2.1 Introduction

The Indian pharmaceutical industry is a successful, high-technology-based industry that has witnessed consistent growth over the past three decades in spite of it operating under severe price competition and government price control. The retail Indian pharmaceutical market is valued at Rs 20,054 crore for the 12 months ending June 2004. During the same period, it grew by 8.1% in terms of value and 8.5% in terms of volume. The compounded annual growth rate (CAGR) of IPI for the period 1999 to 2003 is approximately 11%. In the global context, IPI stands fourth in terms of sales volume and thirteenth in terms of value.

The Indian pharma sector is highly fragmented with more than 24,000 registered units. It has expanded drastically in the last two decades. Formulations account for 81.5% of the market and bulk drugs account for the remaining 18.5%. The leading 250 pharmaceutical companies control 70% of the market, with market leaders holding nearly 7% of the market share. Requirement for 85% of bulk drugs and almost all formulations is met within India itself. There are around 465 main bulk drugs used in India and out of these, around 425 bulk drugs are totally manufactured in India and there is no import of these. Of the remaining 40 bulk drugs, 30 are totally imported, whereas around 10 are partially imported. Out of the 425 bulk drugs manufactured in India, around 60 are also partially exported.

Since independence, efforts of IPI have mostly been directed towards the development of alternative cost-effective manufacturing processes for molecules already invented and patented in other countries. Very little or no effort was invested in R&D towards development of new molecules/products. Over the last few decades, this contracted patent regime in India, recognizing only process patent, has had a negative impact on the development of professional expertise in new chemical entity development as potential therapeutic agent. This in turn also gave lesser exposure to conducting advanced clinical trials and drafting patents and patent related litigation in
the areas of new chemical entities, genetic engineering, combinatorial chemistry, natural products, agro-chemicals and agricultural products.

The confidence and expertise in reverse engineering became counter productive to an extent that it set in the belief that developing new drugs for domestic and global market apparently was beyond our reach. This also created a dominant opinion against product patent regime taking root in the drug policy formulation apparatus at government level and in the boardrooms of major pharmaceutical companies in India. However, success of Dr Reddy’s lab, Ranbaxy, Torrent, Lupin, Wockhardt and Glenmark in vying for global space for the locally developed technologies and new molecules, has started to change the mindset. Simultaneously, new partnerships between academic and commercial organizations within and outside the country have started emerging. The expenditure on R&D by Indian companies has been abysmally low with a few exceptions. In the year 2000, as against world average of 12-15% of sales for expenditure on R&D, Indian companies hardly spent on an average about 1-2%. The spending is around 3.4 % in case of top Indian pharmaceutical companies.

In the years 2003-2004, around 3900 new products have been launched by Indian companies, worth Rs 1578.5 crore which constitute nearly 8% of the market. While older brands have resorted to price increase for growth, the new products are experiencing price decline. As a result of this, Indian companies are no longer dependent on price increases as drivers for garnering growth, but the Multi National Companies (MNC’s) are. Some of the other strengths of the IPI include:

(a) Export orientation

(b) Self-reliance in production (70% of bulk drugs and almost the entire requirement of formulations within the country); World class manufacturing facility in India and in European and American countries.

(c) Low cost of production and products

(d) Low R&D costs and abundance of innovative science and technology manpower

(e) Cost effective source for procuring generic drugs, especially the drugs going off patent
(f) World hub for clinical trials in view of the diversity in population.

Significant increase in R&D investment by almost every company of reasonable size in the last 5 years. Inspite of the price competition, governmental control, process patent regime discouraging original research and low R&D investment, it is globally accepted that IPI is highly profitable and competitive with large presence in export market.

The growth of Indian pharmaceutical industry has been characterized by extensive governmental control and absence of strong patent protection. This paper gives an overview of pharmaceutical industry in India and the likely impact of product patent regime on it. The analysis is based on secondary data published elsewhere. It also reviews the existing patent and drug control laws in India and how they have affected the growth and structure of pharmaceutical industry in the country. Also discussed are strategies to meet the new challenges and the opportunities that Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement presents to pharmaceutical industry in India.

