CHAPTER –IV

PHARMACEUTICAL INDUSTRY AND PUBLIC HEALTH CONCERNS IN INDIA: AN ASSESSMENT

4.2 -THE PLAN OF PHARMACEUTICAL INDUSTRY, AND ITS ROLE AND IMPACT ON SOCIETY

The Indian Pharmaceutical Industry has come a long way from being almost non-existent in the 1970’s to being one of the largest and most advanced Pharmaceutical industries in the world. Globally, the Indian pharmaceutical industry is ranked third largest in volume terms and 10th largest in value terms. The sector is highly knowledge-based and its steady growth is positively affecting the Indian economy. The organized nature of the Indian pharmaceutical industry is attracting several companies that are finding it viable to increase their operations in the country.

The Indian pharmaceutical industry is highly fragmented with about 24,000 players (330 in the organized sector).\(^{104}\) The top ten companies make up for more than a third of the market. Indian pharma companies have a large chunk of their revenues coming from exports. While some are focusing on the generics market in the US, Europe and semi-regulated markets, others are turning their attention to custom manufacturing for innovator companies. Biopharmaceuticals is also increasingly becoming an area of interest given the complexity in manufacture and limited competition.

\(^{104}\)https://www.equitymaster.com, research-pharmaceuticals sector analysis report accessed on 22\(^{nd}\) December 2014 at 8.30 pm
The domestic Pharmaceutical output has increased at a CAGR\textsuperscript{105} of 13.4%. Currently the Indian Pharmaceutical Industry is valued at $8 billion (approx.). It provides employment to millions and ensures that essential drugs are available to the vast population of India at affordable price. India's drugs and pharmaceuticals industry is expected to grow at a compound annual growth rate (CAGR) of 14 per cent to reach a turnover of Rs 2.91 trillion (US$ 47.06 billion) by 2018.\textsuperscript{106}

\textbf{Evolution of industry:}

In India, modern system of medicine is a 20th century phenomena, though the traditional system of medicine has been in practice for many centuries. History of the evolution of Indian pharmaceuticals industry can be divided into four important segments. The first segment starts from 1850-1945. The second period starts from 1945-to the late 1970s. The third epoch for development is from the early 1980s to the early 1990s and till 1995, (till it changed its policy). Lastly, from 2005 to the present time.\textsuperscript{107} For convenience, the early stage of pharmaceutical evolution has been divided into two distinct phases, the pre-independence period and the post-independence scenarios. Before the advent of British rule, the indigenous forms of medicine were in use (Ayurveda or unani) in India. British government introduced allopathic form of medicine in the country. During this period were no production units in India. Foreign companies exported raw materials from India, transformed it into finished products and imported it back, to India. There were sincere efforts by some entrepreneurs to establish indigenous companies, for drug production in the country. Drug production in the country was very low and could hardly meet only 13% of the total medicinal requirement of the total

\textsuperscript{105} Compound annual growth rate
\textsuperscript{106} IBFIndia brand equity foundation, \url{www.ibef.org}, last visited on 22\textsuperscript{nd} dec 2014 and accessed October 2014 report at 8.30 pm
\textsuperscript{107} It will be discussed in detail
medicinal requirement of the country. Indigenous industry, however, received impetus during the second world war due to the fall in the supply of drugs from foreign companies, at this time many more Indian companies were started ex: Cipla, zandu, unichem and etc. with the entry of new firms in the market the production of drugs increased rapidly and indigenous firms were able to satisfy about 70% of the country’s medical requirements. In this period across the globe foreign companies were engaged in production related activities and importance of research and development was not known to them. All the inventions at that period were of individual efforts of scientists and the drug companies were not part of these inventions.  

Production of modern medicine by indigenous units started with the setting up of Bengal Chemical and Pharmaceutical works in 1892, which was followed by the establishment of Alembic Chemical, works in 1907 and Bengal Immunity in 1919. At this point in time, the Patents Act of 1911 was in practice, which facilitated patenting of all the known and possible processes of manufacturing of the said drug besides patenting the drug itself. Hence, the indigenous firms were legally prevented from manufacturing most of the new drugs during the life of the patent secured by the latter, i.e., for 16 years, which could be extended to a maximum of another 10 years if the working of the patent had not been sufficiently remunerative to the patentee. This gave them the monopoly power initially. The domestic firms were also forbidden from processing a patented drug into formulations or importing it. However, the Second World War and the introduction of sulpha drugs and penicillin gave an impetus to the pharmaceutical industry.

A- Evolution of the Pharmaceutical industry in India from independence to until 2005:

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108 See pharmaceutical enquiry committee 1949, pp17-18
109 Sudip Choudhuri, TRIPs and changes in the pharmaceutical patent regime in India, working paper no 535, January, 2005, IIM Calcutta. Pp 14
At the time of independence in 1947, India’s pharmaceutical market was dominated by Western MNCs that controlled between 80 and 90 percent of the market primarily through importation. Approximately 99 percent of all pharmaceutical products under patent in India at the time were held by foreign companies and domestic Indian drug prices were among the highest in the world. The Indian pharmaceutical market remained import-dependent through the 1960s until the government initiated policies stressing self-reliance through local production. At that time, 8 of India’s top 10 pharmaceutical firms, based on sales, were subsidiaries of MNCs.  

The pharmaceutical industry has witnessed tremendous transformation since the 1950s. Post-independence period in India was influenced by phenomenal growth of the global pharmaceutical industry. At the same time there was a significant shift in the structure of the industry mainly because of the global pharmaceutical industry, instead of being mere production units also embarked on the path of massive investment in research and development.

The lack of technology, capital and support from the government were the principal hindrances for Indian companies to embark on the new trajectory of new drug development. Industrial policy statement of 1948 decided to take liberal attitude towards MNCs and in turn witnessed rapid growth as noted by the pharmaceutical enquiry committee 1954. But MNCs did not establish production units in the country because the production of bulk drugs required investments in plant and machinery, whereas importing bulk drugs and processing them into formulation was an easier and more profitable

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110 Shri B.V.Patel Education trust- an update 4th International Symposium on Innovation in Pharmaceutical Science and Technology, Ahamadabad

111 Mazumdar M, “performances of pharmaceutical companies in India, a critical analysis of industrial structure; firm specific resources and emerging state”, http://www.springer.com accessed on 14/8/2014 at 10.20 am
business. In the post-independence era, up to the year 1970 India employed western style patent legislation and recognized product patents in addition to process patents on drugs. As a result foreign companies prospered well in the country with over 90% of market share and 80% of ownership document by them.

