Chapter - VII

SWOT ANALYSIS OF PROSPECTS OF INDIAN PHARMA INDUSTRY
DURING TRIPS AND WTO REGIME

The Indian pharma industry is highly regulated in respect of a) Patents
b) Price and c) Product Quality, by drug price control orders, drugs and
cosmetics acts and the Indian Patents Acts.

The legal framework is such that strengths of the industry have been boosted,
imperfections mitigated and to reduce the threats and cash in on the
opportunities

7.1 Strengths of the Indian pharma industry

- Cost competitiveness, well developed and strong manufacturing base
- Access to pool of highly trained scientists
- Strong marketing and distribution network.
- Rich biodiversity
- Competencies in bio-chemistry and process development of generic
drugs efficiency in reengineering of world class patented medicines by
their original efforts of modifications in their processes

Weaknesses

- Low investments in innovative R & D due to constraints of capital and
resources to compete with MNCs for new drug discovery research and
to commercialize molecules on a world wide basis.
- Lack of strong linkages between industry and academia
- Low medical expenditure and health care spend in the country
- Production of spurious and low quality drugs to a certain extent
tarnishes the image and the reputation of industry at home and
abroad126

126 FICCI - Report on Indian Pharma Industry 2004 Page -10
7.2 WTO membership and its impact

The WTO which is a multilateral trading body, is a polished sword in the scabbard of the industrialised nations for organizing and enforcing global trading governance. Being a member country, India is bound by the trade agreement and policies set out in the charter of the world trade organisation. India has adopted process patent rules directed by WTO to adopt product patent as per the rule of TRIPS\textsuperscript{127}

India has been asked to amend its IPA (Patents Act) to allow product patent instead of process patent. Trade cross retaliation is one prime problem that India will have to encounter, if it does not comply with the specified regulations.

Pre-WTO scenario (prior to 2005) is characterised by rapid consolidation, acquisitions, mergers, extensive copying of patented drugs and the preemptive strengthening of Indian pharma companies to thwart the entry of foreign manufacturers.

On the other hand, the post-WTO scenario is likely to be characterised by soaring drug prices, intense competition, new drug discovery and introduction of foreign drugs into Indian markets, large expenditures on R & D, large scale contract manufacturing, assignments of conducting clinical trials, large scale downsizing and acquisitions and mergers of Indian companies with giant MNCs.

Article 8 and Article 30 of the TRIPS Agreement after 2005, provide some relief to the Indian policy makers. The government with a proactive approach would be able to take full advantage of the lenient provisions set out in the recent TRIPS Agreement.

The opportunities which are open to the new Trips agreement are

\textsuperscript{127} Malla P. Bhasa - WTO & Indian Pharma Industry a study - Infosys Tech, Ltd. Bangalore - SSRN Journal - www.ssrn.com
1) Collaborative research
2) Contract research,
3) Raising research and development expenditure,
4) Developing and exporting of drugs and
5) Manufacturing through licensing by outsourcing contracts to the Indian pharma industry.\(^{126}\)

The contentious issues revolve around compulsory licensing provisions, ceiling products under patents and EMRs (Exclusive Market Rights) making products with the world license.

After 1995 there was a sharp rise in the sealing of patents in India both by Indian and foreign applicants. The number of patent filings that averaged around 3500 per annum had gone up to 10155 filings in 1998, out of which 8229 filings are of foreign applicants.\(^{129}\)

U.S., Japan, Germany, UK and France have contributed approx 74 percent of the total foreign filings in India. Most of the filings were for inventions in drugs and pharmaceuticals.\(^{130}\)

In the last five years that is 1995 to 2002 several foreign drugs and pharma companies like Novo, Nordisk, Chiron cph, pharma NV, Hoechst M Russel, Merck, Vertex Smithkline, Astra A, Ciba-Geigy, Genentech, Eli Lilly, Dupant de Nemours, BASF, Zenca, Rhone- poulene etc have significantly contributed to the patent numbers in India.
Indian pharma companies have initiated focused research and development in their establishments. Notable investments have been made by Ranbaxy, Dr. Reddy's lab, Rallis Indica, Cipla, Wockhardt, Lupin Lab, Dabur Research Foundation, J. B. Pharma, Sun pharma, Kopran, Morepen lab, Nicholas Piramal, (which bought R & D Center from Hoechst) Panacea Biotech, Raptakos Bvett and company and Tablets India ltd.

