40% to 50% of the cost to the rest of the world. In some cases, this cost is as low as 90%.
4. The fact that despite the low level of unit labour costs India boasts a highly skilled workforce has enabled the country's pharmaceutical industry at a relatively early stage

to offer quality products at competitive prices. Each year, roughly 115,000 chemists graduate from Indian universities with a master's degree and roughly 12,000 with a PhD.⁴ The corresponding figures for Germany – just fewer than 3,000 and 1,500, respectively – are considerably lower. After many chemists from India migrated to foreign countries over the last few years, they now consider their chances of employment in India to have improved. As a result, a smaller number is expected to go abroad in the coming years; some may even return.

5. Indian pharmaceutical industry possesses excellent chemistry and process reengineering skills. This adds to the competitive advantage of the Indian companies. The strength in chemistry skill helps Indian companies to develop processes, which are cost effective.

Weakness:

1. The Indian pharmaceutical companies are marred by the price regulation. Over a period of time, this regulation has reduced the pricing ability of companies. The NPPA (National Pharmaceutical Pricing Authority), which is the authority to decide the various pricing parameters, sets prices of different drugs, which leads to lower profitability for the companies. The companies, which are lowest cost producers, are at advantage while those who cannot produce have either to stop production or bear losses.
2. Indian pharmaceutical sector has been marred by lack of product patent, which prevents global pharmaceutical companies to introduce new drugs in the country and discourages innovation and drug discovery. But this has provided an upper hand to the Indian pharma companies.
3. Indian pharma market is one of the least penetrated in the world. However, growth has been slow to come by. As a result, Indian majors are relying on exports for growth. To put things in to perspective, India accounts for almost 16% of the world population while the total size of industry is just 1% of the global pharma industry.
4. Due to very low barriers to entry, Indian pharma industry is highly fragmented with about 300 large manufacturing units and about 18,000 small units spread across the country. This makes Indian pharma market increasingly competitive. The industry witnesses price competition, which reduces the growth of the industry in value term. To put things in perspective, in the year 2003, the industry actually grew by 10.4%

but due to price competition, the growth in value terms was 8.2% (prices actually declined by 2.2%)

Opportunities:

1. The migration into a product patent based regime is likely to transform industry fortunes in the long term. The new patent product regime will bring with it new innovative drugs. This will increase the profitability of MNC pharma companies and will force domestic pharma companies to focus more on R&D. This migration could result in consolidation as well. Very small players may not be able to cope up with the challenging environment and may succumb to giants.
2. Large number of drugs going off-patent in Europe and in the US between 2005 to 2009 offers a big opportunity for the Indian companies to capture this market. Since generic drugs are commodities by nature, Indian producers have the competitive advantage, as they are the lowest cost producers of drugs in the world.
3. Opening up of health insurance sector and the expected growth in per capita income are key growth drivers from a long-term perspective. This leads to the expansion of healthcare industry of which pharma industry is an integral part.
4. Being the lowest cost producer combined with FDA approved plants; Indian companies can become a global outsourcing hub for pharmaceutical products.

Threats

1. There are certain concerns over the patent regime regarding its current structure. It might be possible that the new government may change certain provisions of the patent act formulated by the preceding government.
2. Threats from other low cost countries like China and Israel exist. However, on the quality front, India is better placed relative to China. So, differentiation in the contract manufacturing side may wane.
3. The short-term threat for the pharma industry is the uncertainty regarding the implementation of VAT. Though this is likely to have a negative impact in the short-term, the implications over the long-term are positive for the industry.

Advantages

- **Competent workforce:** India has a pool of personnel with high managerial and technical competence as also skilled workforce. It has an educated work force and English is commonly used. Professional services are easily available.
- **Cost-effective chemical synthesis:** Its track record of development, particularly in the area of improved cost-beneficial chemical synthesis for various drug molecules is excellent. It provides a wide variety of bulk drugs and exports sophisticated bulk drugs.
- **Legal & Financial Framework:** India has a 53 year old democracy and hence has a solid legal framework and strong financial markets. There is already an established international industry and business community.
- **Information & Technology:** It has a good network of world-class educational institutions and established strengths in Information Technology.
- **Globalization:** The country is committed to a free market economy and globalization. Above all, it has a 70 million middle class market, which is continuously growing.
- **Consolidation:** For the first time in many years, the international pharmaceutical industry is finding great opportunities in India. The process of consolidation, which has become a generalized phenomenon in the world pharmaceutical industry, has started taking place in India.

5.2.2 (PESTL)

Technological advancements, tighter regulatory-compliance overheads, rafts of patent expiries and volatile investor confidence have made the modern pharmaceutical industry an increasingly tough and competitive environment. Below is an analysis of the structure of the pharmaceutical industry using the PEST (political, economic, social and technological) model.

Increasing Political Attention:

Over the years, the industry has witnessed increased political attention due to the increased recognition of the economic importance of healthcare as a component of social welfare. Political interest has also been generated because of the increasing social and financial

burden of healthcare. Examples are the UK's National Health Service debate and Medicare in the US.

Economic Value Added:

In the decade to 2003 the pharmaceutical industry witnessed high value mergers and acquisitions. With a projected stock value growth rate of 10.5% (2003-2010) and Health Care growth rate of 12.5% (2003-2010), the value of the global pharmaceutical market is estimated to reach a huge 800 billion dollars by 2009. Only information technology has a higher expected growth rate of 12.6%. Majority of pharmaceutical sales originate in the US, EU and Japanese markets. Nine geographic markets account for over 80% of global pharmaceutical sales these are, US, Japan, France, Germany, UK, Italy, Canada, Brazil and Spain. Of these markets, the US is the fastest growing market and since 1995 it has accounted for close to 45% of global sales making it a key strategic market for pharmaceuticals.

The Social Dimension:

Good health is an important personal and social requirement and the unique role pharmaceutical firms play in meeting society's need for popular wellbeing cannot be underestimated. In recent times, the impact of various global epidemics e.g. SARS, AIDS etc. has also attracted popular and media attention to the industry. The effect of the intense media and political attention has resulted in increasing industry efforts to create and maintain good government-industry-society communications.

Technological Advances:

Modern scientific and technological advances in science are forcing industry players to adapt ever faster to the evolving environments in which they participate. Scientific advancements have also increased the need for increased spending on research and development in order to encourage innovation.

Legal Environment:

The pharmaceutical industry is a highly regulated and compliance enforcing industry. As a result there are immense legal, regulatory and compliance overheads which the industry has to absorb. This tends to restrict its dynamism but in recent years, government have begun to

request industry proposals on regulatory overheads to so as not to discourage innovation in the face of mounting global challenges from external markets.

5.2.3 PORTER'S FIVE FORCES MODEL

1. INDUSTRY COMPETITION

Pharmaceutical industry is one of the most competitive industries in the country with as many as 10,000 different players fighting for the same pie. The rivalry in the industry can be gauged from the fact that the top player in the country has only 6 %(2006) market share, and the top 5 players together have about 18 %(2006) market share.

Thus, the concentration ratio for this industry is very low. High growth prospects make it attractive for new players to enter in the industry. Another major factor that adds to the industry rivalry is the fact that the entry barriers to pharmaceutical industry are very low. The fixed cost requirement is low but the need for working capital is high.

The fixed asset turnover, which is one of the gauges of fixed cost requirements, tells us that in bigger companies this ratio is in the range of 3.5-4 times. For smaller companies, it would be even higher. Many small players that are focussed on a particular region have a better hang of the distribution channel, making it easier to succeed, albeit in a limited way.

An important fact is that, pharmaceutical is a stable market and its growth rate generally tracks the economic growth of the country with some multiple (1.2 times average in India). Though volume growth has been consistent over a period of time value growth has not followed in tandem.

The product differentiation is one key factor which gives competitive advantage to the firms in any industry. However, in pharmaceutical industry product differentiation is not possible since India has followed process patents till date, with loss favouring imitators. Consequently product differentiation is not a driver, cost competitiveness is. However, companies like Pfizer and Glaxo have created big brands over the years which act as product differentiation tools.

Earlier it was easy for Indian pharmaceutical companies to imitate pharmaceutical products discovered by MNCs at a lower cost and make good profit. But today the scene is different with the arrival of the patent regime which has forced Indian companies to rethink its strategies and to invest more on R&D. Also contract research has assumed more importance now.

2. BARGAINING POWER OF BUYERS

The unique feature of pharmaceutical industry is that the end user of the product is different from the influencer (read doctor). The consumer has no choice but to buy what doctor says. However, when we look at the buyer's power, we look at the influence they have on the prices of the product. In pharmaceutical industry, the buyers are scattered and they as such do not wield much power in the pricing of the products. However, govt with its policies, plays an important role in regulating pricing through the NPPA (national pharmaceutical pricing authority).

3. BARGAINING POWER OF SUPPLIERS

The pharmaceutical industry depends upon several organic chemicals. The chemical industry is again very competitive and fragmented. The chemicals used in the pharmaceutical industry are largely a commodity. The suppliers have very low bargaining power and the companies in the pharmaceutical industry can switch from their suppliers without incurring a very high cost. However, what can happen is that the supplier can go for forward integration to become a pharmaceutical company. Companies like Orchid Chemicals and Sashun Chemicals were basically chemical companies who turned themselves into pharmaceutical companies.

4. BARRIERS TO ENTRY

Pharmaceutical industry is one of the most easily accessible industries for an entrepreneur in India. The capital requirement for the industry is very low; creating a regional distribution network is easy, since the point of sales is restricted in this industry in India. However, creating brand awareness and franchisee among doctors is the key for long term survival. Also, quality regulations by the government may put some hindrance for establishing new manufacturing operations. The new patent regime has raised the barriers to entry. But it is unlikely to discourage new entrants, as market for generics will be as huge. Pharmaceutical products continues to increase and the industry thrives. One of the key reasons for high competitiveness in the industry is that as an ongoing concern, pharmaceutical industry seems

to have an infinite future. However, in recent times the advances made in the field of biotechnology, can prove to be a threat to the synthetic pharmaceutical industry.

5.3 OBJECTIVE ANALYSIS

Detailed data and analysis helps the investors to comprehend the changing dynamics in the healthcare Sector. It also helps in analyzing the opportunities critical to the growth of healthcare market in India.

Analysis:

Healthcare industry is the world's largest industry with total revenues of approx US\$ 2.8 Trillion. India's high population makes it an important player in the Healthcare Industry.

According to the Insurance Regulatory and Development Authority, the Indian healthcare industry has the potential to show the same exponential growth that the software industry showed in the past decade. In India, 80% of the healthcare expenditure is borne by the patients and that borne by the state is 12%. The expenditure covered by insurance claims is 3%. As a result, the price sensitivity is quite high and the high-level healthcare facilities are out of reach.

Among the top five therapeutic segments, gastro-intestinal and cardiac therapies are experiencing both high volume and value growth. Ophthalmologicals, cardiovascular, anti-diabetic and neurological drugs continue to top the growth list. The anti-infective, neurology, cardiovascular and anti-diabetic segments have witnessed a high number of new product launches in the recent years. Increasing number of non-insured population in western countries and increasing healthcare expenditure to GDP is resulting in people to opt for treatment options outside their country.

5.3.1 STEPS TO STRENGTHEN THE INDUSTRY

Indian companies need to attain the right product-mix for sustained future growth. Core competencies will play an important role in determining the future of many Indian pharmaceutical companies in the post product-patent regime after 2005. Indian companies, in

an effort to consolidate their position, will have to increasingly look at merger and acquisition options of either companies or products. This would help them to offset loss of new product options, improve their R&D efforts and improve distribution to penetrate into the markets. Research and development has always taken the back seat amongst Indian pharmaceutical companies. In order to stay competitive in the future, Indian companies will have to focus on R&D.

The Indian pharmaceutical industry also needs to take advantage of the recent advances in biotechnology and information technology. The future of the industry will be determined by how well it markets its products to several regions and distributes risks, its forward and backward integration capabilities, its R&D, its consolidation through mergers and acquisitions, co-marketing and licensing agreements.

5.4 COMPETITION

CHINA

China is becoming a major competitor to India, especially in exports of active pharmaceutical ingredients (APIs). China's pharmaceutical industry ranks no.7 in the world and is expected to become the world's 5th largest by 2010. China's domestic drug sales have been estimated at about US\$8 billion in 2003 and the exports are growing at the rate of about 20% per annum.

The reasons for Chinese competitive advantage are:

- The electricity costs are lower in China as compared to India. The power costs range from Rs.1.50 to 2.50 per KWH as against Indian cost of Rs.4.5 to 6.0 per KWH.
- Labour charges are 40% lower in China than India.
- More favourable labour policies like policy of hire and fire in China.
- On the whole China is more cost competitive in manufacturing sector.
- China has already implemented clear intellectual property laws and exclusivity rules that take it one step ahead of India in attracting foreign players. In 1992, a pact was signed with US, which heralded the Product patent regime coming in force in China.
- China has established a large number of profit oriented research and development institutions, which are today independent of government funding in contrast to

institutions in India, which are mostly dependant on government funding.

- The Chinese government provides an income tax holiday of 100 per cent for the first two winning years (profit making years) and 50 per cent for the next three years.
- The companies are also allowed duty free import of capital equipment.
- Lower turnaround time for ships at Chinese ports make it conducive as a base for exports.

JAPAN

Last year, the Japanese pharmaceutical market was the second largest in the world, with a value of \$58.5bn. However, Japan's market has experienced growth at a much lower rate than the other major pharmaceutical markets this year.

Reasons for Japan's Competitive advantage:

For many years the market has been dominated by the pricing and reimbursement policy of the Japanese government, which is arguably the most stringent of all the major governments. A determination to maintain tight cost controls on healthcare in Japan has resulted in the cost of drugs being tightly controlled. The government imposes limits on the price of drugs, and these are reduced every two years.

It is this imposed price control that is the key determining factor in influencing the shape, size and potential of the Japanese pharmaceutical market.

However, the expansion of that market is attributed to several factors:

- Biennial National Health Insurance drug price reductions.
- Increasing R&D expenses
- Intensifying competition between domestic companies and foreign international pharmaceutical companies, especially market leaders
- Restructuring within the pharmaceutical industry in Japan and worldwide
- Non-availability of many leading international products
- Relatively low use of generics
- A regulatory system that has recently become more accessible to international pharma companies

The Japanese pharmaceutical market is at the start of a cycle that will see an increasing number of mergers and acquisitions. The extent of the mergers involving a global pharmaceutical company buying out a smaller Japanese company will depend largely on the pipeline of the Japanese company involved. Global pharmaceutical companies, such as Pfizer, are already establishing a major presence in Japan.

5.6 CONCLUSION

In recent years, pharmaceutical companies in Asia, particularly in China, South Korea and India, have been a success due to their ability to retain their cost advantage while matching the quality standards of the west. Despite an impressive growth, foreign drug makers are particularly concerned with issues on corruption, governmental bureaucracy and intellectual property (IP) protection in these countries. These issues are important particularly when growing drug counterfeiting activities pose a major global public health risk as well as a financial and reputation threat to pharmaceutical manufacturers.

The focus of the Indian pharma companies is also shifting from process improvisation to drug discovery and R&D. The Indian companies are setting up their own R&D setups and are also collaborating with the research laboratories like CDRI, IICT etc.

