CHAPTER - VII

CONSEQUENCES OF HARMONIZED PATENT LAW

It is often asserted that patent regime contemplated under TRIPs agreement is likely to produce some undesired results in the developing countries including India. The regime may help large MNCs to control access to medicine, vital life saving drugs, agriculture, seeds and thereby result in large-scale infringement of human rights. It may also affect the ability of the governments to fulfill obligations to the citizens in promoting general welfare. Thus in this chapter an attempt has been made to ascertain whether the TRIPs complaint patent law has really produced such results or not. Accordingly in this chapter Impact of new patent regime on pharmaceutical sector, public health, agriculture and food, and Indian economy has been discussed.

7.1 Impact of new patent regime on pharmaceutical sector

It is feared that the TRIPs compliant patent system will adversely affect the Indian Pharmaceutical industry. Accordingly it is claimed that, “the TRIPs agreement may have a severe impact, especially in the high technology sectors such as pharmaceuticals, working to the disadvantage of developing countries in two main respects: domestic manufacturers wishing to produce and commercialize products covered by patents will be forced in to licensing agreements involving royalty payments to patent holders; while research and development activities may be hindered since the TRIPs agreement is likely to inhibit reverse engineering, the process by which research based industry products are copied and adapted for developing country usage”.

7.1.1 Drug production

In the process of globalization, the rich nations with their superior financial power, control the scenario and the poor and developing nations are forced to integrate surrendering their economic independence knowing fully well that what they are forced to accept is really prejudicial to their own interest. The structural adjustment program introduced by the Government of India at the behest of WTO created a serious impact on

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India’s drug industry and the health care system. These reform policies have mainly reduced the role of the government, cut in subsidy in the social sector, increase in administered prices, liberalization of trade by reducing tariff rates, providing incentives for foreign investment, privatization of the public sector etc. This is aimed at the withdrawal of the state initiative from the social and welfare sectors like health, education, public distribution etc. with the reduced role of the state under globalization the public sector drug companies are faced with serious problems including imminent closures. Public sector drug companies like Indian Drug and Pharmaceuticals Ltd. (IDPL), Hindustan Antibiotics Ltd. (HAL), Bengal Chemical and Pharmaceuticals Ltd. (BCPL) and Bengal Immunity (BI) have played an important role in the production of essential drugs at affordable prices. Under the globalization process the role of the public sector has been marginalized and they have been made sick. Attempts have been made to either privatise or close them. The penicillin plant in HAL, the biggest in the country has been handed over to private hands. Its Streptomycin plant also has been leased to private company for manufacture of other drugs. IDPL, which is having the biggest pharmaceutical plant in Asia, is closed from 1996 for want of proper financial assistance from the government. The public sector drug companies used to supply raw materials to the small-scale sector companies. Now these companies are facing difficulties in procuring raw materials. Similar is the fate of BCPL, BI and Smith Strainstreet Pharmaceuticals Ltd. (SSPL). These three units were taken over by the government after they were made sick by the private owners. Proper utilization of their capacity could not be made due to lack of will on the part of the government, management at the administrative level. International and National level mergers, acquisitions and takeover have now become a common phenomenon in the pharmaceutical industry. By merger and acquisitions these companies become even larger with more financial power at their disposal over their competitors. In coming days with the help of International financial companies the MNCs will capture and take control of Indian companies to control the Indian market.  

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3 Ibid.
7.1.2 Effect on generic production

Some pharmaceutical companies focus primarily on manufacturing drugs that do not have patent protection—either because patent protection has expired or because their home country does not issue patent on pharmaceuticals. These companies are known as Generic drugs manufacturers. Their cost are close to the basic costs of manufacturing the drugs which are small compared to the costs associated R &D, obtaining first use regulatory approval from an agency such as the food and drugs administration (FDA),and marketing. The business model of generic manufacturers is based upon manufacturing and selling at a cheaper price the same medicines developed by other pharmaceutical companies, as soon as these medicines are off patent.4

Generic drugs are alternatives to brand name drugs and according to WHO requirements they must show pharmaceutical equivalents, which means that the amount of active ingredients dosage form, and strength are identical to those of a compared brand. Quality generic version of off-patent medicines can play a key role in meeting health needs in population around the world. The generic must also be bio-equivalent, meaning the drug must be absorbed in to the bloodstream at roughly the same rate and extent as the pharmaceutically equivalent brand.5

Indian generic manufacturers are currently the world’s lowest cost producers of many of the new approximately 15 widely used drugs for HIV/AIDS. They are also the lowest cost producer of certain combinations of these drugs. India exports two third of the pharmaceutical out-put to developing countries, according to the WHO. Generic competition fuelled by Indian drugs has been largely responsible for reducing the prices of antiretroviral drugs to treat AIDS, in some cases as much as 98 percent of the 700,000 people receiving antiretroviral treatment in developing countries, half rely on Indian generic –MSF said it treats 25,000 people in 27 countries and roughly 70 percent of these patients use Indian made drugs.6

India is the biggest producer of generic drugs and its companies make not only the finished tablets forms of drug, they also make generic version of raw ingredients and chemicals used in the drugs manufacture. Many of these actually export to global pharmaceutical companies to produce their brand name versions. As per, IMS Health for the 12 months ending September 2009, global prescription sales growth of generic drugs rose by 7.7% (up from 3.6% in 2008) against 5.7% for global pharma drugs. Furthermore, generics accounted for 72% of the total US pharma market volume in 2009, an all-time high in the world's biggest pharma market.

The generic industry is not merely engaged in copying work pioneered by others, innovations introduced by generic firms have also improved and updated marketed products for use in resource short communities by designing adaptable dosage regimes. The major generic manufacturers have introduced or are pursuing molecules for both chemical and biological products.\(^7\)

Developed countries have always questioned the safety and efficacy of generic drugs. They say that beyond the question of pricing, the quality, safety and efficiency of generic drugs remain crucial factors. The removal of almost all Indian copy antiretroviral (ARVs) from WHO’s list of pre-qualified ARV products in the year 2004 indicates that quality remains a concern regarding these products, while the ARVs produced by the patent holders meet the world’s highest standards of quality, safety and efficacy.\(^8\)

But Mike Palmido of CPTech argues that while WHO recently removed six antiretroviral produced by Cipla and Ranbaxy from its pre-qualified drugs’ this is not a sign that WHO pre-qualified is flawed. The delisting was due to an audit of an independent Contract Research Organisation (CRO) hired by the drug companies conduct bio-equivalence studies that showed the CROs were not compliance with good clinical and laboratory practices. The drug companies suspended business with this CRO and began retesting their drugs. In November 2004 some of Cipla’s antiretrovirals were put

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back on the pre-qualification lists, while some have used this fact to attack the credibility of the pre-qualification system.⁹

He further says that there are many producers of generic drugs and there are legitimate quality concerns with some of them. In order to be sure generic drug is safe and effective, the purchaser should be sure that it has been approved reliable national regulatory authority such as FDA or pre-qualified by the World Health Organisation.¹⁰

To gain marketing approval from a national regulatory authority, a generic producer must show that its product is bio-equivalent to the branded version of the medicine. Bio-equivalence means that the generic drug releases the same active ingredients into the body at the same rate. The WHO also inspects the manufacturing process and quality of both branded and generic drugs. The one that pass a rigorous inspection process are then “pre-qualified” by the WHO. The pre-qualification process involves inspections akin to those required by the best neonatal regulatory authorities. Companies must have both their test data and their physical facilities inspected.¹¹

Drug prices are lowest in India amongst the Asian countries, but this was not so earlier. In 1965 the drug prices were amongst the highest in the world as India depended heavily on imports for its drugs. It was the Indian patent Act of 1970 which brought it change as it allowed only patenting of the process and not the product. The reason for granting only process patent in the area of drugs and medicines was that they were considered essential to the life and health of the community. It is also reduced the patent period by five to seven years. So all this made way for the local and indigenous industry to manufacture the drug by another process. This helped the indigenous generic drug industry to grow, so as to meet the need of the country and also thus inducing competition so as to reduce drug prices.¹²

But India now has passed a patent (Amendment) Act 2005 that eliminated 35 years of national exemption of medicines from product patent protection. The changed

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¹⁰ Ibid.
¹¹ Ibid.
rules could adversely affect generic production of widely used combination tablets such as glaxo SmithKline’s ‘combiver’. The amendment Act will also prevent the production of newer medicines for any other public health needs.