The size of the Indian pharmaceutical industry both bulk drugs and formulations is estimated at rs 35471 crore in 2003-04, which is just over 1% of the global market (ICRA1999). In 1950 value of the production of the pharmaceuticals was just 10 crore. At present there are about 6,000 units operating in this sector. Investment in the industry has steadily grown over the years from a mere 23-64 crores in 1950 to moderate rs 500 crore in 1980 and went up considerably to reach around 4000 crore in 2003. The role of drug trade has changed, as India was historically dependent on drug imports from transnational companies. The strength of the Indian pharmaceutical trade lies in the formulations market due to its cost advantage compared to bulk drugs, the export of formulations steadily increased from nearly Rs 35 crore in 1980-81.

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112 Pharmaceutical Enquiry Committee 1954
114 IDMA2004
115 Report of commission on macroeconomic and financing and delivery of healthcare services in India, section health access to essential drugs and medicine, page no 185.
GROWTH OF TRADE IN PHARMACEUTICALS IN INDIA IN THE 1980s AND 1990s

**TABLE –NO-1**

<table>
<thead>
<tr>
<th>Growth of pharmaceutical trade</th>
<th>1980s (%)</th>
<th>1990 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bulk drugs export</td>
<td>50.58</td>
<td>24.20</td>
</tr>
<tr>
<td>Formulations export</td>
<td>19.54</td>
<td>30.84</td>
</tr>
<tr>
<td>Total pharmaceutical export</td>
<td>30.31</td>
<td>32.85</td>
</tr>
<tr>
<td>Bulk drugs import</td>
<td>18.13</td>
<td>27.71</td>
</tr>
<tr>
<td>Formulations import</td>
<td>34.54</td>
<td>27.72</td>
</tr>
<tr>
<td>Total pharmaceutical import</td>
<td>20.17</td>
<td>32.97</td>
</tr>
</tbody>
</table>

**Note:** growth rate indicates the compound growth rate

**Source:** IDMA\(^{116}\) and OPPI\(^{117}\) Annual reports.

Indian domestic pharmaceutical companies have made major inroads into the highly competitive generic segments of the world market. It is this market which is fetching a high value for Indian companies and steadily building an excellent infrastructure network around the world. Bulk drug import has been a significant item in the basket of total imports of Indian pharmaceuticals. Pharmaceutical market is extremely competitive but still it is dominated by handful of companies.

\(^{116}\)IDMA, Indian Drug Manufacturers Association

\(^{117}\)OPPI, Organisation of Pharmaceutical Producers of India
Nearly, one third of the Indian population was below poverty line, health conditions make it pertinent to allow for price control. In India, prices of drugs were once considered to among the highest in the world. This trend of high prices has tended to reverse since the 1970s in the wake of government policy measures. To overcome the structural weakness that the sector was suffering from, the government in its industrial licensing policy of 1956 made it mandatory for foreign multinational companies to establish their production unit in the country and produce drugs from the basic stage. Pharmaceutical industry was also included under core group of industries because of social value. During these period not only foreign companies, even public sector units were started in 1947-57, 99% (ninety nine percent) of the total 1704 drugs and pharmaceutical patents in India were held by foreign multinational enterprises which controlled 80% of the market. The Indian pharmaceutical market has characteristics that make it unique. First, branded generics dominate, making up for 70to 80% of the retail market, second, local players have enjoyed a dominant position driven by formulation development capabilities and early investment. Thirdly, price levels are low, driven by intense competition. These characteristics present their own opportunities and challenges.  

The period 1900-1970 signifies the dominance of the multinationals in this field that were basically importing bulk drugs and formulations from abroad. Most domestic manufacturers were engaged in repacking the formulations produced by the multinationals and production was concentrated in the hands of the multinationals. India being a social welfare state, the Indian patent Act of 1970 was framed in manner that ensured the patent rights related to pharmaceuticals could be regulated by the government. The development of

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118McKinsey and company report, pharmaceutical and medical practice india pharma 2020 propelling access and acceptance, realising true potential, page no 13
the pharmaceuticals industry in India is a relatively recent phenomenon. It was during the 1950’s and 1960’s that the pharmaceuticals sector started developing and was a result of western pharmaceuticals giants working with the Indian public sector. In the post-independence era, up to the year 1970 India employed western style patent legislation and recognized product patents in addition to process patents on drugs. As a result foreign companies prospered well in the country with over 90% of market share and 80% of ownership document by them119.

India being a social welfare state, the Indian patent Act of 1970120 was framed in manner that ensured the patent rights related to pharmaceuticals could be regulated by the government. The development of the pharmaceuticals industry in India is a relatively recent phenomenon. It was during the 1950’s and 1960’s that the pharmaceuticals sector started developing and was a result of western pharmaceuticals giants working with the Indian public sector. The Indian pharmaceuticals have come a long way, from being a small player in the 1970’s121.

The Patents Act of 1970 provided impetus for the further growth of the pharmaceutical industry. The Act brought about the abolition of product patents for food, medicine or drug which was earlier granted under the 1911 Act. The 1970 Act provided for process patents in the field of chemicals which included pharmaceuticals... Thus the Indian drug manufacturers by using the technique of reverse engineering which could produce less expensive copies of

120 20th April 1972 read with the patent rules 1972 which revoked patent act1911
the best-selling patent protected drugs. This was possible as there was no provision of product patent though the section 5 of the 1970 Act did make a distinction between process and product patents, so Indian drug manufacturers were able to copy foreign patented drugs.

The Act also provided for pharmaceutical process patents to be endorsed License of Right for three years from the date of sealing a pharmaceutical patent. The Act did not provide for the provision of compulsory licensing. Thus the Indian drug manufacturers by using the technique of reverse engineering which could produce less expensive copies of the Best-selling patent protected drugs. This was possible as there was no provision of product patent though the section 5 of the 1970 Act did make a distinction between process and product patents. So Indian drug manufacturers were able to copy foreign patented drugs without paying a license fee and were able to make it available to the masses at one-tenth of the original price.122

The drug manufacturers could market drugs within 3-4 years of their introduction in the global market which would otherwise take more than 10 years. For instance, companies offered certain drugs to treat HIV positive cases at $140 per annum vis-à-vis at $10,000 per annum charged by the MNCs. Indian drug companies which earlier produced only for domestic consumption have lately been capable of exporting medicines worth 16

thousand crores of rupees.\textsuperscript{123} In 1970 along with the Patents Act, the Drug Prices Control Oder was also passed which helped in lowering the drug prices in therapeutic groups. With the result the Indian pharmaceutical industry by focusing on the process patents and price control framework has emerged as an import dependent industry in the 1950’s to its world recognition as a low cost producer of high quality pharmaceutical products with an annual export turnover of more than $ 1.5 billion dollars. Growth of Indian Pharmaceutical Industry from 2002-03 to 2008-09 are given in table below:

\textbf{TABLE - 2}

\begin{tabular}{|l|c|c|c|c|c|c|c|}
\hline
\hline
\textbf{Domestic Market} & 30365 & 32575 & 34128 & 39989 & 45367 & 50946 & 55454 \\
\hline
\textbf{Exports} & 12826 & 15213 & 17857 & 22216 & 24942 & 30760 & 38433 \\
\hline
\textbf{Imports} & 2865 & 2956 & 3139 & 4515 & 5867 & 6734 & 8552 \\
\hline
\textbf{Total Market Size} & 42326 & 47332 & 52029 & 62566 & 68442 & 78610 & 89335 \\
\hline
\end{tabular}

\textbf{Source}\textsuperscript{124}

\textsuperscript{123}\textsuperscript{Dr.Pr Rankishan Pal, Intellectual Property Rights in India: General Issues and Implications, (2008), p.144}
\textsuperscript{124}\textsuperscript{Annual Report 2008-09, Department of Pharmaceuticals, Government of India}
India, currently exports drug intermediates, Active Pharmaceutical Ingredients (APIs), Finished Dosage Formulations (FDFs), Bio-Pharmaceuticals, Clinical Services to various parts of the world.

Export of drugs and pharmaceuticals from 2002-03 to 2009-10 (May, 09) are given in table below:

**TABLE - 3**

<table>
<thead>
<tr>
<th>Year</th>
<th>Exports</th>
<th>Growth %</th>
</tr>
</thead>
<tbody>
<tr>
<td>2002-03</td>
<td>12826</td>
<td></td>
</tr>
<tr>
<td>2003-04</td>
<td>15213</td>
<td>18.61</td>
</tr>
<tr>
<td>2004-05</td>
<td>17857</td>
<td>17.38</td>
</tr>
<tr>
<td>2005-06</td>
<td>22216</td>
<td>24.41</td>
</tr>
<tr>
<td>2006-07</td>
<td>26895</td>
<td>21.06</td>
</tr>
<tr>
<td>2007-08</td>
<td>30760</td>
<td>14.37</td>
</tr>
<tr>
<td>2008-09</td>
<td>38433</td>
<td>24.94</td>
</tr>
<tr>
<td>April, 2009</td>
<td>3043</td>
<td>14.80</td>
</tr>
<tr>
<td>April 2009-Dec 2009</td>
<td>29551</td>
<td>-</td>
</tr>
</tbody>
</table>

**Source**\(^{125}\)

India’s exports to Latin America have increased by over 81% to touch a figure of US $ 1474.81 million ($ 1.4 billion) during April-December 2004-05 from

\(^{125}\)Directorate General of Commercial Intelligence and Statistics (DGCIS) Kolkata
a level of US $ 812.80 million in the corresponding months of the previous financial year 2003-04. According to the region-wise merchandise trade data available for the period April-December 2004-05 from the Directorate General of Commercial Intelligence & Statistics (DGCI&S) India’s exports to all major destinations are showing an impressive growth. Besides Latin America, exports to Africa are up by 38%; America by 23%; West Europe by 22%; East Europe by 94%; CIS & Baltic States by 7% (although exports to Russia are down by 12%); and Asia & Oceania by over 30% in US dollar terms during April-December 2004-05.

The five top destinations of India’s exports during April-December 2004-05 are Singapore; China; United Arab Emirates; UK; and USA.

Prior to 2005 amendment Indian pharmaceuticals sector utilized the frail patent regime, and established itself among the most profitable industries in the world, accounting for a profit margin to the tune of 327 of sales. In the post-independence era, from 1970 to till recent years, Indian Government took two steps to break the multinational domination and foster a self-reliant indigenous industry. It introduced Drug Control Order (DPCO) to protect consumers against high prices and Indian Patent Act 1970 to recognize process patent (patenting the process used to make a particular drug formulation), but not product patent (patenting the product itself).

These steps made new drugs available cheaply and also promoted import substitution by encouraging local firms to make copies of drugs by developing their own process, followed by bulk production. In 1970, the government introduced DPCO to guarantee its citizen access to essential drugs at a reasonable cost with adequate rate of return to companies without compromising quality. Another derivative effect of the DPCO was that it exempted smaller firms from price controls.
The Indian patent Act ensures that the reasonable requirements of the public with respect to availability are taken care of public interest, particularly public health and nutrition is protected and effectively balances intellectual property protection with public health concerns and national security. Between 1970 and 2005, Indian patent law only allowed for the patenting of processes but not of pharmaceutical products, an important factor that led to a generic industry in India, with exports to many parts of the world. The generic medicines were sold at a fraction of the price of the branded versions. With the change in the Indian law, many are worried that access to generic versions especially of newer drugs will be hampered. Only patents for processes were permitted to be issued, this fact is instrumental in

The domestic industry’s huge success as a worldwide exporter of high quality generic drugs. Pharma manufacturers were benefited from rise in demand for generic products. Along with these, some of the factors that led to the growth in the domestic pharma industry are, low cost operations, research based processes, improvements in API, availability of skilled manpower.

It is till 2005 drugs and their formulations in India were sold as generic (off-patented) drugs. As limited time has elapsed since the implementation of product patent regime, there are very few patented drugs which have entered the market. The patent regime shift in Indian pharmaceuticals would change the market structure from Oligopolistic market structure to a pure monopoly in the drugs market. The monolithic tendencies which are associated with patented drugs are of a much larger magnitude as compared to those with the off-patented drugs. The main concern of introduction of patents is higher prices and displacement of domestic firms which are at a disadvantage in terms of developing innovative drugs. The prices of drugs, whether patented or non-patented, are a function manufacturing costs, imports, presence of large

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127 See supra note 17 chapter 2
firms, therapeutic advantage of the drug and presence of alternative drugs. Thus in India, despite patent free regime in 2005 wide variations were observed in the prices of different brands of drugs along with a variation in the average prices of different molecules in the same therapeutic segment.

The pharmaceutical industry being one of the most technology-intensive industries, the extent and nature of innovation is crucial for countries to prolong their productivity growth and competitiveness in the long run. In broad terms the process of technological change can occur through improvements in the products, production process, raw material and intermediate inputs, and through enhancements in the efficiency of the management system.

Both the Indian central and state governments have recognized R&D as an important driver in the growth of their pharma businesses and conferred tax deductions for expenses related to research and development. They have granted other concessions as well, such as reduced interest rates for export financing and a cut in the number of drugs under price control. Government support is not the only thing in Indian pharma’s favor, though; companies also have access to a highly developed IT industry that can partner with them in new molecule discovery in R&D.  