The steps required to boost the competitiveness of the pharma industry are:

- **Extension of deduction of 150% of R&D expenses.** This would encourage more and more companies to invest in R&D. The government has earmarked 150 crores for R&D. This is just not enough. It should be augmented to at least 2000 crores.
- **To rationalize Drug Price Control Order (DPCO).** The objective of the price control was to ensure adequate availability of quality medicines at affordable prices. In this context, a liberalized price control regime becomes more important.
- **Income tax exemptions should be given on clinical trials and contract research done outside the company and abroad.** This is because India is seen as emerging as a major center for outsourcing of clinical trials for the Pharmaceutical MNCs.
- **The problem of spurious drugs has to be tackled.** Most of the cases relating to spurious drugs remain undecided for years. Hence there is a strong need for setting up separate courts for speedy trials of such offences.

- **India should exploit its know-how in herbal medicines.** Since these medicines do not come under the purview of the TRIPS regime and the research in new chemical entities involves millions of dollars of investment, the Indian companies should engage in R&D in herbal medicine. The companies should try to exploit the Indian traditional knowledge in ayurveda and herbal cures and file as many patents for herbal medicine as they can. For this the government should set up R&D laboratories undertaking research exclusively in the area of herbal medicines and support the companies in their research and patent filing.
- **The government should encourage setting up of USFDA-compliant plants by providing tax holidays for a specified period;** so that the Indian companies can exploit the opportunity arising out of patented drugs and take up marketing of generics in the developed countries like USA.

CHAPTER 6

COMPANY ANALYSIS

6.1 Rationale for Selection of Companies

We have analyzed the top five companies in the Indian pharmaceutical industry for the purpose of doing the quantitative analysis. Our rationale behind selecting the top five companies has been the –SALES AND PROFIT. We selected the top 25 companies and choose top and bottom five.

TOP FIVE COMPANIES

We studied the sales and profit figures of the companies operating in this industry and zeroed in on the following companies:

- CIPLA
- GALOXO SMITH KLINE
- RANBAXY
- SUN PHARMA
- ALKEM

BOTTOM FIVE COMPANIES

On a similar basis, we chose the bottom three companies in the Indian Pharmaceutical industry. These are:

- VINATI ORGANICS
- NEULAND LABS
- AARTI DRUGS
- MARKSANS PHARMA
- SHILPA MEDICARE

We have analyzed the financial position of these companies using the RATIO ANALYSIS. The first step was to identify the key ratios and study the performance of the companies using these ratios as the base. After this, we made inter- firm comparison of the companies, followed by detailed ratio analysis for the last five years.

In the following pages, we will be studying the detailed analysis of all the above mentioned companies.

6.2 Company Background

6.2.1 Cipla

Originally founded as The Chemical, Industrial & Pharmaceutical Laboratories is a prominent Indian Pharmaceutical Company best-known outside its home country for producing low-cost anti-AIDS drugs for HIV-positive patients in developing countries. Cipla makes drugs to treat cardiovascular disease, arthritis, diabetes, weight control, depression and many other health conditions, and its products are distributed in more than 180 countries worldwide. Among the hundreds of generic medications it produces for international distribution are atorvastatin, amlodipine, fluoxetine, venlafaxine hydrochloride and metformin. Today, Cipla is the world's largest manufacturer of antiretroviral drugs (ARVs) to fight HIV/AIDS, as measured by units produced and distributed (multinational brand-name drugs are much more expensive, so in money terms Cipla medicines are probably somewhere down the list). Roughly 40% of HIV/AIDS patients undergoing antiretroviral therapy worldwide take Cipla drugs.

Vision: Cipla started with a vision to build a healthy India. And along the way they have realized, that in their own small way, they could contribute to making the world a healthier place.

6.2.2 Ranbaxy

Incorporated in 1961 and went public in 1973. Ranbaxy Laboratories Limited, India's largest pharmaceutical company, is an integrated, research based, international pharmaceutical company, producing a wide range of quality, affordable generic medicines, trusted by healthcare professionals and patients across geographies. Ranked 8th amongst the global generic pharma companies, Ranbaxy today has a presence in 23 of the top 25 pharma markets of the world. The Company has a global footprint in 49 countries, world-class manufacturing facilities in 11 countries and serves customers in over 125 countries.

Earlier in June 2008, Ranbaxy entered into an alliance with one of the largest Japanese innovator companies, Daiichi Sankyo Company Ltd., to create an innovator and generic pharmaceutical powerhouse. The transformational deal will place Ranbaxy in a higher growth

trajectory. The ranking of the combined entity will be catapulted to the No. 15th position in the global pharmaceutical space and it will emerge stronger in terms of its global reach and in its capabilities in drug development and manufacturing.

Ranbaxy is focussed on increasing the momentum in the generics business in its key markets through organic and inorganic growth routes. It continues to evaluate acquisition opportunities in India, emerging and developed markets to strengthen its business and competitiveness. The Company's growth is well spread across geographies with near equal focus on developed and emerging markets. Ranbaxy has entered into new specialty therapeutic segments like Bio-similars, Oncology, Peptides and Limuses. These new growth areas will add significant depth to its existing product pipeline.

Mission: To become a research based international pharma company.

6.2.3 Glaxosmithkline

Established in the year 1924 in India. It is one of the oldest pharmaceuticals company. The GSK India product portfolio includes prescription medicines and vaccines. Our prescription medicines range across therapeutic areas such as anti-infectives, dermatology, gynaecology, diabetes, cardiovascular disease and respiratory diseases. The company is the market leader in most of the therapeutic categories in which it operates. GSK also offers a range of vaccines, for the prevention of hepatitis A, hepatitis B, invasive disease caused by H, influenzae, chickenpox, diphtheria, pertussis, tetanus and others. With opportunities in India opening up, GSK India is aligning itself with the parent company in areas such as clinical trials, clinical data management, global pack management, sourcing raw material and support for business processes including analytics. GSK is committed to developing new and effective healthcare solutions. The values on which the group was founded have always inspired growth and will continue to do so in times to come.

Mission: To improve the quality of life by enabling people to do more, feel better and live longer.

6.2.4 Alkem Laboratories Ltd

Founded in 1974 by one of India's respected entrepreneurs, Shri Samprada Singh. In the last three and a half decades of its operations, Alkem has successfully emerged as a leading domestic Pharma major in and is rapidly multiplying its international footprint. Alkem has carved out for itself, a special reputation in the field of sales and marketing. In India, the strength of Alkem's sales and marketing, along with its expertise in brand buildings are recognized widely and are considered as amongst the very best. Some of the biggest brands in the Indian Pharma market are the Alkem brands. The Alkem product portfolio encompasses a wide spectrum of therapeutic groups, ranging from Anti bacterials, NSAIDS, Gastro Enterology products, Gynaecology products, CNS and CVS products along with an impressive oncology range. Alkem has shown remarkable success with new products and converted several of them into market leaders. For a company with patented new molecules, seeking sales and marketing partners in India, Alkem emerges as the ideal Indian partner. Alkem also has to its credit, world class manufacturing facilities approved by several regulatory authorities. Alkem's formulation facilities for cephalosporins (oral & sterile), Penicillins (oral & sterile) and General products have been approved by the regulatory authorities of US FDA, Europe, South Africa and Australia. Thus, Alkem offers a plethora of product opportunities for companies interested in sourcing products from India. It has P1+ RATING by CRISIL INDIA

Mission: To be among the top 3 pharma companies of India by 2012 through organic growth, a sizable portion of which should accrue from international associations and partnerships.

6.2.5 Sun Pharma

Started in 1983 with 5 products, they are now an international speciality pharma company with over 7000 people, 17 manufacturing locations (including three in the US and one in Hungary), two research centers and a presence in 30 countries. They are one of the leading pharma companies in India, a rank that we've now been at for more than 5 years. They make they are an international speciality pharma company, with a presence in 30 markets. They also make active pharmaceutical ingredients. In branded markets, their products are prescribed in chronic therapy areas like cardiology, psychiatry, neurology, gastroenterology, diabetology and respiratory. They have the same drive for growth that marked our early days.

In India, they have reached leadership in each of the therapy areas that we operate in, and are rated among the leading companies by key customers. Strengthening market share and keeping this customer focus remains a high priority area for the company. In the post-1996 years, they have used a combination of internal growth and acquisitions to drive growth; important mergers were those of the US, Detroit based Caraco Pharm Labs, ICN Hungary (now called Alkaloida Chemical Company Exclusive Group), and that of the internationally approved plants at Halol, India as well as Bryan, Ohio, US and Cranbury, NJ, US. They have shifted work related to new molecules and drug delivery systems to a company, SPARC, which is listed on the Indian stock exchange.

6.2.6 M/s. Vinati Organics Ltd. (VOL)

A public limited company, listed with Mumbai Stock Exchange. VOL started commercial production at its second unit installed in Lote Parshuram and became the third company in the world to manufacture specialty monomers, 2-Acrylamido 2-methylpropanesulfonic Acid. The plant was installed based on breakthrough technology developed with the aid of National Chemical Laboratories (NCL), Pune. ATBS is a co-monomer having applications in acrylic fibre, water treatment, emulsions, paints and oil field drilling industries. VOL's substantial growth is mainly attributed to its efficient manufacturing and sales practices. Their main strengths are:

1. World-class, inimitable technology
2. State-of-the-art, competitive and cost-effective manufacturing
3. Proximity to Mumbai and JNPT port provides great ease of logistics and access to advanced infrastructure facilities.
4. Environment friendly operations including waste product recycling
5. ISO 9002 certified Distribution Control System (DCS) supplied by Yokogawa, Japan and Rosemount, U.S.A.

6.2.7 Marksans Pharma,

Headquartered in Mumbai (India) is vertically integrated global player with strong presence across the entire value chain from Active Pharmaceutical Ingredient's (APIs) to formulations to biopharmaceuticals. We are also actively engaged in R&D and offers Contract Research and Manufacturing Services (CRAMS) to global pharmaceutical companies. The specialty

focus of Marksans Pharma traverses through a wide array of prescription drugs. These drugs have markets spanning the medical fields of Oncology, Gastroenterology, Antidiabetic, Cardiovascular, Pain Management, Gynaecology and others. Furthermore, Marksans also inroads into complex and intricate markets dealing with Biotechnology and Neuropsychiatry. The R&D capabilities of the Company include chemical synthesis and process optimization, formulation development and specialized drug delivery systems. We have put in place world-class facilities by leveraging state-of-the-art manufacturing technology, incorporating best practices and adhering to stringent regulatory compliances, to ensure that the customer receives products of the highest quality. Plants are built as per US FDA guidelines and approved by venerated UK MHRA, Australia TGA and Brazilian ANVISA health authorities. Marksans Pharma has successfully established itself as a trustworthy name when it comes to customers as well as the pharmaceutical world per se. Needless to mention that it has thus attained global recognition within a very short span of time. The Company straddles across key therapy areas and markets its products in both evolving and developed markets. Marksans is aspiring to be a Multinational Company in a true sense.

Mission: Health care in safe hands

6.2.8 Neuland

Named after Father Nieuwland of Notre dame, it was incorporated in 1984 by Dr. D. R. Rao for the manufacture of Salbutamol Sulphate, with mere 40 employees. It has started its commercial production of Salbutamol Sulphate in the year 1986. It has since grown to become one of the most reliable API source for Pharma Industry with addition of more products in course of years. Today the company with total employee strength of 1000+ is the preferred supplier of APIs with unmatched quality and timely delivery. At present the company is closely working with several companies in Europe and North America for supply of active pharmaceutical ingredients and intermediates.

Mission: To be a preferred source worldwide by developing bulk pharmaceutical products and services through cGMP that consistently exceeds all our customer and regulatory expectations by using the latest technologies.

6.2.9 Aarti Drugs (ADL)

Incorporated in 1984, and is promoted by the Alchemie group. ADL's products, basically used in treating diarrhoea and curing tuberculosis, enjoy a perennial demand. Its customers include Pfizer, Searle, Knoll Pharmaceuticals (formerly Boots Pharma), Glaxo, E Merck, etc. The entire production of its veterinary products, dimetridazole, is exported. Except metronidazole, none of its products are under the DPCO. Its bulk drugs are exported to Germany, Switzerland, France, etc. ADL was awarded a certificate of merit by Chemexcil for its outstanding performance in exports. The company has been given the status of Export House by the Government of India. The company's projects to manufacture secnidazole and dichlofenac sodium were implemented and their production has started.

Mission: We shall become the first choice vendor of bulk drugs and maintain that leadership position.

6.2.10 Shilpa Medicare Limited

Established in 1987. It has carved a niche for itself in the exceedingly competitive and quality-conscious sphere of pharmaceuticals manufacturing. It produce and export consistently high-quality Active Pharmaceutical Ingredients Fine Chemicals, intermediates, herbal products and speciality chemical products using sophisticated technology, meticulously following international specifications. The company has earned its spurs as a successful and reliable partner within the pharmaceutical industry. Buyers within the country and from across the borders count on its fast track integrated process development and finely honed expertise of its skilled and experienced personnel. The Company is already exporting to USA, Canada, Australia, Japan and European Countries viz., Germany, Switzerland, Netherlands, Belgium, Spain, Greece, Cyprus, Italy, United Kingdom etc., South American Countries like Mexico, Brazil, Columbia etc., African Countries like Kenya, Nigeria and West Indies etc., Asian Countries like Singapore, Taiwan, China, Malaysia, Thailand and closer to home to Iran, Egypt, Pakistan and Bangladesh. Shilpa Medicare is synergizing strength through tie-ups for manufacturing products and co-marketing rights, for it believes in working together and sharing success. Being proactive in approach, the company continually

seeks out enquiry's for development of new products drawing from the extensive knowledge-base of its qualified and experienced people as well as sophisticated facilities.

Mission: Shilpa's primary goal is to create cGMP facilities to manufacture Oncology Products that will enable to obtain approvals from EDQM, UK MHRA, TGA Australia, Health Canada and USFDA. By supplying products complying the above regulatory authorities to the pharmaceutical companies worldwide, Shilpa will provide an optimum return on investment to our investors, shareholders and our employees. The common people will also enjoy the highest quality products at an affordable amount.

6.3. Ratio analysis

6.3.1 Introduction

Financial ratio analysis is a fascinating topic to study because it can teach us so much about accounts and businesses. When we use ratio analysis we can work out how profitable a business is, we can tell if it has enough money to pay its bills and we can even tell whether its shareholders should be happy. It also help us to check whether a business is doing better this year than it was last year; and it can tell us if our business is doing better or worse than other businesses doing and selling the same things. Financial ratio analysis is the calculation and comparison of ratios which are derived from the information in a company's financial statements. The level and historical trends of these ratios can be used to make inferences about a company's financial condition, its operations and attractiveness as an investment.

For a layman figures in financial statement are independent figures. But when you want to establish relationship between that figures, there comes ratio analysis in picture. This chapter talks about some of the key ratio that are analysed by our group.

6.3.2 Debt–Equity Ratio

This ratio measures company's financial leverage calculated by dividing its total liabilities by stockholders' equity. It indicates what proportion of equity and debt the company is using to finance its assets. It is calculated by dividing total liabilities to shareholders equity. (Sometimes only interest-bearing, long-term debt is used instead of total liabilities in the calculation) A high debt/equity ratio generally means that a company has been aggressive in financing its growth with debt. This can result in volatile earnings as a result of the additional interest expense. Standard debt equity ratio is 2:1.

