Chapter 2

Indian Pharmaceutical Industry: Present Scenario

More than 90% of unsatisfied customers don't complain
Chapter 2

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2.1 Pharmaceutical Industry-Global Scenario:

As per the world health organisation (WHO) report, almost 80% of the world’s population are relying on traditional systems of medicine in one way or the other. Globalization has opened up opportunities for developed countries to make inroads into the developing countries. Some of the dangers of this trend include biopiracy, patenting of medicine and converting national heritage into private property. Some recent examples which are India specific include the classes of turmeric, piperine and basmati rice.

The "Pharmaceutical Value Curve" developed by Professor Sumantra Ghosal of the London Business School provides a good framework for understanding the global value chain in pharmaceuticals (Refer Fig 2.1).
The complexity of the pharmaceutical business increases rapidly as companies move backwards from being producers of bulk drugs to carrying out research on new molecules. Interestingly, while margins rise consistently through each stage, the complexity follows a hockey stick curve in the final stages of the value chain. Quite clearly, new drug discovery is the domain of only the very large global companies. Here the investment risks involved are high but so are the margins.

a) Production /Sale of Pharmaceutical:

The global pharmaceutical market has increased dramatically during the past two decades. Percentage wise share of the global turnover is as follows:
Table 2.1

Percentage Wise Share of the Global Turnover

<table>
<thead>
<tr>
<th>Region</th>
<th>Market Share in percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>US</td>
<td>41.3</td>
</tr>
<tr>
<td>Europe</td>
<td>23.5</td>
</tr>
<tr>
<td>Japan</td>
<td>15.9</td>
</tr>
<tr>
<td>South East Asia and China</td>
<td>6.8</td>
</tr>
<tr>
<td>Latin America</td>
<td>6.5</td>
</tr>
<tr>
<td>Middle east</td>
<td>2.0</td>
</tr>
<tr>
<td>Africa</td>
<td>1.3</td>
</tr>
<tr>
<td>Australasia</td>
<td>1.0</td>
</tr>
</tbody>
</table>

(Source: Pharma annual survey, 2001)

In billion dollar terms, the turnover of pharmaceuticals and the population in million of some important countries are as follows:

Table 2.2

Turn over of pharmaceuticals and population of some major countries

<table>
<thead>
<tr>
<th>Country</th>
<th>Turnover (billion$)</th>
<th>Population (million)</th>
</tr>
</thead>
<tbody>
<tr>
<td>USA</td>
<td>78.0</td>
<td>260</td>
</tr>
<tr>
<td>Japan</td>
<td>53.0</td>
<td>125</td>
</tr>
<tr>
<td>Germany</td>
<td>17.0</td>
<td>81</td>
</tr>
<tr>
<td>Brazil</td>
<td>7.8</td>
<td>159</td>
</tr>
<tr>
<td>China</td>
<td>6.1</td>
<td>1190</td>
</tr>
<tr>
<td>Canada</td>
<td>4.7</td>
<td>26</td>
</tr>
<tr>
<td>Korea</td>
<td>3.5</td>
<td>67</td>
</tr>
<tr>
<td>Australia</td>
<td>2.1</td>
<td>18</td>
</tr>
<tr>
<td>India</td>
<td>1.8</td>
<td>919</td>
</tr>
</tbody>
</table>

(source: Expresspharmapulse, Dec. 1999)
The forecast for the future is that it will grow at a compound annual growth rate of 6.2% in the next five years to reach $378 billion in 2002 according to the recent IMS report. Both production and sales are heavily concentrated in the developed countries; the US, Europe and Japan account for about 80% of both production and sales. The region wise world consumption of pharmaceuticals has been as follows:

Table 2.3
Region wise world consumption of pharmaceuticals
(Figures in US $ billion, ex-manufacture price)

<table>
<thead>
<tr>
<th>Region</th>
<th>1976</th>
<th>1985</th>
</tr>
</thead>
<tbody>
<tr>
<td>North America</td>
<td>8.761</td>
<td>28.141</td>
</tr>
<tr>
<td>Western Europe</td>
<td>13.111</td>
<td>22.000</td>
</tr>
<tr>
<td>Eastern Europe</td>
<td>6.197</td>
<td>9.600</td>
</tr>
<tr>
<td>Japan</td>
<td>4.020</td>
<td>14.038</td>
</tr>
<tr>
<td>Oceania</td>
<td>0.480</td>
<td>0.700</td>
</tr>
<tr>
<td>Latin America</td>
<td>3.689</td>
<td>5.600</td>
</tr>
<tr>
<td>Africa</td>
<td>1.268</td>
<td>2.700</td>
</tr>
<tr>
<td>Asia (Excluding China &amp; Japan)</td>
<td>2.600</td>
<td>4.700</td>
</tr>
<tr>
<td>China</td>
<td>43.046</td>
<td>94.079</td>
</tr>
</tbody>
</table>

The above table indicate substantial increase in consumption of pharmaceuticals in the developed counties, where as the consumption in developing countries is not growing much when the actual need, keeping the healthcare scenario in view, as much higher. During the last decade, both Chinese and Indian market
have registered substantial increases and are likely to provide the largest jump in the market share during the next five years according to the latest global pharmaceutical forecast, 1998-2002.

b) **Percapita drug consumption:**

Another important element to be taken into account while assessing the world drug consumption is the per capita drug consumption in different countries. It helps to give an idea of the discrepancies that exist between the developed countries.

The value of drug consumption per capita in individual countries has been as follows.

<table>
<thead>
<tr>
<th>Table 2.4</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Values of drug consumption per capita in individual countries (Values in US $)</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>India</td>
<td>0.8</td>
<td>2.3</td>
<td>3.0</td>
</tr>
<tr>
<td>China</td>
<td>2.7</td>
<td>4.4</td>
<td>7.0</td>
</tr>
<tr>
<td>Brazil</td>
<td>10.9</td>
<td>10.3</td>
<td>16.0</td>
</tr>
<tr>
<td>UK</td>
<td>18.3</td>
<td>41.1</td>
<td>97.0</td>
</tr>
<tr>
<td>USA</td>
<td>36.2</td>
<td>110.5</td>
<td>191.0</td>
</tr>
<tr>
<td>Japan</td>
<td>35.6</td>
<td>116.2</td>
<td>412.0</td>
</tr>
</tbody>
</table>

(source /-mww, health4india.corn)

c) **Expenditure on Drug Development:**

The cost of research and the time required to transfer drug from the laboratory to the market has increased substantially. In the US, development time increased from 2 to 7 years and cost from $
54 million in 1976 to $75-100 million in 1985. The cost of drug development has increased for two main reasons.

1. The new generation drug are very complex and their discovery and development require costly technology and

2. The regulatory control has become very stringent safely and other tests than in the past.

Only 28 new drugs were approved in the USA in 1995, and only 40 new drug were introduce worldwide.

2.2 Indian Pharmaceutical Industry - An Introduction:

The Indian pharmaceutical industry is a vibrant, high technology based and high growth oriented industry - attracting attention the world over for its immense potential to produce high quality drugs and pharmaceutical formulations. The pharmaceutical industry is between the most highly R & D intensive industries. In fact, other than drug discovery, marketing has been the most important function in the pharmaceutical industry. The industry is typically characterised by:

1) Very intense competition with about 24000 companies large, big, medium and small fighting for their own place under the sun in more than 17,000 crore market.

2) Continuous drug discovery and rapid introduction of new products.

3) The seemingly disinvesting and almost never ending governmental regulations and policy changes.
4) Stifling price controls, eroding profits and consequently vanishing bottom line.

5) Rigorous control on formulations and an absence of international patent protection resulting in a me-too maze of products with little or no product differentiation.

6) Increasing health awareness among the people and important given to mediclaim.

7) Increasing dominances of trade association and their constant demand for increase in trade margins.

2.3 Role of Pharmaceutical Industry in India:

The pharmaceutical industry plays a very crucial role in building a strong human capital of a country. This in turn, is very essential for economic growth and development. The tremendous role played by this industry is explicitly revealed in the improvement of major health indicators. Life expectancy has risen from 41.2 years in the sixties to the present level of 65 years and it is estimated that it will move closer to 70 by the year 2005, while infant mortality has declined from 146 per 1000 to 75 per 1000. Moreover the increased availability of medicines and health care facilities has resulted in the decline of the death rate from 22.8 per 1000 in 1960 to 9.6 per 1000 in 1999.

At present, per capita annual consumption of drugs in India is about Rs. 95 and with the projected figures for 2000-2001, the per capita
consumption of drug will move marginally to Rs. 160/- per years, which will still be one of progress of the pharmaceutical industry in India.

a) **A Brief History**:

Indian pharmaceutical industry developed at the advent of the 20th century. In 1907, Bengal chemicals and pharmaceuticals was established at Calcutta. Before and soon after independence in 1947, Indian pharma market was dominated by multinationals. In 1948, the share of the Indian companies and MNC's was 33% and 67% respectively. During 1998, the scenario had change with the Indian and MNC respective was 61% & 39%. The Indian pharma sector developed only after 1955 when the large public sector units like Indian drug and pharmaceuticals Ltd. (IDPL) & Hindustan antibiotic limited (HAL) were established. The government patronage also encouraged private sector entrepreneurs. As a result companies like Alembic chemicals, Ranbaxy, Torrent, Cadilla and many more companies graphed the growing demand in the drug market. Ranbaxy alone exported drugs worth Rs. 596/- crore out of its production of Rs. 1334 crore during 1997-98. According to Market sales wise, the Top-10 companies in India during 1999 were:
b) Dramatic Progress:

From a mere Rs. 10/- crores (production value) in 1947, to a whooping Rs. 15000/- crores in 1997-98 the pharmaceutical industry in India has come a long way. Today India manufactures over 400 bulk drugs and around 60000 formulations. The intensity of competition within the pharma industry can be realized the fact that there are more than 1000 bulk drug producers in the country whose total value was Rs. 2,623/- crores, more than 20,000 formulators and more than 60,000 formulations whose value was Rs. 12068 crores being distributed by 5,00,000 chemists all over India today.

c) Industry Structure:

The present day pharmaceutical industry has 3 main sectors:

1. Public sector - e.g. IDPL, Hindustan Antibiotics.
2. Indian private sector - e.g. Alembic, Ranbaxy etc.
3. Foreign sector - e.g. Glaxo, Pfizer etc.
There are presently 24000 firms engaged in the production of drugs and pharmaceuticals.

d) Progress of Pharmaceutical Production:

Production of drugs and pharmaceuticals increased at a faster rate in the recent years than in 1984-85 despite various difficulties faced by the industry particularly by way of substantial increase in the cost of raw materials, packing materials, inadequacy of power and water etc.

e) Investment:

Unlike the global pharma industry where there are a few dominant players, the domestic industry is highly fragmented. Pharma industry is having around 24,000 players with around 300 being in the organized sector, around 13,000 being in the small scale sector and the remaining being a very small without any economies of scale. Total investment in the industry has grown from Rs. 165 crores in 1965 to more than Rs. 1600 crores in 1996.

f) Exports:

Industry has been able to build up on export market for Indian Pharmaceuticals in the face of fierce competition from manufactures in foreign countries with a longer record of
technological growth than that of India. Exports have grown from Rs. 46 crores in 1981 to Rs. 5228.49 crores.

f) The Changing Global Pharmaceutical Market Place:

Pharmaceutical firms face several challenges in their quest to retain their competitiveness. The spiraling cost of drug development and the need to replenish the pipeline for novel new drugs have increased the pressure for enhanced research productivity. While innovation is important, time to market has become critical.