After almost thirty-five years of the process patent system, which encouraged R&D efforts in reformulation and process engineering/ re-engineering for generics, India has seen the dawn of Trade-Related Aspects of Intellectual Property Rights (TRIPS) enabled product patent regime on 1 January 2005. Irrespective of the argument for and against strong patent regime, the time has come when Indian pharmaceutical industry (IPI) has been forced to rethink their approach and find alternatives to their current reverse engineering business models. In the product patent era, R&D initiatives, cost control and marketing efficiencies will assume more importance along with partnerships and alliances in the areas of research, marketing, licensing and production. Present TRIPS framework aims at universalizing the IPR laws in all areas of technology among the member countries of the WTO. Indian patent law of 1970 has been suitably amended to make Indian IPR laws in the field of pharmaceuticals, chemicals and food at par with TRIPS.

The primary mechanism that justifies investment in research and development (R&D) in knowledge-based industries is the protection that patents and other intellectual property rights (IPR) provide to generate intellectual property (IP). Thus,
sustained competitive advantage will depend on the ability of these organizations to create, manage and market 'value-added' intellectual assets to derive the advantage of being 'first in the market'.

The absence of strong patent protection for pharmaceuticals in the country has discouraged the industry from conducting original drug discovery research. Developing countries like, India, China, Brazil, etc., have traditionally provided weak patent and other IPR protection. The staple argument given for weak IPR protection was that enforcing this would impact the employment for millions of locals, cause severe price rise and could have adverse socio-economic and welfare implications especially with stronger pharmaceutical patents. This has been a deterrent for multinationals to market their branded products in such places, as price leverage is practically non-existent due to local low cost re-engineered products.

Globalization is a progression which engages economic inter-dependence of countries world-wide eliminating all obstacles for economic integration as if the whole world is a single village. Evidently, in this process, the affluent nations with greater financial power, manipulate the scenario to their suitability and the poor and the developing nations are compelled to integrate, surrendering their economic independence aware of the consequences towards their own interests. In this process the world financial institutions like the World Bank, IMF and now the WTO advance the interest of the rich countries alone. The Transnational Corporations (TNCs) of the rich nations are practically controlling the world finances. Presently, the world is colonised by global finance and the TNCs sustained by the neo-colonial structure including the World Bank, IMF and WTO are controlling the financial situation world-wide. The developing nations and the third world countries are powerless against global finance and are incapable of controlling its movement within their own national boundaries.

The impact globalization has had on the Indian pharmaceutical industry the pharmaceutical industry in India has progressed constantly since the economic reforms of June 1991 and the re-establishment of Product Patent Act, 1970. Before the economy opened its gates to liberalisation and globalisation, the industry was protected by inward-looking policies which cultivated growth in the firms. The economic reforms resulted in the entry of foreign competitors and inflow of FDI into
the industry. Apart from FDI's contribution to the robustness of India's economic engine, it provided positive externalities (spillovers) in various forms to the domestic pharmaceutical industry and led to improved domestic productivity and competitiveness.

Several countries in the world, including India, have achieved self-sufficiency in knowledge intensive sectors by allowing for a loosely defined intellectual property regime (IPR). The formulation of Trade Related Intellectual Property Rights (TRIPs) world over fundamentally represents a big step in the opposite direction as it refers to a tightening of national IPR systems. Considering India as a representative of a technologically advanced developing country, and pharmaceuticals as an instance of an emerging knowledge intensive sector, the paper examines the impact of TRIPs on the incentives to innovate.

India was coerced to introduce structural adjustment programme at the behest of IMF, World Bank and WTO which generated a severe impact on India's drug industry, health care system, on the labour engaged in the industry and ultimately on the people of the country. These structural adjustment policies are mainly the abridged role of the Government, severing subsidy in the social sector, increase in administered prices, liberalisation of trade by increasing tariff rates providing incentives for foreign investment, privatisation of the public sector, equating foreign companies with Indian companies, de-regulating the labour market etc. This is intended towards the withdrawal of the state initiative from the social and welfare sectors like health, education, public distribution etc.