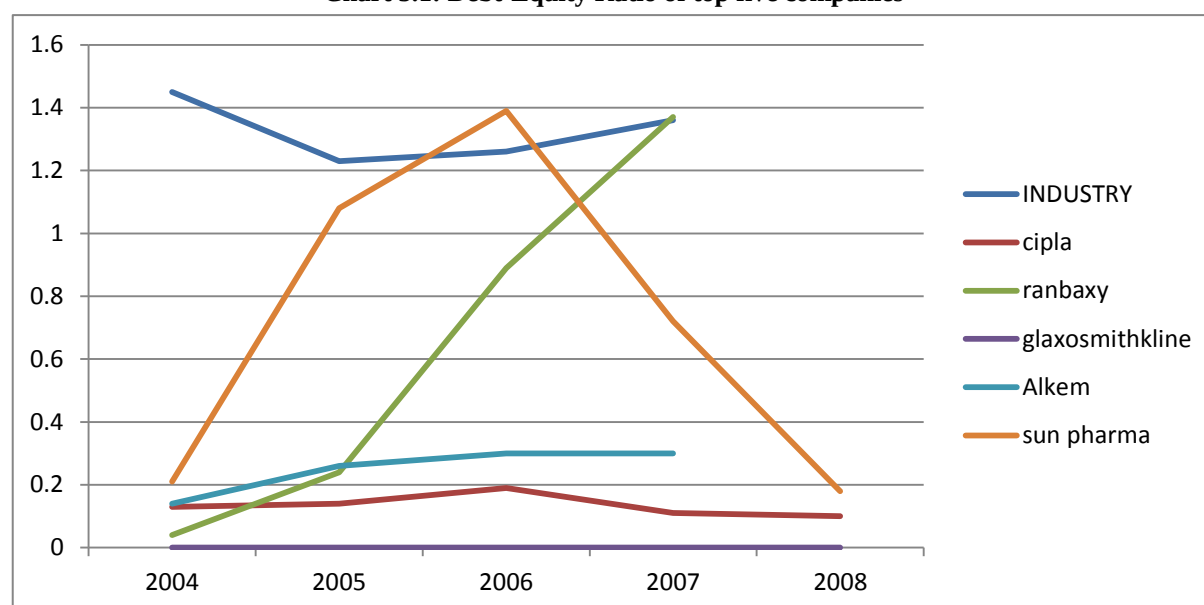
Top Five Companies:

Table 6.1 Debt-Equity Ratio of top five companies

	2004	2005	2006	2007	2008
INDUSTRY	1.45	1.23	1.26	1.36	NA
Cipla	0.13	0.14	0.19	0.11	0.1
Ranbaxy	0.04	0.24	0.89	1.37	NA
GlaxosmithKline	NA	NA	NA	NA	NA
Alkem	0.14	0.26	0.3	0.3	NA
Sun Pharma	0.21	1.08	1.39	0.72	0.18

Source: Capitaline Database

Chart 5.1: Debt-Equity Ratio of top five companies



Source: Compiled by the Group

Interpretation:

It can be seen (from above) that industry ratio in all the years is more than 1. And is some where around 1.25. But company like Cipla has an ratio of 0.13 in 2004 and has reduced gradually to 0.10. This shows that company has less amount of debt and has relatively more of equity. In year 2008 for every 100 rupee capital it has only 10 rupee debt. This may shoot up profit figures as interest liability is very less, but increases the tax amount as higher profits are shown. Ranbaxy has increased to 1.37 relying more on debt than equity, but well within the industry figure. While Glaxo has 0 debt, fully relying on self capital, high volatility is seen in Sun Pharma.

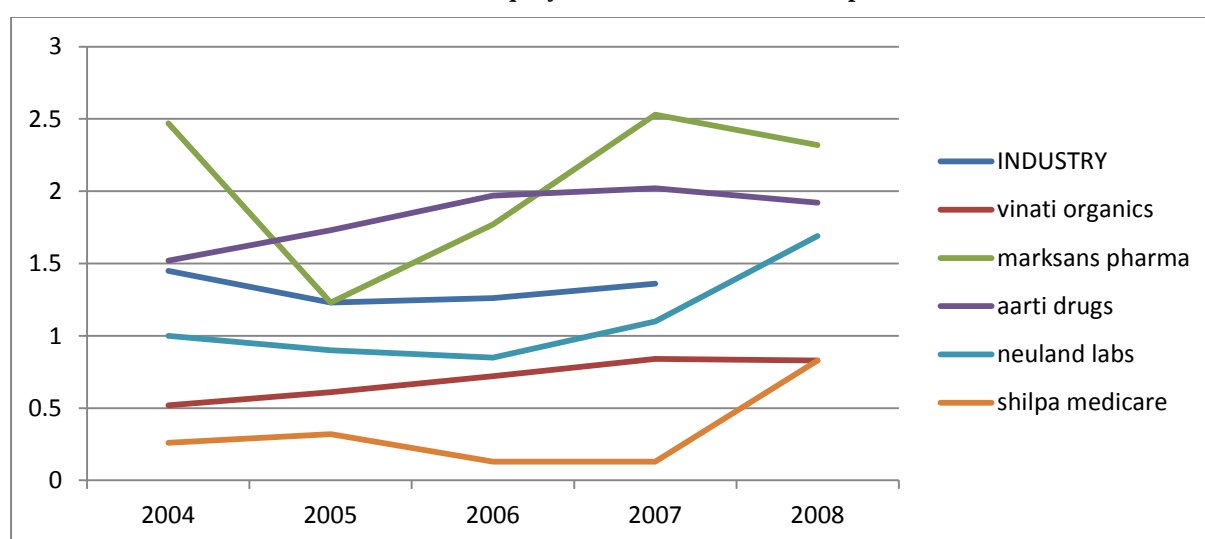
Bottom Five Companies:

Table 6.2: Debt-Equity Ratio of bottom five companies

	2004	2005	2006	2007	2008
INDUSTRY	1.45	1.23	1.26	1.36	NA
Vinati Organics	0.52	0.61	0.72	0.84	0.83
Marksans Pharma	2.47	1.23	1.77	2.53	2.32
Aarti Drugs	1.52	1.73	1.97	2.02	1.92
Neuland Labs	1	0.9	0.85	1.1	1.69
Shilpa Medicare	0.26	0.32	0.13	0.13	0.83

Source: Capitaline Database

Chart 6.2: Debt-Equity Ratio of bottom five companies



Source: Compiled by the Group

Interpretation:

Starting with VINATI, it has consistently maintained the ratio, gradually increasing, but below 1. Marksans have ups and downs inferring that either they are not able to maintain the ratio because of lack of proper financial management or they are very efficient as they are accurately able to predict the further requirements of debt and are able to convert it. Aarti drugs have also this ratio around 2 in last three years. Shilpa initially had a very low ratio but in last year they got good amount of debt, inferring some new projects for which debt is taken, or now into changing their capital structure with a proper balance of debt to equity

6.3.3 Interest Coverage Ratio

This ratio is used to determine how easily a company can pay interest on outstanding debt. The interest coverage ratio is calculated by dividing a company's earnings before interest and taxes (EBIT) of one period by the company's interest expenses of the same period. The lower the ratio, the more the company is burdened by debt expense. An interest coverage ratio below 1.0 indicates the business is having difficulties generating the cash necessary to pay its interest obligations.

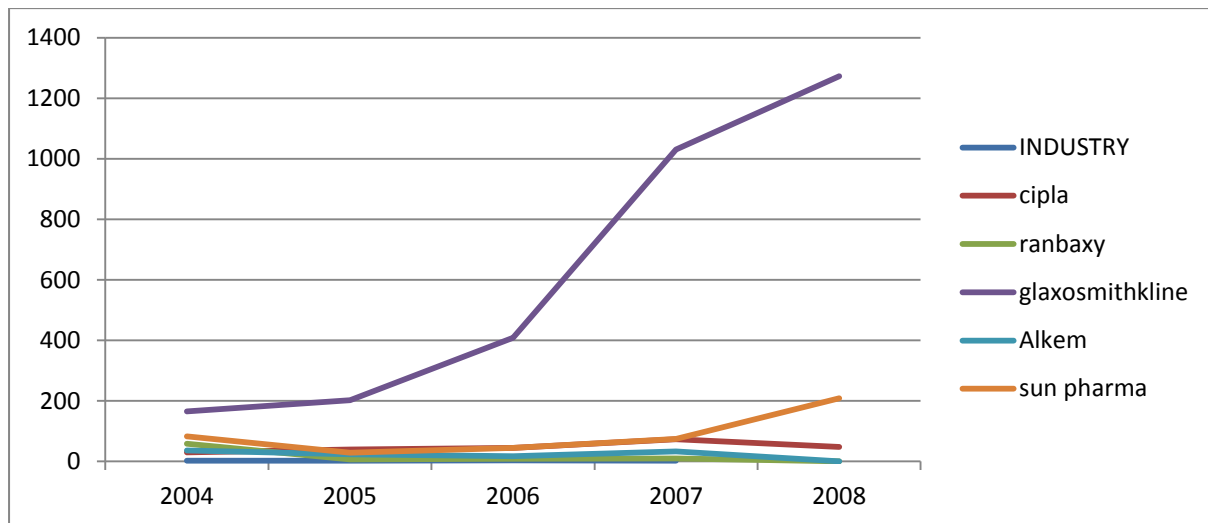
Top Five Companies:

Table 6.3: Interest Coverage Ratio of top five companies

	2004	2005	2006	2007	2008
INDUSTRY	2.82	2.79	3.25	2.56	NA
Cipla	30.28	39.73	45.17	73.4	47.45
Ranbaxy	58.23	6.66	8.58	9.29	NA
GlaxosmithKline	164.9	202.58	408.07	1,030.30	1,272.58
Alkem	36.57	23.1	17.49	33.08	NA
Sun Pharma	82.22	29.2	44.52	73.79	208.94

Source: Capitaline Database

Chart 6.3: Interest Coverage Ratio of top five companies



Source: Compiled by the Group

Interpretation:

From above chart and diagram we can see that the industry ratio is quite well above 2 times, so overall industry ratio needs to be improved. When we see Cipla the ratio is pretty well and is improving year on year, in 2007 it boosted up to 73.4 times and in 2008 its almost 48 times. It either signals that the profits are pretty high, or the company is in thick equity bracket, (i.e. debt in capital structure is less compared to equity). Coming to Ranbaxy, in 2004 the ratio good at was quit at 58.23, but then this ratio drastically declined to almost around 10 in 2007. The main reason behind this is increase of debt capital in capital structure. Their debt in 2004 was 135.86cr, where as in 2005 it went up to 1029.80cr, and finally in 2007 it is 3,503.02cr. GlaxosmithKline has shown a steady increase in this ratio, i.e. from 164.9 times in 2004 to 1,272.58 times in 2008. When we went through their balance sheet we came to know that they have a maintained debt in their capital structure. This increase in ratio is thus because of the operational efficiency by them, which in turn is reflected in profits, and thus in this ratio. Alkem and Sun Pharma also have maintained debt in their capital structure.

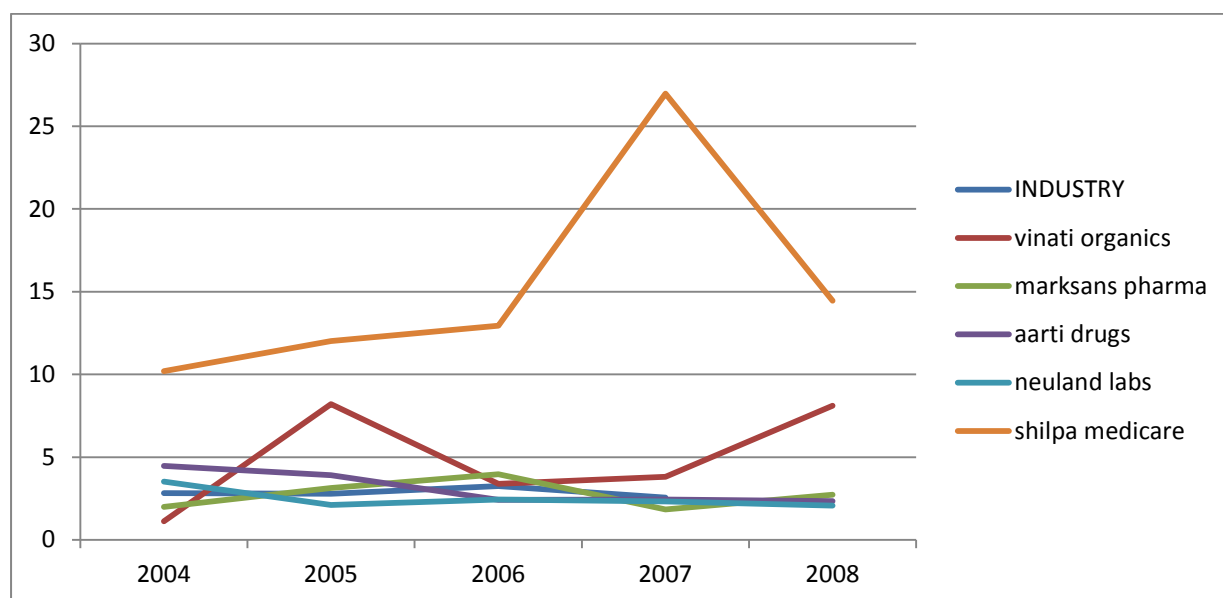
Bottom Five Companies:

Table 6.4: Interest Coverage Ratio of bottom five companies

	2004	2005	2006	2007	2008
INDUSTRY	2.82	2.79	3.25	2.56	
Vinati Organics	1.12	8.2	3.39	3.81	8.1
Marksans Pharma	1.99	3.14	3.97	1.83	2.72
Aarti Drugs	4.46	3.91	2.42	2.43	2.33
Neuland Labs	3.52	2.1	2.44	2.32	2.07
Shilpa Medicare	10.2	12.02	12.94	26.98	14.45

Source: Capitaline Database

Chart 6.4: Interest Coverage Ratio of bottom five companies



Source: Compiled by the Group

Interpretation

From the graph itself we can see that among the bottom five companies, Shilpa healthcare has the best coverage ratio. It stands at approximately 15 in 2008. Next in the line is Vinati Organics whose ratio is also quite convincing standing at 8.1 in 2008. Marksans, Aarti and Neuland needs to improve their ratio. They are near to industry ratio but not improving would be like a gamble, i.e. a slight decrease in their profits could put them in to problems like interest payments using capital because of short of profits.

6.3.4 Current Ratio

This ratio measures a company's ability to pay short-term obligations. It is calculated by dividing current assets to current liabilities. It is also known as "liquidity ratio", "cash asset ratio" and "cash ratio". The higher the current ratio, the more capable the company is of paying its obligations. A ratio under 1 suggests that the company would be unable to pay off its obligations if they came due at that point. While this shows the company is not in good financial health, it does not necessarily mean that it will go bankrupt - as there are many ways to access financing - but it is definitely not a good sign. It senses the efficiency of a company's operating cycle or its ability to turn its product into cash.