Another challenge is to determine the appropriate number and mix of therapeutic segments, which have become increasingly complex in the face of radical changes occurring in many value chain activities of the pharmaceutical industry — particularly R&D (Genomics, Proteonomics), and Marketing (the internet, DTC advertising and patient specific micro marketing spurred by genomics). Synergies that once existed across therapeutic areas (R&D capabilities or a large sales force) may not be adequate to sustain a dominant presence in today's environment. (Refer table 2.5 for the current trend in the allocation of R&D in therapeutic segment).
Another important worry for the global pharmaceutical majors is patent expirations. Between 2000 and 2004 drugs generating $43 bn in US revenues will see their US patents expire or lose market exclusivity. While some competitors have savvy strategies for battling their generic competitors, others like Merck & Co, face the distinct possibility of generics eating into their sales growth after the expiry of the patents.

Another concern for the pharma majors is that governments in many countries are looking at various ways to cut the rising healthcare costs. Indeed, cost containment has become the new buzzword in an increasingly price sensitive market. Pharma companies introducing new drugs not only have to provide better
therapeutic advantage but also do it at a lower cost to lure the users. A growing emphasis on generic substitutes by Managed Care organizations has led to rapid market share erosion for patented products, once the patent expires.

Pricing pressures have become accentuated especially in Europe and Japan, where the government is the largest purchaser of pharmaceuticals. Free market pricing is difficult in these countries. Moreover, many controls have been imposed on doctors. The responsibility for prescriptions, for many common ailments has shifted from physicians to health professionals and administrative staffs in governments who tend to be strongly influenced by costs. Many governments impose price controls in various forms, price freezes, across the board price reductions, government determination of the initial price of a new product, prior approvals for price increases and linking drug price increase to the cost of living. Many national health authorities also use reference prices while making reimbursements to patients.

In the face of these challenges, the scope and need to innovate remain as strong as ever. Indeed, clever pharmaceutical companies can be expected to move into segments, which are less crowded. This automatically means the need to invest heavily in R&D. A clear implication of this trend is that the pressure to
globalize will increase. Otherwise, recovery of R&D costs would be impossible in a reasonable period of time.

The shrinking time during which a drug has exclusivity in a therapeutic class is also putting pressure on pharma companies. Due to the passage of the Drug Price Competition and Patent Term Restoration Act of 1984, the time, companies have to recoup development costs has been greatly shortened. For example, Tagamet, an ulcer drug introduced in 1977, had an exclusivity period of six years before another drug in the same class Zantac was introduced. In contrast, Recombinant, a genetically engineered clotting factor for hemophilia introduced in 1992, had less than one year of exclusivity before the introduction of a competitor product Cognate.

To accelerate the innovation process, many companies are forming strategic alliances. The total number of such alliances grew from 121 in 1986 to 712 in 1998. These alliances are diverse in nature and may involve domestic and foreign pharmaceutical companies, biotech firms, university research centers, contract research organizations, and other parties. They have different objectives such as to draw upon each other's research expertise, bring products to market more rapidly, and more effectively commercialize products after obtaining PDA approval.
As R&D costs go up and the pressure to rationalize research activities increases, the industry has also been witnessing consolidation through mergers. This is the subject of the next section.

g) Mergers and Acquisitions:

In recent times, the pharmaceutical industry has witnessed large-scale consolidation. In the past decade, there have been 29 significant mergers in the pharmaceutical industry (Refer Table 2.6 for major mergers). The early 1990s were relatively quiet in terms of M&A activity and, the combined market share of the top ten leading companies was 27 percent but in recent times, the combined market share of the top ten companies has crossed 45 percent (Refer Table 2.6).

**Table 2.6**  
**Major Drug Mergers**

<table>
<thead>
<tr>
<th>S.No.</th>
<th>Year</th>
<th>Companies</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>1995</td>
<td>Glaxo-Wellcome</td>
</tr>
<tr>
<td>2.</td>
<td>1996</td>
<td>Sandoz-Qba Geigy (Novanis)</td>
</tr>
<tr>
<td>3.</td>
<td>1998</td>
<td>Hoescht-Rhone Poulenc (Avenlis)</td>
</tr>
<tr>
<td>4.</td>
<td>1998</td>
<td>Astra Zeneca</td>
</tr>
<tr>
<td>5.</td>
<td>1999</td>
<td>Monsanto - Upjohn &amp; Pharmacia</td>
</tr>
<tr>
<td>6.</td>
<td>1999</td>
<td>Warner Lambert-Pfizer</td>
</tr>
<tr>
<td>7.</td>
<td>2000</td>
<td>Glaxo SmithKline</td>
</tr>
</tbody>
</table>

(Source: World Review 2001)
There is scope for further consolidation as even today the industry is quite fragmented, with the top pharma company having a market share of only 7 percent.

**Table 2.7**


<table>
<thead>
<tr>
<th>Company</th>
<th>Market share (percent) (1999-00)</th>
<th>Growth (percent)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pfizer</td>
<td>7.1</td>
<td>11</td>
</tr>
<tr>
<td>Glaxo Smithkline</td>
<td>6.9</td>
<td>9</td>
</tr>
<tr>
<td>Merck &amp; Co</td>
<td>5.1</td>
<td>14</td>
</tr>
<tr>
<td>Astra Zeneca</td>
<td>4.4</td>
<td>7</td>
</tr>
<tr>
<td>BMS</td>
<td>4.1</td>
<td>9</td>
</tr>
<tr>
<td>Novartis</td>
<td>3.9</td>
<td>3</td>
</tr>
<tr>
<td>J&amp;J</td>
<td>3.9</td>
<td>11</td>
</tr>
<tr>
<td>Aventis</td>
<td>3.6</td>
<td>0</td>
</tr>
<tr>
<td>Pharmcia</td>
<td>3.2</td>
<td>11</td>
</tr>
<tr>
<td>AHP</td>
<td>3.0</td>
<td>9</td>
</tr>
<tr>
<td>Top 10</td>
<td>45.2</td>
<td>9</td>
</tr>
<tr>
<td>Global Market</td>
<td>100</td>
<td>7</td>
</tr>
</tbody>
</table>

(Source World Review 2001)

The main motive behind mergers is to share the increasing costs of research and development and reduce the risk of bringing a new product to market. Moreover, larger revenue bases are needed for companies to expand because of patent expiration. Consolidation also allows manufacturers to eliminate redundancies and offer a broad range of products in multiple therapeutic categories by rationalizing R&D activities and generating product line synergies.
As far as the Indian pharmaceutical industry is concerned, the implementation of the product patent regime will lead to a shakeout and the number of pharmaceutical companies is expected to dwindle drastically from the existing level of over 25,000 to just around 1,000.

h) Research and Development:

The Indian pharmaceutical industry is among the most highly R & D intensive industries on account of:

1. Rapid obsolescence of products and the need to replace the continuously.
2. Inter disciplinary character of the research needed for new drug discovery.
3. Continuous pressure to reduce the cost of drugs.

The great advances in the developed countries have been due to the large inputs that the countries provided for their R & D work. In India R & D in the area of drugs and pharmaceuticals is carried out in about 143 in house R & D units in industry recognized by the development of scientific & industrial research, six laboratories of the Indian council of medical research & nearly 50 universities.
i) The Generic Market and Its Impact:

The share of generic drugs in the prescription market has more than doubled from 18.6 percent at the end of 1984 to 46.5 percent in 1998 and will increase further in the next five years. Many drugs will lose patent protection over the next ten years and this will sustain the growth of the generic market. Between 2000 and 2005, worth of $41.6 bn drugs (brands exceeding $ 500mn) are going off patent (Refer table 2.8 for major drugs going off patent). Some of these are mega brands with sales have more than $1 bn each. The United States is the biggest generic drug market, followed by Western Europe and Japan.

With the number of drugs going off patent and an increasing erosion of the market price of these products, the market has become highly competitive.

Table 2.8
Major Drugs Going Off-patent

<table>
<thead>
<tr>
<th>Company</th>
<th>Brand</th>
<th>Therapeutic segment</th>
<th>Off-patent date</th>
<th>Annual sales ($ bn)</th>
</tr>
</thead>
<tbody>
<tr>
<td>EMerck</td>
<td>Zocor</td>
<td>Hyperlipidaemia</td>
<td>2.8</td>
<td>2.05</td>
</tr>
<tr>
<td>Talwh-Abbot</td>
<td>Prevacid</td>
<td>Ulcer</td>
<td>2.05</td>
<td>3.1</td>
</tr>
<tr>
<td>Bayer</td>
<td>Opm</td>
<td>Infection</td>
<td>2.03</td>
<td>1.3</td>
</tr>
<tr>
<td>Asua-Zeneca</td>
<td>Losec</td>
<td>Ulcer</td>
<td>2.03</td>
<td>4.6</td>
</tr>
</tbody>
</table>

(Source Business World, April 2000)
All the large companies operating in the generic market are deploying all their resources in the targeted market. The global generic manufacturers - Mylan (marketshare-12.9 percent), Teva (12.3 percent), Apothecia (7.4 percent), Geneva (6.8 percent), Schein (6.8 percent), and 'Vatson 8.3 percent) - have consolidated their industry market share. These six manufacturers accounted for approximately 54 percent of the total generic drug prescriptions in the US in 1999 as against 47.8 percent in 1997.

Developing countries like India have an edge in the manufacture of generic drugs because of low manufacturing and labour costs. Thus, the generic market offers plenty of opportunities to them.