Today it has the largest no. of operating units in the world. Its total value has been estimated as $12000 million and is made up of both Indian and Foreign companies. Irrespective of the argument for and against strong patent regime, Indian pharmaceuticals industry has been forced to rethink their approach and find alternatives’ to their current reverse engineering business models.  

129 See Supra Note 121
The retail Indian pharmaceutical chemical market is valued at Rs. 20.054 crores for the 12 months ending June 2004. During the same period it grew by 8.1% in terms of value and 8.5% in terms of volume. The compounded annual growth rate of Indian pharmaceuticals industry for the period 1999-2003 is approximately 11%. Drugs and Pharmaceuticals ranks 8th in India’s top 10 FDI-attracting sectors. The government of India has allowed foreign direct investment up to 100% through the automatic route in the drugs and Pharmaceuticals industry of the country, on the condition, that the activity should not fall into the categories that require licensing. Pharmaceutical industry accounts for about 2.91% of total FDI into the country. The FDI in Pharmaceutical sector is estimated to have touched US$172 million, thereby showing a compounded annual growth rate of about 62. The Industry has received almost Rs 2141 crore investment from 36 countries through FDI between April 2007 to April 2009 with most of the fund infusion directed to healthcare and biotech ventures.

The central and state government spent approximately rs2000 crore during 2001-02 on procuring of drugs. Apart from this, a few international organizations’ provide funds (cash or in kind) for drugs either through the central government or directly to the states for specific programs for eradication or control of diseases.

High growth has been achieved through the creation of required infrastructure, capacity building in complex manufacturing technologies of active production ingredients(APIs) and formulations, entering into drug discovery through original and contract research and manufacturing (CRAM) and clinical trials and product specific strategies of acquisition and mergers. The domestic sector

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130 AbishekDubey,TRIPs, patents and the Indian pharmaceutical industry- Addressing a new twist in the tail MLJ civil 8/6/08
131 Economic survey of India 2009
had a production turnover of Rs. 47,241 crore from about 10,000 small-scale and 300 large and medium manufacturing units in 2008.

In spite of being the fourth leading suppliers of bulk pharmaceuticals products and active ingredients Indian companies spend a partly proportion of its profit on basic research and original development. Changes are ultimately good for the Indian pharmaceutical industry, which suffered in the past from inadequate regulation and large quantities of spurious drugs. They force the industry to reach a level necessary for global competitiveness. However, they have also exposed some of the inadequacies in the industry today. Its main weakness is an underdeveloped new molecule discovery program. Even after the increased investment, market leaders such as Ranbaxy and Dr. Reddy’s Laboratories spent only 5-10% of their revenues on R&D, lagging behind Western pharmaceuticals like Pfizer, whose research budget last year was greater than the combined revenues of the entire Indian pharmaceutical industry. This disparity is too great to be explained by cost differentials, and it comes when advances in genomics have made research equipment more expensive than ever. The drug discovery process is further hindered by a dearth of qualified molecular biologists. Due disconnect between curriculum and industry, pharma’s in India also lack the academic collaboration that is crucial to drug development.132

This would place Indian firms at a distinctly disadvantages position with regard to MNCs and transnational corporations, which are much better placed to afford a certain degree of research and development, testing, trials, certification and once patented make benefits by way of profits internationally, after making others to pay for their research and development133. The next

132Fink, c ‘How stronger patent protection in India might affect the behaviour of transitional pharmaceutical industries,’ world bank policy research working paper no.2352 .( 2000),
133 See Supra note 123
major concern was the status of patented drugs that are exported to various third world countries. Indian drugs are the principal source of cheap drugs for poor developing countries specially the African nations. 66.7% of Indians exports go to the developing countries. this can be threat for export accounts to counter this problem a new section 92A introduced by the ordinance, which allowed for the manufacture and export a patented drugs to countries having insufficient or no manufacturing capacity to address public health. The 40,000 crore Indian pharmaceuticals industry entered a new and challenging phase leaving behind the copycat era. The Indian pharmaceutical industry is under fast development since the Indian market is opening up immense opportunities for firms.

At the same time it must be accepted that product patents have benefited other segments of the Indian pharmaceutical industry. It is important not to overlook the international competitiveness of Indian firms in innovative research, which will benefit Indian public health in the long run.

### 4.3-PUBLIC HEALTH CONCERNS IN THE WAKE OF EFFECTIVE PHARMACEUTICAL INDUSTRIES

The pharmaceutical industry is world’s one of the high research-intensive industries, generating enormous contributions to healthcare. Patents are granted to create strong incentives for investment in pharmaceutical research and development but that result in monopoly privileges by creating scarcity. This monopoly grant arouses public concern over high prices and the introduction of products of uncertain efficacy or safety. The pharmaceutical

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134 See supra note 110
135 Kushargrapriyadarshi, “patent(amendment)Act” 2006(33) PTCJ 12 –J16
136 It will be discussed in detail chapter
industry has a distinguishing characteristic of imperfect information on the quality of the product. The pharmaceutical products are often obtained on prescription from a physician. Thus, the consumer is not the decision maker. This has serious implications for prices of the pharmaceutical products as the physician is not as sensitive to prices as the direct consumer would be. The presence of monopoly power results in prices that commonly exceed drug production costs by substantial margin.

An intellectual property regime necessarily sets up a monopoly which limits the supply of alternatives for a given chemical entity to a single firm. Despite the existence of several substitutes (either because of other older molecules or due to the absence of product patents), lack of information and reliance on the physician to prescribe a drug lead to the persistence of high price for well-established pharmaceutical products. The effectiveness of the public health system and access to quality health care, especially for the poor has worsened since the decade of the 1990s, due to a variety of policy developments, at both national and state levels: 137

4.4 -RIGHT TO HEALTH AND CONSTITUTIONAL SAFEGUARDS

The history of India shows many systems of medicine existing at the same time, from the Indian Ayurveda and Siddha, and the Unani system from Western Asia, to the new systems brought during European colonization. Today, although traditional systems of medicine continue to be practiced in India with state support, the mainstay of the official public health care system is the internationally recognized system of medical treatment known as allopathic or modern medicine. During British rule the new medical profession became well organized, while pharmacy stood neglected. The present progress of pharmacy education, the pharmaceutical profession and industrial developments in India is a result of the

137 Public health policy brief page no 4
concentrated efforts of many intellectuals and visionaries of the country who worked tirelessly for the profession.

