2. Indian Pharmaceutical Sector - Current Status

2.1 Background

The Indian pharmaceutical industry can be said to have begun with the setting up of 'Bengal Chemical and Pharmaceutical Works' in Calcutta. Subsequently institutes like Kings Institute of Preventive Medicine in Chennai, Pasteur Institute in Coonoor, the Central Drug Research Institute in Kasauli and others were set up. Post-independence, many other public sector companies such as Hindustan Antibiotics Ltd. and Indian Drugs and Pharmaceuticals Ltd. were set up to reduce the imports of important antibiotics and also to meet the county's demand from indigenous production.[1]

The industry is conspicuous by the large presence of private sector which has captured a substantial share in the domestic & external market due to factors such as conducive regulatory environment, past patent policies, low cost of innovation, access to funds from banks to corporate manufacturers, low cost of setting up and running high technology manufacturing facilities, etc. The public sector as in many other sectors contributed to strategic areas but has gradually been overtaken by the private players – an indication of the latter's emerging competitiveness and entrepreneurial capabilities. Indian owned firms currently account for 70 percent of the domestic market, up from less than 20 percent in 1970. In 2005, nine of the top 10 companies in India were domestically owned, compared with just four in 1994.

Today, the pharmaceutical industry manufactures the entire range of therapeutic products and is capable of producing raw materials for the manufacture of a wide range of drugs from the basic stage as well as a range of pharmaceutical machinery and equipment.

Apart from building up domestic capacity, leading Indian companies have established marketing and manufacturing activities in a large number of countries including USA and countries of Europe as well as expanded through acquisitions in these countries.[2] The sector has therefore evolved from being dominated by multinational companies in the 1950's to some imports and indigenous manufacturing in the 1970's and then protected by the legislative provisions of the older Patents Act 1970, to significant indigenous production and subsequent exports.

[1] The industry was given its due by the successive governments in Indian Five year plans and the industry was promoted through direct investment, intellectual property, price regulation and above all the support of scientific research. Ashok Ram Kumar, *TRIPS - Is it a Healthy Prescription for Indian Pharmaceutical Industry*, 2(3) THE ICFAI JOURNAL OF INTELLECTUAL PROPERTY RIGHTS 71, 71 (2003).

[2] See The Economist, "Marauding Maharajas", March 29th, 2007.

The expertise that the Indian pharmaceutical sector developed in reverse engineering and production of generics can be directly attributed to the effects of Governmental policy such as the Patents Act, 1970 which played a major role in shaping the industry and bringing it to the present enviable position. The Act of 1970 excluded product patents on pharmaceuticals, allowing the mushrooming of a vigorous generics industry in India which could meet not only domestic demand for drugs at lower prices but could also export cheaper drugs to other Third World countries.[3] Further, the government policies restricted imports of finished formulations, imposed high tariff rates and introduced strict price control regulation through the 1970 Drugs Price Control Order.

Post liberalization, the pharmaceutical industry has had to reorganize itself to keep pace with the economic reforms as well as the international commitments that were taken on by India. From a regulatory perspective, a large degree of liberalisation took place with the abolition of industrial licensing, 100 percent foreign direct investment, liberalisation of rules related to foreign technology agreements as well as of the import regime. At the same time, international commitments and standards were sought to be introduced into the regulatory regime through the introduction of product patents, the introduction of Schedule M and Schedule T of The Drugs and Cosmetics Act, 1940. Export promotion was sought to be encouraged by the creation of PHARMEXCIL as well as a draft National Pharmaceuticals Policy, 2006 with the objective of, among other things, positioning India as a preferred global destination for pharmaceutical R&D and manufacturing. The recent creation of a separate Department of Pharmaceuticals is only a manifestation of the importance government of India has accorded to the sector.

The new patent regime has also led to the return of the pharmaceutical multinationals, many of which had left India during the 1970s. The multi-national companies are now looking at India not only for its traditional strengths in manufacturing but also as a highly attractive location for research and development (R&D), particularly in the conduct of clinical trials and other services. The consumption potential offered by more than one billion inhabitants, rising affluent customers and the changing lifestyles offer huge potential domestically for the sector.