From the perspective of the generic pharmaceutical industry in India, the TRIPs consistent patent law addresses three sets of issues that could have immediate impact. First, the adoption of new definition for “pharmaceutical substances”, which should be a ‘new entity involving one or more inventive steps’. The second is the exclusion of ‘mere discovery of a new form of known substances’ and ‘new use of known substances’ from the ambit of patenting, which could prevent grant of patents on formulations. And the third, protecting the interest of producers who are already producing the products that may be granted patent protection in the new regime. The last mentioned issue has assumed importance given that India was required to accept “mail-box” applications from 1st January 1995, which are being examined after the product patent regime was introduced in 2005.13

It is virtually important that the scope of patentability, definition of pharmaceutical entity is laid down in a clear and unambiguous manner. This step would go a long way in reducing the number of patent litigations, which are threatening to increase. The obvious targets are patents that are being sought for drugs that can be used for treating diseases like HIV/AIDS, Cancer, and T.B. Two significant developments have taken place. The first involved Novartis patent on a drug called Gleevec’ used for the treatment of Cancer. Product patent application for Gleevec was made using the “mailbox” provisions. The EMRs were granted in November 2004 but the grant of the patent was opposed and the opposition was finally upheld in January 2006. The second case involves Glaxosmithkline’s combivir, a fixed dose combination of two AIDS drugs (Zidovudine and lamivudine or AZT/3TC). Opposition to the grant of this patent was submitted on March 31, 2006 by two civil society groups, the Indian Network of people living with HIV/AIDS and the Manipur Network of positive people. The opposition was based both on technical and health grounds. The Indian groups opposing the patent are

arguing that ‘Glaxo’s combivir’ is not a new invention but simply the combination of two existing drugs.\textsuperscript{14}

One of the more contentious issues that the third amendment of the Patent Act had to address was the future of the generic producers in India who are currently producing the products and whose product patent applications are in the “mailbox”. These producers would have to cease operations in India should patent rights be granted to such products under the new dispensation.\textsuperscript{15}

Section 11A of the Patents Act 1970, as amended in 2005 protects the interests of such generic producers whose business interests may be affected in the product patent regime. This section states that “the patent holder shall only be entitled to receive reasonable royalty from such enterprises which have made significant investment and were producing and marketing the concerned product” before January 1, 2005, and “which continue to manufacture the product covered by the patent on the date of grant of patent”. In addition to this, is provided that “no infringement proceedings shall be instituted against these enterprises"\textsuperscript{16}

Although this provision is expected to provide succor to the generic producers, it would have to face a number of imponderables. First, the threshold for assessing whether or not a given level of investment can be considered ‘significant’ is not clear. The lacuna regarding the definition of ‘significant’ poses threat of infringement suits as the patent holder may challenge any definition of significant investment that may be proposed to extract high royalty payments.\textsuperscript{17} A further problem may be encountered while defining the term “reasonable royalty”. According to an Organisation of Economic Cooperation and Development (OECD) study, firms have reported that in some cases royalty payments can exceed 20% of their net sales.\textsuperscript{18} And in South African, Glaxo SmithKline demanded a royalty of 25% before the Courts intervened. A higher royalty will increase the price of generic drugs and this in ultimate analysis would militate against the

\textsuperscript{14} \textit{Ibid.}
\textsuperscript{15} This stems from the fact that the patent rights can be used to prevent anyone from making, using, offering for sale, selling or importing the product covered by the patent.
\textsuperscript{16} Section 11A, Patents (Amendment) Act 2005.
\textsuperscript{17} \textit{Supra} note 13.
existence of the generic producers whose main purpose is to supply medicines at affordable prices.\textsuperscript{19}

It is feared that in this big shake up number of medium and small pharma companies will be forced to pull down their shutters. This would mean few thousands of employees going without jobs. Companies which do not have enough R&D competence and origination and who want to be in the race and survive may be forced to go in for mergers, joint ventures, etc, companies may have to increase their R&D spending and allocation to almost double. The industry feels that the TRIPs in its present form, tipped in favour of developed nations and multinational pharmaceutical firms and it is not trade related about TRIPs that the right to trade is being exploited by developed countries.\textsuperscript{20}

In India the first product patent has been granted by the controller general of Patents in March 2006 to Rouche India Pvt. Ltd., the Indian arm of Swiss drug maker F.Hoffmann La Roche, for its biotech drug pegasyis (Peinterferonaopha-2a). Pegasyis, a recombinant DNA technology drug, is one of the advanced drugs in the interferon series of proteins, which has various end used, mainly for treatment of serious viral infections and consequent diseases like cancer.\textsuperscript{21}

It has specific application in adults who have hepatitis and signs of liver damage. Many Indian companies like Hyderabad based Shantha Biotechnics, market interferon drugs in India. Now these companies either have to discontinue production and marketing of interferon drugs or continue marketing and production by paying heavy royalty.

\subsection*{7.1.3 Effect on drugs prices}

Much of the debate on the impact of product patents on the pharmaceutical industry in India has centered on the issue of price of the patented product and their accessibility. While it is true that a positive association is observed between stronger protection and prices of drugs, it is also true that prices decline with the expiry of patent. In the US, rapid reduction in the price of drugs after the expiration of the patent has been

\textsuperscript{19} \textit{Supra} note 13.
\textsuperscript{20} Ashok Kumar, “TRIPS-is a healthy prescription for Indian Pharma Industry?”, \textit{The ICFAI Journal of Intellectual Property Rights}, Vol. 2, No. 3, August 2000, pp.73-74.
reported. Though more competition among generic drug producers result in substantial price reduction for those drugs, yet increased competition from generics does not result in aggressive response in price behavior by established brand name products.\textsuperscript{22}

In India when amoxycilin was first produced by a multinational, the price of the drug was very high. However with the local manufacturers stepping into produce the indigenous version of the amoxycilin, the price of the same declined rapidly. It should be admitted that adoption of the process patents along with the domestic regulations that restricted the role of multinationals resulted in the growth of the domestic industry. In the late 90’s the pharmaceutical industry of India reached position of near sufficiency in formulations. After a long time experience of having a negative balance of trade in pharmaceutical products, India started enjoying positive balance of trade from the late 80’s. In production volume India accounts 8 percent of world’s pharmaceutical production. The number of pharmaceutical manufacturers increased from a mere 200 in 1950-51 to more than 600 in 80’s which reached a phenomenal figure of 23,790 in 1998-99, of this a sizeable percentage of firms belong to the small scale sector. It is estimated that out of 28.6 million workforces in the pharmaceutical industry, about 4.6 million is employed in the organized units and the rest are engaged in distribution and ancillary industry. These units produce drugs that are not under patent protection and are analogous to products that are already there in the market. Hence, competition is severe among the pharmaceutical units in India, which is one of the important reasons for the relatively lower prices of the medicines in India.\textsuperscript{23}

But the TRIPs agreement has imposed the wide-ranging changes which have been adopted in India. The changes imposed by TRIPs includes increasing the duration of all patents to 20 years, broadening the scope of patentability and the introduction of product patents for medicines. It has been feared that these legislative modifications will eventually lead to higher prices in India and the product patent regime mandated by

\textsuperscript{23} Ibid.
TRIPs will make even life saving drugs, particularly for diseases of the developing world, unaffordable to its vast population.\textsuperscript{24}

Critics have argued that patent should be granted only for pharmaceutical process and not products; process patents provide a weak protection, as there might be many ways of producing drugs that are bioequivalent, if product patent is granted for drugs it lead to monopoly and consequent increase in the prices of drugs.