2.4 The Changing Face of the Indian Pharmaceutical Industry:

Traditionally, the critical success factors in the domestic pharmaceutical industry have been reverse engineering, low-cost manufacturing, and strong relationship with both physicians and the trade. The proposed changes in patent regulations, and a shift in the demographics are about to change the rules of the game. Consequently, the Indian pharmaceutical market is undergoing the following changes:

- Increased impetus for companies to invest in product research.
- Increased incidence of lifestyle diseases due to higher life expectancy and industrialization.
- Impact on drug prices due to the reduced scope of the DPCO.
Consolidation of India's retail distribution structures, and the creation of drug-purchasing groups as health insurance gains momentum.

Basic research is not only time consuming but is also risky. Compared to basic research, analogue research, which focuses on a particular compound, is less costly and risky. In analogue research, the market is aware of the existing molecule.

Indian companies can play a significant role in conducting clinical trials owing to a variety of comparative and strategic advantages. India has a vast pool of medical professionals. In fact, India stands next only to the US with respect to the available pool of qualified doctors. India also has a huge number of patients exposed to a wide spectrum of diseases.

Fig. 2.2
R & D Strategy of Indian Companies

- Lead Molecule
- Pre-clinical
- Clinical Trial-1
  - Developed countries
  - Clinical Trial-2
  - Clinical Trial-2
- Clinical Trial-2
- Clinical Trial-1
  - India
  - Licensing deal
  - Clinical Trial-1
    - Developed Countries
    - Clinical Trial-2
      - Developed Countries
      - Clinical Trial-3
        - Developed Countries
Animal testing, blood tests, cardiogram and CT scan (which contribute significantly to the costs of trials) can be done very efficiently in India. However, India has to overcome disadvantages such as regulatory hurdles and the perceived lack of credibility of the experimental data generated locally, if it wants to emerge as a big player in at least some phases of drug testing.

As the process patent regime nears its end, to be replaced by product patents, Indian companies are looking at various options to strengthen their R&D capabilities.

**Licensing arrangement**: Tying with MNCs for carrying out clinical trials, (pre and post-clinical studies, under licensing agreement milestone payment) is one of the options for Indian pharmaceutical companies. Till date only Dr. Reddy's Lab has a licensing arrangement with Novo Nordisk for its two antibiotics molecules on completion of pre-clinical studies.

**Clinical trial**: If the licenser is skeptical about commercial success and there is no tie-up, the company can carry out clinical trials in developed countries. The cost of this approach can be prohibitive. Dr.
Reddy's followed this strategy in the case of second anticancer molecule and commenced clinical trial phase-1 in Netherlands.

*Outright sale:* Another option for Indian companies is an outright sale of a molecule on completion of pre-clinical studies. Till date, no Indian company has reported such a deal.

*Contract research:* Indian companies may receive lead molecules from MNCs for completing pre-clinical studies in India. The molecule remains patented in the name of the MNCs. Indian companies can utilize their R&D infrastructure for working on the lead molecules on a cost plus basis.

**Policies And Regulation (DPCO):**

The government promulgated the drug price control order (DPCO) in 1979 with the objective of insuring abundant availability of essential drugs at reasonable prices keeping in sync with the socialist credentials of the successive governments. DPCO is considered very important and powerful by the pharma industry due to the fact that the DPCO can override the industrial policy of the state.

As per the DPCO of 1987, prices of 142 drugs and several thousands formulations produced from these drugs were controlled which
accounted for 72% of the turnover of the industry. This list was later revised in 1995 to 76 drugs, which were retained under the DPCO.

The DPCO has two other adverse effects as well. The first is that it drives Indian companies to concentrate on drugs out of the preview of price control like cough medicine etc. The second is that it encouraged the growth of small sector by exempting them from price control. This lead to proliferation of small scale units.

2.5 Segmentation in the Indian Pharmaceutical Industry:

In terms of value chain, industry is divided into two categories Bulk drugs and formulations. Drug intermediaries are used for the production of bulk drugs, which are either sold directly or meant for active consumption by the companies for production of formulations.

a) Bulk Drugs:

It covers all products and preparations used in the production of pharmaceutical formulation. With production of only Rs. 18 crores in 1965, the bulk drugs industry has managed tremendous growth. Despite facing many hurdles like request standards of drugs importers, this industry has managed to maintain its position of a net foreign exchange earner for the country.
b) **Formulations:**

A formulation is a medicine processed out of one or more drugs. It also contains either ingredient like binders for improving cohesiveness and fillers to provide acceptable size. They are usually in the form of tablets, capsules and injectable. The major players in the formulations segment are MNCs. But some leading companies like Ranbaxy, Lupin, Cipla, Wockhardt, etc. also have major presence.

The formulation segment of the industry has seen a quantum jump in its output in the last decade. The production of formulation has witnessed tremendous growth from a level of Rs. 1,945 crores in 1985-86 to Rs. 15,078 crores in 2001-2002.

The pharma market can also be segmented on the basis of the therapeutic segments. Major players by product groups are as follows:

<table>
<thead>
<tr>
<th><strong>Table 2.9</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Product Group of Drug &amp; % Share of Pharmaceutical Companies</strong></td>
</tr>
<tr>
<td><strong>Product Group</strong></td>
</tr>
<tr>
<td>Antacids</td>
</tr>
<tr>
<td>Vitamins</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>Non-steroidal drugs</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>
2.25

<table>
<thead>
<tr>
<th>Product Group</th>
<th>Company</th>
<th>Share %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anti-T B Drugs</td>
<td>Novartis</td>
<td>12</td>
</tr>
<tr>
<td>Anti-bacterials</td>
<td>Cipla</td>
<td>19</td>
</tr>
<tr>
<td></td>
<td>Ranbaxy</td>
<td>14</td>
</tr>
<tr>
<td>Anti-allergies</td>
<td>Hoechst</td>
<td>15</td>
</tr>
<tr>
<td>Cold preparations</td>
<td>Alembic</td>
<td>73</td>
</tr>
<tr>
<td>Analgesics &amp; Anti Pyretic</td>
<td>Smithkline (crosine)</td>
<td>12</td>
</tr>
<tr>
<td></td>
<td>Glaxo-welcome</td>
<td>11</td>
</tr>
<tr>
<td></td>
<td>Themis pharma (Metacin)</td>
<td>10</td>
</tr>
<tr>
<td></td>
<td>Hoechst (Novalgin)</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>Reckitt &amp; colman (Disprin)</td>
<td>3</td>
</tr>
</tbody>
</table>

(Source: www.pharmabiz.com)

2.6 Progress of Pharmaceuticals After Patents Act, 1970:

The features of the patent act of 1970 were constructed on the basics of balancing of rights and obligations & ensuring that patent monopolies are not perpetuated. Due to these features, the pharmaceutical industry progressed satisfactorily. This is evident from the following analysis.

a) Progress Research:

Due to the absence of product patent in the field of basic drugs manufactured by the domestic sector, there are nearly 425 basic drugs manufacturers meeting the indigenous demand as well
as some for exports to other countries. These range from Acetazolamide, Amoxycillin, Ampicillin, Analgin, Aspirin, Caffein, Ephedrine, Heparin, Ibuprofen to Quinine, Sulbutamol, Trizoline & Vitamines.

The table below indicates the time lag between the introduction of some of the new drugs in the world market and their introduction in India after the domestic enterprises developed their own technologies to manufacture them.

Table 2.10
Introduction of drug in world market and in India

<table>
<thead>
<tr>
<th>Drug</th>
<th>Introduced In World Market</th>
<th>Introduced in India</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ibuprofen</td>
<td>1967</td>
<td>1973</td>
</tr>
<tr>
<td>Salbutumoi</td>
<td>1973</td>
<td>1976</td>
</tr>
<tr>
<td>Mebendazole</td>
<td>1974</td>
<td>1976</td>
</tr>
<tr>
<td>Rifampicin</td>
<td>1974</td>
<td>1980</td>
</tr>
<tr>
<td>Cimetidine</td>
<td>1976</td>
<td>1981</td>
</tr>
<tr>
<td>Bromhexin</td>
<td>1976</td>
<td>1982</td>
</tr>
<tr>
<td>Naproxen</td>
<td>1978</td>
<td>1982</td>
</tr>
<tr>
<td>Captopril</td>
<td>1981</td>
<td>1985</td>
</tr>
<tr>
<td>Ranitidine</td>
<td>1983</td>
<td>1985</td>
</tr>
<tr>
<td>Norfloxacin</td>
<td>1984</td>
<td>1988</td>
</tr>
<tr>
<td>Acyclovir</td>
<td>1985</td>
<td>1988</td>
</tr>
<tr>
<td>Ciprofloxacin</td>
<td>1985</td>
<td>1989</td>
</tr>
<tr>
<td>Astemizole</td>
<td>1986</td>
<td>1988</td>
</tr>
</tbody>
</table>

(source: pharma business, June 1998)
Thus, the pharma industry has been able to produce basic covering various therapeutically groups, achieving near self sufficiency in the production of bulk drugs in the country.

b) Production:

Earning of eleven leading Indian pharmas grew by 23% in the financial year just ended and their performance in 1999-2000 hinges on domestic sales and the government's pharmaceutical pricing policy. Net sales in 1998-99 grew an average of 13.2%. Average profile growth was heavily infused by Rhone poulence (INDIA) LTD, earning, which grew 134.7% and Novartis, which rose 95%. Companies that were exposed to the Russian market were squeezed by its economic debacle; Hoechst Marrion Russel was badly hurt because it had 20% of the Russian market.

Dr. Reddy's net profit was 677.16 million rupees. Glaxo posted 15% rise for the full year. Many firms faced the problem of increasing off-take of generic formulation opposed to branded formulations.

Ranbaxy, Cipla, Cadilla, Lupin and Torrent enterprises have emerged as major Indian companies meeting requirements of all kinds of drugs.
Table 2.11
Major Buyers of Indian Drugs
(% of total Exports-1990)

<table>
<thead>
<tr>
<th>Country</th>
<th>% Share</th>
</tr>
</thead>
<tbody>
<tr>
<td>USSER</td>
<td>33%</td>
</tr>
<tr>
<td>USA</td>
<td>14%</td>
</tr>
<tr>
<td>EUROPE</td>
<td>16%</td>
</tr>
</tbody>
</table>

(% of total exports -1999)

<table>
<thead>
<tr>
<th>Country</th>
<th>% Share</th>
</tr>
</thead>
<tbody>
<tr>
<td>USA</td>
<td>16%</td>
</tr>
<tr>
<td>Russia</td>
<td>8%</td>
</tr>
<tr>
<td>Europe</td>
<td>20%</td>
</tr>
<tr>
<td>Brazil</td>
<td>10%</td>
</tr>
</tbody>
</table>

(source :- pharma business, June '000)

Table 2.12
% Share by Corporate Ownerships.