Purely Indian institutions such as National Institute of Immunology, Osmania University, Hindustan Antibiotics, IIT, Themis chemicals, Sree Chitra Institute of medical science, Tropical Botanic Garden research institute, CSIR have also initiated patent filings in the drug and pharma areas for processes such as anti inflammatory agents, analgesics, contraceptive, cardiovascular, anti cancer, herbal and ayurvedic medicines etc.\textsuperscript{131}

\textsuperscript{131} Dr. P. Ganguli - Intellectual property rights and pharma industry saket handbook page 113
7.3 Success stories of Indian pharma patents

Cipla has secured an international patent for an umniprazole formulation in the US, Europe, Australia and South Africa. Bioved pharma has been granted a US talent right for its product Artex for control of astha, lower back pain, joint pain etc. Artex is India's first Ayurvedic drug to get the US patent. It can also control other inflammatory disorders. Sidmach Lab of US has approved 15 Wockhardt's novel drug delivery system products and bulk drugs. Ranbaxy's antacid Ranitidine 75 mg has received an international patent. Morepan Labs Claritine has been approved by the US FD Administration. Glaxo India and Ranbaxy have signed an agreement for co-marketing in India and Nepal, an advanced dosage of Cephalexin Ranbaxy is likely to get an international patent for the same. Dr. Reddy's Lab got $4.25 million from Novo Nordisk of Denmark for its anti-diabetes drug DRF 2593. Reddy Lab's Antilles, DRLs 100 percent subsidiary in the US has got global patents for its drugs. Zydus Group of Germany has setup a 100 percent export oriented unit to manufacture and marketing formulations of Indian origin. Thus Indian companies find that infinitely large number of opportunities are open to them due to the TRIPS regime, rather than a few threats, which can be tackled easily.

Table 7.1: Patents filed and granted in food and general

<table>
<thead>
<tr>
<th>Item</th>
<th>1986-87</th>
<th>94-95</th>
<th>97-98</th>
</tr>
</thead>
<tbody>
<tr>
<td>Foods</td>
<td>34</td>
<td>125</td>
<td>112</td>
</tr>
<tr>
<td>Foods gen</td>
<td>21</td>
<td>49</td>
<td>58</td>
</tr>
<tr>
<td>General Filings</td>
<td>579</td>
<td>1030</td>
<td>2317</td>
</tr>
<tr>
<td>General gradations</td>
<td>448</td>
<td>450</td>
<td>434</td>
</tr>
</tbody>
</table>

(This is a quote which has its limit upto 97-98)

During post 1995 period, of about 13 years Indian food processing and pharma companies have obtained thousands of dollars by patents, on the basis of merit.
Corporate houses started restructuring their businesses and acquired technical expertise by collaborations, mergers and acquisitions, totaling about 426132

Contract research got deals with $3.9 billion and it has got in at a rate of 20 to 30 percent per annum and the big companies have managed IPR protection to small pharma companies in India. Novartis will get approval to the 40 percent of the discoveries made by University of Perkeley's college of natural resources. Sandoz got patent rights to all scripps discoveries. Bayer got advantage of Euoppen patent to its "Quinoxalin" - useful for HIV patents. Marketed into collaboration with Isis pharma to treat patients infected with Hepatitis C. Similarly Eli Lilly, Protein Design lab, Bristol Meyer, Squibbs have offered their patent rights for the manufactured drugs by their subsidiary firms in India.

After 2005 a large number of global drugs are going off patent as per the provisions of WTO. India will get many advantages to increase its worldwide sales

Table 7.2 : Value of drugs expiring from 1999 - 2005

<table>
<thead>
<tr>
<th>Year of expiry</th>
<th>Number of off patent drugs</th>
<th>World wide sales in 1999 of best selling drugs $ billion</th>
</tr>
</thead>
<tbody>
<tr>
<td>1999</td>
<td>4</td>
<td>1.76</td>
</tr>
<tr>
<td>2000</td>
<td>9</td>
<td>8.6</td>
</tr>
<tr>
<td>2001</td>
<td>9</td>
<td>11.5</td>
</tr>
<tr>
<td>2002</td>
<td>7</td>
<td>5.6</td>
</tr>
<tr>
<td>2003</td>
<td>4</td>
<td>2.9</td>
</tr>
<tr>
<td>2004</td>
<td>8</td>
<td>6.5</td>
</tr>
<tr>
<td>2005</td>
<td>10</td>
<td>11.8</td>
</tr>
</tbody>
</table>

Source : D. P. Ganguli - IP fights and pharma industry - Saket pharma handbook, 1998 p.119
7.4 Indian pharma industry and effects of the WTO regime

The Indian pharma industry is valued at Rs.11000 crore and has seen growth rates of 15 to 20 percent consistently since 1995. Generics account for 60 to 80 percent of the total sales. Only 30 percent of the Indian pharma companies rely on allopathic medicines. With every one percent rise in the GDP there should be a corresponding 1.40 percent increase in health expenditure (Dubey's research 1998)

There are about 6000 companies in the small sector, which constitute the unorganised sector (The Economic Times 1995). Due to rise in urban population from 18 percent in 1960 to 27 percent in 1992 and more than 30 percent in past 2000, R & D market has received biggest growth stimulus.