Drugs that have been in the market till 1995 would in no way be affected. Drugs which were introduced during the period 1995 to 2005 were all pending as patent applications. It is estimated that there were around 3000 applications. If the patent officer granted patents rights to any of those applications, then the price of the drug would increased by 10\% or more. This is because any person other than the patentee if wishing to manufacture then will have to pay royalty. This had been seen to happened in the case of anti-cancer drug called Glivec, Exclusive Marketing Right (EMR) of which was granted to a Swiss multinational company Novartis, leading to a ten fold increase in its price, thus causing misery to thousands of patients. The new amendments have now clarified that such Indian companies, which are already producing these drugs, can continue to produce them, after paying a royalty even if the drug is patented. But the most important and hardest hit was the drugs which were introduced after 2005 and if, patented would definitely led to monopoly by a drug company. And with monopoly granted and with no competition the drug company would have soar up the price of the drug. Let it not be assumed that price will increase by few rupees, but rather it was exorbitant. Rough estimates suggest that prices increased by at least by 15 to 20 times. A cancer drug that costs Rs.9000 to 12,000 shoot up to Rs.1.20 lakhs. Antiretroviral drugs for HIV patients jump from Rs.7000 to nearly Rs.2 lakhs for a one-year course. With the field of biotechnology growing leaps and bounds, it is hoped that in future many new drugs would be in the market. In fact this is what would help the multinational drug companies to reap huge profits. The earlier abilities of the Indian drug companies to quickly produce these drugs have been taken away.\textsuperscript{25}

\textsuperscript{24} M.D. Nair, \textit{The Hindu}, January 31, 2002.
Take the example of a typical “Anti-psychotic drugs” in the treatment of schizophrenia, a common and lifelong mental illness. The prices of locally produced brands are far lower than those of multinational companies. As a result even prestigious public hospitals such as the National Institute of Mental Health and Neuroscience (NIMHANS) in Bangalore are increasingly prescribing the locally produced drugs, which have fewer side effects and ensure better quality of life. If the patent application pending for one of these drugs, ‘olanzapine’ is successful, cheaper local versions of it will no longer be available to patients here. No doubt more drugs in this category and others will soon follow suits.26

Specific concerns have been expressed that the TRIPs agreement could cause escalation of prices for medical technologies and pharmaceuticals in developing countries. At the same time it has been argued that product patent protection is necessary to encourage innovation and many drugs might not have been developed without the granting of patent protection. Some observers contended that the TRIPs agreement may lead to perverse transfer of technology and a significant decrease as in local production. Since the pharmaceuticals are important component in addressing the major causes of diseases burden, including infectious diseases, depression, and for confronting major determinants of health such as tobacco, the balance between innovation and accessibility of new technology is a crucial policy issue.27 Within the health sector, the protection of pharmaceutical patents has been the subject of controversy. There is disagreement as to the need for innovation in pharmaceutical research and development, as opposed to the need to avoid cost escalation. The evidence supporting each of these propositions is summarised below.

Proponents of a more comprehensive global system have pointed out that patents are more important to drug industry than any other corporate sector: patent protection is crucial for development of new products. Since the development of new chemical entities takes long time and carries high risk for inventors, patent protection is deemed to be

26 Supra note 12.
crucial for continuing innovation. It has been argued that evidence so far indicates that intellectual property rights do contribute to increased innovation.\textsuperscript{28}

On the other hand, a study of 95 countries over the period 1950-89 found that 91.7\% of the pharmaceutical patents originated in only 16 countries, and that no patents were filed in 64 countries. The innovation argument of the large pharmaceutical companies has also been questioned because a large share of the resources for research is provided by government, such as occurs in the USA.\textsuperscript{29}

No consensus has emerged on the effect of the TRIPs agreement on pharmaceutical prices. On the one hand studies from developing countries argue that as the TRIPs agreement comes into effect massive drug price escalation will ensue. India had only provided for pharmaceutical process patent, and it was argued that a strong patent system would establish “monopoly of the worst kind and that massive price increase would result. This argument is supported by evidence that price increases for selected pharmaceuticals are directly related to the “patent system practiced in these countries”. At present 70\% of Indian population cannot afford modern medicines and it was argued that this proportion would increase if product patent protection were introduced.\textsuperscript{30}

Other evidence also supports the price escalation hypothesis. For example study in Argentina estimated that the introduction of product patents would result in price increase about 27\%, a reduction in consumption of medicines by 45.5\% and an increased annual expenditure of US $ 194 million. According to an analysis of the situation in Argentina, Brazil, China, India, Mexico and the republic of Korea product patents would result in minimum welfare loss of US $ 3500 million to US $ 10800 million.\textsuperscript{31} A study in

\begin{itemize}
\item \textsuperscript{30} Supra note 12.
\item \textsuperscript{31} Nogues J, “Social costs and benefits of introducing patent protection to pharmaceutical drugs in developing countries”, \textit{The Developing Economies}, 1993, 31(1), pp.24-53.
\end{itemize}
Malaysia, where product patent protection already exists, found that prices of pharmaceuticals were 20-76% higher than in India, reflecting the “profit maximizing” nature of the market.\textsuperscript{32} The Indian Ministry of Trade estimates that product patents will increase drug prices 5-10 fold.\textsuperscript{33}

An alternate way of estimating what the likely impact of patent protection on drug price will be to see what happens when patents expires in countries where policy is enforced strictly. Some evidence on this is available for the United States, which is known to have one of the strongest patent protection policies and where generic competition appears very fast in the market once such protection expires.

For example, Scherer reports that for many years Pfizer sold the antibiotic ‘Tetracycline’ at U.S. $ 30.60 per bottle of 100 capsules. When Pfizer’s patent was challenged, competing firms sold the generic product at U.S. $ 2.50 per bottle. Furthermore he asserts that, “many similar cases of price cost margins on the order of 90 percent for patented drug products have been identified”. Other examples also illustrate the impact of generic drug competition. One hundred tablets of 2 mg pills of ‘valium’ are wholesale priced at around U.S. $ 830, while the generic ‘Dia Zepam’ sells for around U.S. $ 815. One hundred tablets of 600 mg pills of ‘motrim’ are wholesale priced at around US $ 25 while the generic Ibubrofen is priced around U.S. $ 14. Another example mentioned by the president of the American association of retired persons, asserts that its members pay U.S. $ 15.95 for a three months supply of Bolar’s version of Dyazide and U.S. $ 31.95 for SmithKline brand name product. The same source asserted that there might be a ten to one difference in the price of different arthritis drugs.\textsuperscript{34} The following table shows significant price difference between generic and brand name drugs in US.

\textsuperscript{34} Supra note 6.
Table-1: Comparative U.S. Price between generic and brand name companies

<table>
<thead>
<tr>
<th>Mg.</th>
<th>Brand Name</th>
<th>Prices(U.S.)$</th>
<th>Generic Name</th>
<th>Prices(U.S.)$</th>
</tr>
</thead>
<tbody>
<tr>
<td>250</td>
<td>Lidomet</td>
<td>15.1</td>
<td>Metyldopa</td>
<td>10.0</td>
</tr>
<tr>
<td>4</td>
<td>Ristocort</td>
<td>74.3</td>
<td>Triamcinolone</td>
<td>11.3</td>
</tr>
<tr>
<td>400</td>
<td>Actrim</td>
<td>31.9</td>
<td>Sulfamethoxazole</td>
<td>17.7</td>
</tr>
<tr>
<td>50</td>
<td>Enadryl.cap/Tab</td>
<td>15.5</td>
<td>Dephenydramine</td>
<td>3.2</td>
</tr>
<tr>
<td>4</td>
<td>Ecadron</td>
<td>93.6</td>
<td>Dexamethasone</td>
<td>35.5</td>
</tr>
<tr>
<td>250</td>
<td>Iabinese</td>
<td>28.0</td>
<td>Chlorpropamide</td>
<td>7.8</td>
</tr>
<tr>
<td>250</td>
<td>Iuril</td>
<td>6.0</td>
<td>Chlorothiazide</td>
<td>3.7</td>
</tr>
<tr>
<td>250</td>
<td>Lagyl</td>
<td>79.3</td>
<td>Metronidazole</td>
<td>44.0</td>
</tr>
<tr>
<td>1</td>
<td>Yadeergin</td>
<td>31.8</td>
<td>Ergoloid Mesylat</td>
<td>14.8</td>
</tr>
<tr>
<td>25</td>
<td>Ygroton</td>
<td>19.3</td>
<td>Chlorothiazide</td>
<td>9.5</td>
</tr>
<tr>
<td>25</td>
<td>Ndocin</td>
<td>28.1</td>
<td>Indomethcin</td>
<td>17.0</td>
</tr>
<tr>
<td>20</td>
<td>Asix</td>
<td>9.0</td>
<td>Furosemide</td>
<td>5.5</td>
</tr>
<tr>
<td>10</td>
<td>Ibrax</td>
<td>22.0</td>
<td>Chlordiazepoxide</td>
<td>5.2</td>
</tr>
<tr>
<td>500</td>
<td>Rinase</td>
<td>16.5</td>
<td>Tolbutamide</td>
<td>6.4</td>
</tr>
<tr>
<td>4</td>
<td>Eriactin</td>
<td>18.1</td>
<td>Cyproheptadine</td>
<td>8.0</td>
</tr>
<tr>
<td>25</td>
<td>Essanatine</td>
<td>18.1</td>
<td>Dipyridamole</td>
<td>10.9</td>
</tr>
<tr>
<td>250</td>
<td>Erramycin</td>
<td>37.2</td>
<td>Oxytetracycline</td>
<td>10.8</td>
</tr>
<tr>
<td>25</td>
<td>Ofranil</td>
<td>20.4</td>
<td>Imipramine</td>
<td>4.5</td>
</tr>
<tr>
<td>300</td>
<td>Tylenol/Codeine</td>
<td>10.2</td>
<td>Acetaminophen</td>
<td>5.4</td>
</tr>
<tr>
<td>10</td>
<td>Asodilan</td>
<td>22.8</td>
<td>Isoxuprine</td>
<td>6.2</td>
</tr>
</tbody>
</table>