<table>
<thead>
<tr>
<th>Year</th>
<th>companies</th>
<th>Share of corporate ownership</th>
</tr>
</thead>
<tbody>
<tr>
<td>1970</td>
<td>Indian</td>
<td>15%</td>
</tr>
<tr>
<td></td>
<td>MNC</td>
<td>85%</td>
</tr>
<tr>
<td>1982</td>
<td>Indian public sector</td>
<td>2%</td>
</tr>
<tr>
<td></td>
<td>Indian private sector</td>
<td>48%</td>
</tr>
<tr>
<td></td>
<td>MNC</td>
<td>50%</td>
</tr>
<tr>
<td>1993</td>
<td>Indian public sector</td>
<td>1%</td>
</tr>
<tr>
<td></td>
<td>Indian private sector</td>
<td>60%</td>
</tr>
<tr>
<td></td>
<td>MNC</td>
<td>39%</td>
</tr>
</tbody>
</table>

(source :- pharma business, June 1998)
Within the span of 20 years Indian private sector has tremendous increase in percent share by corporate ownership than MNCs and public sectors.

**Table 2.13**

Sales and Shares of Big Companies In Indian Market, 1992

<table>
<thead>
<tr>
<th>Company</th>
<th>Sales (Rs. Mn)</th>
<th>Shares (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indian</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ranbaxy</td>
<td>1,689</td>
<td>4.4</td>
</tr>
<tr>
<td>Cadilla</td>
<td>1,467</td>
<td>3.8</td>
</tr>
<tr>
<td>Cipla</td>
<td>1,175</td>
<td>3.0</td>
</tr>
<tr>
<td>Lupin</td>
<td>1,031</td>
<td>2.7</td>
</tr>
<tr>
<td>Alembic</td>
<td>1,008</td>
<td>2.6</td>
</tr>
<tr>
<td>MNCs</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Glaxo</td>
<td>2,137</td>
<td>5.6</td>
</tr>
<tr>
<td>Pfizer</td>
<td>963</td>
<td>2.5</td>
</tr>
<tr>
<td>Hoechst</td>
<td>951</td>
<td>2.5</td>
</tr>
<tr>
<td>Boots</td>
<td>930</td>
<td>2.4</td>
</tr>
<tr>
<td>Burroughs-wellcome</td>
<td>826</td>
<td>2.0</td>
</tr>
</tbody>
</table>

*(source: www.pharmaopening.com)*

Ranbaxy is major player in Indian private sector unit due to innovative research and development activities and renewed marketing strategies with share of 4.4%

**2.7 Introduction of GATT**

India's signing the general agreement on Tariff and trade (GATT) in April 1994 brought a wave of change in the Indian pharmaceutical

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Industry. TRIPS, a section of GATT which has major implication on our prevalent patent system (process patent) is bound to create a series impact in the fortunes of the pharmaceutical industry. With the signing of the GATT, India is required to amend its archaic patent law to include product patent thereby forcing the Indian companies to take license from a patent holder for the production of new drugs.

Indians were very good in process technology and Indian scientists could develop their own process once any new molecule was introduced in Indian market within a span of 3 to 5 years. This is because India was not a signatory to the Paris convention & was not member of GATT at that time.

New molecular introduction with minor variation in process technology by Indian companies was called as PIRACY by original researcher.

However with the policy of industrial liberalisation and to bring a global discipline, a number of issues connected with international agreement on trade related aspect of intellectual property right have been discussed and the negotiation conclude in 1993. The outcome of the final Uruguay round of discussion is the GATT agreement 1994, the final text signed by 115 countries who are members of WTO.
a) **Objectives of GATT Agreement:**

1. Reciprocal and mutually advantageous arrangement.
2. To decrease custom duties and other barrier to trade like quantitative restriction, regulation of subsidies.
3. Elimination of discrimination to international trade Ex-national product and imported product.
4. To promote liberalisation.

GATT is a global organisation, which governs world trade. It consist of 108 member nations including India. The last round of talks-better known after GATT director general, Arther Dunkel-began in December, 1986. Till now, 107 counties have accepted the proposals, which will come into effect in May, 1995.

The future over drug patenting has created lot of debate in the pharmaceutical circles. The Indian drug & pharmaceutical industry has great apprehension and feels threatened by the switch over, under the new GATT, to process patenting from the present product patenting. The throat apparently is in new drug that will come under patent. This point to the magnitude of additional resources to be mobilised in research and development.
It is evident that a strong R & D base is the key to prosperity and progress of the nation and hence compulsion for tomorrow. Therefore what is needed and required is a coordinated effort by both the industry and the government to face the challenges that lie ahead to have smooth working if we sign the Dunkel agreement.

But there is yet, another side to the picture, we are aware that already 75-90% of essential drugs are "off-patent" and the remaining 25% will go "off-patent" ten years hence, by when the new law world have come into force.

The Discussion with regards to TRIPS have been entirely on patents since in other related laws the Indian laws are in line with international standards. Even with regard to patents, the controversy centers mainly on the adverse impact it may have on drug and pharmaceuticals. With regard to life savings drugs that might be developed in future, the new agreement for a safeguard by permitting compulsory licensing for public non-commercial use.

It is important to recognize that India cannot take unilateral action. We cannot tell the world to go its own way while we go ours. The alternative to GATT is, as already mentioned, a series of bilateral agreement that India will have to sign with each of its trading partners. An international agreement reached through a
process of negotiation and through a process of give and take is much better than an agreement with an individual country. In a bilateral agreement, the economically powerful country can dictate matters. The Dunkel proposals from a package. If there are positive features from India's point of view, there are negative features too. We must frilly back the proposals that are in our interest & seek to change those which could create difficulties for us.

b) GATT and Patents:

Uruguay round began in 1986 and was scheduled to end in December 1990. Negotiations concluded on 15th December 1993. The talks were aimed at rewriting the rules of free trade. According to Mr. Arthur Dunkel, the author of the original draft and former GATT Director General "The GATT system offers a framework of support for integration of the world economy and at the same time, a source of positive outside pressure to achieve much needed domesite reform" For enterprises which operate on a global scale, regional markets must be eventually integrated with global disciplines and global markets.

Most developing countries feel that with the new rules within the GATT framework, they will face more difficulty in obtaining the latest technology from industrial nations.
Since 1983, growth in trade volume has outpaced rise in output, reflecting partly, long term changes in the world economy. These changes, according to GATT, include the rising share of manufacturers in world trade, the stimulus to trade from foreign investment and technological and communication advances reducing "economic distance" between countries.

GATT is a treaty to which most industrialised and many developing countries belong. Its central principles are that countries may not discriminate among trading partners, keeping out imports from one but accepting them from another and may not unfairly subsidises their own industries or flood international markets with goods at unfair low prices. To police the system, GATT runs a quasi-Judicial arbitration procedure. Then, on the principle that restraints on trade (by import tariffs or otherwise) impoverish everybody, GATT organises negotiations (such as the present) in which members strike deals among themselves on the levels at which tariffs apply to various classes of traded goods and the ranges of goods to which GATT's rules apply.

Regionalism and multilateralism are two sides of the same coin. GATT is a binding contract between 117 Governments which together account for 90 per cent of world merchandise trade. The
objective of the contract is to provide a secure and predictable international trading environment for the business community and a continuing Job creation and trade can thrive. In this way, the multilateral trading system contributes for growth and development through the world.

Some people see the Uruguay Round, and in particular the new issues of trade in services, trade-related intellectual property rights (TRIPS) and trade-related investment measures (TRIMS), as attempts by the rich industrial countries to re-colonise the Third-World.

The introduction of 'the new issues' was an attempt to limit the autonomy of developing countries, curbing their right to intervene through protection, regulations and subsidies to promote development and benefit their people.

There is no consensus among economists that worldwide adoption of developed-country standards of legal protection for intellectual property could, raise economic welfare. Any improvement would depend mainly in the extra stimulus given to invention and raised product standards in return for the extra cost to LDC in payment for all forms of intellectual property and sacrificed earnings from copies.
The Uruguay Round of trade negotiations. Which was initially seen as a threat to the freedom of developing countries especially in trade in services and intellectual, property rights, has begun to look more and more like their last defence against arm-twisting by the rich nations, headed by the US.

Successful completion of the Uruguay Round will go a long way toward setting IPR disputes. The prospective agreement on IPR includes considerable compromise between the interests of developed and developing countries. In addition, by placing future negotiations in the multilateral framework provided by the GATT, potentially damaging bilateral disputes may be avoided.

A world trade agreement is needed to open markets in Asia, particularly Japan, to European exports. Without GATT it is impossible One would realise the significance when one sees that China withdrew from the GATT in J1950, and now wants to rejoin in the previous position of founding member It also wishes to be recognised as a developing country.

The new areas where texts have been drawn up cover trade-related investment measures (TRIMS), intellectual property rights (TRIPS) and trade services. The TRIPS agreement seeks to protect intellectual property with respect to copyright, trademarks,
geographical indications, industrial designs, patents, integrated circuit designs, the production of undisclosed information and the control of uncompetitive behaviour in contractual licenses. The agreement also establishes mechanisms for the enforcement of these rights and for dispute settlement. This round of talks has been particularly controversial because the GATT ambit is being expanded to cover not only trade in goods but also trade in services (GATS), intellectual property rights (TRIPS) and trade related investment measures (TRIMS).

c) **Duration of Patent Grant:**

Historically, there has been no consensus as to what the duration of a patent grant should be. This fact has been recognised by the Paris Convention Which leaves individual members free to decide on the period of protection they wish to provide under their national laws. GATT alters this century-old convention in respect of the term of a patent. Instead of the flexibility provided under the parts Convention a uniform duration of patent term for all countries is sought to be introduced Article 37 of the TRIPS Agreement stipulates that the term of the patent protection as 20 years from the filling date. This is particularly true of the GATT regime on intellectual property rights. It wants all countries to switch over to
twenty-year product patents from 2005 A.D. During the interim ten year period, countries without product patents will undertake not to copy any drug registered for patenting after April 1, 1995 the date when the new GATT agreement is to come in force. This is called "pipeline protection"

To tighten the patent rights, GATT provides for an 'exclusive patent protection of 20 years', which was a dream for several technology exporting countries. Patent laws, thus hereafter grants the inventors exclusive control over the use of the invention or innovation. Regarding this, the National Working Group on Patent Laws in its memorandum submitted to the Cabinet Committee expressed the possibility of more stringent and larger monopoly over India's trade and manufacture by the multinational companies (MNCs).