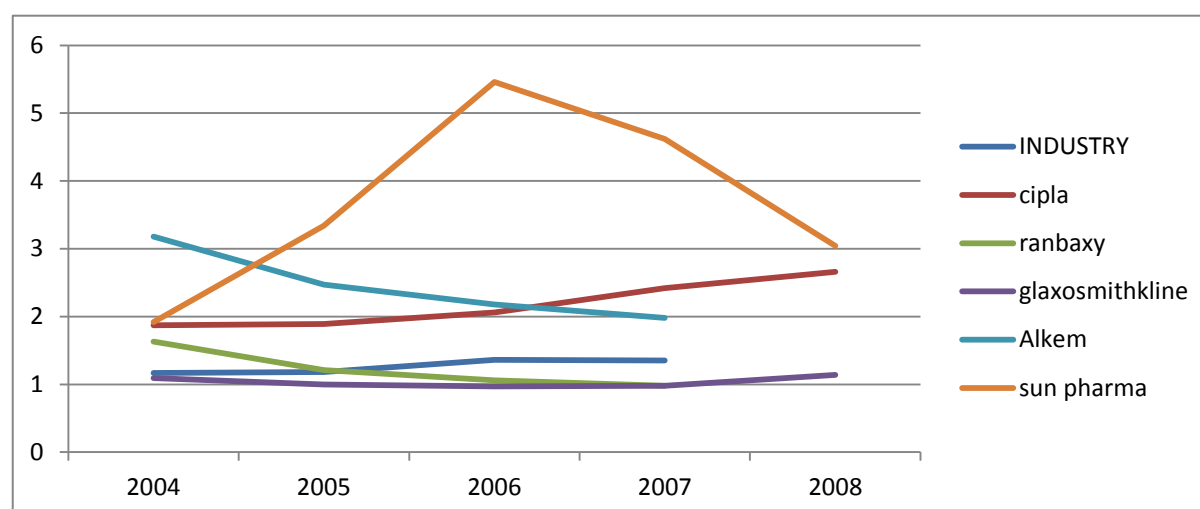
Top Five Companies:

Table 6.5: Current Ratio of top five companies

	2004	2005	2006	2007	2008
INDUSTRY	1.17	1.18	1.36	1.35	NA
Cipla	1.87	1.89	2.06	2.42	2.66
Ranbaxy	1.63	1.21	1.06	0.98	NA
Glaxosmithkline	1.09	1	0.97	0.98	1.14
Alkem	3.18	2.47	2.18	1.98	NA
sun pharma	1.92	3.34	5.46	4.62	3.04

Source: Capitaline Database

Chart 6.5: Current Ratio of top five companies



Source: Compiled by the Group

Interpretation:

Current ratio of the industry is quite well above 1, which shows the financial health of the entire industry is good, and at this point of time if all current liabilities stand due then they all would be satisfied leaving the current assets in positive figure. But the ideal current ratio is 2:1 and this need to be yet achieved. But there is a big question here that current assets include stock as well as prepaid expenses, and in current scenario, if we have to sell all the stock to satisfy the current liabilities, what if the stock would fetch you the price below even its cost price or what you estimated?. So therefore companies rely more on quick ratio rather than on current. If we see in the chart we can infer that all the top five companies have a current ratio above 1, with Cipla and Sunpharma having it even figures in 2plus. Ranbaxy ratio is declining over period of time. Same is the case with Alkem and GlaxosmithKline.

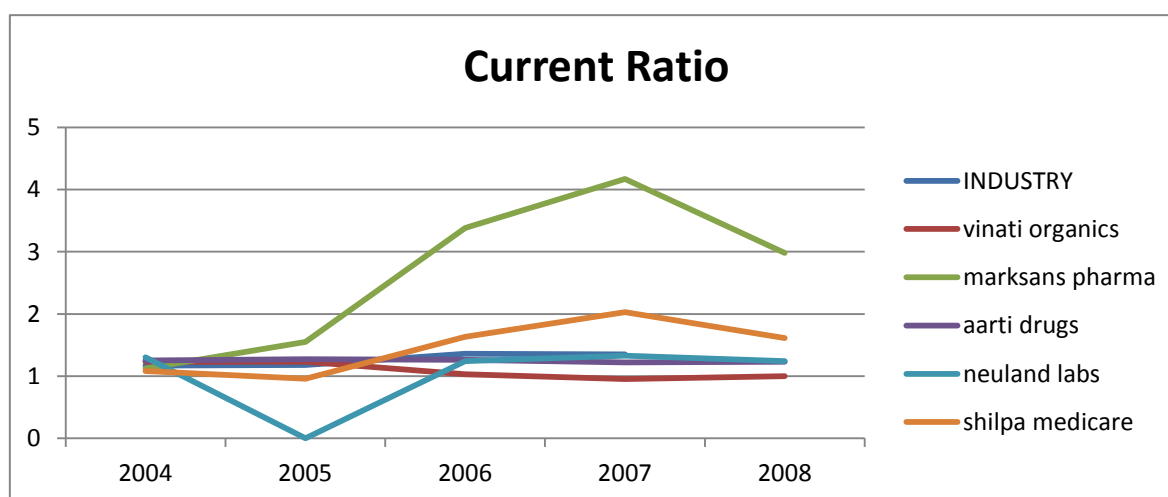
Bottom Five Companies:

Table 6.6: Current Ratio of bottom five companies

	2004	2005	2006	2007	2008
INDUSTRY	1.17	1.18	1.36	1.35	NA
Vinati organics	1.23	1.23	1.03	0.95	1
Marksans pharma	1.12	1.55	3.38	4.17	2.98
Aarti drugs	1.25	1.27	1.26	1.22	1.23
Neuland labs	1.3	1.21	1.24	1.33	1.24
Shilpa Medicare	1.08	0.96	1.63	2.03	1.61

Source: Capitaline Database

Chart 6.6: Current Ratio of bottom five companies



Source: Capitaline Database

Interpretation

Even our bottom five companies have an current ratio above one. Only Marksans have the ratio above the ideal figure i.e. 2:1. Rest all have it below 2. Vinati has to take care of this ratio as trend of it shows that it is declining and even in 2007 it has a ratio below 1, and in 2008 exactly 1, showing not so good health of the company. Aarti has maintained it on and below 1.25, needs to be improved if want to come in ideal bracket. Same is the case with Neuland. Shilpa's latest ratio is 1.61. So overall except for Marksans all other companies need improvement.

6.3.5 Fixed Asset Turnover Ratio

Fixed asset turnover is the ratio of sales to the value of fixed assets. It indicates how well the business is using its fixed assets to generate sales. Generally speaking, the higher the ratio, the better, because a high ratio indicates the business has less money tied up in fixed assets for each Rupees of sales revenue. A declining ratio may indicate that the business is over-invested in plant, equipment, or other fixed assets.

Fixed asset turnover= Sales/Average net fixed asset

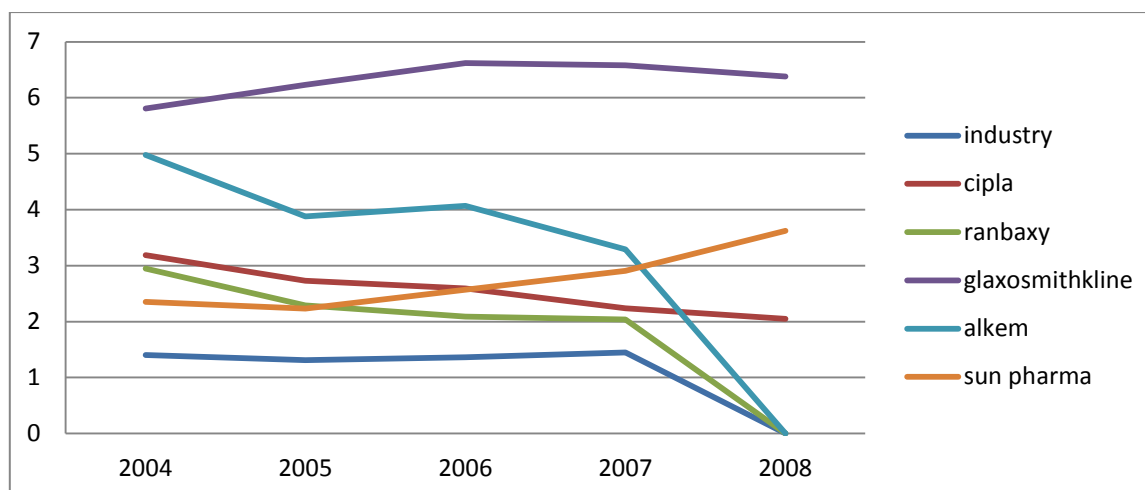
Top Five Companies:

Table 6.7: Fixed Asset Turnover of top five companies

	2004	2005	2006	2007	2008
Industry	1.4	1.31	1.36	1.45	NA
Cipla	3.19	2.73	2.59	2.24	2.05
Ranbaxy	2.95	2.29	2.09	2.04	NA
GlaxosmithKline	5.81	6.23	6.62	6.58	6.38
Alkem	4.98	3.88	4.07	3.29	NA
Sunpharma	2.35	2.23	2.57	2.91	3.62

Source: Capitaline Database

Chart 6.7: Fixed Asset Turnover Ratio of top five companies



Source: Compiled by the Group

Interpretation

This graph shows the comparative fixed asset turnover of top 5 companies chosen by us. We can see that Glaxosmithkline has the best fixed asset turnover ratio. This means that it is well able to use its fixed asset to generate sales. Alkem fixed asset ratio is seeing a steep fall. This is because it has over invested in Plant, machinery and other assets and its sales have not increased to that extent. All the companies' ratio is better when compared to the industry.

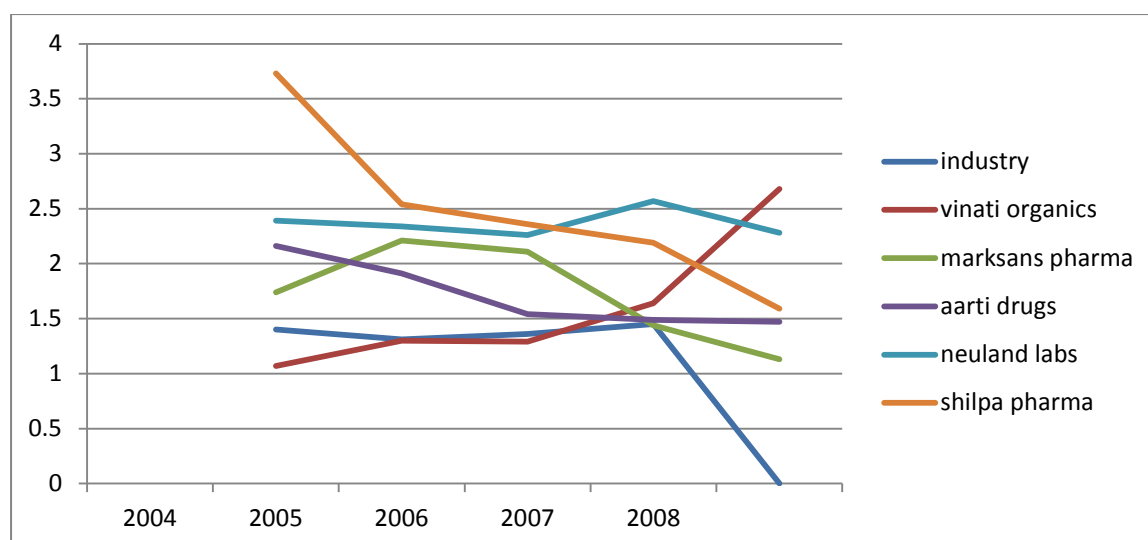
Bottom five companies:

Table 6.8: Fixed Asset Turnover Ratio of bottom five companies

	2004	2005	2006	2007	2008
Industry	1.4	1.31	1.36	1.45	NA
Vinati organics	1.07	1.3	1.29	1.64	2.68
Marksans pharma	1.74	2.21	2.11	1.44	1.13
Aarti drugs	2.16	1.91	1.54	1.49	1.47
Neuland labs	2.39	2.34	2.26	2.57	2.28
Shilpa pharma	3.73	2.54	2.36	2.19	1.59

Source: Capitaline Database

Chart 6.8: Fixed Asset Turnover Ratio of bottom five companies



Source: Compiled by the Group

Interpretation:

This graph shows the fixed asset turnover ratio of bottom 5 companies chosen by our group. We can see that Shilpa Medicare has the best fixed asset turnover ratio. But it's declining due to the company's investment in fixed asset. The ratio of Vinati organics is rising steadily. This shows that company is well able to utilize its fixed asset to generate sales.

6.3.6 Inventory Turnover Ratio

This ratio shows how many times a company's inventory is sold and replaced over a period. A low turnover implies poor sales and, therefore, excess inventory. A high ratio implies either strong sales or ineffective buying.

Inventory turnover= Cost of goods sold/Average inventory

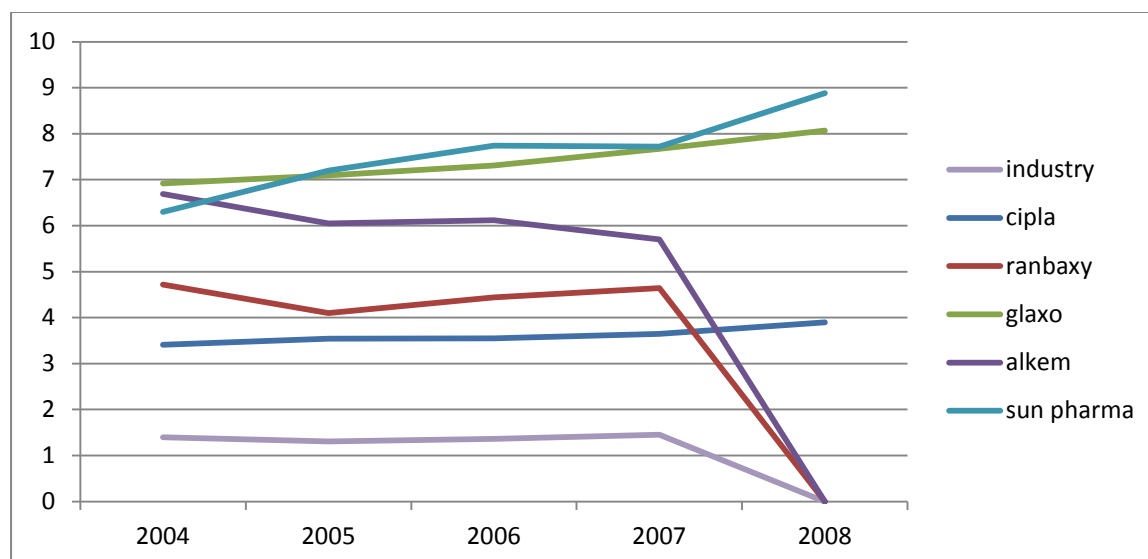
Top Five Companies:

Table 6.9: Inventory Turnover Ratio of top five companies

	2004	2005	2006	2007	2008
Industry	1.4	1.31	1.36	1.45	NA
Cipla	3.41	3.54	3.55	3.65	3.9
Ranbaxy	4.72	4.1	4.44	4.64	NA
Glaxosmithkline	6.92	7.09	7.31	7.67	8.07
Alkem	6.69	6.05	6.12	5.7	NA
Sun pharma	6.3	7.2	7.74	7.72	8.88

Source: Capitaline Database

Chart 6.9: Inventory Turnover Ratio of top five companies



Source: Compiled by the Group

Interpretation:

The above graph shows the Inventory turnover ratio of top 5 companies chosen by us. We can see that Sun pharma has the best Inventory turnover ratio and it is constantly rising. This is a good sign for the company and it shows that company is able to convert its inventory into sales. After Sun pharma, GlaxosmithKline has good inventory turnover ratio. All the companies' turnover is better in comparison to the industry.