Major reductions in drug prices after patent expiration have also been reported in other countries. The literature has also noted significant price differences between drug prices in developing countries with weak or no patent protection and industrial countries providing strong patent protection.

The following table shows the significant price difference between drug prices in India with Pakistan, Indonesia, U.S.A and U.K.

35 Source: Katz and Goisman (10), books.google.co.in/books?isbn=1585627763. Accessed on 19-6-1012.
Table-II: Comparison of Prices of Select Drugs in Different Dosages (Rs.)

<table>
<thead>
<tr>
<th>Therapeutic segment</th>
<th>Drug Formulation</th>
<th>India</th>
<th>Pakistan</th>
<th>Indonesia</th>
<th>USA</th>
<th>UK</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antibiotic</td>
<td>Ofloxacin, 200mg, 10 tablets</td>
<td>25</td>
<td>216.66</td>
<td>441.67</td>
<td>2377.76</td>
<td>595.84</td>
</tr>
<tr>
<td>Antiulcerant</td>
<td>Ranitidine 150mg, 10 tablets</td>
<td>5.19</td>
<td>64.39</td>
<td>634.08</td>
<td>2030.16</td>
<td>792.68</td>
</tr>
<tr>
<td>Cardiovascular</td>
<td>Atenolol 50mg, 14 tablets</td>
<td>5.60</td>
<td>62.42</td>
<td>322.56</td>
<td>809.60</td>
<td>NA</td>
</tr>
<tr>
<td>Anti cancer</td>
<td>Imatinib Mesylate 100mg, 10 tablets</td>
<td>850</td>
<td>8516.66</td>
<td>9821.96</td>
<td>9329.76</td>
<td>9863.28</td>
</tr>
<tr>
<td>Anti biotic</td>
<td>Ciprofloxacin 500mg, 10 tablets</td>
<td>29</td>
<td>368.36</td>
<td>926.75</td>
<td>2552.44</td>
<td>1079.20</td>
</tr>
<tr>
<td>Anti biotic</td>
<td>Norfloxacin 400mg, 10 tablets</td>
<td>17.59</td>
<td>104.73</td>
<td>130.63</td>
<td>1782.88</td>
<td>277.40</td>
</tr>
<tr>
<td>Anti-inflammatory</td>
<td>Diclofenac 50mg, 10 tablets</td>
<td>1.34</td>
<td>36.79</td>
<td>161.12</td>
<td>733.48</td>
<td>191.52</td>
</tr>
<tr>
<td>Anti ulcerant</td>
<td>Omaprazole 20mg, 10 tablets</td>
<td>9.90</td>
<td>358.80</td>
<td>634.08</td>
<td>2030.16</td>
<td>792.68</td>
</tr>
<tr>
<td>Cardiovascular</td>
<td>Diltiazem 60mg, 10 tablets</td>
<td>30</td>
<td>50.23</td>
<td>32.50</td>
<td>410.52</td>
<td>86.64</td>
</tr>
<tr>
<td>Cardiovascular</td>
<td>Amlodipine Besylate 5mg, 10 tablets</td>
<td>5.90</td>
<td>87.05</td>
<td>228.78</td>
<td>696.96</td>
<td>353.40</td>
</tr>
<tr>
<td>Antihistamine</td>
<td>Cetrizine, 10mg, 10 tablets</td>
<td>7.80</td>
<td>31.03</td>
<td>166.67</td>
<td>928.40</td>
<td>193.04</td>
</tr>
<tr>
<td>Anti-Cancer</td>
<td>Carboplatin, 150 mg vial</td>
<td>693</td>
<td>1662.78</td>
<td>3702.60</td>
<td>21625.12</td>
<td>4652.72</td>
</tr>
<tr>
<td>Cholesterol Reducing</td>
<td>Atorvastatin, 10mg, 10 tablets</td>
<td>24</td>
<td>483.85</td>
<td>565.95</td>
<td>1087.68</td>
<td>489.44</td>
</tr>
<tr>
<td>Cholesterol Reducing</td>
<td>Lovastatin, 20mg, 10 tablets</td>
<td>28.90</td>
<td>159.34</td>
<td>433.33</td>
<td>1180.96</td>
<td>N.A.</td>
</tr>
<tr>
<td>Anti-asthmatic</td>
<td>Salmeterol</td>
<td>200</td>
<td>1407.56</td>
<td>1980</td>
<td>4043.16</td>
<td>7412.28</td>
</tr>
<tr>
<td>Urology</td>
<td>Doxazosin 2 mg, 10 tablets</td>
<td>25</td>
<td>124.60</td>
<td>341.56</td>
<td>748.88</td>
<td>382.28</td>
</tr>
</tbody>
</table>

The reason for low cost of drugs in India is the absence of product patenting and consequent generic competition in the market. With many competitors in the market MNCs brought down the drug prices with no other option. It was competition in the market brought about by the public sector and the private Indian indigenous industry, which compelled them to bring down the prices of the drugs.

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India has a huge pharmaceutical industry, which has prospered in the past because of cost effective manufacturing. In the new product patent regime it has been feared that India will be out of the run in international generic market, where as generic manufacturers from other countries such as Brazil, China and Thailand will fill the demand for cheaper medicines.

For AIDS patients India’s three-in-one fixed dose combinations are cheap, convenient to use and ensure better compliance. These are under patent protection abroad, but are manufactured by giant Indian companies such as Ranbaxy and Cipla and costs $ 350 per patient per year, as against the cost of the same combinations of patented products which costs $ 10,000 to 15,000 per patient per year. The new patent Act is likely to adversely affect treatment of millions with HIV/AIDS globally as resistance developed to current medicines. New generation of more expensive AIDS medicines innovated by multinational companies may not be made available at reduced price because all such medicines invented post January 1995 will now be covered by products as well as process patents.\(^\text{37}\) Therefore the new controversial legislation continues to be vociferously opposed by health advocates both in India and overseas.

The main aim of introducing amendments to Indian Patent Act is to keep up to the conditionality of World Trade Organisation, to that India gets in to the competitive global market. But alas! The competition is among awful un-equals. Of the global medications market with sales of US $ 350 billion, India’s share of US $ 3 billion accounts for slightly less than 1 percent. One billion Indians spend as much in one year on pharmaceuticals as do seven million Swiss. What we in India consume in medication costs less than that booked net profit of the Swiss chemical giant Novartis. Why cannot the North Grant the South the same liberal independence in protection of invention that Switzerland in particular has claimed for itself over and used for its benefit.\(^\text{38}\)

The Pharmaceutical Research and Manufacturers of America (PhARMA) as they state in their report of 2000 to NTE (National Trade Estimate Report on Foreign Trade)


that it estimates the loss attributable to the Indian Intellectual Property System (Process Patent Regime) to be approximately $500 million dollar a year. It reveals the concern of US drug MNCs regarding the change of patent laws in India.\textsuperscript{39} The Indian Patent Act 1970 not only allowed new drugs to be made available at cheaper prices, it also lead to the creation of a platform for Indian companies to become global players. This process had just started and Indian companies had started competing with global companies for generics. It is really this threat that has prompted US companies to induce change. For long the United State government’s position on patents is indistinguishable from that of its drug companies. So long as these global giants dominate global policy decisions, the developing country governments will continue to act to the tunes of the WTO through US drug firms or US government.