However the per capita consumption of drugs in India being Rs.42 per annum is one of the lowest in the world (Kothari 1997) India produces 350 out of the 500 bulk drugs consumed in India, thereby meeting 70 percent of its bulk drugs requirement and produces 20000 different formulations for 90 percent of their needs. The growth in bulk drugs production is very high on account of increasing exports.

Most of the Indian pharma firms started in early 1960s as licensees for the products of MNCs. They took advantage of reverse engineering skills. They took manufacturing of drugs, and discovered how to manufacture them by using other processes usually the cheaper ones. Hattangadi (1998) points four factors conducive to the growth of Indian pharma industry.

They are 1) Population, 2) Penetration of infrastructure 3) Ability of people and government purchase 4) New products.

Under regulatory environment before 1995, 75 percent of drugs prices were under the control of DPCO and India mostly depended on process patents rather than product patents. After the membership of WTO, less than 50
percent drugs are under control of DPCC and import duties are reduced from 42 percent to 32 percent, product patents are also being encouraged.

After 2005 India is going to further liberalise the pharma trade and grant protection to its product patents.

Prior to the regime of WTO, the market size was of Rs.10,000 crore growing at 15 to 20 percent per annum. There were over 23000 manufacturers. During 1995 to 2005, import duties had to be reduced as per the WTO dictates. There was more active consolidation of market by advertising brand acquisition and small players going out of business by acquisitions and mergers. In post 2005 years the basis of competition has shifted to research and development and marketing.

7.5 The major policy changes introduced on Sept 15, 1994 were
1) Industrial licensing for all bulk drugs and the formulations was abolished except 5 identified bulk drugs reserved for the public sector and specific cell/tissue targeted formulations.
2) Automatic approval of foreign investments upto 51 percent has been allowed in all drugs
3) Automatic approval for foreign technology agreements
4) To keep drugs with an annual turnover of Rs.4 crore or more under price control
5) A more efficient mechanism for ensuring quality control by setup of National Drug Authority
6) A separate department for the promotion and development of Ayurvedic, Unani, Homeopathy systems of medicines, under the Ministry of Health. Since the post 1990s, the price of drugs have increased thereby increasing annual turnover, the span of control actually has increased.

---

133 Dr. Vinnie Verma - Indian pharma Industry - some issues in the coming decade - article in Saket's Pharma Hand Book Page 301 & 302
7.6 Major Issues to be confronted during WTO regime

Consolidation in the industry: There is massive fragmentation with about 23000 drug manufacturers with Top 8 players holding about 30 percent of the total market. (The Strategist Quarterly 1998) It is because there is a general deficiency of having product patents. Due to the advantage of product patents there is a worldwide trend of mergers, acquisitions and consolidation of the small units. In 1996, there was a merger between Ciba Geigy and Sandoz to the formulation of Novartis. In 1998, Glaxo and Smith K Beecham merged. Nicholas Piramal is another example of a successful merger.\textsuperscript{134}

Table 7.3: Some other acquisitions on pharma industry during 1994 to 1998

<table>
<thead>
<tr>
<th>Sr. No</th>
<th>Acquirer</th>
<th>Acquired Assets</th>
<th>Date</th>
<th>Business Gameplan</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Cynamid</td>
<td>Wyeth Labs</td>
<td>Feb 97</td>
<td>Global market</td>
</tr>
<tr>
<td>2</td>
<td>Cynamid</td>
<td>Wyeth Labs</td>
<td>Feb 97</td>
<td>Huge market share</td>
</tr>
<tr>
<td>3</td>
<td>Dabur</td>
<td>Binaca Brand</td>
<td>May 97</td>
<td>consolidation</td>
</tr>
<tr>
<td>4</td>
<td>Glaxo</td>
<td>Burroughs Wellcome</td>
<td>May 97</td>
<td>consolidation</td>
</tr>
<tr>
<td>5</td>
<td>Hoechst Marion</td>
<td>Roussel</td>
<td>May 98</td>
<td>Global market size</td>
</tr>
<tr>
<td>6</td>
<td>Johnson &amp; Johnson</td>
<td>Coldarim brand</td>
<td>Dec 97</td>
<td>To get larger market share</td>
</tr>
<tr>
<td>7</td>
<td>Nicholas Piramal</td>
<td>Roche Products</td>
<td>Aug 94</td>
<td>To get larger market share</td>
</tr>
<tr>
<td>8</td>
<td>Nicholas Piramal</td>
<td>Hoechst R &amp; D</td>
<td>April 98</td>
<td>Improve R &amp; D</td>
</tr>
<tr>
<td>9</td>
<td>Ranbaxy</td>
<td>Cross Lands Labs</td>
<td>Jan 97</td>
<td>Enter dermatologicals</td>
</tr>
<tr>
<td>10</td>
<td>Ranbaxy</td>
<td>Vorin Labs</td>
<td>Dec 96</td>
<td>Back intergradations</td>
</tr>
<tr>
<td>11</td>
<td>Reckitt &amp; Colman</td>
<td>Burnol brand</td>
<td>Dec 97</td>
<td>Consolidation</td>
</tr>
<tr>
<td>12</td>
<td>Sandoz</td>
<td>Ciba Geigy</td>
<td>Mar 96</td>
<td>Global market</td>
</tr>
<tr>
<td>13</td>
<td>Sun Pharma</td>
<td>Gujrat Lyker</td>
<td>Sept 96</td>
<td>Back intergradations</td>
</tr>
<tr>
<td>14</td>
<td>Wockhardt</td>
<td>Merind</td>
<td>Feb 89</td>
<td>Increased market</td>
</tr>
</tbody>
</table>