GATT puts down detailed specifications which have to be followed on drawing up national patent law. Nothing has been left out. These would have their ramifications in three main areas:

(i) Patentable Subject Matter i.e. the fields of activity that a patent regime is to cover,
(ii) duration of a patent grant and
(iii) conditions governing working of patents.
What this implies for countries like India, which have seen the generation of novel processes for the production of patented chemicals, including drugs, is that all the producers using such new processes would have to prove that they are not infringing any patent rights. The proposed change does not augur well for the future of local enterprise in these countries, which may find it difficult to cope with this challenge from the proposed patent regime.

2.8 Impact of GATT on Indian Pharma Sector:

In a large democracy like ours with its multitude of problems, 'reforms' are difficult to bring about. But they are not impossible. Virtually hundreds of studies need to be carried out in different sectors to understand problems more clearly, acceptable finding solutions within limited resources. Following are Impact of GATT on Indian pharma sector:

1) There is urgency in our country for taking up Health Economics studies covering Government and civic health services as well as private sector. The scrutiny has to be strict and the decisions may have to be relatively harsh as there is large expenditure on health in private sector.
2) We cannot escape rigorous considerations of Pharmaco-economics for any new drug and the process must start right at the drug approval level and must continue till it reaches end of product 'life-cycle'.

3) Such studies would help us in getting the best out of pharmaceutical products offered and save our scarce resources. Most important is that many of the diseases now do not kill because of very effective drugs. On the other hand, they do not cure completely, leading to progressively heavy burden of impaired, disabled or handicapped population. This can be minimised by being conscious of Pharmaco-economic status of each and every drug the physician would be using.

4) In order to supply patented drugs to the poor at low rates, the country will have to earmark a big amount of its resources every year. Undoubtedly, this will increase the country's dependence on international financial institutions and other developed countries for additional resources to meet the expenditure through borrowing.

5) Currently available drugs in our country-more than 95% which are not under patent can fulfill our needs.
6) In the pharmaceutical sector India is quite competitive and the prices will be affected mainly due to decontrol of prices rather than introducing product patents.

7) While there is no need to fear the act of granting product patents in the pharmaceutical sector, considering imports as tantamount to working patents should not be acceptable to India. There is also no major danger or loss to the country in accepting the 20 year duration of patents.

8) Greater importance to R&D and substituting non-patented drugs for patented drugs are called for in the pharmaceutical sector.

9) India's dependency for technology on the US in particular and the developed countries in general has been increasing.

10) There cannot be two opinions that administration of the patents has to be streamlined and patents Act must be modified to bring it in line with modern day realities.

11) Prospects for ‘off-patent’ bulk drug exports are going to be higher in short-term future atleast and putting more emphasis on this area would benefit domestic industry to a great extent.
2.9 **Trips and Its Impact on Patents:**

Intellectual property has particularly received special attention since the Uruguay round of negotiation discussed trade related intellectual property right. The Uruguay round covered seven different forms of intellectual property patent, copyright & related right, trade marks, industrial designs, geographical indications, integrated circuits and undisclosed information.

a) **Definition:**

Intellectual property rights are the rights given to persons over the "creations" of their minds. They usually give the executor an exclusive right over the use of his/her creation for a certain period of time.

b) **A Look at the TRIPS Agreement:**

Contrary to popular belief, intellectual property legislations not only cover patents but also the acquisition and use of a range of rights covering types of certain creation including that of an aesthetic character (e.g. artistic work and design) information and signs of a property commercial value (e.g. trademark) among other. Patent is that type of intellectual property rights a major application of which occurs in the pharmaceutical sector.
Before the conduct of the TRIPS negotiation within the GATT there exist a number of intellectual organizations and convention regarding the protection of intellectual property. The world intellectual property organisation (WIPO-a United nations specialized agency) has been particularly active in the development of new forms of protection as well as applications of new technologies of patents & copyright.

c) TRIPS Agreement and Indian Patent Act:

Indian patent office have been accepting patent application for pharma product since Jan 1-1995 & keeping them in a mailbox to be taken up for examination after Jan 1-2005. Leading industrial countries believe this approach is largely a compromise solution necessitated by the lack of proper legislative support which is not sufficient to ensure legitimacy for the filed product patent application. On exclusive marketing right there has been no legislative or administrative action taken so far. So on both the issues INDIA has defaulted with respect to its agreed obligations.

WTO has set Oct. 22-1999 as dead line by which India has to provide information about introduction of either product patent or exclusive marketing right for pharmaceuticals in line with
dispute settlement panel report which want in to the complaint filed by the European unions.

With lack of resistance from INDIA cleared the path of the report which ruled that countries patent laws were not in accordance with TRIPS agreement has formally been adopted by dispute settlement board.

So India has lost its opportunity to appeal against the dispute panel ruling and had been pushed in to a situation where it has to introduce product patent right away or opt for the transition period available to developing countries by making provisions for exclusive marketing right for products which have been patented else where.

As & on today, India has a process patent regime regarding pharmaceutical product. Therefore Indian patent act 1970 has to be changed to bring it in line with the international laws on patenting of pharmaceutical product.

Being a developing nation, India has a grace period of five years to change its patents Jaws under the agreement on TRIPS.

The provision is that the product must have been registered for a patent and has received marketing right in any of the WTO
member countries. Thus, it is a backdoor method for granting monopoly right.

Furthermore, there is a gray area here too. If marketing right is granted only for five years, what will be its position for the remaining five years until the country in question actually amends its patent laws.

Typically a patent is granted for 17 to 20 year. Although for some products in a few countries the period is as short as five years, once issued, it can be treated or licensed like other forms of personal property.

The exclusive right and scope by of the patent system are fought to be enlarged in the TRIPS Agreement in article 28 as follows "A patent shall confer on its owner the following exclusive rights"

a) Where the Subject matter of a patent is a product, to prevent third parties not showing owner's consent from the act of making, using and offering for rase, selling or importing for these purposes of that product.

b) Where the subject matter of a patent is a process, to prevent third parties not having owner's consent from the act of using the process, and from the act of using, offering for
sale, selling are importing for these purposes at least the product obtained directly by that process" In order to be patented, an invention needs to meet the requirement of:

i) Novelty (previously unknown to public)
ii) Non obviousness (containing sufficient innovativeness to merit protection) and
iii) Industrial applicability (usefulness).

Following are clear concerns of the TRIPS agreement vis-a-vis the pharmaceutical sector:

1. The introduction of product patents may imply significant social cost due to the higher prices charged for medicaments.

2. The access to local firms of protected technology will become more difficult because of the enforcement of the patent holders bargaining position through investment in R&D.

3. There is no possibility that the most dynamic segment of the pharmaceutical market, where the prospects of growth are highest, will be excluded from the domestic firms.
2.10 a) An Overview of World Trade Organisation (WTO):

Right since its inception on January 1, 1995, the world trade organisation (WTO) has been a subject of intense and often an acrimonious debate. The WTO has come to replace the general agreement on tariffs and trade (GATT), which was in existence from 1948 to 1994. Along with the international monetary fund (IMF) and the World Bank, GATT happened to be the third pillar of the Breton woods system. GATT, which was a multilateral treaty, used to govern world trade in goods only, while the WTO has now acquired a much wider and ever increasing scope and coverage.

As of now, 138 countries are WTO members, with 34 observers, of which atleast 20 countries, including China and Russia, are waiting eagerly to become the WTO members. These countries account for about 95% of the world trade; the coverage will increase to 98% when China joins the WTO. All members have to sign 28 agreements arrived at the final Uruguay round negotiations; 25 of these agreements are in the area of goods and services including GATS, TRIMS, TRIPS, dispute settlement, etc. All these agreements are binding on all members.
In theory, the WTO is the most democratic world organisation, with each member (wither the mighty USA or the poor Bangladesh) having one vote; decisions are taken largely based on consensus; and majority voting takes place in rare cases only. This is of its most distinctive feature in comparison with the IMF and World Bank. In practice, however, it is the Quad countries (USA, EU, Canada and Japan) with their share of about 80% of the world trade that dominate the decision-making, thanks to the lack of cohesion among developing countries. Usually, developing countries with a few exceptions, (sometime like India or Brazil, etc.) fall in line on the pressure or inducement from developed countries. There is very often no commonality of issues among the developing countries.

b) Objectives & the Strategic Framework of WTO:

Before, preceding further, a word about the drive towards globalization. We are living in an era wherein world trade has been expanding at a pace faster than world output; capital flows are overwhelming the world trade; daily transaction in foreign exchange are manifold of the average daily world output as well as world trade; WTO regime is endeavoring to expand continuously the scope of multi-literallism not only in trade of goods and services, but also in the areas of investment.
Further, the spectacular progress in information technology is virtually transforming world financial markets into a single entity with a phenomenal increase in cross border capital flows as well as in the operation of MNCs.

In such a rapidly globalising environment, how feasible is it for the Indian economy and industry in particular, to remain unaffected? It is evident from the literature on the subject of globalization that, "many of the countries that are insufficiently integrated with the world economy are among the poorest". The data on world trade and capital flow bear eloquent testimony of the pace of globalization in the last few decades.

Thus, world export rose from $ 61 bn. in 1950 to $ 315 bn. in 1970 to $ 3,447 bn. in 1990 and further to $ 5,460 bn. in 1999. In addition, trade in commercial services amounted to $ 1,340 bn. in 1999. Over this period, the share of world export to world output has grown from 6% to 16%. Likewise, FDI flows have increased to a record $ 855 bn. in 1999. While, three have fourth of this ($ 636 bn.) were attracted by developed countries, some of the developing countries, especially China has been a major beneficiary in recent years. The high performing Asian economies so also, some of the Latin American counties have consistently secured tremendous
Trade in goods; trade in services; Trade Related Investment Measures (TRIMs); trade related Intellectual Property Rights (TRIs); dispute settlement mechanism; and dumping and anti dumping rules, etc.

d) The WTO Ministerial Conference:

For performing such massive tasks, the WTO has evolved its unique organisational structure. In this, the ministerial conference assumes immense importance. It is the highest policy-making body of the WTO dealing with several macro issues. The first biennial ministerial meet was held in Singapore in December 1996 to review the working of the WTO as well as to take up four new issues:

The relationship between trade; competition policy; transparency in government procurement and trade facilitation. The Singapore ministerial meet also established working group to deal with the three issues and directed the WTO council for trade in goods to handle the last issues.