What will the disappearance of generics do to the price of drugs in the market? The sources in Geneva tells that pharma has claimed that 15 percent of the Indian market includes drugs under patent. If this is calculated would amount to Rs. 3,000 crore. So 3000 crore worth of drugs would get into a patent regime and their generic versions would have to be scraped. The other indicator to estimate what could be the volume of patented drugs, currently used in the country, would be through the applications pending in the patent office. These are growing since the ordinance was passed. In July 2005 the Union Ministry of Commerce and Industry told Parliament there were 4,792 pharma applications in the mailbox. In February 2005 the same ministry reported there were 5,636 such applications pending at the Indian Patent Office. But it is not clear how many of those were really for new chemical entities. The industry says this is the crux of the problem of the current amendment which does not restrict the patents to a new chemical entity and it may lead to huge distortion. This is further compounded by an inexpert patent office and will lead to many of these ostensibly new but actually evergreen applications being cleared and patents being granted. Many of such products may already be in the market. A number of pre 1995 molecules can come under patents in India.\textsuperscript{40}

\textsuperscript{40} The Pill Bill: What this does to Prices, Down to Earth, March 31, 2005, p.31.
The Government has its own calculations. The Union Ministry of Commerce and Industry maintains prices will not spiral. It says 97 percent of the drugs are off patented and that none of the 354 drugs in the essential list are patented. But the question still remains is, “97 percent of what? The number of drugs sold in India or 97 percent of the turnover of the industry not under patents? There are 60,000 drugs sold on the market and if it is calculated based on the minister’s assumption, then three percent of that number is 2,000 drugs, who is to say which these 2000 drugs are, and what their annual turnover is? Calculating further, three percent of the Rs. 20,000 crore industry would amount to a turnover of 600 crore. The US government and industry estimation puts it close to 3000 crore. Still what this does to price? After all it can be argued that market conditions will not allow the companies to sell at much higher rates.41

In other words can India learn from experience of other countries, which have followed the US TRIPs approach? When the peoples commission used this indicator, they found the comparative prices of some drugs sold in Pakistan and Indonesia, were between 4 to 29 times higher than India.

The Commission on Intellectual Property Rights in its report declared that the internationally mandated expansion of intellectual property rights unlikely to generate significant benefits for most developing countries and likely to impose higher costs for medicines.42

Similarly, the Parliamentary Standing Committee of the Rajyasabha in its Third Report on the Dunkel Draft proposals opined that TRIPs agreement is an attempt by the industrial countries to strengthen their monopoly over the technology regardless of the fact that such an approach is protectionist, anti-competition and anti-liberalisation. The Committee expressed its concern that TRIPs agreement would have a ‘grave impact’ on

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41 Id, p.32.
drug prices and posed the danger that the indigenous drug industry would be gobbled up by the foreign multinationals.43

The argument for a strong patent regime for pharmaceutical companies is often made by them on the basis that there is heavy investment cost for R&D that goes into the creation of new drug. It is however important to examine these claims properly. A look at 1996-2002 annual reports of US drug company throws light on this issue poorly explored area. Top nine drug companies spent a total of $ 45.4 billion on marketing, advertising and administration and only $ 19.1 billion on R&D in 2004.

Big drug companies try to explain that they need strong patent, because it takes $ 500 million to bring a single drug to market. A prominent drug industry advisor, points out that this is bogus figure for several reasons. Firstly it is a fact that most of the so-called new drugs are not innovations. Indeed in excess of 40% of the industry’s R&D is aimed at producing minor variations of existing drugs and not for developing new drugs. Secondly the fastest growing sector of the drug companies is marketing sector and not R&D. For example there are 90,000 drug representatives pestering doctors to prescribe their products. Their wages and salaries is whooping sum of $ 12 billion.44

This clearly shows how pharmaceutical companies have kept the public in the myth of how they are spending their capital. Basically it is the public who are suffering because the money comes out of their pockets when they increase the prices of the drugs to cover-up their R&D costs.

The following bar diagram shows R&D for new products as reported on US income tax return.45

Marketing Versus Research and Development.\(^{46}\)

Industry revenues $430 billion

Turf war between Big Pharma and generic companies, which was largely restricted to exorbitantly priced life-saving drugs for cancer and HIV, is now spilling over

to other chronic ailments like diabetes, and threatening to change dynamics of the nearly Rs.70,000 crore Indian pharma market.

Triggering a full-blown fight with US-based Merck, domestic generic company Glenmark has launched a more affordable version of the multinational’s blockbuster anti-diabetes drug Januvia. The move expected to heighten tensions between MNC’s and domestic generic companies which have been embroiled in patent disputes over the last couple of years.

Glenmark’s launch could also throw up a different patent challenges for the regulators, which have seen two prominent cases where the compulsory licence route was used to launch life-saving drugs at just a fraction of the original.

Glenmark has priced its diabetes drug around 30% cheaper than Merck’s Januvia, and the savings to patients could be nearly Rs. 5,000 a year.

Merck’s diabetes therapies Januvia and Janumet, launched in the Indian market in 2008, are part of the ‘gliptin’ family. The drugs together are nearly Rs.200-crore brands, making them one of the fastest growing medicines, and are ranked No.2 in the oral diabetics market.47

The Supreme Courts’ order rejecting a plea to grant patent protection for Glivec, a cancer fighting drug from Novartis, is a landmark. It will greatly strengthen the quest for access to affordable medicines in India. The decision affirms the idea that a patent regime loses its social relevance when a drug is priced beyond the reach of the vast majority of a country’s people. That pharmaceutical companies of “blockbuster” patented molecules and even older “evergreened” medicines is an irony, because making additional copies of a drug is not expensive. On the other hand, cost control and dispensing of essential medications in government-run health facilities is affected, because many States have no centralised procurement system. It is unsurprising, therefore, that less than 10 percent of medicines sold in India are under patent, while the vast majority are branded generics. The court order should prompt producers of patented drugs to move towards liberal licensing and low cost manufacture in India, the pharmacy of the South that produces Rs. 100,000 crore worth of medicines annually and sells nearly two thirds within the country.

47 The Times of India, Tuesday, April 2, 2013, p.11.
It is a matter of concern that at least a dozen pharmaceutical innovations used in the treatment of cancer, HIV/AIDS, and Hepatitis B and C are not affordable to even the upper middle classes, and impossible to access for the poor.

It would be a gross distortion to paint the Glivec order, which follows the compulsory licensing of Bayer’s drug Nexavar, as an innovation killer. There is evidence to show that major pharma companies recover more than the cost of innovation of a drug in a single year from the United States market alone. Moreover, the costing done by industry has come in for criticism from scientists and policymakers on the grounds that the bloated, irrelevant investments of recent decades are used as the baseline to make calculations. It should not, as the industry claims, cost a billion dollars to produce a new drug; the informed estimate is a third of that figure. The contested field of drug discovery now calls for greater scrutiny of costs and therapeutic value, and control of prices through various legal avenues available under the Indian Patents Act and the TRIPs as confirmed by the Doha Declaration. It would naturally strengthen the case for grant of patents and consensus pricing, if the industry opens its books for verification. Until the golden mean is reached, governments with vast populations that are denied access to medicines due to economic reasons can justifiably use unilateral price control mechanisms.48

7.2 Public health and Patent law

Access to health care including medicines is a basic human right that should have higher status than international trade agreements. The right to access to health care implies a duty of states to create conditions, which would assure to all medical service and medical attention in the event of sickness. This duty is strict with respect to a “minimum core obligation”. There is pressing constitutional obligation on the state to take all measures at its disposal to reduce the price of essential drugs.