Is globalization a boon or a curse for the Indian pharmaceutical industry?

The Patent Act was introduced in 1970, and was effective from 1972. This Act doesn't permit product patents on medicines, agricultural products and atomic energy. This is Act is most appropriate for developing nations. Process patents are permitted for 5-7 years. Primarily, with the assistance of the Act, India is currently self-sufficient in the manufacturing and production of basic drugs spanning various groups of drugs. Indian scientists developed new processes for 107 drugs. Indian companies are, at present, among the world leaders in the production of bulk drugs from basic stages. Today, the prices of drugs in India are comparatively cheaper than many other
countries. As per, UNIDO, India is recognized to produce its own drug needs with its own technology and manpower indigenously. Today, approximately 23 thousand factories on different scales are producing drugs in India.

2.2 Dilution of Drug Policy and Drug Price Increase

Unlike consumer goods, drugs are not purchased by the preference of a person, but on a doctors’ prescription. Consumers have no choice of their own on this matter.

Prices of drugs are increasing by leaps and bounds along with the prices of other commodities in recent times. The drug manufacturers are flouting the Drug Price Control Order (DPCO). The DPCO was first introduced in 1970. In 1970 most of the drugs were under price control. In 1987 this was diluted and the number of drugs which were restricted declined to 347, in 1987 it was brought down to 163 drugs and in 1994 only 73 drugs were under DPCO. Even then industry is not happy; they want the control to be abolished totally. They have already demanded decontrol of 17 bulk drugs and further recommended full decontrol within 3 years time (Economic Times, 28th September, 1998). Many developed countries of Europe control drug prices directly. In the U.K., the government determines the profit level of drugs supplied by individual companies. A company has to reimburse excess profits to the Department of Health.

A recent study shows that the prices of many life-saving bulk drugs have gone up steeply. Drugs policies in our country are decided not by the need of our people, the pattern of diseases or by the purchasing capacity of the people, but by the profit motive of the industry and the Central Government is playing the role of a silent onlooker.

2.3 Impact on Public Sector

With the reduced role of the state under globalisation the public sector drug companies are faced with serious problems including imminent closures. Public sector drug companies like Indian Drugs and Pharmaceuticals Ltd. (IDPL), Hindustan Antibiotics Ltd. (HAL), Bengal Chemicals and Pharmaceuticals Ltd. (BCPL), Bengal Immunity (BI) and Smith Stanistreet Pharmaceuticals Ltd. (SSPL) played an important role in the production of essential drugs at affordable prices. Under the
globalisation process the role of the public sector has been marginalised and they have been made sick. Attempts have been made to either privatise or close them. The Penicillin Plant in HAL, the biggest in the country, has been handed over to private hands. Its Streptomycin plant also has been leased to a private company for manufacture of other drugs. IDPL which is having the biggest pharmaceutical plant in Asia is closed from 1996 for want of proper financial assistance from the government. The public sector drug companies used to supply raw materials to the small scale sector companies. Now, these companies are facing difficulties in procuring raw materials. Similar is the fate of BCPL, B.I. and SSPL. These three units were taken over by the government after they were made sick by the private owners. Proper utilisation of their capacity could not be made due to lack of will on the part of the government, mismanagement at the administrative level and high level corruption.

It is not because of any inherent weakness but due to the lack of political will, deliberate efforts to destroy them, corruption and mismanagement that these public sector units have been rendered commercially unviable.

With the pharmaceutical industry taking a leap towards biotechnology development world-wide, only the public sector drug companies, with the backing of the Central Government, could have faced the challenge effectively from the MNCs in the new situation.

2.4 Mergers and Acquisitions

International and national level mergers, acquisitions and takeovers have now become a common phenomenon in the pharmaceutical industry. Internationally American Home Product merged with Cyanamid, SKB with Sterling, Rhone Poulenc took over Fashions, BSF with Boots, Glaxo with Burroughs Welcome, Ciba Geigy with Sandoz, Warner Hindustan with Parke Davis, Hoechst with Rhone Poulenc etc. are some of the examples of big take overs. By mergers and acquisitions these companies became even larger with more financial power at their disposal over their competitors.