\textsuperscript{134} Dr. V. Verma - Indian Pharma Industry some issues - Sakets pharma hand book page 304 and 305
7.7 Emphasis on R and D

After 2005, Indian companies were compelled to move from 'process to move from product patents' in drugs due to the dictates of TRIPS. Dr. Reddy's Lab raised its R & D budget to Rs.36 crore in 2005, from Rs.7.2 crore in 1997. (2 percent of its turnover) Ranbaxy started spending Rs.50 crore (about 4 percent of its turnover) on research of patented medicines.

New drugs introduction (NDI) is a very expensive activity and Indian companies will not be able to afford adequate resources in competition with mighty MNCs. The average cost of one NDI is about $ 400 million and this amount can be recovered only after 10 to 12 years.\[35\]

Recently Pfizer spent US $ 2 billion per annum for 150 discovery products. Glaxo - welcome spent US $2 billion per annum for 93 discovery products. In competition to the US MNCs, these investments seem to be very poor and inadequate. Because of the capital deficiency Indian companies will be compelled to go in for strategic alliances by taking advantages of huge scientific pool of manpower and scientists and comparative cost advantages of low labour costs. The other option is to take contracts of clinical tests. The third option is to develop analogue molecules or superior versions of existing drugs. The fourth option is to take contracts from MNCs of finding out process development skills and Novel Drug Delivery System (NDDS)

Another splendid opportunity is that by 2003 Human Genome Project which will map all the 60 to 80000 genes in the human body will be through and science of using genetic information to predict a person's in disposition to a particular disease, will become full-fledged and an era of predictive medicine will abate a global market of US $ 50 millions (Rs.6,45,000 Cr.) by the year 2005-06.
Indian companies should take benefits of acquiring international accreditations of quality of these products.

These is need to identify a suitable strategy to face an intense global competition in the coming decades. Strategic alliances with MNCs will be just mandatory.\textsuperscript{136}

7.8 The effect of changing Intellectual property regulation on Pharma Industries of India and China\textsuperscript{137}

To meet obligations under the Agreement on TRIPS, China enacted regulation in 2002 extending pharma patents to 20 years and data exclusivity for six years and India amended its Patent Law of 1970 in 2005 by accepting the directives of WTO regarding product patents.

There were two probable threats viz likely displacements of Indian and Chinese firms by the entry of the MNCs in their domestic market by likelihood of the end of the supply of low priced medicines and sudden escalation of the average price level of the drugs and medicine in both India and China.

The introduction of product patents means that Indian firms would have reduced revenue options for the scale of drugs domestically, since generic copies of newer drugs would become illegal. To compensate for this revenue loss, Indian firms were forced to increase their exports to the more profitable regulated markets as evidenced by the large concentrator of FDA approved manufacturing plans. (More than any other country besides the U.S. numbering 60) During the last 18 years of WTO regime, Indian pharma industry has witnessed a large amount of revolutionary changes of

\textsuperscript{136} Dr. Vinnie Verma - Indian Pharma Industry - some issues - Saket pharma Handbook ed 2000 page 308 Seen and used other references


\textsuperscript{137} Cheri Grace - The effect of changing intellectual property on Pharma industries of India and China - DFID Health Systems Resource Centre - June 2004
consolidation, mergers, acquisition, concentration and extinction of very small individual pharma units. The bigger firms have become richer and smaller firms have become poorer. The share of the entire domestic pharma market controlled by the big firms has become greater. The bigger firms have increased focus on product innovation. Research and Development for introduction of new products, getting business outsourcing contracts from the MNCs and they have shown special interest in obtaining markets in developed countries, with a view to raise their total earnings by taking advantage of high prices of medicines in the advanced world.

The pharma giant companies from the developed countries are keen to take full advantage of China as one of the lowest cost source of pharmaceutical ingredients.