The second ministerial meet, which was held in Geneva in 1998, was more of a celebration of the fiftieth year of GATT. However, some new issues were also taken up like e-commerce,
trade and environment, labour standards, fresh rounds of industrial
tariff negotiations, textiles and clothing, transparency in WTO
functioning, problem of developing countries, unilateral action by
developed countries, etc. Besides, the ground was prepared for a
comprehensive new round of talks-the millennium round-
particularly at the instance of the EU and its allies.

The third ministerial meet was held at Seattle in early
December 1999, and was expected to discuss many crucial issues,
including the preparations for the millennium round of
negotiations, it was to review the progress on new issues raised at
the Singapore meet, including the problems of less developed
countries. In short, the trust was to be on the implementation of the
existing agreements (built-in-Agenda) as well as on some new
issues, such as: (i) E-commerce, (ii) Trade & environment, (iii)
transparency in WTO's work process, and (iv) trade and labour, etc.

The Seattle meeting received unprecedented world wide
attention thanks to the massive anti-trade demonstrations that
disrupted talk and the successful conduct of discussions and
decisions on the formal agenda. The 'mobilisation against
globalisation' was spearheaded by an unwieldy mix of consumer
groups, labour union, environmentalists and other activities. The
WTO came to be portrayed by critics as "the power house of globalisation, seen as a malign force or even as a conspiracy". Unfortunately, however, what was not easily recognised is the fact that globalisation has become inevitable, thanks to the forces of economics, technology and international relations. Further, the present surge in global integration is essentially driven by advances in communications and computing technology.

e) **Areas of Concern for Indian Industry**:

WTO offers both challenges and opportunities for the Indian industry. Obviously, challenges are far more serious and striking given the lack of competitive strength of Indian industries. Already, India has experienced almost a decade of market oriented reforms and many serious problems are coming to the surface:

1. The economy in general and industries in particular are victims of high cost (both manufacturing and transaction costs);

2. The technology gaps of several years are too glaring. Even more worries some are the difficulties in securing technology transfers from developed countries.

3. The perennial problems of infrastructure bottlenecks and the consequent constraints on global bench marketing;
4. Hard core reforms (e.g. exit policy, privatisation, etc.) are still politically difficult for implementation and hence, there is a virtual lack of flexibility in operations. The necessary legislative and administrative framework for dealing with problems of industrial sickness is found wanting, thereby hindering the move towards competitive industrial restructuring.

5. As a consequence, Indian products or services are not competitive in terms of price, quality and delivery schedule. Except for computer software, gems and jewellery, garments and to some extent leather and low value engineering goods, not, may other Indian products are export competitive.

6. Market-access in developed countries is fraught with difficulties since most of them are practice "neoprotectionism" in various forms (tariff and non-tariff barriers), back loading of MFA (multy-fibre agreement);

7. Most developed counties are unreceptive to India's problems and are always demanding larger market access into India, including exhorting her to fulfill WTO compliance on many issues earlier than required;
8. India's share of world exports is a meager 0.5% and her share of trade in world services is even less; hence, it does not command any bargaining strength in WTO level negotiations;

9. Last, India's political economy is not very stable. The prevailing system of coalition governance is not conducive for prompt and effective policy changes and their implementation.

Obviously, most of these problems are of our own making and will have to be resolved by our own internal efforts. At the WTO negotiating table, we can only raise, issues applicable to global trade, which do not comply with its given provisions and conditionality. Which effective negotiations are a must, we can neither procrastinate the day of reckoning nor reverse the imperatives of WTO driven globalisation of the Indian economy.

f) **Trade Related Intellectual Property Rights (TRIPs):**

The subject of intellectual property right or trade-related Intellectual Property Right (TRIPs) has always been very controversial. Intellectual property (IP) refers to "a creation of human mind that is of value to the society, while intellectual property rights (IPRs) are rights granted by the state to persons over creation of their
mind". The WTO agreement on TRIPs covers nine categories of intellectual property:

1) Patents;
2) Plant and seed variety;
3) Micro-organism;
4) Copyright and neighboring right;
5) Trade marks, including services marks;
6) Industrial designs;
7) Geographical indications;
8) Integrated circuits; and
9) Trade secrets.

For each of these, certain norms of protection are prescribed. These norms do not necessarily have to be attained overnight. There is a transition period allowed. Legislations in most of these items are at various stages of formulations and implementation.

Under the TRIPs agreement, India has agreed to accept applications from January 1, 1995 onwards. The applications will be received in the 'mailbox' and will be examined only with effect from January 1, 2005. Further, the TRIPs agreement also makes it obligatory for India to grant exclusive marketing rights (EMRs) to pharmaceuticals and agro-chemicals, which have been given product patents and marketing approval in another member country of the WTO. India's major concerns in the area of IPR are:
1. Granting of product patents of pharmaceuticals and agrochemicals;

2. Patenting of micro-organism or life forms, including patenting of products based on our bio-diversity and traditional knowledge in other parts of the world; and

3. Establishing an effective sui-generis system for the protection of new plant varieties, plant breeders' rights, which recognises and rewards the traditional contribution of rural communities to the conservation of bio-diversity.

The product patent systems for pharmaceuticals and agro products have already become effective from January 1, 1995. By implications, this means that Indian industry, which enjoyed the freedom to do reverse engineering of new patented products that come to the market sometime after 2005. It has been observed that it takes atleast 3 to 5 years for a new patented drug to come the market. India's concern should not be on EMRs, but more on how to manage the product patent system in the future and address our public interest concerns. For this purpose, enactment of the required patents legislation complying with the provisions of the TRIPs agreement is imperative. Besides, there is an urgent need for modernising our patent office and strengthening the manpower
involved in the administration of the patent system. There are many other contentious issues such as:

(i) matters relating to biological recourses under TRIPs;
(ii) conservation of traditional community knowledge, bio-diversity and the EPs of the community;
(iii) safeguards against EMRs; and
(iv) the Sui-Generia systems, patenting of micro-organism, etc.

The patents (amendment) act, 1999 was expected to be ratified by the legislative process coming into force effectively from January 1, 2000. But the public opinion, as is to be expected, is sharply divided. There is an urgency of spearheading a movement towards the implementation of a national intellectual property policy. India with its tremendous potential of bio-diversity and intellectual capital will have much to gain from well administered patents system. The threat perception about escalation in pharmaceutical product prices is surely important from the short-term point of view, but effective TRIPs will go a long way to bring in foreign direct investment (FDI) and facilitate significant R & D activity.

g) Concluding Observations - Massage to Indian Industry:

This article obviously cannot deal with the all-pervasive scope and coverage of the WTO. We have sought to highlight
many crucial issues. But many others like general agreement of trade in services (GATs), multi-fibre agreement (MFA) dealing with phasing out of the export quota structure of textiles and clothing products, sanitary and phyto-sanitary measures have not been commented upon. The objective here is essentially to provide a glimpse of the WTO and its strategic framework.

Surely, we have been a witness to rapid spread of influence of the WTO and the consequential forces of globalisation. The major challenges before industry is to accept the inevitable and vigorously work towards exploiting opportunities likely to be unleashed by globalisation. Undoubtedly, the WTO will impact each and every business, and each and every aspect of various businesses. Having said this, let us recognise the combinations of a few crucial 'positives' and 'negatives' of the new WTO scenario.

1. The WTO is for transparency of policies, rules and procedures and for multilateral conformism. It is not for insular and protected economic, trade and investment regime.

2. The WTO is for greater and greater market access; it is not for import restriction or import substitution.
3. The WTO does not believe in mere focus on export orientation, but is consistently and passionately seeking outward orientation in economic policies of member countries.

4. The WTO is not for unrestrained or imprudent use of capital resources in the development strategy, but for deploying capital on the basis of comparative and competitive advantage of nations.

5. The WTO is not for subsidies, but for wider and effective use of pricing mechanism for allocation of resources domestically and globally.

6. The WTO is for internal deregulation serving to compliment the process of trade and investment liberalisation.

7. The WTO is for promoting climate for FDI flows based on undistorted trade and investment regime; it is not for substitution of trade by investment being protected through tariffs and restrictive import licensing system.

8. Last, the WTO is for competition and globalisation. Therefore, member countries are under compulsions to observe critical macro level disciplines - be it fiscal stability,
be it price stability or be it exchange rate management. Consequently, it is not for soft options, be it high tariffs, be it QRs, be it subsidies or be it lack of transparency in the policies, procedures and rules governing trade and investment.

Having said this, there invariably will be proponents and opponents of both the WTO and globalisation. It is no one's case that commitment to the goals of WTO alone will deliver growth and prosperity across the world, leave alone in India. The ultimate aim of all these global and domestic, efforts is to expand domestic wealth and ensure trickling down of prosperity for the betterment of material lot of million of our own people.

The WTO happens to be an on-going process, and Indian industry has to be ever vigilant to respond to the challenges in a more positive and proactive way with the support and co-operation of our own policy makers.

h) Impact of WTO on Indian Pharmaceutical Industry:

i) Impact of Product Patent Regime:

The specific fall out of the changes that would be made in the patent laws on the basis of the provisions in the TRIPS agreement would be manifold. The consumer will be
hit by high prices and erratic available of pharmaceuticals, medicines etc. and the domestic industry would face the question of survival.

ii) Impact on Prices:

It is accepted that pricing included development expenses. Beginning with R&D expenses to the stage of plant and machinery, all expenses go to the costing of finished product. But the amount recoverable on an annualised basis is related to both the market forces and the laws of the land. The main impact of the proposed globalisation of patents would be on the prices of medicines which would go up several times higher making it extremely difficult for the poor people of India to afford them.

iii) Impact on Availability:

The availability of new drug from indigenous sources of the domestic companies would be totally out of question. Dependence upon imports would go up.

iv) Impact On Medium & Small Scale Sector:

The existing industry, particularly in the medium and small scale sectors will over a period of a decade or so after the introduction of new patent regime, face serious degrowth as they will have no possibility of taking up new products. Even
for the existing products or process, new patents will be taken, creating difficulties for companies to market their existing products.

v) The Acceptance of TRIPS, Transfer of Technology:

The acceptance of TRIPS is likely to accelerate. Most of the leading drug multinational companies are present in India having substantial equity participation in their Indian counterparts. With the policy permitting them to increase the share-holding, they have already expressed interest in bringing their latest technologies to manufacture additional bulk drugs to improve present facilities. Indian indigenous sector have better opportunities to enter into technical collaboration with the firms underrepresented in India.

vi) New Drugs:

Most of the new drugs permitted during the last five years are still covered by the patent and their formulation in India are manufactured from imported bulk drugs. The sources of such imports are mostly other than the original manufactures and are likely to dry out as a result of GATT. Their continued availability will depend upon the
vii) Impact On Research & Development:

To establish an identity in the international market, research and development activities have to be strengthened with, substantial investment by Indian firms. As a result of the availability of the patents in drugs and medicines, multinational companies potential in R&D sector, sales turnover and world-wide infrastructure for patenting and promotion of their products. Further to achieve significant performance on the basic R&D front in India, government will have to come forward in a big way to support public and private efforts on a long term basis.

viii) Future Strategies to Face New Challenges:

Now that the GATT is a reality and will come into force within agreed time-frame, the Indian companies are visualising the best possible means to encounter the situation. The more forward looking and internationally minded among them have evolved a two-fold strategy.
1. To strengthen R&D capabilities during the 10 year transitional period.