India has federal constitution in which administrative subjects are divided between union and state government under the seventh schedule. While some items like public health, hospitals, sanitation, etc, fall in the state list, items having wider ramifications at the national level are in the concurrent list on which both union and the state can legislate. People of India adopted themselves the constitution of India in 1950.

Constitution of India being source of all laws, civil, political, social and economic rights to the people of India, Social and economic rights are termed as the building blocks of a coveted society. These rights are higher to any other legal right which stems out of a statute. Inherent in every individual, the realization of socio economic rights by the society is a must to faster growth, development and sustainability.\(^{138}\) In our constitution, the fundamental rights are contained in Part–III and those consist of civil and political rights, Part –IV rests with socio–economic and cultural rights in directives principles of the state policy. The socio–economic and cultural rights are considered to be unenforceable and non-justifiable rights that provide guiding principles for the working of the constitution and include rights such as education, right to work equal pay for equal work etc. Since, it depends on the resources available with the state.

The intellectual property regime in India draws its feet from the constitution of India.\(^{139}\) In recent years, the rationale behind accord and protection to intellectual property has been diluted.\(^{140}\) Such dilution has resulted from a

\(^{138}\)Dr udaya Shankar and SaurabhBindal’s Book on Right to Health in the Intellectual Property Era.\(^{138}\)edition:2013 published by Satish upadhay, New Delhi page no 64

\(^{139}\)Entry 49, list 1, schedule 7 read with Article 246 of the constitution of India., 1950

\(^{140}\)Philippe cullet, Human rights and Intellectual Property Protection in the TRIPs Era.29, human rightsand public policy paper 4032007
focal shift of such a protection of the interests of private individuals.\textsuperscript{141} The over enthusiastic private parties to assert their rights have contributed to the majority of intellectual property litigation in India.\textsuperscript{142} In the present society people are more bothered about their private rights than public rights and public fails to realize legions of socio economic rights. Hence, constitution, which is protector and guarantors of socioeconomic rights is protecting and balancing both private interest and public interests.

Every human being is entitled to the enjoyment of the highest attainable standard of health conducive to living a life indignity.\textsuperscript{143} It is the duty of the state to not only provide for the maintenance of life but also for the maintenance of dignified life.\textsuperscript{144} The right to health in broader connotation refers to all the three kind of rights. It relates to civil and political rights in relation to the protection provided to respect physical integrity. It relates to social and economic right to the extent it seeks to safeguard that the individual does not suffer social and economic injustices with respect to his health. It is cultural in nature because it seeks to safeguard that the individual’s health services are sufficiently adapted to one’s cultural background.

The idea of right emanates from premise that human rights are based on dignity and well-being of an individual and justice, equality, liberty and fraternity. Conditions leading to healthy life must be available and accessible to all.\textsuperscript{145} Right to health must be understood as a right to enjoyment of variety of facilities, goods services and conditions necessary for the realization of the

\textsuperscript{141}Susan Cell, Intellectual Property Historical Perspective; contest ion and settlement 38 loy LAL rev267(2004)
\textsuperscript{142}See http://www.financialexpress.com/news/bayer-drugs-cipla-to-sc-over-anticancer-drug-patent/584075
\textsuperscript{143}General comment no.14, UN Doc. E/C12/2004/4
\textsuperscript{144}Maneka Gandhi v/s union of India, AIR 1978 SC 597
\textsuperscript{145}See supra note 141, page no 67.
highest attainable standard of health. Health issues are central to human wellbeing and dignity, and thus are central to human rights.

The constitution of India refers to significance of the right to health in general and for specific class of individuals in particular. Article 47 speaks about duty of the state with regard to maintaining public health as the state shall regard raising of the level of nutrition and standard of living of its people and the improvement of public health as among its primary duties and in particular the state shall endeavor to bring about prohibition of the consumption, except for medicinal purposes of intoxicating drinks and of drugs which are injurious to health. Hence, it is the right of all individuals and it is duty of a state under its obligations to fulfill this duty. This directive principle also mandates the state to ensure immediate realization of the rights with available resources. Health is central to development. The agenda for global health is changing in a number of important ways, which have a bearing on how priorities for development are defined in the future and how they should be measured. In this regard, human rights based approach to right to health is essential. The right of everyone to enjoy the highest attainable standard of physical and mental health is recognized in numerous global regional and national treaties and constitutions.

The progressive realization of civil, cultural and political as well as economic and social rights is a prerequisite for sustainable growth and human development. Irrespective of where one lives, gender, age or socio-economic status being healthy and having access to quality and effective health care services is a fundamental importance for all people. While at the same time

146General comment no.14, United Nation DOC./E/C.
147Un System Task Team on the post-2015 on Development Agenda page no.5
healthy populations are essential for the advancement of human development, well-being and economic growth.\textsuperscript{148}

Public Health is State’s Priority: In one of the earliest instances of public interest litigations -Municipal Council, Ratlam vs. Vardhichand& Others,\textsuperscript{149} the municipal corporation was prosecuted by some citizens for not clearing up the garbage. The corporation took up the plea that it did not have money. While rejecting the plea, the Supreme Court through Justice Krishna Iyer observed: “The State will realize that Article 47\textsuperscript{150} makes it a paramount principle of governance that steps are taken for the improvement of public health as amongst its primary duties.”

It was only in 1991 in \textit{CESC.ltdvssubhashchandra}\textsuperscript{151} that the Supreme Court placed reliance on international instruments and declared that the right to health was of fundamental right. “The term health implies more than an absence of sickness. Medical care and health facilities not only protect against sickness but also ensure stable manpower for economic development. Facilities of health and medical care generate devotion and dedication to give the workers’ best, physically as well as mentally, in productivity. It enables the worker to enjoy the fruit of his labour, to keep him physically fit and mentally alert for leading a successful economic, social and cultural life. The medical facilities are, therefore, part of social security and like gilt edged security, it would yield immediate return in the increased production or at any rate reduce absenteeism on grounds of sickness, etc. Health is thus a state of

\begin{itemize}
\item [148] ibid
\item [149] 1980 Criminal Law Journal 1075
\item [150] Article 47. Duty of State to raise the level of nutrition and the standard of living and to improve public health- The State shall regard the raising of the level of nutrition and the standard of living of its people and the improvement of public health as among its primary duties and, in particular, the State shall endeavour to bring about prohibition of the consumption except for medical purposes of intoxicating drinks and of drugs which are injurious to health.
\item [151] AIR 1992SC 573
\end{itemize}
complete physical, mental and social well-being and not merely the absence of
disease or infirmity. In the light of Article 22 to Article 25 of the Universal
Declaration of Human Rights, International Covenant on Economic, Social
and Cultural Rights and in the light of socio-economic justice assured in our
Constitution, right to health is a fundamental human right to workmen. The
maintenance of health is a most imperative constitutional goal whose
realisation requires interaction by many social and economic factors.”