Low priced / high volume domestic markets have been and are likely to remain relatively more attractive to Indian Chinese and Brazilian pharma firms; given their existing network and expertise in there markets. The good news is that the availability and pricing of approx 90 percent of medicines in India and China including most the WHO model list of essential medicines should not be affected by the introduction of product patents. Enhanced IP has certainly encouraged increased development of new medicines.

The domestic pharma market in India is worth approximately $4.3 billion 75 percent of which supplied by Indian firms and the remainder by MNCs. In 2002 China's domestic market was worth approx $6 billion and IMS health projects and market growth of 18 percent per annum to $ 10 billion by 2005. This makes China the world's Tenth largest market, ranking just after Canada and Mexico. Chinese firms produce about 70 percent of the domestic requirement of medicines.

---

138 IMS data for May 2003 - May 2004
139 Goldman Sechs 2004
140 Morgan Stanley 2004
China is the second largest producer of pharma ingredients in the world, with an annual output of 81 lakh tonnes in 2003. Chinese firms rank first in the world in the production of five pharma chemicals viz penicillin (28000 tonnes or 60% of the world total) Vitamin C (98000 tonnes of which 54000 tonnes) are sold abroad, terramycin (10000 tonnes 65% of the world total) and doxycycline / hydrochloride\textsuperscript{141}.

India's total production is worth $ 7.3 billion which is approx. 1.5 percent of the global pharma market of $ 480 billion but in terms of volume is estimated at more than 20 percent of global consumption\textsuperscript{142}. The large difference between value and volume comes about due to the high volume, low priced segment of the global market 44 percent of the total Indian exports, are sent to highly regulated market of US, Europe, Japan and Australia and remaining 56 percent are exported to less regulated market of developing countries\textsuperscript{143}.

The government and pharma organizations of Thailand get 90 percent of its raw materials for ARV production from India\textsuperscript{144}. The three South African producers capable of making ARVs get 100 percent of their raw materials from India\textsuperscript{145}.

Raw material supply from India and China also dominates the Brazilian ARV market\textsuperscript{146,147}. Indian ARV supply in Malawi and Kenya is crucial and Indian firms are major suppliers of EPI vaccines (Expanded Programmes on Immunization) to UNICEF and recently developed novel Hepatitis B vaccine\textsuperscript{148}. Approximately 9 lakh people are currently on ARV therapy world wide, out of which 5 lakh belong to developed countries. Indian firms currently supply medicines to about 40 percent of the global patients\textsuperscript{149}. Indian firms

\textsuperscript{141} Pharmaceutical business news 2004
\textsuperscript{142} Goldman Sachs 2004 page 1
\textsuperscript{143} Pharma Business News 2004
\textsuperscript{144} Achava Eksaengsri - Dy. Director Govt. Pharma Org. Thailand personal communication
\textsuperscript{145} Stavros Nicoaus - Dir Aspen Phamaçare S Africa
\textsuperscript{146} Golden Sachs 2004
\textsuperscript{147} ARV = Antiretroviral treatment
\textsuperscript{148} The lancet 2004
\textsuperscript{149} http://www.arert.org/aidsdrugs/africa2.htm
have got a wider access reaching product segments that treat diseases prevalent in poor countries.

There have been strong negotiations at government level with patent originators. Therefore, annual price for triple therapy has come down from 10,000 to 350 in a single year e.g. in Brazil ARV prices came down by 8290 times within five years of 21st century by successfully launching 'local generic production'\textsuperscript{150}.

The governments normally squeeze price of medicines from public welfare consideration, therefore MNCs will have to offer lower prices, so as to reduce their costs if they want to maintain profitability. Subcontracting to lower cost firms in India, is one way to achieve the lower cost. As per the WTO resolution a large number of patent expiries between 2005 to 2007 will create further opportunities for countries like India. About $60 billion worth block busters will open legitimate generic competition, India being strong in reverse engineering and production of generics is bound to have the advantage of sales growth of its pharma products\textsuperscript{151}.

The cost of research and development has also been escalating in the US and Europe. Despite doubling of research and development expenditure between 1995 and 2002 American FDA approved only 17 NCEs in 2002, as against 56 NCEs approved during 1980 to 1996. This implies that MNCs will need to find ways to increase their R & D productivity by assigning through joint partnerships with firms in India, China, Brazil, etc, which are emerging countries in the global pharma industry. India has proven skills in product and process development therefore it has a special advantage in competition among prospective developing nations. India also has a large pool of scientific manpower available at low cost and has large domestic demand for its sustainable growth.

\textsuperscript{150} Cheri Grace - DFID - June 2004 - page 15
\textsuperscript{151} Cheri Grace - DFID - June 2004 p.16
As of 1999 the Indian pharma industry accounted for 70 percent of the bulk drugs and 80 percent of the formulations, making the country self-sufficient in drugs. The industry is highly fragmented, no single company has more than 7 percent market share and the largest five companies account for just 20 percent of the total market. Indian pharma industry therefore has very intense competition among about 6000 firms. Most of them have launched funding, very popular brand medicines of their own and solid funding due to good profit percentage.