2. To enter into strategic alliance with research-based companies abroad for setting up joint ventures in India of licensing in patented new drugs.

Both the government policy of granting automatic approval for joint ventures in which foreign investment is up to 51 percent (which is applicable to the drug industry) and the new incentives being considered for total R&D should go a long way to encourage indigenous companies to adopt the future strategy.

2.11 Opportunities for Indian Pharmaceutical Industry:

Under implications of patents (Amendment) act 1999, the Indian pharmaceutical industry have following opportunities.

1) Increase in flow of technology transfer and fair direct foreign investment resulting growth of developing countries improving dissemination of knowledge at the global level.

2) Increased, resources devoted to research and development of new molecules more suited to their own needs i.e. stimulant to innovation.
3) Improvement in the welfare of the population resulting from a wider range of better quality products.

4) The end of brain drain from developing countries to industrialized countries caused by the absence of protection for their invention in their countries of origin.

5) The implementation of product patent system assumes a strong research background of the industry which can conceive and deliver newer drug molecule and sophisticated novel drug delivery system at an affordable prices.

6) Indian pharmaceutical industry must continue to upgrade its GMP standards quality system so as to meet the ever demanding requirement of the international agencies.

7) Development of superior process technologies for generic drugs, further upgradation of quality systems to meet the even more stringent requirements also to carry out research for patent worthy inventions are some of the challenges before the pharmacist.

8) India has one of the largest pool of scientific talent in a variety of disciplines related to pharmaceutical R&D, which can be harnessed for the discovery and development of new drugs including those which are specially needed for some of the endemic diseases of the developing nations.
9) Development of new drug: Drug discovery and development have to be included in the R &D strategy. In other words, the focus of R&D will have to be changed from the innovation at new process to that of invention of new product. For example Dr. Reddy's Laboratory, a leading Indian manufactures has focused its R &D expenditure on the development of new drugs for cancer, bacterial infections and diabetes. They have set up a research facility at the cost at Rs. 8 crores. However a couple of structural weaknesses have to be taken into account. First, given the small size of Indian firms, even a sharp increase in R&D activities will not generate sufficient funds for the development of new drugs. Secondly, Indian firms lack manpower and institutional mechanisms to launch new drugs successfully in the foreign market. The focus of R &D should be on:

i) The development of in-house drugs which existing in the needs of India and other tropical countries where TNCs have little or no interest in introducing drugs according to their needs.

ii) Production of indigenous drugs catering to the needs of India.

10) Production of Off-Patented Drugs: A realistic assumption is that in near future, all patent drugs will emerge as one of the important manufacturing activities of Indian pharmaceutical firms. Off-patent
(generic) drugs made by Indian firms are going to meet most of the domestic demand. With increasing concentration of Indian firms in generic drugs, its export prospect is very high. Currently the world market for generic drug is $20 bn. and expected to grow to 40 bn. by 2005.

In order to take this opportunity, leading Indian firms (like Ranbaxy, SOL, East India pharmaceuticals) are building their capacities to produce generic drugs. However Indian firms are going to face strong competition from other developing countries, and even some developed countries. Therefore, the long term success of Indian firms depends on improved efficiency in turns depends on Improved efficiency and exploration of new south-south market co-operation, both at the producer's and consumer's level.

11) Production of Patented Drugs Under License : Global drug development and production are undergoing structural changes in recent times. The reasons for such changes are :

a) Exponential increase in the cost of drug development.

b) shortening of product life.

c) Stiff competition from generic drugs in order to gain maximum revenue within a short period, Indian firms are
trying to get licenses from global pharma business to produce and market on-patent drugs. However, two discernible facts are worth mentioning.

i) Global pharma companies not having much stake meridian market will not hesitate to give license to Indian firm and.

ii) Companies with large subsidiaries in India (like Glaxo, Pfizer) are likely to introduce licensed drugs through their subsidiaries only.

12) Marketing of Imported drugs: Another opportunity for Indian pharma firm is marketing of imported drugs. Many Indian firms are interested in entering into long-term arrangements with global business for example, Ranbaxy has entered into an alliance with Eli Lilly.

The new and liberalised drug policy has removed import restriction from all but eight categories of drugs. The removal of import resections and proposed changes in the regime will lead to an increase in drugs import.

13) Export of patent based new molecules cleared: The ministry of health has allowed pharmaceutical companies to export new molecules, that are covered under international patents but are not licensed to be marketed in India. Permission for such export had
been withdrawn around eight months back on the ground that some of the drugs manufactured under this arrangement found their way into the domestic market even though they were not approved for sale in the country.

2.12 Threats to Indian Pharmaceutical Industry:

The introduction of product patenting will affect the Indian pharmaceutical industry to a large extent. Due to patents (amendment) act 1999 under TRIPS agreement Indian pharma sector may face following problems.

a) Dilution of Drug Policy & Drug Prices Increases:

The main impact may be in the price of medicines which would go up several times making it extremely difficult for poor people to afford them. If a product could be made in India before the new trade pact comes into force, the prices could be reasonably fixed for that product. Two other factors would reinforce this up-trend in prices:

i) The Indian firm will have to adopt the licensing route to introduce drugs patented by the MNC's, and such licensing agreements usually dictate the prices at which the drugs are to be sold in the market.
ii) The Indian firm may seek to compensate for the loss of the profitable process, patent route of marketing new drugs, by that may be restricted to manufacturing in the future.

Unlike consumer goods, drugs are not purchased by the preference of a person but on doctor's prescription. Consumers have no choice of their 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 floating 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. 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.
Here are prices of twelve essential drugs before the liberal decontrol at DPCO in 1995 and 1998.

Table 2.14
Prices of Important Drugs Under DPCO

<table>
<thead>
<tr>
<th>Name of the drug</th>
<th>Treatment</th>
<th>Packing</th>
<th>(Rs. Price)</th>
<th>0% Increase</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>1995</td>
<td>1998</td>
</tr>
<tr>
<td>Diazepam</td>
<td>Depression</td>
<td>10</td>
<td>3.13</td>
<td>9.50</td>
</tr>
<tr>
<td>Ampicillin</td>
<td>Antibiotic</td>
<td>4</td>
<td>12.85</td>
<td>13.15</td>
</tr>
<tr>
<td>Cephalexin</td>
<td>Antibiotic</td>
<td>10</td>
<td>45.07</td>
<td>113.15</td>
</tr>
<tr>
<td>Ethambutol</td>
<td>Anti TB</td>
<td>10</td>
<td>5.90</td>
<td>33.00</td>
</tr>
<tr>
<td>Rifampicin</td>
<td>Anti TB</td>
<td>10</td>
<td>24.00</td>
<td>64.00</td>
</tr>
<tr>
<td>Pirazinamide</td>
<td>Anti TB</td>
<td>10</td>
<td>17.01</td>
<td>46.95</td>
</tr>
<tr>
<td>Lignocaine Hcl</td>
<td>Anaesthetic</td>
<td>30ml</td>
<td>4.16</td>
<td>12.40</td>
</tr>
<tr>
<td>Promethaxin Hcl</td>
<td>Antiallergic</td>
<td>10</td>
<td>1.25</td>
<td>23.00</td>
</tr>
<tr>
<td>Antacid Liq</td>
<td>Gastritis</td>
<td>200ml</td>
<td>13.00</td>
<td>23.00</td>
</tr>
<tr>
<td>Oxyfedrine Hcl</td>
<td>Anti-angina</td>
<td>10</td>
<td>10.44</td>
<td>21.41</td>
</tr>
<tr>
<td>Discopyramid e- phosphate</td>
<td>cardiac-problems</td>
<td>10</td>
<td>16.50</td>
<td>50.46</td>
</tr>
<tr>
<td>Dipyramidole</td>
<td>Anti angina</td>
<td>10</td>
<td>2.00</td>
<td>4.73</td>
</tr>
</tbody>
</table>

(source:- Pharmatimes, nov'2000)

The above list is only indicative. Hundreds of such examples can be given. Further under the WTO[TRIPS] agreement & imposition of product patent regime the prices of all new drugs (patented ) will go up without any control at domestic law. The DPCO will become further irrelevant & Indian people's accessibility to newer drugs will be restricted only to the rich
country Below are high prices of some new drugs introduced in 1997 in the Indian market.

Table 2.15
High Prices of Some of The New Drugs Introduced in 1997 in the Indian Market

<table>
<thead>
<tr>
<th>Drug</th>
<th>Company</th>
<th>Strength</th>
<th>Packing</th>
<th>Price (Rs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sporanox</td>
<td>Ethnor</td>
<td>100 mg</td>
<td>4</td>
<td>173.00</td>
</tr>
<tr>
<td>Lumicil</td>
<td>Novartis</td>
<td>250mg</td>
<td>14</td>
<td>1247.00</td>
</tr>
<tr>
<td>Spariex</td>
<td>Sunpharma</td>
<td>200 mg</td>
<td>6</td>
<td>154.00</td>
</tr>
<tr>
<td>Rispid</td>
<td>Panacea</td>
<td>50ml</td>
<td>1</td>
<td>141.00</td>
</tr>
<tr>
<td>Livial</td>
<td>Infar</td>
<td>100ml</td>
<td>28</td>
<td>1225.00</td>
</tr>
<tr>
<td>Pipracil</td>
<td>Cyanamid</td>
<td>2ml</td>
<td>vial</td>
<td>215.78</td>
</tr>
<tr>
<td>Amate</td>
<td>Mescopharma</td>
<td>50mg</td>
<td>12</td>
<td>180.00</td>
</tr>
<tr>
<td>Adnojet</td>
<td>Inca</td>
<td>3mg</td>
<td>vial</td>
<td>210.00</td>
</tr>
<tr>
<td>Roxisara</td>
<td>Sarabhai</td>
<td>300mg</td>
<td>6</td>
<td>165.00</td>
</tr>
<tr>
<td>Celex</td>
<td>Glaxo</td>
<td>250mg</td>
<td>4</td>
<td>140.00</td>
</tr>
</tbody>
</table>

(Source-Paper of A. Guha, in the seminar held at New Delhi in May 1998)

Briefly stating increase in drug pricing takes place by imposition of product patent greatly affected by following costs.

i) Administration & enforcement costs.

ii) Increased royalty payment.

iii) Displacements of 'pirates' (denotes an economic agent riding free on the intellectual property of mother agent, irrespective of legality.)

iv) opportunity cost of increased R & D

v) Anti competitive effects (loss in consumer surplus)
b) **Mass Ending of Jobs:**

With the reduction of custom duties on foreign imports many drugs manufactured in India have become unviable compared to the foreign goods in the Indian market. As a result of this, the owner of factories are closing down their units and throwing the workers out of employment. M/s Boehringer Mannheim and Parke Davis who were the lone producers of chloramphenicol in India stopped their production as its prices in the international market were cheaper than the cost of product in India. M/s Sarabhai chemicals closed down their vitamin 'c' plant for a similar reason.