To the question whether right to health is a positive or negative right, while
the Supreme Court has on an occasion implicitly held that, the right to health
was a positive right, on most occasions its treatment has been as a negative
right. A negative fundamental right casts an obligation on the State not to act in
a manner that would deprive a citizen of her fundamental right. On the other
hand, a positive fundamental right would mandate the State to take proactive
measures to fulfil its obligation.

Time has come for the Courts to recognize that the right to health and health
care is a positive fundamental right that cannot be contingent upon the
financial capacity of the State. Meanwhile, the people’s movements and
communities have now begun struggles to stop the State from privatizing and
thus unregulated commercialization of the health care which further violates
the right to the health of the citizens. The activists in the health field will have
to use both these strategies to urge the state to provide health care to all
citizens and also to stop the state from unleashing commercialization and
privatization of health care on the other. Using the Right to Life as the broader
framework, the Court rulings would be useful tools for all those who join
hands to pursue a vision ‘Health for All, Now’. In *Vincent parikurlangara vs.
union of India*\(^{152}\) the Supreme Court observed “In a welfare state, therefore it
is the obligation of the state to ensure that the creation and the sustaining of
conditions congenial to good health”.

\(^{152}\)AIR1987sc990-(1987)2scc165
The declaration on the Right to Development, which states unequivocally that, the right to development is a human right, which was adopted by the United Nations in 1986 by an overwhelming majority. The Declaration on the Right to Development came almost thirty eight years after the adoption of the Universal Declaration of Human Rights, according to which human rights constituted both civil and political rights (Articles 1 to 21) and economic, social and cultural rights (Article 22 to 28).

The right of everyone to the enjoyment of the highest attainable standard of physical and mental health is recognized in article 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR). To achieve the full realization of this right, states have the responsibility to create conditions that would ensure to everyone medical service and medical attention in event of sickness.¹⁵³

The content of right to health has been explained in general comment no 14 of the Committee on Economic, Social and Cultural Rights (ICESCR.) accordingly, the essential elements of right to health are:

a) The availability of a functioning public health system and health care facilities including hospitals, clinics, trained medical professionals and essential drugs;

b) Universal access to health services in both physical as well as economic terms. Hence state should not do more investments in expensive curative health services but concentrate on primary and preventive healthcare services which benefit a larger section of the population; and

¹⁵³UN Sub-commission on the promotion and protection of human rights, liberalization of trade in services and human rights: report of the high commissioner/CN.4/sub.2/2002/9, june 25 2002, para 29
c) The state must ensure the quality of health services\textsuperscript{154}. Besides the UN, the right to health as a fundamental right has also been recognized by the constitution of WHO and reiterated in the Alma-Ata Declaration of the international conference on primary health care. The declaration had set the attainment by all peoples of the world a level of health suitable for leading a socially and economically productive life by the year 2000, as a main social target for the governments, international organization and world community.\textsuperscript{155} Though the time set has missed but the objectives set there in still remain valid and they should be observed in this process.

d) The starting point for a consideration of the operational aspects of intellectual property system with regard to access to drugs is that access to essential drugs is a Human Right\textsuperscript{156}.

e) Article 21 of the Indian constitution provides Right to life and it shelters various rights. It includes Right to Health, which implies, “The Right to a variety of facilities and conditions necessary for the realization of the highest attainable standard of health”. The Right to health is one of the economic, social and cultural human right that requires affirmative government action to create better condition for people rather than just governmental restraint vis-a-vis citizens. The first expression of this right is an international legal instrument came in the constitution of W.H.O in 1946\textsuperscript{157}. Since India is a founding member of UNO, UDHR & ICESR, Art. 25 of UDHR\textsuperscript{158} and Art 12 of ICESCR, world Health Declaration (1998) adopted by the world health Assembly speaks about Right to

\begin{footnotesize}
\textsuperscript{154}ibid \\
\textsuperscript{155}International conference on Primary Health care, Alma-Ata, USSR, September 6-12, 1978, Declaration of Alma-Ata \\
\textsuperscript{156}Kumar Avinash, Human rights to health, satyam law international publications 2007 \\
\textsuperscript{157}See supra note 138 page 1 \\
\textsuperscript{158}Universal Declaration of Human Rights
\end{footnotesize}
health. Hence, it is the responsibility of all the members’ countries to provide right to health to all its citizens.

f) The World Health Organization’s Drug policy, clearly aims at providing a health for all and accessibility of primary healthcare and medicine to all the human beings of the world, irrespective of colour, creed and economic status\textsuperscript{159}.

In the year 2000 with the launch of Jan SwasthyaAbhiyan people’s health initiative in India, civil society group sought to prioritise the right to health and health care on its agenda. Support of legal documentation is required to realize Right to Health as a Fundamental Right. This scheme with the support of the National Human Rights Commission brought into focus the issue of health care as a right and highlighted the denial of health care within the public health system through public hearings conducted across the length and breadth of the country between June and December 2004.\textsuperscript{160} There is no regulation on either health services or on quality of and access to health services.\textsuperscript{161} Health is a state subject and hence the Union Government alone cannot make a difference. How does the government propose to help State Governments to achieve health goals and commitments? We suggest that, the Union Government engages actively the State Governments on these issues of resource allocations and help strengthen both curative and preventive health care across the country.

Public Health & Human Rights: TRIPs has always been highlighted as the trade agreement prioritizing the economic concerns. The “Product Patent
Regime” in particular has been criticized for ignoring the state’s legal obligations for protection of its citizen’s right to self-determination, food, housing, work, health and education as promised in the International Covenant on Economic, Social and Cultural Rights. The same has been observed by UN Sub-Commission on the Promotion and Protection of the Human Rights in August 2001 and the Sub-Commission adopted a resolution on “Intellectual Property Rights and Human Rights”.

The resolution stressed that the promotion and protection of Human Rights in conformity with the Charter of the UN, is the first responsibility of governments. The resolution also advised the WTO in general and council on TRIPs, in particular to take fully in to account the state’s obligations under the international human rights instruments. The Resolution also advised the government to integrate into their national and local legislations and policies, provisions, in accordance with international human rights obligations and principles and hence protect the social foundation of intellectual property. The new amended Indian patent Act, as such, does not affect the rich and elite. It, however, seriously affects the availability and affordability of medicines in India.