7.9 Cost advantage of Indian firms

1. Indian pharma firms have lower costs - estimated to be 1/8th in Research and Development and to one fifth in manufacturing compared to western firms.
2. Civil construction is $8 to $12 per sq.ft. v/s $75 in the U.S. material costs used for reactors resells and other equipment is also much lower. Therefore Indian firms have to incur comparatively lower costs.
3. The cost of an Indian lab analyst/chemist is 1/5th to 1/8th of the U.S. cost. Higher-level scientists have three times less salaries than their western counterparts.
4. Indian companies are extremely proficient in speedy generic drug development. Therefore more productive per unit of cost. They have highly efficient cost structure for bulk actives.
5. Clinical study costs in India, compared to US are ten times less.
6. Cost of sales representatives is also very low being $4000 per year, which again roughly is ten times less than the average salary of sales representatives in US.

7.10 IP as a driver of change

As per the dictates of the WTO the Indian government has amended its Patent Law of 1970 and has endorsed the serious importance of the Product Patents since 2005. This is certainly going to radically change the status of

---

152 Annual report, Department of Chemicals 1999
153 Adapted from J P Morgan 2003
the Indian pharma Industry. The age old traditional strategy of copying on patent drugs will no longer be allowed. They will consequently need to look towards export market and focus on product innovation, either by competing or cooperating with the MNCs.

**Strategic choice for Indian Firms**

Compete and / or cooperate?[^154]

<table>
<thead>
<tr>
<th>Product Innovation</th>
<th>High</th>
<th>Low</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specialty generics or NCEs targeted towards traditional markets</td>
<td>Vanilla generics targeted towards traditional markets</td>
<td></td>
</tr>
<tr>
<td>Specialty generics or NCEs targeted towards traditional and new markets</td>
<td>Vanilla generics targeted towards traditional and new markets</td>
<td></td>
</tr>
</tbody>
</table>

Narrow  ——— World wide market scope ——— Wide

<table>
<thead>
<tr>
<th>Compete</th>
<th>Co-operate</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Plain vanilla and specialty generics</td>
<td>• Provide contract manual for MNCs</td>
</tr>
<tr>
<td>• Develop lower risk NDAs</td>
<td>• Supply API to MNCs</td>
</tr>
<tr>
<td>• Develop follow - on biologics</td>
<td>• Partner with MNCs for their sales</td>
</tr>
<tr>
<td>• Challenge IPRs on regulated markets</td>
<td>• Provide clinical outsourcing</td>
</tr>
<tr>
<td>• Invest in research and development for proprietary NCEs</td>
<td>• Research and Development collaboration</td>
</tr>
</tbody>
</table>

[^154]: Cheri Grace DFID Health Systems Resource Centre 2004 page 19.
7.11 Compulsions of changing strategies due to TRIPS

1. Some Indian firms have adopted multi stage strategy of moving up the product value chain and increasing exports to regulated markets. Leveraging these comparative cost advantage, these firms can plan to target plain vanilla generics sales in the short term and to develop more difficult to manufacture generics such as injectables, lower risk NDAs and follow on biologics in the medium term. In the last stage they will enter into the area of product patented innovative drugs.

2. India has a large concentration of FDA approved manufacturing plans next to US, numbering 60. During 1998 to 2003, India’s pharma exports have increased by 40 percent and there is a stable role of export growth of about 12 percent per annum.

3. Indian companies have started acquiring European firms targeting the regulated markets of France, Italy and Spain.

7.12 Moving up to the product value chain

About $600 billion worth of blockbusters will open up to legitimate generic competition with effect from 2005 onwards and Indian firms who have core competency in this field, are expected to get opportunities of supplying generic versions of the blockbusters.

Moving up the product value chain refers to developing and marketing increasingly complex / innovative products which readily get higher prices as a premium for its quality. Cipla is the world leader in CFC free inhalers. Dr. Reddy’s and Wockhardt have their new drug delivery technologies thus there is a large scope for injectables, bio-generics and reformulated older molecules, to Indian companies.

7.13 Bio Tech, Biogenerics and Vaccines

The biotech market has grown to more than $ 9 billion in 2007 - 08, from $1/2 billion in 2004-2005. Many new companies are involved in this sector which is

\[\text{205}\]
employing about 7000 persons per annum. The sectoral annual growth rate is 25 percent per annum.