In coming days, with the help of international financial companies the MNCs will capture and take control of Indian companies to control the Indian market.
To match the situation created by international mergers and takeovers, Indian companies are adopting the same path. For example Wockhardt took over Merind and Tata Pharma, Ranbaxy took over Croslands, Nicholas Piramal took over Roche, Boehringer, Sumitra Pharma. The inevitable results are job loss of workers. Because of overlapping of jobs large numbers of workers are declared surplus. After merger Glaxo-Welcome and Ciba-Sandoz announced a reduction of 15 thousand and 10 thousand of their work force respectively world-wide. Upjohn and Pharmacia decided to close 24 of their 57 plants in different countries after their merger.

Some countries are adopting the 'buy and grow' method. They are taking over some popular brands and increasing their business. SKB took over Crocin from Duphar, Ranbaxy took over 7 leading brands from Gufic, Dr. Reddy's Lab purchased 6 products of Dolphin and two each from Pfinex and SOL Pharma. Sun Pharma purchased all leading brands of NATCO, after selling the popular brands the companies are becoming sick and closing their shutters throwing the workers on the street.

The governments permission to the MNCs to come to India with 100% equity have threatened the existing companies with the same origin and their workers.

Through the process of mergers, acquisitions and takeovers MNCs will gradually perpetuate their grip on the Indian industry by the creation of a limited number of mega companies having monopoly control and domination world wide. In the absence of competition people will have to pay any price as it happens in the sellers market.

2.5 Drug Price Control Order (DPCO)

In 1970, the government introduced the DPCO to guarantee its citizen access to ‘essential drugs’, at a reasonable cost with adequate rate of return to companies without compromising quality. In response to the DPCO, many firms discontinued the production of the controlled item and concentrated on production of nonessential drugs and other combinations to escape the control. As a result, essential drugs were more difficult to access than before the introduction of DPCO. Another derivative effect of the DPCO was that it exempted smaller firms from price controls, thereby encouraging them to participate in the pharmaceutical industry. This caused small companies to be represented more prominently than might otherwise be expected. To
address the aforementioned problems while still adhering to its objectives, the government issued a revised DPCO in 1995. The DPCO of 1995 declassified 70 out of 146 drugs, dropped some clauses that favoured small companies, and exempted newly (locally) produced products from price controls.

2.6 National Pharmaceutical Pricing Authority (NPPA)

The NPPA was established in 1997, to improve the speed and transparency of the process of fixing the prices of bulk drugs and formulations. It is expected to reduce the time lag between price revisions, thereby providing stable margins for formulations, and revise the list of bulk drugs under price control within reasonable time.

In the period between 1995-2005 and there after, status quo has been seen with respect to cost of the drug and it is expected to continue that way till 2007. But after 2007 and particularly after 2010, as MNC’s and research based Indian companies start launching their patented molecules, the cost of the drug is going to increase\(^1\). The availability of drugs in antibiotic segment and other agents used for tropical infections may not be affected but the availability of life-style drugs like the one used to grow hairs, relieve impotence, fight cholesterol, ulcers, depression, anxiety, allergies, arthritis, diabetes and high blood pressure will be affected as most of the MNC’s are engaged in new drug development in this area only. Imports are expected to remain constant or at the same level as they are now but novel drugs in phase III or IV clinical trials, that enjoy patent protection and have been developed by MNC’s to be used for the treatment of cancer or AIDS, may increase. What will be the volume of such imports are not clear since it will depend on the Government health policy and its ability to implement compulsory licensing clause under TRIPS provision. Exports opportunities are bound to increase in the coming years due to contract/custom manufacturing, in-licensing and abbreviated new drug application (ANDA) route for generics. Post 1995, Indian pharma industry has seen lots of voluntary initiatives in increased R&D spending and activities, which are bound to further increase in the coming years.
Why Strong Product Patent Regime for Pharmaceuticals?