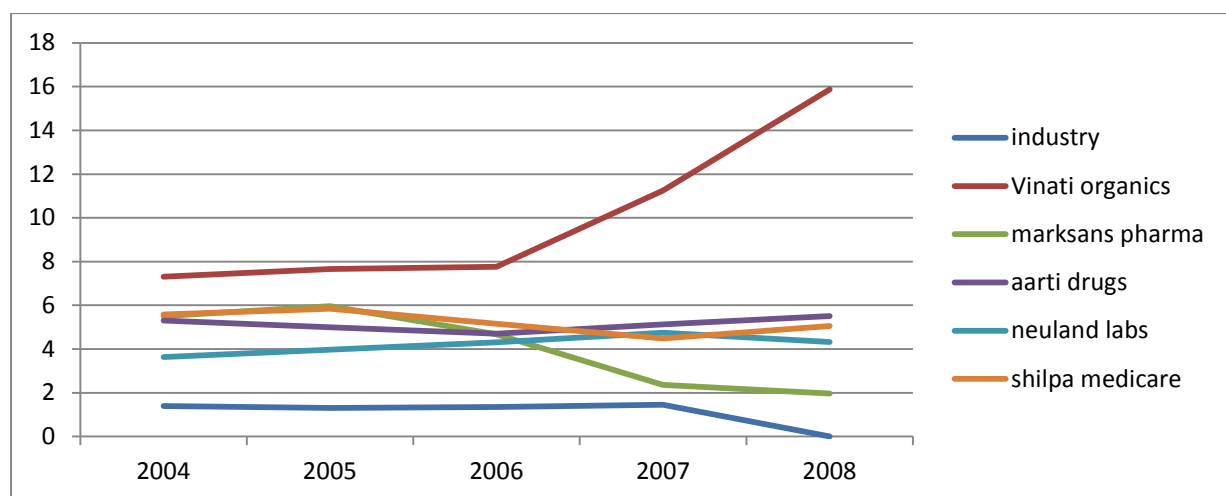
Bottom Five Companies:

Table 6.10: Inventory Turnover Ratio of bottom five companies

	2004	2005	2006	2007	2008
Industry	1.4	1.31	1.36	1.45	NA
Vinati organics	7.31	7.66	7.76	11.24	15.87
Marksans pharma	5.51	5.97	4.67	2.37	1.97
Aarti drugs	5.31	5	4.71	5.13	5.51
Neuland labs	3.63	3.98	4.31	4.75	4.32
Shilpa Medicare	5.59	5.84	5.16	4.49	5.05

Source: Capitaline Database

Chart 6.10: Inventory Turnover Ratio of bottom five companies



Source: Compiled by the Group

Interpretation:

The above graph shows the Inventory turnover ratio of bottom 5 companies chosen by our group. Vinati organics has the best inventory turnover ratio. And after 2006 there has been a steep rise. This is a good indication for the company and it shows that it is able to convert its inventory into sales quickly. All other companies' turnover is not significant but it's good in comparison to the whole industry.

6.3.7 Debtors Turnover Ratio

Debtors turnover ratio indicates the relation between net credit sales and average accounts receivables of the year. This ratio is also known as Debtors' Velocity. This ratio indicates the efficiency of the concern to collect the amount due from debtors. It determines the efficiency with which the trade debtors are managed. Higher the ratio, better it is as it proves that the debts are being collected very quickly. Debtors Turnover Ratio = Net Credit Sales/Average Accounts Receivables

Where, Average Accounts Receivables = [Opening Debtors and B/R + Closing Debtors and B/R]/2

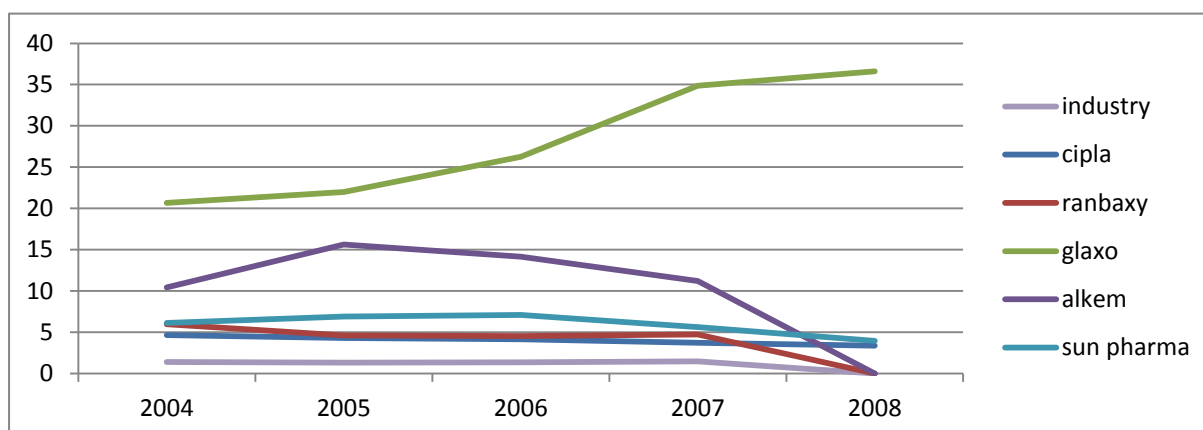
Top Five Companies:

Table 6.11: Debtors Turnover Ratio of top five companies

	2004	2005	2006	2007	2008
Industry	1.4	1.31	1.36	1.45	NA
Cipla	4.63	4.29	4.13	3.71	3.38
Ranbaxy	5.97	4.6	4.51	4.72	NA
GlaxosmithKline	20.67	21.97	26.24	34.88	36.6
Alkem	10.42	15.61	14.15	11.19	NA
Sun pharma	6.13	6.9	7.09	5.61	3.96

Source: Capitaline Database

Chart 6.11: Debtors Turnover Ratio of top five companies



Source: Compiled by the Group

Interpretation:

The above graph shows the Debtors turnover ratio of top 5 companies chosen by our group. GlaxosmithKline has the best Debtors turnover ratio. This shows that company has managed to collect its debtors quickly and is well able to rotate its stock. Alkem debtors turnover is seen a rise and then fall for continuous two years. This is not a good sign for the company and it shows its inefficiency to collect its debtors.

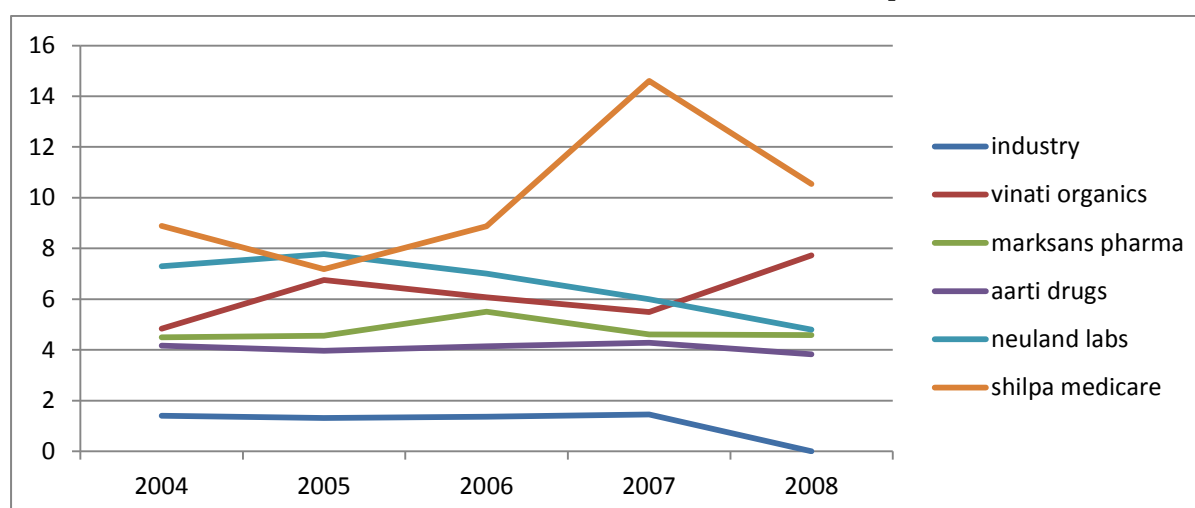
Bottom Five Companies:

Table 6.12: Debtors Turnover Ratio of bottom five companies

	2004	2005	2006	2007	2008
Industry	1.4	1.31	1.36	1.45	0
Vinati organics	4.84	6.75	6.07	5.49	7.73
Marksans pharma	4.49	4.56	5.51	4.61	4.58
Aarti drugs	4.16	3.96	4.14	4.28	3.83
Neuland labs	7.3	7.77	7.01	5.99	4.8
Shilpa Medicare	8.89	7.18	8.88	14.6	10.54

Source: Capitaline Database

Chart 6.12: Debtors Turnover Ratio of bottom five companies



Source: Compiled by the Group

Interpretation:

The above graph shows the Debtors turnover ratio of bottom 5 companies chosen by our group. In this graph we can see that Shilpa Medicare debtor's turnover ratio is good in comparison to other companies. This shows that Shilpa Medicare is able to collect its debtor efficiently. Neuland labs debtor turnover has fallen in the recent years. All other companies' debtor turnover is good when compared to overall industry.

6.3.8 Solvency Ratio

This ratio tells us the company's ability to meet long-term obligations. The solvency ratio measures the size of a company's after-tax income; excluding non-cash depreciation expenses, as compared to the firm's total debt obligations. It provides a measurement of how likely a company will be to continue meeting its debt obligations.

Solvency ratio = $\frac{\text{after tax net profit} + \text{Depreciation}}{\text{Long term liabilities} + \text{Short term liabilities}}$

Top Five Companies:

Table 6.13: Solvency Ratio of top five companies

Company	Solvency Ratio
Cipla	45.49%
Ranbaxy	14.20%
GlaxosmithKline	24.01%
Alkem	48.65%
Sunpharma	28.60%

Source: Capitaline Database

Interpretation:

Cipla has a solvency ratio of 45.49%, which is considered as being financially healthy. Its net profit is 45% in comparison to its liability. Ranbaxy has a solvency ratio of 14.2% which says that its net profit is 14.2% in comparison to its debt obligations. A higher net profit or lower debt would have resulted in better solvency position for the company. GlaxosmithKline has a solvency ratio of 24.01% which is considered healthy. This means that its net profit is 24% to its liability obligations. Alkem laboratories have a solvency ratio of 48.65% which indicates that its net profit is 48.65%. This is a healthy indicator as far as company solvency is

considered. Sun pharma has a solvency ratio of -28.60%. Its net profit is negative in comparison to its liabilities which is a bad indicator. The company has bad solvency position.

Bottom Five Companies:

Table 6.14: Solvency Ratio of bottom five companies

Company	Solvency Ratio
Vinati	35.72%,
Marksans pharma	3.59%
Aarti	13.15%
Neuland	8.17%
Shilpa	15.83%

Source: Capitaline Database

Interpretation:

Vinati organics has a solvency ratio of 35.72%, which is a good indicator as far as solvency of the company is considered. Marksans pharma has a solvency ratio of 3.59%. This tells us that its net profit is 3.59% of its total debt. This is a bad indicator. Aarti drugs have a solvency ratio of 13.15%. This tells us that its net profit is 13.15% of its total debt. Neuland labs have a solvency ratio of 8.17%. Its net profit in comparison to total debt is 8.17% .The Company should increase its net profit or decrease its debt. Shilpa Medicare has a solvency ratio of 15.83%. This tells us that the company has a net profit of 15.83% in comparison of total debt.

6.3.9 PBIDTM %

Profit Before Interest Depreciation and Tax Margin: It shows the company's profit percentage before deducting Interest, Depreciation and Tax.

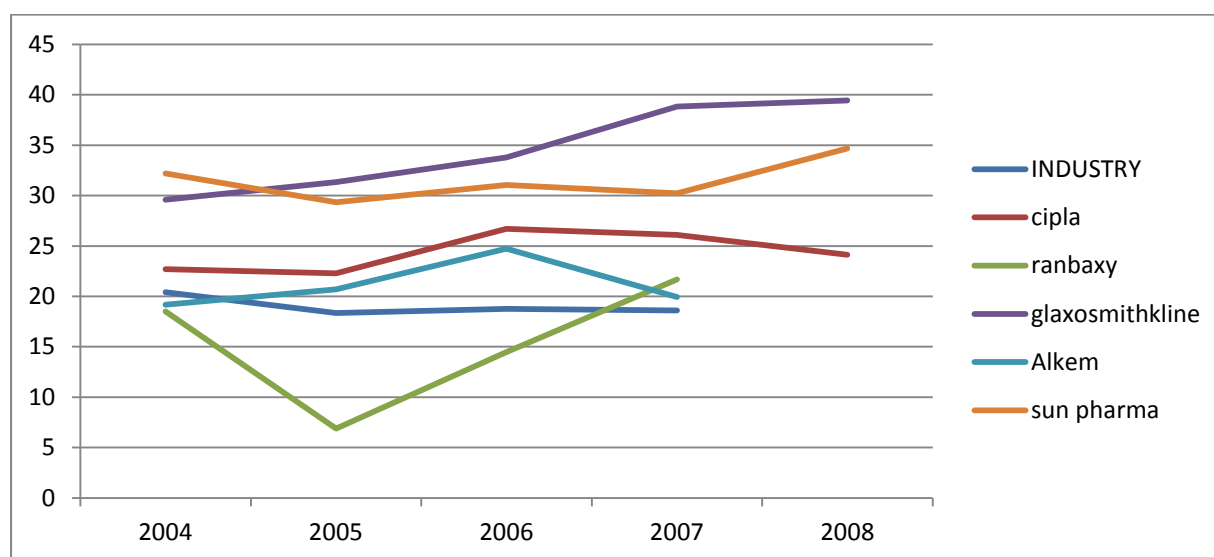
Top Five Companies:

Table 6.15: PBIDTM% of top five companies

	2004	2005	2006	2007	2008
Industry	20.41	18.35	18.75	18.59	NA
Cipla	22.7	22.27	26.69	26.11	24.14
Ranbaxy	18.51	6.88	14.47	21.67	NA
GlaxosmithKline	29.6	31.34	33.78	38.84	39.44
Alkem	19.16	20.7	24.73	19.93	NA
Sun pharma	32.18	29.34	31.04	30.21	34.68

Source: Capitaline Database

Chart 6.15: PBIDTM% of top five companies



Source: Compiled by the Group

Interpretation:

The industry earning before Interest Depreciation and Tax Margin is app 19%. Only important thing that need attention here is that this earning percentage after deduction of IDT needs to be above the cost of acquiring this capital, or above the bank rate offered by bank for term deposits. From the chart we can see that Cipla has an excellent profit % figuring at

22plus. And the results of Glaxo and sunpharma are even better falling under 30plus figures. Alkem and Ranbaxy have it around 20%. Overall percentage is quite good. When profit is considered, earning is difficult, even more difficult is maintaining the benchmark that has been achieved. So companies over here need to take care of that.