Public health aims to understand and influence the social, cultural and economic determinants of health as well as to study and structure health systems as efficient channels for health services delivery. Public health is thus, a discipline built on the academic tradition of inquiry involving research, teaching and professional practice to prevent disease and promote health in populations.

48 The Hindu, Tuesday, April 2, 2013, p.8.
India is experiencing a rapid health transition. It is confronted both by an unfinished agenda of infectious diseases, nutritional deficiencies and unsafe pregnancies as well as the challenge of escalating epidemics of non-communicable diseases. This composite threat to the nation’s health and development needs a concerted public health response that can ensure efficient delivery of cost-effective interventions for health promotion, disease prevention and affordable diagnostic and therapeutic health care.\(^{49}\)

The patent system has to further the public interest while at the same time fairly rewarding innovators. The public interest is served by ensuring access to essential drugs for all, not just for the wealthy or those with drug insurance. If people do not have access to life saving drugs it does not make sense to provide incentive for their innovation.\(^{50}\)

### 7.2.1 TRIPs agreement and human rights

Human Rights refers to universal rights of human beings regardless of jurisdiction or other factors, such as ethnicity, nationality, religion or sex. Human rights and fundamental freedoms are birth right of all human beings; their protection and propagation is the first responsibility of all governments. Health is a fundamental human right. The constitution of India directs the state to regard the improvement of public health as among its primary duties. Abundant availability on a continuous basis, at reasonable prices of essential life saving and prophylactic medicines of good quality is cornerstone of new measures. In the case of *Vincent Panikur Langar v. Union of India*,\(^{51}\) Hon’ble Supreme Court has also reaffirmed the principle ‘public health to be a matter of top priority’. In the above mentioned case the Supreme Court has opined as follows: “Attending to public health, in our opinion therefore is of high priority perhaps one at the tops”. Further, it states that “it is the constitutional obligation of the state to provide adequate medical services to the people to preserve human life, whatsoever is necessary for this purpose has to be done”.


\(^{51}\) AIR 1987 SC 990.
In the case of *State of Punjab and others v. Ram Lubhaya Bagga and others*, the Supreme Court has declared that the obligation of the state to protect the citizen’s right to life and health to be its ‘sacrosanct’ and ‘scared’ duty.

Health is one of the fundamental basic needs of all human beings. International Convention on Economic Social and Cultural Rights recognizes the right to the ‘enjoyment of the highest attainable standard of physical and mental health.’ UN Charter expressly states that in the event of conflict between state’s obligation under the UN Charter and their obligations under “any other international agreement”, their obligations under the UN Charter shall prevail. Of many new areas that captured global attention protection of intellectual property through WTO TRIPS regime for achieving the objectives of globalization remained the most controversial. Protagonists of globalization considered uniform norms for the international protection of intellectual property rights, particularly in the new areas of biotechnology, information technology etc., as a key factor to reap the benefits of globalization, the promoters of human rights strongly feel that this has the potential to deny the poor of their basic human rights. Even though the TRIPs has included many new areas of intellectual property, the provisions concerning patent are going to have maximum impact on the protection of the human right of larger section of the population.

Critics are concerned that TRIPs will not only reduce competition and increase prices, but by doing so, will threaten both human rights and the development process. UN human rights bodied have altered governments to the “apparent conflicts between the intellectual propriety rights regime embodied in the TRIPs agreement on the one hand and international human rights law on the other” and reminded all governments of the primacy of human rights obligations over economic policies and agreements. They have called on member states to refrain from taking measures, which would limit equal access

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54 Article 103, UN Charter.
56 UN Sub-Commission for the promotion and protection of Human Rights, 52nd session, Agenda Item 14, 17 August 2002.
to medicines “used to treat HIV/AIDS or the most common opportunistic infections that accompany them”. It is now accepted that there is a right to access to treatment.\(^57\) The independent UK Commission on Intellectual Property Rights, which comprised wide range of international experts, concludes that TRIPs may harm development and it is inappropriate to apply the same standards to all nations regardless of national wealth. Standards of Intellectual Property Protection that may be suitable for developed countries may produce more costs than benefits when applied in developing countries, which rely in large part on knowledge penetrated elsewhere to satisfy their basic needs and foster development.

And while the World Bank estimates that Intellectual Property Protection will lead to increased foreign investment in middle-income countries, it estimates that full implementation of TRIPs would mean a loss to developing countries of $ 20 billion in patents for all sectors including health.\(^58\) Human rights treaties have not devoted significant attention to the impacts of intellectual property on the realisation of specific rights such as the right to health. However, the relationships have been considered in general terms. An analysis of relevant articles and of the intentions of the states negotiating them brings out several important elements. First human rights treaties recognise the importance of scientific and technological development, they also acknowledge the possible tension between the interests in inventors and the interest of society at large in benefiting from scientific advances. The balance between the two is tilted towards the society in general rather than the inventor. Further the interests of investors must be understood within the context of all the other human rights protected under international human rights conventions.\(^59\)

India has stopped producing affordable generic versions of new medicines. This means that vital medicines for treating AIDS and other diseases will be more expensive throughout the developing world. TRIPs agreement obliges India to grant 20 years patent protection of pharmaceutical products. So the generic production of new medicines is

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\(^58\) World Bank, Global economic Prospects and the Developing Countries 2002; Making trade worse for the world’s poor, October 2001.
illegal.\textsuperscript{60} The threat of high priced new medicines matters for health care in India, which has more people living in absolute poverty. It also matters for rest of the developing world, since India has been major supplier of generics including low cost antiretrovirals, and is the one of the very few developing countries with a sophisticated pharmaceutical industry capable of producing generic versions of new drugs. The issue is not just the price and availability of treatments for HIV/AIDS or for TB and malaria. Hepatitis C, for example, affects 170 million people worldwide the great majority in developing countries, but the cost of treating one patient with patented drugs is US $30,000 per year. Government of poor countries cannot afford such high prices for medicines when running a health system on very limited resources. When timely availability of generic version is a matter of life and death for millions of the poor and suffering, and more than 1000 people die untreated every day in India from pandemics like AIDS/HIV, TB, Malaria etc. a delay in introduction of generic versions of effective new drugs would directly result in denial of treatment to lakhs of the poor dying and suffering from such pandemics. Such delay by the introduction of product patenting for medicines would be total abdication of duty and violation of fundamental right to life under Article 21 and state’s constitutional obligations.\textsuperscript{61}

Growing concern of the developing countries about the implications of TRIPs led to the Doha Declaration, signed by WTO Ministers in November 2001. The Doha Declaration affirmed that the TRIPs agreement “should be interpreted in a manner supportive of WTO member’s right to protect public health and, in particular, to promote access to medicines for all”.

7.2.2 Access to medicines

The term “access to medicines” encompasses the array of problems that render it difficult or impossible for the world’s low-income inhabitants to obtain medication that could otherwise reduce greatly the disease burden under which they suffer. The problem include different medical infrastructure, imbalances between prices and ability to pay and


\textsuperscript{61} Ibid.
the lack of incentives to develop medicines specific against diseases endemic mainly in low-income nations.⁶²

During the 20⁰ century there were numerous technological breakthroughs in pharmaceutical therapy, making it possible to cure or at least alleviate most of the diseases that historically killed millions of individuals each year. But the ability to purchase those medicines is concentrated in relatively affluent nations, where the vast majority of pharmaceutical sales occur. At the other extreme roughly 60 percent of the world’s population live in nations defined by the United Nations in 2000 as “low income”, with per-capita gross national product averaging less than $530 in 1998. The World Health Organisation estimated that in 1999, those nations made only 2.9 percent of the world’s pharmaceutical purchase. WHO has predicted that by expanding accesses to available health interventions, and especially essential medicines, 10.5 million lives could be saved annually by the year 2015. Lack of access to medicines and complementary health care in turn perpetuates a vicious spiral: poor health impairs productivity and economic development while low productivity keeps the citizens of the least developed nations too poor to afford appropriate health care.⁶³

In their effort to combat the burden of disease, health authorities at world Health Organisation in individual less-developed nations since 1977 have published “model list” of so called “essential drugs”. Drugs have been included on the list in part because of their proven efficacy and partly because of their relatively low cost. Low cost in turn has been achieved by emphasising generic drugs. More than 90 percent of drugs on WHO’s model list have been generics. However this emphasis was threatened by the emergence of epidemics of HIV/AIDS and related opportunist disease such as resistant tuberculosis and cryptococcal meningitis. Virtually all of the drugs effective against all of those diseases were patented and, at least initially, available only at costs for a year’s treatment exceeding total average income of citizens in low income nations. Contributing to concern over this situation was the inclusion of the so-called TRIPs agreement culminating in the Uruguay Round Treaty, signed in April 1994 and implemented in

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⁶³Ibid.
1995. Up to that time many less developed nations, did not grant patent rights on pharmaceutical product inventions. TRIPs required signatories to the treaty to begin awarding such patents with some transitional provisions. This posed special problems, up to that time the newest and most effective drugs might be available generally from India and other nations that had not awarded pharmaceutical product patent. TRIPs provisions began to bind on India and other nations and their ability to continue supply of low cost generics atrophied.