Price of the patented product and their accessibility in India has been the focus of concern ever since the question of adopting product patent has come to front. The fundamental reason why pharmaceutical progress is dependent on IPR protection is the staggering cost of new chemical entity (NCE) development as a potential drug molecule and high attrition rate in the development cycle. Recent studies indicate that 1 out of 5000 molecules synthesized during applied research, eventually reaches the market. Other estimates indicate that of the 100 drugs that enter the clinical testing Phase I, about 70 complete Phase I, 33 complete Phase II, and 25-30 clear Phase III. Only two-thirds of the drugs that enter phase III is ultimately marketed. Without strong patent protection, pharmaceutical companies cannot attract the investment needed to conduct this expensive, high-risk research. The overall cost is further inflated if the opportunity cost of such high investment for such a long time with no guaranteed return is taken into account.

Table 2.1—Comparison of development time and cost of new chemical entity

<table>
<thead>
<tr>
<th>Year</th>
<th>Development Time (Years)</th>
<th>Development Cost* (Million)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1970</td>
<td>15</td>
<td>54</td>
</tr>
<tr>
<td>1990</td>
<td>12</td>
<td>231</td>
</tr>
<tr>
<td>2000</td>
<td>10</td>
<td>608</td>
</tr>
<tr>
<td>If started today</td>
<td>8-10</td>
<td>&gt; 800</td>
</tr>
</tbody>
</table>

*Plus the opportunity cost of risk prone investment

Without strong patent protection, fewer drugs will be developed and the flow of medicines to the public would be greatly slowed to the detriment of patients, public health and economic development throughout the world. Profits are diminishing due to imitation in drugs and pharmaceuticals. In 1998, the ‘Big Pharma’ (top 20 largest pharmaceutical companies across the globe based on market capitalization) company’s price per earning ratio was twice (2.18 times) that of the global stock market and since then the gap has been gradually on the decline. By 2003, this gap
was narrowed down to 1.28 times. During this period, sales performances of new molecules also fluctuated with a real decline in 1999-2000 and thereafter the sales performance showing a climb. Since the duration of exclusivity is gradually decreasing due to introduction of newer congeners of the molecule, the companies indulge in litigation and compromising marketing strategies to prolong their exclusive rights.

Inspite of the substantial increase in R&D budgets in the last several years, the number of new compounds introduced in the market fell sharply in the late 1990s and has been around the historic average ever since. Also, there is a growing realization that the companies can no longer rely on blockbusters alone. Almost 90% of the new molecules introduced earn less than 180 million dollars (USD) in annual sales and out of that close to 35% molecules are never profitable. Around 5% of the introduced molecules earn 180 to 460 million USD. Only a dismal 1-2% of the molecules are capable of earning more than 1 billion USD and attain the blockbuster status.

2.7 Major Opportunities for IPI within Present TRIPS Framework

Under the present TRIPS framework, irrespective of the fact that it is a MNC or an Indian company, the edge exists for only those companies which are innovative in their product profiles and who are continuously innovating and introducing new products. Various opportunities that IPI can exploit to get maximum mileage out of the present TRIPS framework is as given below:

1. The focus needs to be changed from export oriented activity to a global marketing. This involves establishing strategic marketing alliances in developed markets that will provide access to distribution networks and enable Indian pharmaceutical companies to operate as profit sharing partners. This also involves adopting vertical integration in a planned manner into the distribution and using chain, starting from developing markets and moving up to developed markets.

2. More emphasis should be given on rapid development of processes, which are innovative and non-infringing for products (especially for blockbuster products with difficult chemistry) going off patent internationally. It is worth mentioning
that of the 250 essential drugs (as listed by WHO), only 10-15% are under patents.

3. Generic opportunities are going to increase by leaps and bound in the coming years. The generics are capable of providing the same therapeutic drug level in the body as the reference drug. And to overcome the rising health care bills, the Government and Insurance companies in America and other west European countries are looking for safer low cost alternatives. A rough estimate indicates that Indian companies have already garnered 5% of the US $17 billion US generic market. Indian companies can reap rich dividends if they launch their products in segments like injectable, technology-intensive drugs and drugs in new dosage forms, where competition is low and a drastic price fall is less likely.