The concerns of the poor and the overall critical health scenario should have been the guiding factor. Co-relation of the Patents Act of 1970 with the National Health Policy is also an important factor to ensure success of the health policy. Similarly, there should be co-relation of the patent system with the National Pharma Policy for strengthening the pharma industry and National R&D policy for strengthening the research base. The patent regime in this country should be devised so that the utmost priority is granted to securing the people’s rights of access to affordable and quality healthcare, without monopoly.
The Members are free to adopt a more stringent regime than the one required by the TRIPS Agreement (Article 1). WTO acknowledges the need for members, to meet objectives regarding development and public health. Accordingly, protection of patents has to fall within a National space in which governments are responsible for meeting these objectives. A significant development in relation to TRIPS and public health was the adoption of the declaration on the TRIPS Agreement and public health at the WTO Fourth Ministerial Conference in Doha Qatar, on November 14 2001 (the Doha declaration). The latter declaration was followed much public scrutiny, activism by civil society, and demands by developing countries especially over the impact of trips on issues such as access to essential medicines in developing countries.

Measures are needed to be taken by Government with regard to national list of essential medicines and it should form the basis of drugs to be considered for intensive price monitoring ceiling prices and for imposition of price controls. The Indian competition Act 2002 has all the required provisions of law and merely needs to be accurately implemented in order to ensure that there is balance between both, although the path of TRIP’s compliance has certain stumbling blocks, nevertheless, there are reasonable simple and significant steps which the industry along with the government can take to alleviate the predicaments and transfigure them from blows to books.

Without paying a license fee and were able to make it available to the masses at one-tenth of the original price. The drug manufacturers could market

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162 Samira gevnnif, TRIPs plus Agreements and issues in access to medicines in developing countries: Journal of IPR, Sep 2007 pp 471-479
164 Intellectual property and human development, chapter 2nd, ipr and medicine towards global health equity, available at www.piipa.org
drugs within 3-4 years of their introduction in the global market which would otherwise take more than 10 years. For instance, companies offered certain drugs to treat HIV positive cases at $140 per annum vis-à-vis at $10,000 per annum charged by the MNCs. Indian drug companies which earlier produced only for domestic consumption have lately been capable of exporting medicines worth 16 thousand crores of rupees. In 1970 along with the Patents Act, the Drug Prices Control Order was also passed which helped in lowering the drug prices in therapeutic groups. So the Indian pharmaceutical industry by focusing on the process patents and price control framework has emerged as an import dependent industry in the 1950’s to its world recognition as a low cost producer of high quality pharmaceutical products with an annual export turnover of more than $1.5 billion dollars.

It is Prior to 2005 amendment Indian pharmaceuticals sector utilized the frail patent regime, and established itself among the most profitable industries in the world, accounting for a profit margin to the tune of 327 of sales. In the post-independence era, from 1970 to till recent years, Indian Government took two steps to break the multinational domination and foster a self-reliant indigenous industry. It introduced Drug Control Order (DPCO) to protect consumers against high prices and Indian Patent Act 1970 to recognize process patent (patenting the process used to make a particular drug formulation), but not product patent (patenting the product itself).

These drugs made new drugs available cheaply and also promoted import substitution by encouraging local firms to make copies of drugs by developing their own process, followed by bulk production.

In 1970, the government introduced DPCO to guarantee its citizen access to essential drugs at a reasonable cost with adequate rate of return to companies

164 Supra note 122
166 Supra note 123 pp150
without compromising quality. Another derivative effect of the DPCO was that it exempted smaller firms from price controls.

The Indian patent Act ensures that the reasonable requirements of the public with respect to availability are taken care of public interest, particularly public health and nutrition is protected and effectively balances intellectual property protection with public health concerns and national security.

Today it has the largest no. of operating units in the world. Its total value has been estimated as $12000 million and is made up of both Indian and Foreign companies. Irrespective of the argument for and against strong patent regime, Indian pharmaceutical industry has been forced to rethink their approach and find alternatives to their current reverse engineering business models\textsuperscript{167}.

The retail Indian pharmaceutical chemical market is valued at Rs. 20.054 crores for the 12 months ending June 2004. During the same period it grew by 8.1% in terms of value and 8.5% in terms of volume. The compounded annual growth rate of Indian pharmaceuticals industry for the period 1999-2003 is approximately 11%\textsuperscript{168}.

In spite of being the fourth leading suppliers of bulk pharmaceutics products and active ingredients Indian companies spend a partly proportion of its profit on basic research and original development. The 40,000 crore Indian pharmaceuticals industry entered a new and challenging phase leaving behind the copycat era\textsuperscript{169}. The Indian pharmaceutical industry is under fast development since the Indian market is opening up immense opportunities for firms.

This would place Indian firms at a distinctly disadvantages position with regard to MNCs and transnational corporations, which are much better placed

\textsuperscript{167}Supra note 119 pp 269-280
\textsuperscript{168}Supra note 121
\textsuperscript{169}Kushagrapriyadarshi, patent(amendment)Act 2006(33) PTCJ 12 –J16
to afford a certain degree of research and development, testing, trials, certification and once patented make benefits by way of profits internationally, after making others to pay for their research and development\textsuperscript{170}.

The pharmaceutical industry is the world's second-largest by volume and is likely to lead the manufacturing sector of India. India's bio-tech industry clocked a 17 percent growth with revenues of Rs.137 billion ($3 billion) in the 2009-10 financial year over the previous fiscal. Bio-pharma was the biggest contributor generating 60 percent of the industry's growth at Rs.8,829 crore, followed by bio-services at Rs.2,639 crore and bio-agri at Rs.1,936 crore.\textsuperscript{171}

During the current year 2009-10, Pharma was among the few sectors that managed to expand its revenues despite global recession and financial crises. Strong domestic demand, growing preference for generics worldwide and favorable rupee-dollar exchange rate helped the Indian Pharmaceutical sector. Aggregate income of the drugs and pharmaceuticals companies for the first two quarters of the current year grew by 13 per cent and 7.8 percent respectively as compared to previous year. As per Centre for Monitoring Indian Economy (CMIE), the estimated growth in aggregate income for the next two quarters is 9.5 per cent and 10.2 percent respectively.\textsuperscript{172}

The Indian pharmaceuticals industry has grown from a mere US$ 0.32 billion turnover in 1980 to approximately US$ 21.26 billion in 2009-10. The country now ranks 3rd in terms of volume of production (10% of global share) and 14th largest by value.\textsuperscript{173}

\textsuperscript{170}Abimanyughosh and deep chain kaabir, balance of competition and intellectual property laws in the indian pharmaceutical sector, JIPR Vol.xii, may 2007. pp293-302 page
\textsuperscript{171}www.ibef.com
\textsuperscript{172}www.kpmg.com
\textsuperscript{173}Supra note 171
4.5- THE RELEVANCE OF PROCESS PATENTS IN THE PHARMACEUTICAL SECTOR AND THEIR IMPLICATIONS

There is an ongoing debate about the rationality of price controls in a regime where drugs can be manufactured through alternative processes as was the case in India before 2005. In a regime of only process patents, competition was expected to bring the prices down close to the marginal costs. However, there are wide variations in the prices of the same drug sold by different manufacturers under different brand names. The growing pressure upon the Indian pharmaceutical industry through the Indian patent (Amendment) Act 2005 has opened public discussion on the issue of price regulation on drugs once again.