The worst impact of TRIPs that the pharmaceutical industry is foreseeing is the end of reverse engineering; companies now may have to increase their R&D spending and allocations to almost double. The industry feels that the TRIPs in its present form tipped in favour of developed nations and multinational pharmaceutical firms. It has been said that it is not trade related about that TRIPs and that the right to trade is being exploited by developed countries.\textsuperscript{64}

The Commission on Intellectual Property Rights in its report reveals that intellectual property system as a whole is less advantageous for developing than developed countries in many areas of importance to development, such as health, agriculture, education and information technologies. The system increases the cost of access to medicines that developing countries cannot afford.\textsuperscript{65}

The TRIPs agreement has extended the period of patent protection to twenty years and this will be disadvantageous to Indian drug industries. Because this allows a particular company (mostly MNCs) to sell the drug in the market for a longer period without competition, which otherwise would have reduced the price of the drug. In fact the achievements of Indian pharmaceutical industry in bringing down global prices is attributable to the limited protection for the period of five years for pharmaceutical processes provided under Indian Patent Act 1970 and is extremely important to make medicines available when people need it most. For example, pencillin, a life saving antibiotic was produced in the foreign country during 1941 and in India it was produced only during 1963. It took twenty two years for the drug to be produced in Indian market. Similarly streptomycin another life saving essential medicine used for Tuberculosis was

\textsuperscript{64} Ibid.
\textsuperscript{65} Supra note 20, pp.73-74.
produced in foreign market during 1947 but produced in Indian market in 1963. Thus it took 16 years for the drug to be produced in the Indian market. All this was before 1970, and things changed as the new patent Act was brought into functioning in 1970. Salbutamol a drug used to treat Asthma was produced in the foreign market in 1973 and it was produced in India in 1977 just 4 years after. Similarly, mebendazole, a drug used to treat common intestinal worm infestation was produced for the world market in 1977 and it was produced in India in 1978, just one year after. This early production of the drug in the Indian market was as great boom to the patients. All this early availability of the medicines will be missed now and a dying patient in need of life saving drug will have to be told to wait till the medicines are easily available for him at a cost that he can afford. The following table illustrates this matter.

*Production of Drugs by Indian Companies*

<table>
<thead>
<tr>
<th>Drug</th>
<th>Production abroad</th>
<th>Production in India</th>
<th>Time lag</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Before 1970</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sulfadizine</td>
<td>1940</td>
<td>1955</td>
<td>15 years</td>
</tr>
<tr>
<td>Penicillin</td>
<td>1941</td>
<td>1963</td>
<td>22 years</td>
</tr>
<tr>
<td>Streptomycin</td>
<td>1947</td>
<td>1963</td>
<td>16 years</td>
</tr>
<tr>
<td><strong>After 1970</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sulfadizine</td>
<td>1973</td>
<td>1977</td>
<td>4 years</td>
</tr>
<tr>
<td>Penicillin</td>
<td>1974</td>
<td>1978</td>
<td>1 year</td>
</tr>
<tr>
<td>Norfloxain</td>
<td>1987</td>
<td>1988</td>
<td>1 year</td>
</tr>
<tr>
<td>Mebendazole</td>
<td>1997</td>
<td>1998</td>
<td>1 year</td>
</tr>
</tbody>
</table>

The 1970 patents Act was formulated after an exhaustive process of discussions within the country both inside and outside the Parliament starting from the Justice N.Rajgopal Ayyaanger committee Report of 1959. The Act of 1970 was hailed as model legislation for developing countries since it balanced the interest of patentee with those of the public. But the WTO agreement has changed the whole scenario.

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66 *Supra* note 12.
One of the arguments put forward to suggest that product patent will not push the cost of medicines up is that drugs used for common ailments are already in the generic category having gone off patents year ago. This is misleading because new and better drugs required for the effective treatment of many illnesses are constantly being produced and ought to be accessible to all.  

Another fundamental problem of access to medicines is the lack of innovative drugs targeted specifically towards diseases prevalent only in third world, e.g. sleeping sickness, chagas disease and leishmaniasis. Because low income nations have such limited purchasing power that multinational pharmaceutical firms lack demand-based incentives for research and testing on drugs targeted toward so-called “tropical” diseases and resistance strains that continue to evolve. A study of Medicines San Frontiers revealed that among 1,393 new drug chemical entities introduced into world markets between 1975 to 1999, only 13 drugs were indicated for tropical diseases.

7.3 Agriculture and food

The importance of the agricultural sector in developing countries cannot be overstated. Agriculture provides food and jobs and is often the basis of community life. Around 70 percent of the world’s poorest people live in rural areas and are dependent on farming.

A resilient agricultural sector requires a highly diverse range of plants and animals in order to keep breeding varieties that can cope with disease, changes in climate and other challenges that farmers, fishers and herders face.

IPRs jeopardize agricultural diversity essential to present and future food supplies– yet they are becoming increasingly prevalent in agricultural sectors for several reasons. IPRs are a useful way to maximize profits, essential to the private sector who increasingly dominates all aspects of agriculture. In parallel, the rapid development of biotechnology and genetic engineering has multiplied the potential value of genetic resources and thus the desire of companies to have legal means – via IPRs – to benefit

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67 Ibid.
from that potential. Furthermore, the World Trade Organization (WTO) Agreement on Trade-Related Intellectual Property Rights (TRIPS) has made minimum IP standards in agriculture a requirement for all its Members, thus serving, since the mid-1990s, as a vehicle for raising IP standards all over the world.69

Even though one could trace the history of protecting intellectual property in plant varieties and seeds to the eighteenth century, serious attempts started only in the early periods of the twentieth century. It was the legislation of USA, Germany, Hungary, Italy, Netherlands, Austria, etc. in the 1930s which really lead to private monopolization of plants and seeds business. It was these global seeds men who raised the question of intellectual property protection in the international forum. The International Union for the Protection of New Varieties of Plants (UPOV) in 1961 gave more strength and vigour to these global seeds men to further exploit the genetic resources not only from their countries but also from the gene-rich South. The Convention inter alia mandates the member countries to provide protection of seeds for commercial marketing. This led to the large scale shifting of seed companies from the production of fruits and ornamentals to that of agricultural seeds. The significant impact of this is the success of Green Revolution. This in turn eroded the genetic resources leading to the beginning of Gene Revolution, which reveals the importance and need for exercising control over genetic resources. Realising the importance of genetic resources in the Green Revolution, the Multinational Companies (MNCs) tried to get control over the genetic resources available in the world by creating germplasm banks with the help of world organizations. The majority of these germplasm banks are located in the developed countries. With the programmes of these world bodies these developed countries were able to collect maximum germplasm from the gene-rich South. They preserved it and made it available to the scientists in both public and private sectors for research and development. It was also found that the research benefits of these public research organisations were exploited by the private seed companies for making profits without the payment of royalties. The products of the research have been monopolised and sold back to the South. Thus, after

collecting and preserving the genetic varieties in their germplasm banks, they started destroying the genetic varieties available in the South by introducing the Green Revolution. The use of new high yielding variety (HYV) seeds, especially the hybrid varieties, by the farmers made them to lose their traditional varieties and further pushed them into the hands of big seed companies for their survival. While this is going on, the UPOV Convention has been constantly revised to tighten the intellectual property protection. The most recent one is the 1991 amendment which takes away the exemption clause in the original Convention on the farmers' right to reuse the seeds and the breeders' right to use it for further research. Since they were not satisfied by this, attempts were made to internationalise the monopoly system by introducing new provisions in the Trade Related Intellectual Property Rights (TRIPs) agreement.  