4. Cost effective R&D for the development of low cost bulk drugs, formulation and discovery research as well as clinical studies for the worldwide markets need to be carried out. Discovery research on a therapeutic segment for one molecule involves Rs 150-200 crore in India compared to US $650-800 million in developed countries, to be spent over a period of 8-10 years.

5. Exploiting TRIPS enabled compulsory licensing and parallel imports. Compulsory licensing refers to the right of the Central Government to force the holder of the patent, in the “public interest”, to compulsorily license out the product on agreed commercial terms. Parallel imports refer to the concept of shop around the world for cheaper imports.

6. Government can use affordability as the low threshold for drug pricing, based on annual per capita spending of its citizen, on health care. Annual per capita expenditure in India is merely US $3 when compared to US $191 and 227 in USA and Germany respectively. Even Pakistan has an annual per capita expenditure of US $7. In such case, Government reserves the right to render a patent void if the patent holder fails to make or import the product or even fails to sell it at prices affordable to average citizens.

7. Patenting of tropical bio-diversity should be emphasized so as to prevent patenting of Neem, Turmeric, Basmati and other components of indigenous
system of medicine by outsiders. This will help ensure IPR protection to herbal and botanicals to MNC exploitation and also revenue earnings for Indian companies dealing in them.

Many Indian pharmaceutical companies have already geared up for facing the reality of product patent. Several new developments have already taken place in their R&D and strategic efforts. The strength of the industry is in developing cost-effective technologies in the shortest possible time for drug intermediates and bulk actives without compromising on quality. Accordingly, generic drug manufacturing is going to be the main growth driver for the future. India is set to capture a large portion of this market by leveraging its inherent strengths in technology, R&D facilities and trained human capital. Some of the measures that have been adopted by Indian companies include:

(a) Increased efficiency of R&D investment (details are presented under the section ‘Newer R&D Initiatives’) in the last 5 years in terms of number of patents filed or granted. For example, from India have been Ranbaxy with 124 (as against 66 applications in 2003) applications. In 2004, other Indian organizations, which filed for patent protection, were Cipla, Jubilant Organosys, Vaman Technologies (R & D) and Matrix labs with 32, 16, 12 and 12 applications respectively. Hetero Drugs and Wockhardt Ltd had filed 10 applications each.

(b) Top Indian companies have devised unique R&D models to significantly decrease the cost and risks involved in the discovery of new drug or new chemical entity. As against the global average of $1.5-1.7 billion for developing a block buster molecule Indian companies will be able to do it at just $300-400 million.

(c) Major companies have been establishing offshore production facilities. The Indian pharma industry has the highest number of plants approved by the US Food and Drug Administration (FDA) outside US.
(d) Collaborations/alliances in discovery research and product development tie-ups between Ranbaxy-Eli Lilly, Ranbaxy-Bayer, Dr Reddy’s-Novonordisk, Dr Reddy’s-Novartis, Torrent-Novartis and Cadila-Schering AG are only representative examples to make a case in this regard.

(e) ANDA leverage has been another area where Indian companies have shown remarkable progress. During the financial year 2004-05, as many as 11 Indian pharma companies have filed about 150 ANDA with the US FDA. It also has the largest number of drug master files filed which gives it access to the high growth generic bulk drugs market.

(f) Indian companies are acquiring generic share of global players or niche R&D of start-up companies in US and Europe. This would give Indian companies a strong foothold to already established manufacturing, marketing and distribution network in US and Europe in addition to the proprietary technologies of the target company. Some of the high profile acquisitions by Indian pharma majors abroad are listed in table 2.

(g) India could well become the hub of clinical research for pharmaceutical companies across the globe in coming years. India offers a 40% cost advantage for doing bioequivalence study when compared to US\textsuperscript{23}. But if the recent decision by WHO to remove anti-retro viral (anti-AIDS) drugs manufactured by Indian companies (Ranbaxy, Cipla and Hetero drugs) due to unsatisfactory bioequivalence data, is any indication then Indian clinical research organizations should upgrade their good laboratory and good clinical practices including documentation and data storage. It is often accepted that Indian clinical research organizations that do bioequivalence studies for less, actually compromise on data storage and documentation\textsuperscript{23}. As a result, retrospective analysis of data and reconstruction of the study results are not possible.

