Pharmaceuticals Industry - Overview

The Indian pharmaceutical industry ranks among the top five countries by volume (production) and accounts for about 10% of global production. The industry's turnover has grown from a mere US$ 0.3 billion in 1980 to about US$ 21.73 billion in 2009-10. Low cost of skilled manpower and innovation are some of the main factors supporting this growth. According to the Department of Pharmaceuticals, the Indian pharmaceutical industry employs about 340,000 people and an estimated 400,000 doctors and 300,000 chemists[4].

Indian pharmaceutical industry is truly international with leading international manufacturers competing in Indian domestic market and several Indian pharmaceutical companies having a significant presence in international market, especially in the generics segment. The Indian Pharmaceutical Industry is one of the biggest producers of the active pharmaceutical ingredients (API) in the international arena. India is among the top 20 pharmaceutical exporting countries and the exports have grown very significantly at a CAGR of around 19% in the 11th plan period[5]. Indian drugs are exported to around 200 countries in the world with highly regulated markets of USA, UK etc. The major therapeutic categories of export are anti-infective, anti-asthmatic andante-hypertensive.

Evolution of Indian Pharmaceutical Industry

Phase I (Pre 1970)

- Set up of 2 public sector drug companies i.e. HAL & IDPL in1961
- FDI in the industry was minimal
- Full IPR - Patent regime recognized product & process patents (major entry barrier)
- Import substitution policy, yet country dependent on imported bulk drug
- Small number of firm & Limited production capacity
- Market dominated by MNCs through subsidiaries

Phase II (1970-1995)

- IPA w.e.f 1972. Act only recognized process patent and not product patent
- Foreign patented drugs could be reverse engineered and distributed in India without paying royalty to the patent holder
- Price control under legislation of DPCO
- FERA
- Hatch-Waxman Act
- Statutory term of a patent was shortened to 5 years from its being granted or 7 years from application, whichever is shorter
- MNCs were discouraged to introduce to new products to India
- Increase in domestic firms
- Small scale units receiving incentives from govt
- Increase in prduction of bulk drugs & formulations
- Increase in import tariff, industry became more export oriented

Phase III (1995 onwards)

- WTO came into effect
- Patent policies to be TRIPS compliant by 2004
- WTO initiatives, tariff & non- tariff related measures
- Companies have to transform themselves from reengineering to innovation
- Clinical research, new drug development and their profit redirected to generic business for R&D
- Low cost manufacturing helped Indian companies to further penetrate export markets

[4]Statistics given by Department of pharmaceuticals
[5] XII plan working group report on pharmaceutical sector

The Indian pharmaceutical industry's emergence on the global landscape as a strong generics player was due to the IPA introduced in the year 1970, which allowed only process patents in pharmaceutical products. IPA enabled domestic players to build technical expertise in reverse engineering of patented medicines by modifying the manufacturing process. India became an efficient producer of generic drugs and cost of products came down making it more affordable.

Post 2005 and re-instituting "product" patents, it ended protection for Indian companies and terminated legal reverse engineering or copying of patented foreign pharmaceuticals drugs.

To meet the short fall in revenues, many of India's leading pharmaceutical companies turned to foreign acquisitions and exports, and positioned them to offer generic versions of these drugs, especially to the U.S.This was a good move considering the dynamics in U.S market where there is a greater acceptance of generic drugs unlike India.