[3] Shamnad Basheer, *Policy Style Reasoning at the Indian Patent Office*, 2005 INTELLECTUAL PROPERTY QUARTERLY 309.

2.2 Current Status

The pharmaceutical sector is emerging as one of the major contributors to Indian exports with export earnings rising from a negligible amount in early 1990s to Rs.29,139.57 crores by 2007-08. The exports of Drugs, pharmaceuticals & fine chemicals of India were growing at a compounded annual growth rate (CAGR) of 17.8% during the five year period 2003-04 to 2007-08.

The total size of the industry is estimated at US$18bn at the end of the year 2007. The Indian domestic pharmaceutical market size is estimated at US$10.76bn in the year 2008 and is expected to grow at a high CAGR of 9.9% percent till 2010 and thereafter at a CAGR of 9.5% till 2015.

Currently, the Indian pharmaceutical industry is one of the world's largest and most developed, ranking 4th in volume terms and 13th in value terms. The country accounted for 8 percent of global production and 2 percent of world markets in pharmaceuticals. Most of the domestic pharmaceutical drug requirements are met by the domestic industry. In the segment of Active Pharmaceutical Ingredients (APIs) India ranks third in the world producing about 500 different APIs.

2.2.1 Current Place in World

India is currently recognised as a high-quality, low-cost skilled producer of pharmaceuticals. It is seen not only as a manufacturing base for APIs and formulations, but also as an emerging hub for biotechnology, bioinformatics, contract research, clinical data management and clinical trials. The country's pharmaceutical industry, as evidenced in the paragraphs which follow, has shown tremendous progress in terms of infrastructure development, technology base creation and a wide range of production.

India exports full basket of pharmaceutical products comprising intermediates, APIs, Finished Dosage Combinations (FDCs), biopharmaceuticals, vaccines, clinical services, etc., to various parts of the world. The country has achieved the distinction of providing healthcare at very low cost while maintaining profitability.

At present, India is among the top 20 pharmaceutical exporters world-wide and with the largest number of US FDA inspected plants (119 plants), outside the USA. Various other agencies like MHRA UK, MCA South Africa, TGA Australia , HPB Canada have approved scores of plants in India .

India accounts for over one third of drug master files (DMFs) in USA. (Refer Tables & Charts-1, 2, 3 & 4 and Appendix I for list of Indian companies having active type II DMFs with US FDA). Thirty percent of all approved ANDAs in the US are from India, ranking the country number 2 next only to USA. Needless to mention scores of approvals by UK MHRA and various other agencies are also being filed from India.

Even in patent challenges, India ranks only next to USA with a share of 21 percent of patent challenges. Undeniably India is an emerging leader in pharmaceuticals.

Table 1: Final ANDA Approvals by Country (2007) (figs. in Nos.)

Country	Numbers
USA	169
India	132
Israel	40
Germany	25
Canada	24
Switzerland	19
Iceland	14
Jordan	11
Other	25

Source: Thomson Scientific,

Table 2: Country-wise Number of Patent Challenges (As on Mar. 2008)

Country	Numbers
USA	200
India	113
Israel	89
Canada	43
Switzerland	34
Iceland	17
Germany	10
Other	32

Source: Thomson Scientific

Table 3: Comparison of Drug Master Filings (Type II) by India, China & World (1998-2007) (Figs. Nos.)

Year	India	China	World Total
1998	32	27	316
1999	26	6	199
2000	33	9	201
2001	47	6	238
2002	55	20	264
2003	115	19	360
2004	160	25	435
2005	233	70	615
2006	267	78	627
2007	274	90	656

Source: Thomson Scientific

Table 4: FDA Approved Indian API Facilities

Year	Annual	Cumulative
1985	0	0
1990	1	1
1995	10	11
2000	33	44
2005	75	119

Source: Thomson Scientific

2.2.2 Current Status of Generic Biopharmaceuticals

Fermentation, one of the segments of biotechnology, has been instrumental in shaping Indian antibiotics segment in the early decades of growth of Indian Pharmaceutical industry with remarkable contribution from Hindustan Antibiotics Ltd. (HAL), Sarabhai group, and a few others. However, due to lower energy costs in China in the past, fermentation industry has moved to China not only from India but also from several other countries.