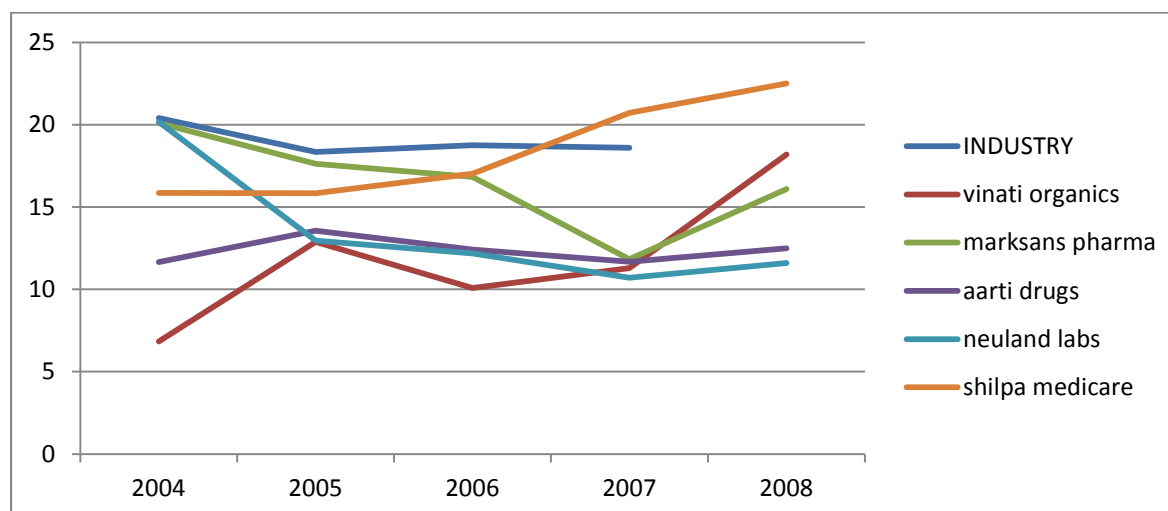
Bottom Five Companies:

Table 6.16: PBIDTM% of bottom five companies

	2004	2005	2006	2007	2008
Industry	20.41	18.35	18.75	18.59	
Vinati organics	6.84	12.88	10.09	11.29	18.18
Marksans pharma	20.1	17.63	16.82	11.83	16.08
Aarti drugs	11.66	13.57	12.42	11.68	12.49
Neuland labs	20.18	12.95	12.18	10.71	11.6
Shilpa Medicare	15.85	15.84	17.02	20.72	22.51

Source: Capitaline Database

Chart 6.16: PBIDTM% of bottom five companies



Source: Compiled by the Group

Interpretation:

When we come to bottom five companies, we see that none of the company have profit % figuring 30plus as we saw in top five companies. The best performer in this slab of companies is Shilpa Medicare having profit % above 20 in 2007 as well as in 2008. Even Vinati has shown quite reasonable growth but still have not touched 20plus mark. Marksans

over here has shown a declining trend. Same is the case with Neuland. Needs to take care of this. Aarti needs to improve its earnings as its percentage is not at all satisfying. Even debt ratio of Aarti is around 2:1, inferring that deduction of interest will also have an good impact on this profit.

6.3.10 PBITM%

Profit Before Interest and Tax Margin: It shows the company's profit percentage before deducting interest and tax margin, but after deducting depreciation. It's after PBITM that interest and tax is deducted. So here debt and cost of it plays an important role. Suppose if there is no debt in capital structure, then directly tax is deducted and dividends are paid.

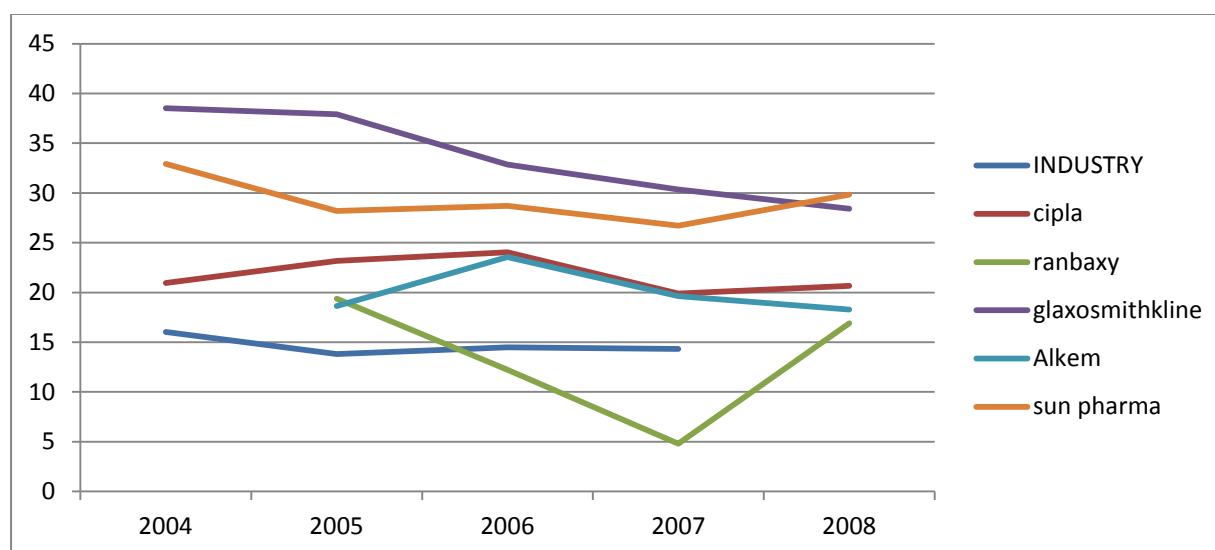
Top Five Companies:

Table 6.17: PBITM% of top five companies

	2004	2005	2006	2007	2008
Industry	16.04	13.82	14.48	14.31	NA
Cipla	20.95	23.18	24.04	19.9	20.66
Ranbaxy	NA	19.37	12.23	4.81	16.91
GlaxosmithKline	38.51	37.9	32.84	30.34	28.42
Alkem	NA	18.63	23.56	19.62	18.29
Sun pharma	32.93	28.2	28.7	26.72	29.82

Source: Capitaline Database

Chart 6.17: PBITM% of top five companies



Source: Compiled by the Group

Interpretation:

Overall industry ratio is quite reasonable at around 14plus%. Glaxosmithkline and sun pharma have very good percentage of around 30%. Very much attractive investment for investors. Cipla is also consistent in maintaining 20plus figure. Ranbaxy and Alkem needs to take care in this area as their percentage is even not touching 20 mark.(except or one year). now here if company is operating on thick debt then this percentage will further decrease when interest is deducted. So improvement is needed over here

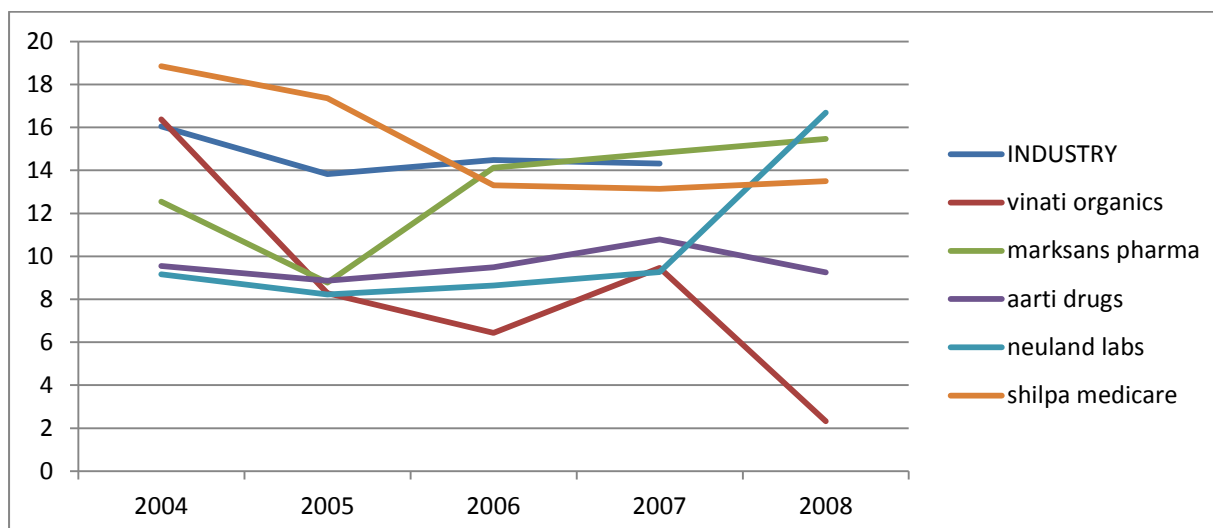
Bottom Five Companies:

Table 6.18: PBITM% of bottom five companies

	2004	2005	2006	2007	2008
Industry	16.04	13.82	14.48	14.31	NA
Vinati organics	16.37	8.29	6.44	9.46	2.32
Marksans pharma	12.54	8.78	14.12	14.81	15.47
Aarti drugs	9.55	8.87	9.49	10.78	9.25
Neuland labs	9.16	8.22	8.64	9.26	16.68
Shilpa Medicare	18.85	17.36	13.31	13.14	13.49

Source: Capitaline Database

Chart 6.18: PBITM% of bottom five companies



Source: Compiled by the Group

Interpretation:

Here we can see that none of the company is touching the 20plus% mark. Infact companies like Vinati and Aarti needs to give more attention over here as it is seen that their % is very

low and is almost near to interest rate of term deposit in banks. So needs improvement in this area. Marksans and Neuland have reasonable return %. Even Shilpa has maintained it to 13% since last three years. Long term growth is very important for shareholders. So companies need to maintain this have to grow showing less volatility.

6.3.11 ROCE%:

Return on Capital Employed: This ratio indicates the efficiency and profitability of a company's capital investments. It is calculated by simply dividing EBIT to difference of total assets and current liabilities. ROCE should always be higher than the rate at which the company borrows; otherwise any increase in borrowing will reduce shareholders' earnings.

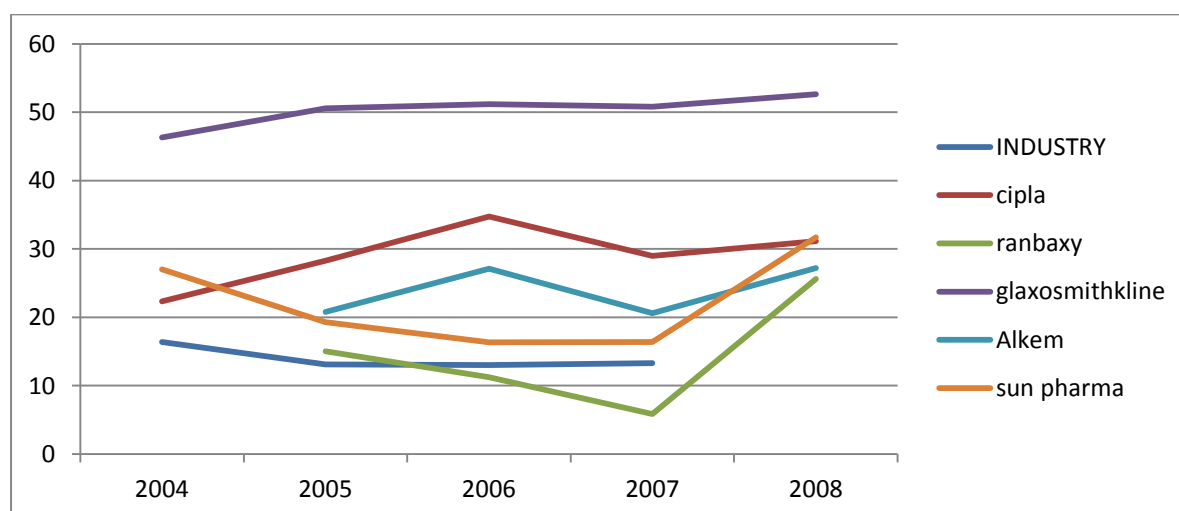
Top Five Companies:

Table 6.19: ROCE% of top five companies

	2004	2005	2006	2007	2008
Industry	16.37	13.11	13	13.31	NA
Cipla	22.31	28.28	34.75	28.96	31.15
Ranbaxy	NA	15	11.22	5.82	25.59
Glaxosmithkline	46.3	50.57	51.16	50.82	52.61
Alkem	NA	20.79	27.08	20.58	27.2
sun pharma	27.01	19.3	16.31	16.37	31.71

Source: Capitaline Database

Chart 6.19: ROCE% of top five companies



Source: Compiled by the Group

Interpretation:

Here we can see that overall industry ROCE% is around 13%. Now if this industry can get their capital borrowed at less than this % only than they should go for it or else it will reduce shareholders' earnings. The best performer in this ratio is GlaxosmithKline. 52.61% in 2008 shows efficient and effective allocation of capital. Even Cipla ROCE is quite good around 31% in 2008 shows that they can borrow funds up to 31%, which itself leaves them with a very good scope of borrowing. Ranbaxy in this is showing improvement from 2007 to 2008 finally at 25.59% return leaving with a good scope of borrowing. Alkem and Sunpharma also have quite good percentage, sunpharma at 31 and Alkem at 27. So overall companies have a good ROCE in 2008.

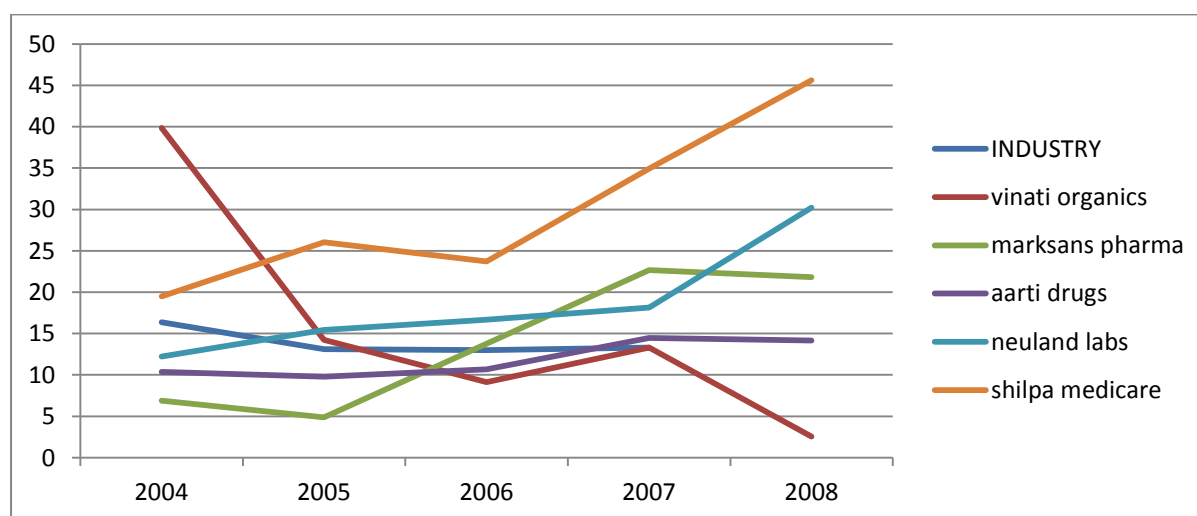
Bottom Five Companies:

Table 6.20: ROCE% of bottom five companies

	2004	2005	2006	2007	2008
Industry	16.37	13.11	13	13.31	NA
Vinati organics	39.85	14.23	9.13	13.3	2.54
Marksans pharma	6.87	4.87	13.78	22.65	21.83
Aarti drugs	10.35	9.79	10.69	14.45	14.15
Neuland labs	12.22	15.43	16.67	18.14	30.21
Shilpa Medicare	19.49	26.04	23.7	34.94	45.62

Source: Capitaline Database

Chart 6.20: ROCE% of bottom five companies



Source: Compiled by the Group

Interpretation:

The best performer in this ratio among these bottom five companies is Shilpa Medicare having ROCE at 45% in 2008 leaving a very good scope of borrowing. Marksans and Neuland also have shown good progress (as what trend shows). Aarti also has quite satisfying % in 2008 but improvement is needed in this area for Aarti. One company which has drastically reduction in this area is Vinati; they just can't afford to borrow any more funds.