(h) Contract manufacturing is another area where Indian companies are bound to excel. Setting up a plant is 40% cheaper in India compared to developed countries and the cost of bulk drug production is 60-70% less. The MNC’s prefer to outsource the bulk drugs as well as formulations, as it is the lowest value added activity in the pharmaceutical business, contributing not more than
6-8% of selling price. The global players focus their own resources on research and outsource manufacturing of formulations. Outsourcing cuts down on their capital investments. According to International Medical Statistics (IMS), half of the big pharmaceutical companies worldwide have moved towards outsourcing through long-term strategic alliances. Only 28% of pharmaceutical companies across the globe went in for in-house capacity expansion of bulk activities over the last two years. Some of the global pharmaceutical companies that outsource extensively are American Home Products, Pharmacia & Upjohn, Bristol Meyers Squibb and Glaxo-Wellcome. Indian companies like, Ranbaxy, Lupin labs and Nicholas Piramal are the first Indian companies to have obtained manufacturing contracts from MNC’s. The trend is expected to accelerate in the future.

Table 2.2—Recent major acquisitions abroad by Indian pharmaceutical companies

<table>
<thead>
<tr>
<th>Acquirer company</th>
<th>Target company</th>
<th>Deal ($ million)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ranbaxy</td>
<td>Aventis (France)</td>
<td>70.00</td>
</tr>
<tr>
<td>Wockhardt</td>
<td>CP Pharmaceuticals (UK)</td>
<td>17.72</td>
</tr>
<tr>
<td>Wockhardt</td>
<td>Espharma GmbH(Germany)</td>
<td>11.00</td>
</tr>
<tr>
<td>Cadila Health Care</td>
<td>Alpharma SAS (France)</td>
<td>6.18</td>
</tr>
<tr>
<td>Jubilant Organosys</td>
<td>PSI Supply (Belgium)</td>
<td>16.52</td>
</tr>
<tr>
<td>Dabur India</td>
<td>Redrock (UK)</td>
<td>5.02</td>
</tr>
<tr>
<td>United Phosphorous</td>
<td>Aciflorfen compound of BASF (Germany)</td>
<td>NA</td>
</tr>
</tbody>
</table>

The pharmaceutical Industry has shown high interest in India due to its sustained economic growth, health care reforms and patent related legislations. Driven by increasing affordability, shifting disease patterns and modest health care reforms, the total consumer spending on health care products and services in this country grew at a compounded annual rate of the percent from 2000 to 2005. The pharmaceutical industry, which accounts for 15% to 20% of total health care spend, grew at a compounded annual rate of 9% during this period. The pharmaceutical industry is a knowledge driven industry and is heavily dependent as research and development for new products and growth. Pharmaceutical industry has seen major changes in the recent years that place new demands on payers, providers and manufacturers. Indian pharmaceutical industry is poised for high consistent growth over the next few years, driven by a multitude of factors. In this context it became important that the drivers of the marketing strategy are thoroughly studied.
India is now among the top five pharmaceutical emerging markets. The Indian pharmaceutical industry has been growing at a compounded annual growth rate (CAGR) of more than 15 per cent over the last five years and has significant growth opportunities. The Indian pharmaceutical sector is expected to grow five-fold to reach Rs 5 lakh crores (US$ 91.45 billion) by 2020, as per Dr A J V Prasad, Joint Secretary, Department of Pharmaceuticals (DoP). The industry, particularly, has been the front runner in a wide range of specialities involving complex drug manufacture, development, and technology. With the advantage of being a highly organized sector, the numbers of pharmaceutical companies are increasing their operations in India. The pharmaceutical industry in India is an extremely fragmented market with severe price competition and government price control. The industry meets around 70 per cent of the country's demand for bulk drugs, drug intermediates, pharmaceutical formulations, chemicals, tablets, capsules, orals, and injectables.