7.14 Indian ranks third in Asia in terms of biotech patent filings. The bio tech sector is more developed on the generics side with five main Indian companies advanced in this area viz. Biocon, Wockhardt, Shanta Biotech, Panaceabio and Bharat Biotech. Labour and land costs for these firms are significantly below those of their western counterparts and the time to set up a manufacturing plant in India is about 1 to 1.5 years and compared to 2-3 years in the west. Therefore Santa Biotech has quoted ex-U.S. prices for insulin at $110,000 kg compared to $55000 kg for insulin manufactured in India. There are still technical and regulatory barriers in exporting bio generics to the regulated markets of western countries.

7.15 Vaccine manufacturing
Many MNCs have pulled out of the low margin vaccine business, the number of players has shrunk from 26 in 1967 to 8 in 1996 and finally to 4 players in 2003 (Mercer Mg Report 2002) India has vast scope to enter into this line. At present 60 percent UNICEF requirement for immunisation vaccines are being fulfilled by India, Indonesia, Cuba and Brazil.

The Serum Institute of India is the world's largest manufacturer of DPT vaccines (Mercu Mg Report 2002)

7.16 Vaccine and R & D
India is quickly becoming a global leader in new vaccine development, due to abundance of natural and human resources. The Rota-viral vaccine has been released about 4 to 6 months ago and is being administrated to infants, below 5 months of age. The formulations of combination vaccines offering protection against influenza, hepatitis B and DPT are in clinical trials. Dengue vaccine is being developed under the Indo-US partnership. Vaccine for
HIV/AIDS was also developed by ICMR (Indian Council of Medical Research) and the International AIDS vaccine initiative Indian scientists have developed vaccine against malaria. Once the FDA of US and European Medicines Agency approve the vaccines a vast scope for Indian vaccine exports will be possible.

India's drug outsourcing market is at $470 million, it is expected to grow 30 percent per year hitting $800 million by 2005 and more than $1.5 billion by 2010. India produces about 1.25 lakhs chemists and chemical engineers each year, who traditionally find jobs in Reverse Engineering Activities involved in pharma industry.

7.17 Clinical trials opportunities
Clinical trials in India are cheaper (almost 1/3rd of the cost of western companies) because Indian companies can hire services of researchers, nurses and computer staff at less than a third of western wages. Clinical costs in India are estimated to be 30 to 50 percent lower than those in the West. Indian companies can supply intermediates of the quality standards to major MNCs. Bharat biotech has got contract manufacturing of HI6TITER vaccine. Ranbaxy, Nicholas Piramal, Dr. Reddy's Lab, Dabur and many other have got contracts of manufacturing partnership.

7.18 Risks and competitive threats due to TRIPS and WTO resolutions
Indian firms have weaknesses and threats which are as follows:

1. Indian companies are relatively new in regulated market and have no experience to manage large product promotion, entailing regulatory filings, fostering alliances and legal skills to win on patent litigations.

2. US based generics companies such as Watson, Ivax and Apotex have secured manufacturing agreements with Indian bulk manufacturers.

158 Ibid - DFID Health Systems Resource Centre 2004 - p 26
therefore, in the medium term the cost advantages can be enjoyed by the fully integrated Indian companies like Dr. Reddy's, Ranbaxy and Sun etc.

3. The impending declaration in patent expiries post 2007 present another right to Indian firms.

4. There is the reputation risk that the entire industry will face if one player cuts corners with regard to GLP/GMP patents.

5. Indian firms have a shortage of skills in the area of patent writing.

6. There is a risk of protectionism in developed markets since there will be problems of retrenchment and unemployment in US and EU economies.

7.19 Implications of radical changes in Indian pharma industries

Due to the mighty competition of western MNCs, 22,000 small units operating in the unregulated sectors, are likely to experience financial stress over the next few years, culminating in market exit of the less competitive firms and resulting in a more consolidated market structure. Western patent holders can give from increased sales to the large domestic Indian market of 300 million middle class people in India, which is larger than its own domestic market.

7.20 Prospects for Indian pharma firms and access to world class market circle

The Indian pharma industry has been an important supplier domestically and to the less regulated markets of Africa, Asia, and Latin America. Due to acceptance of international Patent Law in 2005 and the growing capacity of the Industry Indian firms are expected to become a major participant in the global market place including the regulated markets of US and EU. Indian companies have started developing new drug delivery systems or alternative formulations of existing molecules and novel products of research and development.
It is also likely that Indian firms serving their traditional low priced - high volume markets may increasingly focus on the more lucrative markets in the West; however this concern is unwarranted. The reason is Indian firms will not like to lose their established traditional market and will simultaneously try to secure western market by matching incremental investments without losing their core competency. Moreover, western MNCs may obviously not be interested in low priced Indian market.