6.3.12 RONW%:

Return on Net Worth or Owner's Funds: This ratio shows the money available for the equity shareholders and it is calculated by dividing difference between PAT and Preference Dividends to net worth. It tells that how much profit a company generates with the money shareholders have invested.

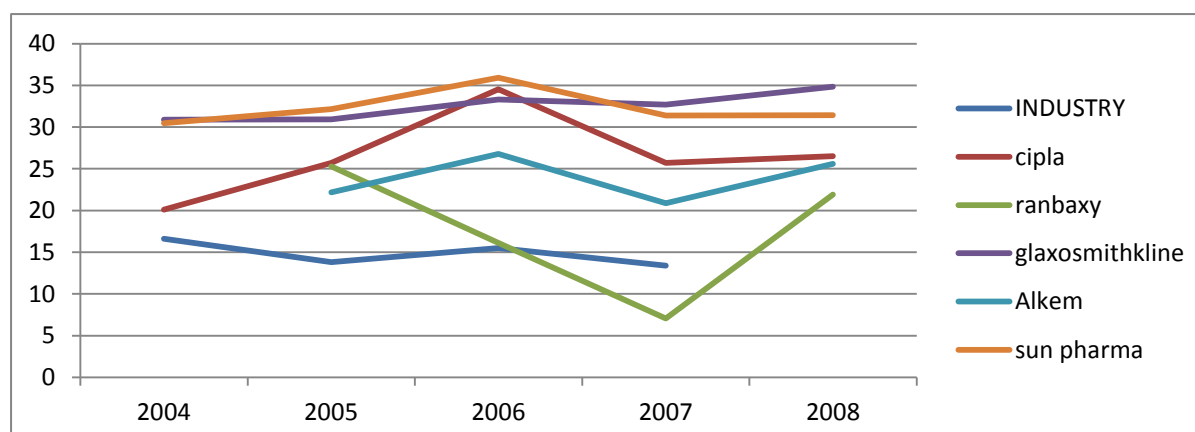
Top Five Companies:

Table 6.21: RONW% of top five companies

	2004	2005	2006	2007	2008
Industry	16.63	13.83	15.5	13.38	NA
Cipla	20.12	25.69	34.55	25.7	26.51
Ranbaxy	NA	25.28	16.1	7.07	21.9
GlaxosmithKline	30.89	30.94	33.32	32.71	34.83
Alkem	NA	22.17	26.79	20.87	25.61
Sun pharma	30.47	32.15	35.93	31.38	31.44

Source: Capitaline Database

Chart 6.21: RONW% of top five companies



Source: Compiled by the Group

Interpretation:

Industry RONW% is averaging around 14%, which needs to be improved as investors may find good opportunities in other industry and may think on switching their investment. Glaxosmithkline is giving the highest return of around 35% satisfying the investors at its best. Even sunpharma has shown consistent returns of 30plus %. Returns of Cipla, Ranbaxy and Alkem are in 20plus figures, where volatility in Ranbaxy is pretty high. Consistency is what needs to be taken care of here, as investors also look in long term perspective, and return over here is entirely of shareholders, so this ratio needs to be well taken care of.

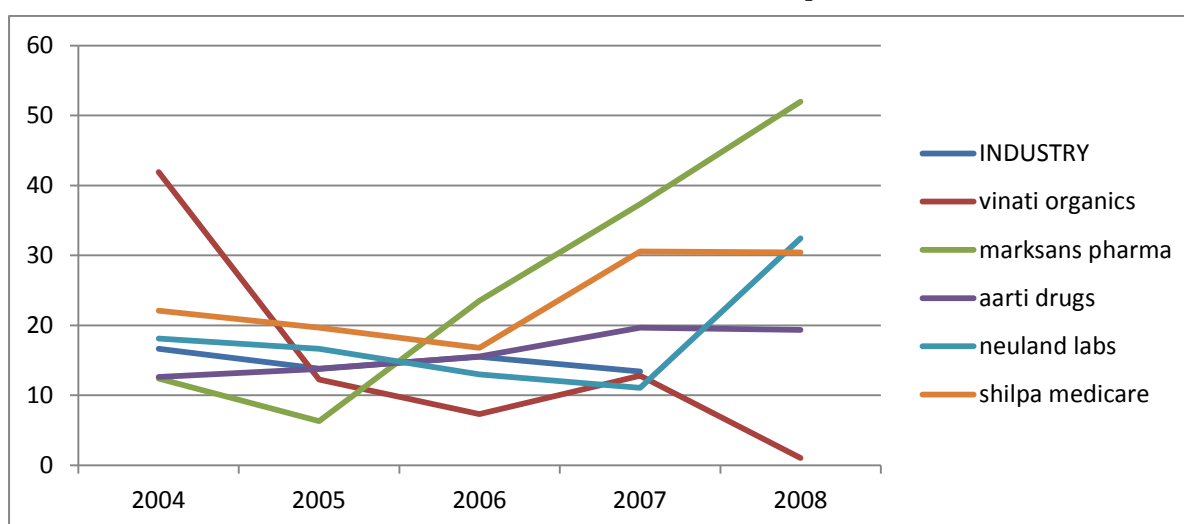
Bottom Five Companies:

Table 6.22: RONW% of bottom five companies

	2004	2005	2006	2007	2008
Industry	16.63	13.83	15.5	13.38	NA
Vinati organics	41.9	12.27	7.3	12.82	1.02
Marksans pharma	12.38	6.32	23.51	37.33	51.97
Aarti drugs	12.6	13.75	15.54	19.66	19.33
Neuland labs	18.12	16.64	12.98	11.06	32.44
Shilpa Medicare	22.07	19.66	16.79	30.55	30.4

Source: Capitaline Database

Chart 6.22: RONW% of bottom five companies



Source: Compiled by the Group

Interpretation:

Excellent performance in this area is seen with Marksans, along with maintained growth. Even Shilpa Medicare and Neuland labs has shown 30plus % in 2008, good return on investment for shareholders. Vinati has gone down drastically in this area and has shown downward trend. Needs to take care of this. Operating efficiency needs to be looked upon and try to improve in this area.

6.4 Conclusion

Above were some of the key ratios of top five and bottom five along with industry comparison that are analyzed by our group. From that we have ascertained that among top five companies, GlaxoSmithKline and Sun Pharma are the best performers, and among the bottom five, Vinati and Aarti need to improve their performance. Our group has tried to establish some kind of a meaningful relationship between the figures of the financial statements of top five, bottom five and industry, and has used tables and charts for better understanding of the performance of the companies.

CHAPTER 7

RECENT TRENDS IN PHARMACEUTICAL INDUSTRY

7. Trends in the Pharmaceutical Industry

From the account of the global and Indian pharmaceutical industry, one would have attained an untainted picture of the pharmaceutical industry and its growth trajectory. At this point, it is imperative to ascertain the recent trends in the pharmaceutical industry from the Indian perspective. The following would play a central role in defining the shape of the industry in the near future:

7.1. Clinical Trials

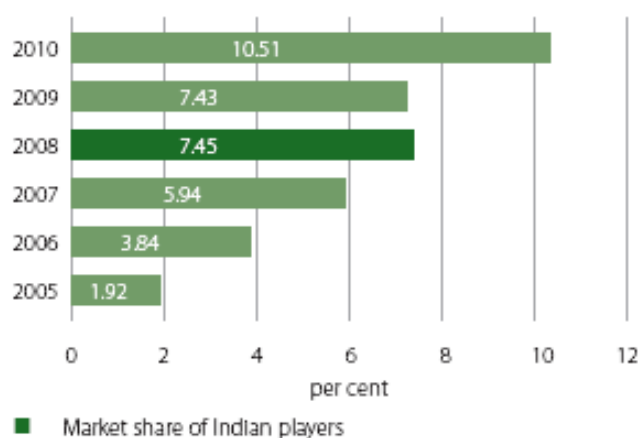
Clinical trials are conducted to allow safety and efficacy data to be collected for new drugs or devices. They are performed at a rather advanced stage of drug development. More and more clinical trials are poised to be moved away from developed countries to countries like India, China, and Russia due to several factors, most importantly cost. India would emerge as a favourable site for clinical trials as it possesses other advantages such as a large patient pool, established players and facilities, and competitive workforce. Concurrent clinical trials (trials of the same drug in different places around the world) have been legalized in India since 2005.

The number of applications received by the DCGI (Drugs Controller General of India) for conducting clinical trials has been rising since 2005. In 2005, the figure was 100, growing to 170 in 2006 and 200 in 2007. In 2008, the number of applications increased significantly to 350. According to a study by management consultancy firm Zinnov on the Indian pharmaceutical industry, the clinical trials industry in India is set to grow at a CAGR of 31 per cent to become a US\$ 608 million industry by 2012.

7.2. Generics and Biosimilars

The generics market in India is growing at a healthy pace as against the markets in U.S. and Europe where the growth rate has slowed down gradually in the last few years. Moreover, globally there is more focus on the use of generics as they are much cheaper than non-generics and hence can be instrumental in containing public healthcare expenditure.

Graph 7.1: Market share of Indian Players



Source: IBEF report

The opportunity for Indian pharma companies is sizeable as generic drugs manufactured in India are now being accepted worldwide, and leading companies like Ranbaxy, Cipla and Dr. Reddy's are making way for others. By 2010-11, share of Indian companies in the U.S. market is expected to be more than 10 percent. Moreover, companies are not risking concentration by focusing only on the U.S. market by increasing attention to the European market for generics.

Biosimilars are cheaper copies of biotech medicines. The market for biosimilars is huge in the U.S. and recent legislation has opened the doors for biosimilars in the country. Companies such as Dr. Reddy's, Biocon, Intas Biopharmaceuticals, and Wockhardt, who have invested crores of rupees in research, development, and manufacture of biosimilars would benefit from this. However, the road to success in case of biosimilars is rocky at present as there are still several legal and other hurdles to overcome in the U.S. and European markets.

7.3. Lifestyle Drugs and Geriatrics

Rising incomes in the past decade have thrown open a niche category of drugs known as lifestyle drugs. Lifestyle drugs are medicines that cure 'conditions' associated with lifestyles such as hair growth solutions, anti-smoking solutions, weight-loss tablets, anti-pregnancy pills, anti-ageing pills, etc. The market for lifestyle drugs is huge in developed countries such as the U.S. and the U.K. In India, the market for such drugs has been growing gradually and,

the way things seem, would continue to grow and become a niche market within the pharmaceutical segment. Weight-loss drugs are already popular in India. Anti-smoking solutions are gathering pace due to increased awareness of the ill-effects of smoking among the public and support from the government. Recently, Pfizer India partnered with the government's health department to establish a large number of smokers rehabilitation clinics throughout the country.

Geriatric drugs are largely ignored by the Indian pharmaceutical industry. Although there are difficulties with respect to marketing geriatric medicines in the country, the segment being ignored means that old people are not receiving sufficient attention from the industry for age-related diseases like enlargement of prostate, Alzheimer's disease, hypertension, loss of memory, weakness, loss of hearing, and medical problems like vision (cataract), degenerative joint disease, neurological, cardiovascular, and urinary diseases. It is important to take the segment seriously not only from an economic point of view (as today's young population would grow old and hence demand for geriatric medicines would be high) but also from a moral perspective.

7.4. Patent Expiries

A large number of patents of 'blockbuster' drugs held by large companies such as GlaxoSmithKline, Pfizer, etc., are set to expire with 5 years from now. The patent expiry would lead to the opening up of a huge market for these drugs to Indian pharmaceutical companies. This is because, it would be legal to copy popular drugs such as Pfizer's Lipitor and market them under a different brand as they go off-patent. According to a study by Frost & Sullivan titled U.S. Generic Pharmaceuticals Market Outlook, the market earned revenues of \$24.71 billion in 2006 and is expected to earn \$49.49 billion in 2013. Moreover, Indian pharmaceutical companies can produce these drugs and market them within India itself. According to a report by global pharmaceutical market intelligence company, IMS Health, the Indian generic manufacturers will grow to more than US\$80 billion as drugs worth US\$20 billion faced expiry in 2008.

Since patents play a crucial role in the pharmaceutical industry, expiries are creating waves in the global pharmaceutical scene. Their effects are witnessed mainly in the form of a number of mergers and acquisitions, which serve as a defensive measure against the revenue loss

suffered due to them. The values of such deals are extra-ordinarily high and they bring with them mass layoffs and job cuts.

7.5. Increased R&D Spending

If the pharmaceutical industry is to level-up, spending on research and development needs to rise substantially. India has been a source of chemistry research and development for the last three decades. While India's track record of developing generic drugs and strength in process chemistry is second to none, its success in the emerging field of drug discovery is debatable. In the area of innovation, India has not made any real progress. According to Rashmi Barbhaiya, an industry insider, "The very strength that contributed to the success of the generic industry may have contributed to an apparent lack of success on the innovation side as the requirement for the two are quite different—short term vs long term commitment, high success rate vs high failure rate, local vs global mindset and above all, developing non-infringing chemistry processes vs incorporating biology in designing new molecules."

Despite significant improvements in research facilities and spending by companies in the last decade, there remains a lot to be done in the field of research and development if India is to shift from a cost-driven, low value destination to a research-driven, high-value destination of choice.

An effective means of progressing in the field of R&D is through alliances and partnerships. There have not been any alliances involving two Indian pharmaceutical companies. However, lately a large number of instances of foreign pharmaceutical companies entering into alliances with Indian counterparts have been recorded, the most recent being Eli Lilly, a foreign company, and Zylus Cadilla entering into a drug development deal. More such alliances are expected in the near future.