India has vast pharmaceutical market, and is rightly celebrated in international crises for making medicines very affordable and low priced. But within India, it is a scenario of un-affordability and poor access amid plenty. The Indian Patents Act, 1970 ensured the availability of cheap generic drugs by adopting the process rather than product patent for medicines and further, having relaxed provisions regarding compulsory licensing and import substitution. Of course, since India signed the TRIPS Agreement the Patent Act has been amended to do away with a substantial number of these protections. Thus in future, newer generic drugs that are cheaper than the branded ones will become difficult to access.

The new patent regime brings in lot of promises for the industry in India but it might not be good for the small players in the industry, as they may not be able to survive in the environment leading to the consolidation of the industry. At the same time the law provides an attractive opportunity to MNCs to step-

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174 IMPF Policy Notes for Parliamentarians On access to Medicines, page no 9 by S.Srinivasan and Dr. Anurag Bhargava, CENTAD Publications.

175 Health care in India edited by advmihirdesai and advkamayanibalimahabal, published in august 2007 page no 89, www.cehat.org
up product launches from their parents product stable there by providing competition to their domestic peers.

The government policies, programs & initiatives enabled the Indian pharmaceutical industry. A smooth transition from process patent to product patent regime has resulted in its emergence as a global leader in generic manufacturing field. Indian generic drug manufacturers have been manufacturing generic versions of branded drugs. Under the Act generic drug manufacturer that had made significant investment and marketing the product before January 2005 can continue marketing the product in the new regime. The act grants them immunity from infringement suits from patent holders. They would only have to pay a reasonable royalty to the patentee. While the law has stated that the generic manufacturers would have to pay a reasonable royalty rate should have been fixed in the amendment Act, based on the practice adopted by Canada for many years or fixed at 5% as existing in South Africa.

Patent has assumed great importance in recent times since its basic function to promote innovation is an essential component of economic growth and social evolution. Patent is not just an incentive to invest in the innovation process per se, but is also increasingly important for Trade & Industry worldwide. For developing countries like India, patent is an essential component of the framework to attract foreign investment & foster Technology transfer. In the coming days are going to reap a big advantage for the innovator companies and the era are for innovations.

It has been a long journey for the Indian pharmaceutical industry from being merely an import dependent to emerge as self-reliant producer and an innovation driven developing country competition to the global market. The government of India has employed a variety of policy tools to develop domestic pharmaceutical sector and to protect it from large multinational firms
operating in and dominating the industry. While the Indian policy regime has succeeded in bringing out its pharmaceutical sector among the fastest growing in the world, it has also created its own limitations in pushing forward its productivity and technological activities. The fragmented nature of policy that encouraged a large number of small and medium-sized pharmaceutical firms appears to have placed a constraint on the scale of production and capabilities to further upgrade technological strength. The shift towards strong patent regime postulated by TRIPS coupled with policy liberalization of the past decade or so like liberalization of foreign investment, trade and industrial policy has opened up new competitive challenges for the Indian pharmaceutical sector.

After the TRIPs agreement came into force it was argued that there were enough flexibilities in the TRIPs for protecting interest of the generic industries, so as to achieve the goal of providing affordable drugs. The flexibility include freedom to determine the scope of subject matter for product protection\textsuperscript{176}, to determine the grounds on which compulsory license could be issued\textsuperscript{177}, in identifying excepting to patent\textsuperscript{178} providing provisions for parallel import\textsuperscript{179}, and protection of test data\textsuperscript{180}, etc.

Countries adopted various approaches to implement the obligations and tried to protect public interest of providing access to affordable drugs. But it was realized that it is difficult to provide access to new drugs in many cases.

\textsuperscript{176} Art 27 of the TRIPs used the standards of novelty, inventive step and capable of industrial application to identify inventions for grant of patents.
\textsuperscript{177} Art 31 of the TRIPs gives the freedom
\textsuperscript{178} Art 30 identifies three steps to determine the limitation and exceptions to patent
\textsuperscript{179} Art 6 of the TRIPs makes it clear that for the purposes of dispute settlement under this agreement subject to the provisions of art 364 nothing in this agreement shall be used to address the issue of exhaustion of IPR
\textsuperscript{180} Article 39-3 deals with this
Under objectives of the TRPS agreement\textsuperscript{181} the protection and enforcement of IPR rights are subject to social and economic welfare. They are intended to benefit society as a whole and do not aim at the mere protection of private rights. Further under Art. 8 provide that members may adopt measures to protect health, among other over-reaching public policy objective such as nutrition and socio-economic and technological development. Moreover, significant number of firms who had already taken steps to increase their production and program me of action of the 2005 change will become global players, in the process of creating jobs and wealth, generating significant tax revenue to the government.

Indian pharma companies are going to face stiff competition from the global companies. Indian companies can go either for collaboration or concentrate on producing and marketing generic drugs. This futuristic conclusion is based on the realistic assumption regarding poor research and market penetration strategies by the Indian companies.

The Indian pharmaceutical industry is poised for growth and its support by its quality human resources with the knowledge and technology base, coupled with the institutional infrastructure, which has been developed over the past few decades. Profitable value realization by the Indian pharmaceutical industry would only be possible if an enabling national environment is created that is conducive to innovation.

In a regime of only process patents, competition was expected to bring the prices down close to the marginal costs. However, there are wide variations in the prices of the same drug sold by different manufacturers under different brand names. The growing pressure upon the Indian pharmaceutical industry through the Indian patent (Amendment) Act 2005 has opened public discussion on the issue of price regulation on drugs once again.

\textsuperscript{181} Art. 7 of TRIPS
India being member of all human rights Conventions and at international level, Article 12 of the International Convention on Economic, Social Cultural right, speaks about right to health. General comment No 149 of UNESCO has four aspects of health care system. Health aspect should be studied by looking into availability of medicines, its accessibility to the common man and how people have accepted the quality of medicines. Hence for any good health system, it is based on quality of medicines, its availability of medicines and accessibility is required to measure good health care.