**Categories of potential IP impact in India**

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Box A</td>
<td>Box B</td>
<td>Box A</td>
</tr>
<tr>
<td>It is legal for generic companies to continue to market generic version of the originator’s products in India or to introduce new generics</td>
<td>It is not yet known whether other generic companies can market generic various of the originator’s products in India</td>
<td>It is illegal for generic companies to market their generic versions of the originator’s products in India</td>
</tr>
</tbody>
</table>

Most first line ARVs fit in this category

Some second time ARVs and important cancer drugs that fit into this category

**Price increases of the non patented segment (90 to 95 % of market)**

The patented segment in the Indian market happens to be only 10.9 percent of the total sales value of the top 500 pharma products in India (1993 IMC data) 95 percent of the drugs on the WHO model essential drugs list are no longer under patent protection. Therefore prices of both categories of the drugs will not be affected by the introduction of product patents in India.
The subset of products have little or no competition

<table>
<thead>
<tr>
<th>Regulated market patent status</th>
<th>Quadrant A</th>
<th>Quadrant B</th>
<th>Quadrant C</th>
<th>Quadrant D</th>
</tr>
</thead>
<tbody>
<tr>
<td>On patent</td>
<td>Price controlled via therapeutic competition</td>
<td>Price controlled via generic competition</td>
<td>Price controlled via Theraupeutic Competition</td>
<td>Price controlled via Therapeutic competition.</td>
</tr>
<tr>
<td></td>
<td>Price controls domestic purchasing power</td>
<td></td>
<td>Compulsory licensing or importing</td>
<td>Price controls domestic purchasing power</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>domestic purchasing power</td>
<td></td>
</tr>
<tr>
<td>Off patent</td>
<td>90 to 95% of drugs price controlled via generic competition</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Off patent</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

7.21 Patent status in India
QB, QA and QD positions do not pose any serious problems to Indian pharma industry. QC may disturb the 10 to 15 percent patented segment of the total Indian market price of patented product as they are likely to rise partly due to imports or partly due to consolidation of monopoly powers of Indian firms by driving out small and weak Indian firms operating in the unorganised sector.

7.22 IP and access to new medicines.
One of the advantages of introducing product patents is the increase in incentives to develop new products, thereby improving the number of new drugs to treat health problems. The world class medicines will be easily available to the upper middle class Indians who can afford to buy them. Indirectly patented regime will induce Indian pharma firms in developing research and development activities and of new products of international patent standards. The following data proves this trend.
Reported research and development expenditure by Indian pharma firms (1991 to 2000)

<table>
<thead>
<tr>
<th>Year</th>
<th>R &amp; D Expenditure</th>
</tr>
</thead>
<tbody>
<tr>
<td>1991</td>
<td>$36.5 million</td>
</tr>
<tr>
<td>1992</td>
<td>$29.4 million</td>
</tr>
<tr>
<td>1993</td>
<td>$37.0 million</td>
</tr>
<tr>
<td>1994</td>
<td>$39.8 million</td>
</tr>
<tr>
<td>1995</td>
<td>$44.6 million</td>
</tr>
<tr>
<td>1996</td>
<td>$44.5 million</td>
</tr>
<tr>
<td>1997</td>
<td>$51.5 million</td>
</tr>
<tr>
<td>1998</td>
<td>$66.0 million</td>
</tr>
<tr>
<td>1999</td>
<td>$61.2 million</td>
</tr>
<tr>
<td>2000</td>
<td>$73.6 million</td>
</tr>
</tbody>
</table>

(percent annual rise is around 1.5 to 2 percent for the decade)

Source Morgan Stanley, 2003

The Indian drug policy control order has exempted price and products in India for the next 10 years with effect from 2006 onwards. The 10 year tax holiday on income arising from research and development, has granted a stimulus to big Indian giant firms, who can afford to spend on research and development activities.

Ranbaxy, Dr. Reddy's Lab, Cipla, Sun pharma, Glaxo Smithkline, Wockhardt, Aurobindo, Cadila, Lupin, Davis Lab, Matrix Lab and Nicholas Piramal, these 12 firms have consistently raised their annual budgeted expenditure on research and development by about 3 to 8 percent of their total annual sales.

Another 112 Indian ANDA submissions were done in 2003, compared with 40 filings in 2001. The number of DMF filings by Indian companies have been steadily increasing in recent years past 2001. Nearly one half of all FDA, DMF
and ANDA applications in 2004 came from Indian firms (Golden Sachs -
pharma equity analysis)

The Indian government funded "Knowledge Partnership" (Indian drugs and
pharmaceuticals programme) are primarily concentrated on diseases like
cancer, diabetes and cardio vascular problems, as well as tropical diseases
and TB. The pharma companies focus mostly on products of the rich such as
drugs for hypertension, obesity, ulcers, etc. which can find markets in rich
countries of the western economies.

To sum up, the TRIPS and the WTO regime have opened flood gates of
unprecedented number of opportunities to the Indian pharma industry and have
created relatively lesser threats and challenges to the same.