**Table 2.16**

<table>
<thead>
<tr>
<th>Company</th>
<th>Year</th>
<th>Reduction of work force</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glaxo</td>
<td>1995</td>
<td>1564</td>
</tr>
<tr>
<td>Hoechst</td>
<td>1996</td>
<td>1049</td>
</tr>
<tr>
<td>Knoll pharma</td>
<td>1995</td>
<td>600 (all workers)</td>
</tr>
<tr>
<td>Smith kline Beecham</td>
<td>1995</td>
<td>208</td>
</tr>
<tr>
<td>E-Merck</td>
<td>1995</td>
<td>194</td>
</tr>
<tr>
<td>Rhone Poluenc</td>
<td>1996</td>
<td>700</td>
</tr>
<tr>
<td>Hindustan Ciba Geiqy</td>
<td>1993</td>
<td>907</td>
</tr>
<tr>
<td>Duphar interfan</td>
<td>1996</td>
<td>154</td>
</tr>
<tr>
<td>Bayer</td>
<td>1996</td>
<td>590</td>
</tr>
<tr>
<td>Abbott</td>
<td>1996</td>
<td>370 (all workers)</td>
</tr>
<tr>
<td>Roche</td>
<td>1996</td>
<td>320 (all workers)</td>
</tr>
<tr>
<td>Boehringer mannheimium</td>
<td>1997</td>
<td>325</td>
</tr>
<tr>
<td>Parke Davis</td>
<td>1997</td>
<td>650</td>
</tr>
<tr>
<td>Pfizer</td>
<td>1995</td>
<td>215</td>
</tr>
<tr>
<td>Unichem</td>
<td>1997</td>
<td>328</td>
</tr>
</tbody>
</table>

(Source: Annual reports of respective companies and interaction with the office bearers of unions)
Thus, the total payment on voluntary retirement schemes by firms (MNC'S and Indian private sector) are more than Rs.200 crores in the last three financial years.

c) **Impact on public sector:**

With the reduced role of the state under globalisation and new product patent regime, the public sector drug companies are faced with serious problems including imminent closures. Public sector drug companies like Indian drugs and pharmaceutical ltd.(IDPL), Hindustan Antibiotics Ltd.[HAL], Bengal chemicals and pharmaceuticals ltd. (BCPL), Bengal immunity (BT) & Smith Stainistreet pharmaceuticals ltd (SSPL) played an important role in the production of essential drugs at an affordable prices. Under the globalisation process, the role of the public sector has been marginalised & they have been made sick with the pharmaceutical industry taking a leap towards biotechnology development worldwide, only the public sector drug companies with the backing of the Control government could have faced the challenge effectively from the MN's in the new situation.

d) **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 cyanamide, SKB with sterling, Rhone poulenc took over Fashions. BSF with boots, Glaxo with Burroughs welcome, Ciba giegy with Sandoz, Warmer Hindustan with Parka Davis, Hoechst with Rhone Poulenc etc, are some of the examples of big takeovers by merger and acquisitions. These companies become even larger with more financial power at the disposal over their competitors. Given below some top pharma company merger in the world with their financial Value, step towards capturing Indian pharmaceutical market.

Table 2.17
Some Top Pharma Company Merger in the World

<table>
<thead>
<tr>
<th>Company</th>
<th>Merger</th>
<th>Year</th>
<th>Value of merged company</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dow chemicals</td>
<td>Maxion labs</td>
<td>1986</td>
<td>6.21 bn</td>
</tr>
<tr>
<td>Bristol Mayers</td>
<td>Squibb corp</td>
<td>1989</td>
<td>12.09 bn</td>
</tr>
<tr>
<td>Beecham group</td>
<td>Smithkline &amp; French</td>
<td>1989</td>
<td>7.9 bn</td>
</tr>
<tr>
<td>American home product</td>
<td>American Cyanamid</td>
<td>1994</td>
<td>9.7 bn</td>
</tr>
<tr>
<td>Hoffinan La Roche</td>
<td>Syntex lab</td>
<td>1994</td>
<td>5.3 bn</td>
</tr>
<tr>
<td>Illy lily</td>
<td>pcs Health system</td>
<td>1994</td>
<td>4 bn</td>
</tr>
<tr>
<td>Sandoz</td>
<td>Gerber</td>
<td>1994</td>
<td>3.7 bn</td>
</tr>
<tr>
<td>Astra</td>
<td>Zeneca</td>
<td>1998</td>
<td>67 bn</td>
</tr>
<tr>
<td>Hoechst A.G.</td>
<td>Rhone Poulenc</td>
<td>1998</td>
<td>11 bn</td>
</tr>
</tbody>
</table>

(source:- Pharma Times, Nov '2000)

In the coming days, with the help of international financial companies the MNCs will capture and take control of Indian
companies to control the Indian market by international mergers and take over. Indian companies are adopting the same path, for example, Wockhard 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 number of workers are declared surplus.

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 Pfimex and SOL pharma.

Thus, through the process of mergers & acquisition 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.

**e) Options for the Government:**

Indian government had amended the existing patents act 1970 to meet immediate requirement of allowing filling of products patent applications and applications for exclusive marketing rights.
The present government as well as many political parties has been for far too long obsessed with the idea of a world without monopoly in the area of drugs even if it is for a short period.

While the filing of a product patent by itself is not of any great consequence of this point in time as they would be taken up for prosecution only after January 1, 2005 the more sensitive issue is the one related to the grant of EMR. It is true that EMR is a backdoor alternative to a patent, since it provides protection exclusivity.

In a way, it is worse than the monopoly granted by a patent, since under EMR, protection is granted without any guarantee of a valid patent, as the corresponding patent application has not been examined. However, the conditions required to be satisfied for an EMR are rather stringent and are subject to scrutiny by our regulatory agencies. Their conditions are:

i) A corresponding patent should have been issued in a member country.

ii) The product should have been cleared for marketing by the respective regulatory agency of that country.

iii) The drug controller of India should give marketing permission based on pre-clinical and clinical documentation and further clinical trials.
iv) An application for EMR should have been filed after satisfying the first three conditions.

In reality the EMR provisions under the TRIPS norms are indeed only a paper tiger for the simple reason that the time frame required to satisfy all the prerequisites would be eight to ten years. Since the provisions apply only for patents filled after January 1, 1975 it is unlikely any EMR application can be filled in India before 2003.

Even then it would take at least two years for Drug controller General of India to fully evaluate the application after gathering. Additional information based on clinical trials. Issues of high priority are:

i) The need for a further dialogue with the WTO on the question of allowing an equitable compulsory licensing system.

ii) Clarity on protection of microbiological and biotechnological inventions.

iii) Legislation on geographical indications.

iv) Protection, through new and appropriate legislation at the biodiversity assets of India.
Intellectual property protection should be defined in the broadest context of our national assets and interests, and the time has come for our leaders to take proactive and innovative role, rather than being reactive and defensive when confronted with international treaties and agreements, which are not always to our likings.

Broadly the government of India has two options:

i) Introduce an effective regulatory mechanism for "checks and balances" on the availability access and prices of essential drugs and

ii) Develop research facilities for the introduction of new drug catering to the needs of the country.

f) **Impact on Medium and Small Scale Sector:**

The existing industry, particularly in the medium and small scale sector will over a period of a decade or so after the introduction of new patent regime face serious degrowth, as they will have no possibility of taking up new products. Even for the existing products or process new patents will be taken, creating difficulties for companies to market their existing products.

The small players, which have been making copies, fear that they will not have sufficient capital or technology to invent new
drugs that can be patented. As a result they feel the market will be polarized in favour of foreign multinationals. The larger times on the other hand, are in full support of patents, which they hope will attract foreign investment, and there by stimulate Joint ventures and research.

**g) Impact of De-licensing and Tariff Reduction:**

De-licensing and tariff reduction have had a major impact on Indian drug industry. On the other hand drug manufacturers are now free to manufacture and export any quantity of drugs, but on the other hand they are being hit by foreign competition. Production cost remain high in India for power and interests rate (at 18%) Therefore, the incentive to import drug is greater than to manufacture domestically. Small producers are importing the raw materials and merely formulating the drug locally. As a result, local manufacturers are unable to compete with the influx of cheaper imports. The small players are struggling to survive without protection. The industry is being forced to increase productivity and lower production costs.

The result is that the small scale units have slowed down production & diversified into non-pharmaceutical products and those are not under price control.
h) **Impact of patent protection:**

The indigenous capability will be hit hard. Consumers will have to pay higher prices. The infrastructure created by local industry will remain unutilized, local production will be confined to making age old drugs, denying the benefits of new drugs and innovations. Local producers will have to wait for 20 years for the patent to expire on a new drugs before they can start to manufacture it by which time a new drug in the market will probably undermines its value. India will revert back to pre-1970 Scenario where everything was being imported. Today while India is under increasing pressure to provide market access to foreign companies, India can't export its drug to Western market due to non tariffs barriers in the form of social and environmental regulations. This is undermining India's comparative advantage by way of lower prices. Recently the Europe threatened to impose countervailing duties on Indian drug exports because they were cheaper than locally produced drugs. Thus, while our generic drugs are subjected to non tariffs barriers, our consumers will be hit by higher prices for new drugs.