2.8 Market Size

The domestic pharmaceutical market is expected to register a strong double-digit growth of 13-14 per cent in 2015 on back of increasing sales of generic medicines, continued growth in chronic therapies and a greater penetration in rural markets. The cumulative drugs and pharmaceuticals sector has attracted foreign direct investments (FDI) worth US$ 10,308.75 million during April 2010 to February 2013, according to the latest data published by Department of Industrial Policy and Promotion (DIPP).

2.9 Growth

Drug sales to retailers in India registered a growth of 7.7 per cent in February 2013, according to a data compiled by market research firm AIOCD AWACS. This was probably due to a high base given the strong performance last year and higher substitution of branded drugs with their unbranded equivalents. Among the listed companies, ZydusCadila topped the list, recording 25.3 per cent growth in February. Other companies that managed to grow faster than the industry include Sun Pharma (14.8 per cent), JB Chemicals (13.7 per cent), IPCA Labs (13 per cent), Lupin (11.6 per cent), Glenmark (10.3 per cent) and Cipla (9 per cent).
2.10 Exports

The Ministry of Commerce has targeted Indian pharmaceutical sector exports at US$ 25 billion by 2014 at an annual growth rate of 25 per cent. Last year, the industry registered exports of US$ 13 billion at a growth rate of 30 per cent, as per Dr P V Appaji, Director-General, Pharmaceutical Exports Council of India (Pharmexcil). The Government has also planned a 'Pharma India' brand promotion action plan spanning over a three-year period to give an impetus to generic exports. “Of the export markets, Indian pharmaceuticals will focus on the US market which presents significant opportunities for the next two years for generics, due to patent cliffs and recent changes in healthcare policies,” said the India Ratings report on outlook for Indian pharmaceuticals for 2013.

2.11 Generics

In the years between 2000 and 2005, according to the IMS, the pharmaceuticals are expected to rise in value from $362 billion to $561 billion in constant prices – a rise of some 55%.

Estimations show that $100 billion of products face patent expiry by 2004 (Cap Gemini Ernst& Young, 2002). This represents an immense opportunity for generic companies, whose global market is worth $20 billion per annum. Moreover, the prevailing strategy is that generic companies with “first to market” products capture the market, enjoy a high market share, create barriers to entry for the competition and create brand awareness for their products (Scrip Reports, 2002). Timing of the new product introduction and therefore the speed to market become a key issue for all manufacturers in this industry.

Generics will continue to dominate the market while patent-protected products are likely to constitute 10 per cent of the pie till 2015, according to McKinsey report ‘India Pharma 2015- Unlocking the potential of Indian Pharmaceuticals market’.

Dr Reddy's Laboratories Ltd has launched Finasteride tablets, a bio-equivalent generic version of Propecia (Finasteride) tablets, in the US market. The tablets are used for treating male pattern hair loss.
CONCLUSION

Our outlook on the Indian Pharmaceutical Industry remains favourable, reflecting our view that earnings growth will continue, benefitting from healthy growth in the domestic formulations business and steady growth expected in the U.S/Europe generics space on back of patent expiries. In the U.S, companies with a robust and selective product pipeline, presence in niche/complex segments and diversified therapies would continue to exhibit a relatively strong earnings profile.

Emerging markets, with growing spend on healthcare and strong branded generic market offers profitable growth opportunities for generic business. Besides emerging markets, the gradually evolving generics opportunity in Japan, the second-largest market in the world (after United States) also offers generic players the opportunity to pursue long-term investments. On the CRAMS front, Indian players are focusing on providing services across the value chain spanning from development stage to commercial scale production. Relatively lower exposure to small biotech companies has been a risk mitigant during the downturn for these entities. With several drugs going off-patent and big pharma increasing exposure to cost efficient sourcing locations, opportunities remain favourable for CRAMS players to provide developmental services and subsequently graduate to commercial scale production.

Key challenges facing the industry are potential implementation of the new pricing policy in India, increasing competitive pressure in the chronic segments, aggressive approach such as authorized generics by innovators in the US and healthcare reforms in European markets are some of the factors that could impede profitability for pharma companies.

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