Vaccines, large molecules, monoclonal antibodies and recent therapeutics demand significant capabilities in chemistry and biology. IMS Health estimates that biotechnology products accounted for over 10 percent of global pharmaceutical sales. A significant portion of new drugs in the recent years are from biopharmaceuticals segment. The revival of this once strong sector seems to have begun in India as is witnessed by the success of some of the emerging players such as, Serum Institute, Biocon, Panacea Biotech, Venkateswara Hatcheries, Wockhardt, Shanta Biotech, Bharat Biotech, etc.

2.2.3 Impressive Investments in Capacity Building and Capabilities

The combined total investment (Gross Block) of 561 pharmaceutical companies listed on Bombay Stock Exchange as per the latest company filings available (as at the end of June 2008) stood at Rs.40,461.7 crores (net fixed assets stood at Rs.29,325crores). Further, as per Centre for Monitoring Indian Economy (CMIE) database 'Capex,' an investment of Rs.5,903.1 crores in some 550 projects under implementation and new investment projects in 637 new proposals announced valued at approx. Rs.5,861.8 crores would result in the new investment of Rs.11,764.9 crores, which is an increase of 29 percent over the existing investment. Some major projects under implementation or announcement are given at Appendix II.

2.2.4 Research & Development

Data for 596 Indian pharmaceuticals companies, whose sales and R&D investment figures are available with CMIE database 'Prowess', reveals that a total of 151 companies invested in R&D activities as at the end of June 2008 (Refer Table 12 & chart 12). The total investment in R&D stood at Rs.2,973.2 crores which is 9.9 percent of the sales of these 151 companies. (Refer Appendix III).

Nevertheless, the domestic industry is still spending far too little on basic R&D, which may not increase substantially due to the size of their balance sheets and profitability and hence the requirements of the drug discovery remain unaddressed.

Table 5: Investment by Top 20 Indian Pharmaceutical Companies* (figs. in Rs. Crores)

Sl. No.	Company Name	Sales	Research & development expenses	Investment in R& D as % of Sales
1	Ranbaxy Laboratories Ltd.	3,656.2	460.5	12.6
2	Dr. Reddy's Laboratories Ltd.	4,146.2	292.8	7.1
3	Sun Pharmaceutical Inds. Ltd.	1,722.1	188.3	10.9
4	Cipla Ltd.	3,658.0	175.7	4.8
5	Cadila Healthcare Ltd.	1,758.5	161.8	9.2
6	Lupin Ltd.	2,051.7	142.1	6.9
7	Wockhardt Ltd.	1,189.0	126.7	10.7
8	Torrent Pharmaceuticals Ltd.	895.2	112.1	12.5
9	Panacea Biotec Ltd.	843.0	107.2	12.7
10	Aurobindo Pharma Ltd.	1,991.0	96.7	4.9
11	Matrix Laboratories Ltd.	775.7	92.1	11.9
12	Orchid Chemicals & Pharmaceuticals Ltd.	934.2	63.0	6.7
13	U S V Ltd.	659.2	59.6	9.0
14	Ind-Swift Laboratories Ltd.	356.1	58.5	16.4
15	Biocon Ltd.	887.2	47.9	5.4
16	Glenmark Pharmaceuticals Ltd.	838.8	43.3	5.2
17	Strides Arcolab Ltd.	395.2	37.5	9.5
18	Dabur Pharma Ltd.	322.0	35.7	11.1
19	Piramal Healthcare Ltd.	2,001.3	35.3	1.8
20	Alembic Ltd.	722.6	34.5	4.8

Source: CMIE database 'Prowess'

2.4.5 Health Tourism and Services

The health tourism market in India was estimated at US$333 million in 2004, growing by about 25 percent and this is predicted to become a US$2 billion-a-year business opportunity by 2012. India is witnessing a surge of patients from developed countries as well as from Africa, South & West Asia because while the cost of comparable treatment in India is about 1/8th to 1/5th of the cost in the Western countries, the quality of Indian healthcare delivery (in certain institutions) is world class. An added impetus has come from expanding health care budgets in developed countries due to rising costs of healthcare in these countries and increasing old age population. This challenge also offers us an opportunity to extensively upgrade our tertiary level of health care infrastructure. This report has not looked into this issue at greater length as the subject would be better studied under tourism sector.