7.6. Contract Research and Manufacturing Services (CRAMS)

An emerging sub-market of the pharmaceuticals market is the CRAMS market. The Indian contract research outsourcing industry reached US\$175 million in 2006. There is an increasing trend of Indian Clinical Research Organisations becoming preferred vendors for outsourcing activities in the early drug discovery phase, with high margin contracts such as researching and /or developing proprietary technologies for the client, according to research

by Indian Brand Equity Foundation. According to the same research, the value of contract research would be US\$1-2 billion by 2010 and approximately half of this would come from clinical research. The report also mentions that by 2010, the demand for contract manufacturing would be US\$30 billion. Indian manufacturers can exploit this opportunity and are in a favorable position to do so. For instance, India has the largest number of US FDA-approved plants apart from the U.S. itself. Pharma contract manufacturing in India was US\$ 590 million in 2007, and is expected to grow at a CAGR of 31 percent to reach US\$900 million by 2010.

The trend of creating strategic alliances in the areas of drug discovery and development is gathering steam as mentioned earlier. Such alliances may expedite the process of transforming from chemistry based to biology based (which implies movement from low level to high level) in the R&D area.

7.7. Consolidation

Recently, there have been a number of high value consolidations (mergers or acquisitions) in the international space of the pharmaceutical industry. Pfizer Inc acquired Wyeth for \$68 billion and the combined entity is set to be the world's single largest pharmaceutical company. Following this, Merck and Schering Plough merged. The Roche-Genentech deal also made waves in the pharmaceutical industry conforming beliefs that more consolidations are inevitable. This is due to factors such as pricing pressures and patent expiries. Such mergers and acquisitions are fuelled mostly by huge cash reserves of companies.

In the present economic environment, consolidation seems to be among the few ways to cut costs and thrive in the industry. Consolidation helps to reduce expenditure, especially in the field of R&D and marketing, and may create synergies that lead to increased bottom line. The consolidation fever is set to spill over to India as a number of companies are burdened with huge debt and their share prices are attractively low. There may be consolidation between companies within India itself or deals may involve Indian and foreign companies.

According to PricewaterHouseCoopers India, "Due to global consolidation, pricing pressures, regulatory compliance issues and leverage taken on books for past high-priced acquisitions, larger Indian pharma companies are feeling the pressure and there will be substantial consolidation within the Indian market."

CHAPTER 8

INDIAN PHARMACEUTICAL SECTOR- **THE FUTURE SCENARIO**

8. INDIAN PHARMACEUTICAL SECTOR: FUTURE SCENARIO

8.1 Introduction

India's pharmaceutical industry has arrived at a cross roads. Well positioned compared with China as an arena for drug development and reliable, low cost manufacturing, India's pharmaceutical capabilities are strong and growing fast. Some large Indian players have already moved into global markets, and represent an emerging force as developers of generics.

The involvement of global pharmaceutical companies as partners will speed the emergence of big Indian pharmaceutical companies in global markets. And the pace of investments and partnerships is picking up. Global pharmaceutical companies are attracted to India's capabilities, as well as its large and growing market. But alongside opportunity, India also represents threat to global pharmaceutical. For one, the largest Indian firms have excelled at reverse engineering and legal tactics to challenge the primacy of branded blockbuster drugs with low-cost generics. For another, despite moves by the Indian government last year to bring its laws into conformity with the World Trade Organization; concerns persist among global drug makers over the lack of IP protection, lax restrictions on parallel trade and regulatory uncertainty. Moreover, from the outside in, global pharmaceutical companies don't see innovation as a key asset of Indian pharmaceutical yet.

The savviest global companies are partnering with Indian firms for cost-effective, highly skilled activities such as large-scale clinical trials and production of active pharmaceutical ingredients, with drug discovery and early development likely to follow. To reach India's vast market, global players are creating partnerships to provide affordable medicines, in some cases acquiring older products that are off patent.

8.2 Future Outlook

The multibillion-dollar pharmaceutical industry grows mainly through knowledge wealth creation. This sector has transformed a lot over the years. Over the years pharmaceutical has grown in the form of pharmaceutical sciences through research and development processes. It is related to product as well as to services. Liberalization, privatization and globalization (LPG) have helped the Indian pharmaceutical companies to achieve international recognition. It's remarkable to note that today several Indian pharmaceutical companies are approved by US FDA and are listed at NASDAQ.

The Indian stock market may be dreading a possible US recession but Indian pharmaceutical companies seem unfazed by slowdown fears, the pharmaceutical industry is expected to continue with its good performance in the first quarter of 2008-09 with over 25 % growth in revenues and about 45 per cent rise in net profit riding on better sales in the domestic and export markets. The industry will gain from the depreciation of rupee as well.

With the global generics market outside the US, Europe and Japan projected to grow to \$52 billion by 2009; Indian pharmaceutical companies are diversifying their markets. The future of pharmaceutical innovation in India will be critically influenced by the present, and before we can look to the future of pharmaceutical in India, we must look at the current environment. The global population is currently in a period of intense change, radically affecting the healthcare industry.

Indian pharmaceutical companies are vying for the branded generic drug space to register their global presence. Companies like Glenmark Pharmaceutical, Lupin, Aurobindo and Jubilant Organosys are amidst raising funds for lucrative acquisitions in the US and Europe. Besides, Indian companies tapping the US market would face the possibility of non-tariff barriers. Recently, the European Union has held that various benefits granted by the government to exporters in India were in the nature of subsidies and imposed an anti-subsidy duty. Such arbitrary imposition of duties by the US authorities cannot be ruled out.

The country currently exports over US\$1 bn of bulk drugs and formulations. A 50% growth over the market over a 7–8 year period (assuming that sales from existing products continue) is hardly sufficient to sustain in an entire industry. Pharmaceutical industry in India is playing a vital role in the healthcare area of the nation. With the implementation of product patent from the year 2005, there will be a tough competition for the global market share. Pharmaceutical companies will have to focus more intensively on R&D activity to survive the competition. As we are moving towards globalization, there is a need for strategic planning to meet the challenges posed by the product patent era. In the present context with the available expertise, manpower and skill, the Indian Pharmaceutical Industry will fight successfully for the global market share.

India can emerge as a centre for development of low cost bulk drugs and formulations, since R&D and clinical studies are easier and cheaper. Indian pharmaceutical firms can emerge as R&D outsourcing hub for the MNCs in the shorter run.

R&D investments by Indian pharmaceutical companies is just about 4% of their turnover. Internationally, this is between 12-15% for big pharma companies. Some of the large companies in India are trying to increase it to 8-12%; the figure has already touched the Rs 1,000 crore mark.

With established pharma companies entering the field, biotech companies are also exploring a new class of drugs which global majors may find attractive for further development. Smaller pharma companies are also investing in biotech manufacturing facilities to tap this emerging opportunity.

8.3 Pharmaceutical Special Economic Zones

The proposed pharmaceutical SEZs are expected to further boost India's pharmaceutical exports segment. 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 pharmaceutical 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 is also small. SEZs— which have good infrastructure facilities and

technology— can help these pharmaceutical companies develop a global mindset. Gujarat is set to witness tremendous benefits from the development of SEZs, as it already has an established pharmaceutical ecosystem with excellent infrastructure facilities. India's integration in the global pharmaceutical industry. For Indian companies, focus has been the key to growth. With pressure growing in commodity generics markets, the most successful Indian pharmaceutical firms have paid close attention to operating efficiency and cost structure.

8.4 Challenges Ahead

The new patent laws also mean that global pharmaceutical companies, which in the past limited their activities to manufacturing or joint-ventures in India, will now be able to invest more in research and development facilities for new drug discovery. A number of global players, including GlaxoSmithKline, Merck, Novartis, AstraZeneca and Pfizer, have a significant presence in India today. Shahani points out that India already has the highest number of U.S. FDA-approved facilities outside the U.S. But other challenges lie ahead. While tighter patent laws and global market conditions open the doors for Indian drug companies to become more active players on the global stage, there growing concerns over these developments. More than half the survey respondents say they are concerned with the lack of intellectual property protection in India. Although the new patent laws meet WTO requirements, doubts linger over whether the laws will be enforced. Many also expressed concern about lack of control over parallel trade as well as regulatory uncertainty. Following are a few challenges we face:

1. Mergers and Acquisitions

Currently, as the generics business is weighed down by stiff competition and declining R&D productivity, alliances and partnerships is the need of the hour for the pharmaceutical industry rather than the preference. In recent times, most of the leading players have inked M&A deals across the globe. In 2006, the domestic pharma sector executed more than 40 deals with 32 cross border transaction worth US\$ 2000 mn and it includes deals like Dr Reddy's acquisition of Betapharm of Germany for Euro 480 mn (Rs 2550 cr) and Ranbaxy Terapia buy in Romania for US\$ 324 mn (Rs 1250 cr approx). In 2007, Indian pharma sector witnessed 25 Mergers & acquisition deals, with 15 cross border transaction worth US\$ 600-700 mn.

2. Attracting and retaining a skilled workforce

The pharmaceutical business is knowledge and experience business and people have always been one of the most important resources for any pharmaceutical or biotech company. We can talk about brand but the people in a company, in particular in their behaviour, represent a living brand. We can focus on intellectual property but that is the creation of the people, and people joining or leaving a company will add to or reduce the sustainable intellectual property. We can talk about markets, but to access any market you need people with a good understanding of that market and the culture and values of customers and suppliers. Increasingly we talk about regulation and compliance as though they are some abstract function of a company. In practice we are describing the collective values and integrity of the individual members of staff, and the way they are motivated to behave in particular situations. So people are key but how any organisation ensure that it can attract, recruit, develop, and motivate those individuals with the competencies that will set that business apart from those of competitors. The first challenge is that there are increasing signs that the labour market is moving in favour of the employee rather than the employer. There is growing demand for skilled people but traditional labour markets are providing fewer new people with the right qualifications and experience; and companies are still trying to recruit people with ever-more-specialised knowledge. It is possible to recruit from new markets, but this is a new competence for many companies.

3. Controlling operating costs

It is accepted knowledge that the pressure to control and reduce costs is one of the next major challenges to be faced by the pharmaceutical industry. But how is this done and what is the best approach? Understanding and controlling operating costs is a critical first step to developing or sustaining competitive advantage. Increasing generic competition, imminent patent expiries (revenue can decrease by up to 60% at patent expiry), shorter pipelines and the emergence of China as a low cost manufacturing base all contribute to constantly eroding margins. To maintain or increase margins in the future, leading pharmaceutical companies have to start taking a proactive approach immediately to understanding costs. As the pharmaceutical industry embraces these new challenges, the companies that emerge at the forefront will be those who address the issues now and are able to account for all the costs throughout their organisation. To achieve this advantage, companies have to start recognising

and targeting costs today. Research & Development (R&D) costs are spiralling as companies race to discover the next blockbuster, but where is the money to fund this research going to come from? These questions are important as the costs of operations are concerned.

- How are costs distributed throughout your company?
- Where should you focus your cost reduction efforts for greatest benefit?
- How are you going to use to tackle these costs?
- Have you identified all the hidden costs?
- How do you compare to the best-in-class?
- What is your baseline and what can you achieve?
- Where are you going to start?

Cost is complicated, ranging from back office through manufacturing and quality to sales. To gain real benefits a structured programme of cost identification and improvement has to be in place.

4. Infrastructure

Compared with western industrial nations, energy prices are low but companies must expect repeated power cuts and offset fluctuations in the electricity network with the help of emergency power generators. In many areas, the hot and humid climate makes high demands on climate technology at production plants and on the refrigeration of finished products. Insufficient energy supply also leads to a situation where production hours must be handled very flexibly. This shortage can only be eliminated in the medium term and will require maximum effort. However, India's government intends to expand power generation capacities to roughly 240 GW by the end of the 11th five-year plan in 2012. This would mean a more than 100 GW, or nearly 90%, increase on today's total. Moreover, the country's lacking transport infrastructure is increasingly turning into a major obstacle. The pharmaceuticals industry is especially dependent on road transport. However, the major transport links are chronically congested and many are in a poor state of repair. Of the total road network covering just over 3.3 million kilometres, only about 6% are relatively well built National and State Highways. In many cases, there are no paved surfaces or there is only one lane for all traffic. But the government has launched an extensive investment programme entitled the National Highway Development Programme, to be implemented by the middle of the next decade.

5. Impact of new patent law

Legal changes in India in 2005 made it considerably more difficult to produce “new” generics. Foreign pharmaceuticals, which enjoy 20 years of patent protection, can no longer be copied by means of alternative production procedures and sold in the domestic market. Hence, a reorientation was required in India’s pharmaceutical industry. It now focuses on drugs developed in-house and contract research or contract production for western drug makers. Thus this transition phase of reorientation is a challenge for the industry.

8.5 Conclusion

India is becoming an integral part of the global pharmaceutical value chain and many Indian companies are participating in this global growth potential through their organic as well as inorganic initiatives. Pharmaceutical companies from India have also contributed significantly to this process through acquisitions of foreign assets or by having export-led business models. Going forward, as India further increases its dominance in the world pharma market, India with its growth enablers and strong building blocks can become a global pharmaceutical hub. However, this would call for an enormous change in mindset and transformation to attract global capital and talent. The path to globalisation is full of opportunities but also fraught with risks. Companies which would develop the right framework that would help them capitalise on this opportunity and mitigate risks will benefit the most.

CHAPTER 8

CONCLUSION

Conclusion

After analyzing the industry from the global, Indian, and individual organizations' perspective it remains impossible to predict its future due to several reasons such as the flurry of shape-shifting activities taking place at the global level, uncertainty about the various roles emerging markets will play in the near future, growing public concern about the ethicality of the practices of large pharmaceutical companies (usage of the term 'blockbuster' drugs, for instance), intentions of leaders of several developed nations (Barack Obama, the President of U.S. in particular) to bring down healthcare costs, and so on.

The drugs and pharmaceutical industry is among the few industries that stands apart from others because of its peculiarities. It is similar to the entertainment industry and the telecommunication industry in that it has a set of idiosyncrasies. Understanding the industry from a local as well as global viewpoint has revealed, among other things, this: India's importance in the global drugs and pharmaceutical industry has grown substantially and continues to grow. Significant advances have taken place in the field of research and marketing in the past decade. The level of professionalism in the management of pharmaceutical companies has also risen.

A number of Indian players have entered foreign nations, a large share of them doing so by marketing their drugs there directly. Indian companies have also purchased companies across the globe, from the United States to UK, Ireland, Germany, France, Belgium, Italy, Poland, Romania in Europe, to South Africa and to Japan and Singapore in Asia. Since 2000, there have been more than 60 foreign acquisitions by Indian companies. Dr. Reddy's Labs acquisition of Betapharm of Germany for US\$ 597 million stands fourth amongst the top ten acquisitions by Indian companies based on deal value. Ranbaxy's acquisition of Terapia SA of Romania for US\$ 324 million is in the fourth place in the same list. Such acquisitions have widened the companies' markets and provided them access to knowledge and technology that would have otherwise taken years to get a hold of.

Most important about the Indian chapter of the drugs and pharmaceutical industry is that it is not dependant on foreign aid and neither is it incapable of going beyond where it stands at present. What remains to be known is whether India will follow the path of the I.T. industry

and become a outsourcer/low-cost hub or will it do something not preceded by any other industry by climbing onto the global innovation map. Although the latter is far more desirable than the former, the current state of events does not indicate that the industry is turning in that direction. Regardless of what path is followed, the availability of skilled labour and world-class manufacturing facilities, progress in Research and Development (R&D), the managerial capabilities of Indian pharmaceutical majors, favourable industry outlook, etc., multiply to create an enviable future for the industry, given the plight of other industries the present economic scenario.

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