7.3.1 The Indian position on plant and seed varieties

Since Independence, realising the importance of food security for the people, the Government took the initiative to improve agricultural productivity. Though there was no agricultural policy resolution like the industrial policy resolutions till recently, the focus on agriculture in the Five Year Plans makes the Government's policy towards agriculture very clear. It was indeed a progressive policy. In addition to giving subsidy to the farmers, there was heavy input in the R & D through Government sectors. The intellectual input for the development of HYV seeds for the Green Revolution in India goes to the credit of the committed scientists. Till recently they have produced nearly 2000 improved varieties of seeds answering the standards prescribed under the Seeds Act. Since the R &D work was at the cost of the Government, Parliament decided not to give any intellectual property protection to these breeders in the form of monopoly. Section 3(a), of the Patents Act read together will make it very clear that plant and seed varieties are not inventions for intellectual property protection in India. These new varieties are treated as common property for the free exploitation by the farmers to increase productivity. Thus in the Indian context the germplasm which were traditionally...
preserved and used by the farmers, were taken from them, improved, converted and given back to them for use without collecting any royalties. Since R &D work was kept under Government control, the Government also took steps to create seed corporations to undertake production of quality seeds and make them available to the farmers. The National Seeds Corporations, State Farms Corporation of India and 13 State Seeds Corporations were originally undertaking the reproduction and distribution of seeds. Because of the inefficiency created in these institutions they could not meet the demands of the farmers. Instead of rectifying the defects in these institutions, the Government decided to provide the Government-bred varieties to the private sector freely to produce quality seeds and make them available to the farmers. The private corporations made huge profits without spending much on R &D. It appears that today these private sectors are trying to destroy the public seed companies though they are interested in preserving the large scale R &D investment of the Government to continue for a few more years. This is because of their vested interest to get the fruits of the Government research without burdens. The New Seed Development Policy of 1988 permitting the foreign seed corporations to operate in India also helped them to advance arguments for monopolising the seed industry. The outcome of this exercise was the demand from these private companies in 1989 for the protection of intellectual property in the new seed varieties. It is in this context that one must look at the TRIPs provision on seed and plant varieties and their impact on Indian agriculture.\textsuperscript{71}

### 7.3.2 The TRIPs Agreement on Plant Varieties

The attempt in the TRIPs is to internationalise the patent system which was hitherto in the national regime. The Paris Convention, after recognising the need to give freedom to member countries depending upon their technological and economic development to enact suitable patent laws, gave only broad guidelines in this regard. The TRIPs provisions not only internationalise the traditional items covered by the Patent law but also introduces new items which were kept outside the domain of the patent system because of various fundamental reasons. Thus, the TRIPs provisions brings within the scope of patent law life forms, plant varieties, biotechnology etc. As far as plant and seed

\textsuperscript{71} \textit{Ibid.}
varieties are concerned it is mandatory to give either patent protection or "an effective sui generis system. It is also mandatory that these provisions must be reviewed by the GATT four years after entering into the agreement to create WTO. It appears that with reference to plant varieties the option to go for a Plant Breeders Right (PBR) system seems to be only a temporary arrangement and in the long run one has to provide a more effective and powerful monopoly protection under the patent system. In other words, the option given to start with PBR is the first step towards the patenting of plant and seed varieties. Assuming that a country can opt for PBR system, it may not be possible to keep the farmers' exemption and the breeders' exemption in the system. This will be considered as an ineffective sui generis system as contemplated by the TRIPs. If a developing country were to opt for a patent system in plant and seed varieties it is needless to emphasize that the position is going to be further worse. All the new proposed provisions like rights of patent, term of patent, shifting the burden of proof in process patent etc. will have a serious impact on agriculture. It is in this context one must enquire into the possible consequences India is going to face in the field of agriculture.72

7.3.3 The increasing corporate presence in the agricultural sector

Since the beginning of the 20th century, food production has been increasingly monetized, making farmers throughout the world more dependent on suppliers of inputs (such as chemicals, credit and machinery) on intermediaries (for transport and processing) and on buyers of farm produce (retailers).

These processes are increasingly linked. What food is produced, how and at what price it is sold is, in many places, determined by a handful of private companies who provide agriculture-related goods and services.

The seed is the basic unit of agricultural production and the basis of life itself. Its self-reproducing quality has long prevented it being sold on an industrial scale: why would a farmer purchase seeds when he can just replant those harvested from the previous crop?

Indeed, for millennia, farmers have saved harvested seeds for re-sowing and exchange. Seeds are carefully selected on the basis that the plants producing them possess

72 Ibid.
desirable traits – such as high yields, disease resistance or drought tolerance. This enables ongoing development of crops adapted to local conditions.

In most of the developing world, seed breeding continues to be carried out by farmers. However, scientific and technological advances in the early 20th century opened the way for private companies to become major players in industrialized country seed markets. A significant contributing factor to the gradual corporate dominance of seed breeding was the development of hybrids. Hybrids offer farmers uniform crops (well-suited to mechanized, industrial agriculture) and – often – higher yields. Crucially, as hybrids only produce true hybrid crops once, a farmer wanting to continue producing those crops has to buy new seeds each year – thus ensuring a relatively stable market for commercial hybrid producers.

However, hybridization does not work for some economically important crops, such as wheat or soy. If a farmer purchases non-hybrid seed from a commercial breeder one year, there is no obligation for her to do so again the following year and she can re-sow, exchange, multiply or sell the harvested seed to other farmers. This limits the commercial seed industry’s means of retaining clients and increasing profitability.

The seed industry is now developing new technologies to limit plant reproduction, the most contentious being seeds genetically modified to produce sterile offspring or to propagate only if applied with a certain chemical. These technologies have not yet been mainstreamed and much of the industry’s efforts are focused on promoting legal means, via intellectual property rights, to control seeds.73

Basmati is the south Asian pride but was patented by Rice Tec. The Multinational Company (MNC) was able to retain some parts of the patent, even after a huge campaign from civil society organisations. Basmati is an important food and income source for small farmers. Small farmers receive two mounds (40 kg) of other rice grains in exchange for one mound of Basmati rice because of its higher value. They get higher prices primarily because of its higher prices in international markets. As long as American rice could be sold as Basmati, the cheaper ‘Basmati’ rice will harm exports. Small farmers are facing a disaster. Their important crop will have no value. So MNCs of developed

countries are getting benefits from TRIPs and the poor farmers in developing countries are being plunged deep into the crises.\textsuperscript{74}

**7.3.4 Farmers’ rights**

Patents provide the right-holder with a 20-year monopoly over all uses of an invention, provided it is new, involves an inventive step and is capable of industrial application. In plants, patents may apply to a number of biological materials and processes (including seeds, plant cells or isolated DNA sequences), but ultimately give the right-holder control over the seed.

Farmers cultivating patented seeds do not have any rights over the seeds they plant; they are merely licensees of a patented product. When buying patented seeds, farmers are often obliged to sign contracts agreeing not to save, re-sow or exchange the seeds.

Patents are only granted to plants or plant parts that involve an ‘inventive step’, raising again the question of exclusive rights to those who took only the most recent step in developing the variety.

Farmers’ rights are customary rights of farmers to save, use, exchange and sell farm-saved seed; to be recognized, rewarded and supported for their contribution to the global pool of genetic resources as well as to the development of commercial varieties of plants; and to participate in decision making on issues related to crop genetic resources. Farmers’ rights are conceived as largely collective or communal in nature and tend to be non-exclusive, since they promote sharing and exchange of materials and knowledge.

The concept of farmers’ rights was coined to counterbalance the expansion of PBRs and patents, which threaten to restrict the ability of farmers to maintain and develop agricultural biodiversity and fail to recognize farmers’ contributions to the breeding of plant varieties – including varieties now protected by IPRs.\textsuperscript{75}

There has been a focus on the rights of the farmers to preserve the seeds, the preservation of biodiversity and the rights of the traditional farmers for preserving it and


\textsuperscript{75}Farmers’ right in India. www.cojer.org>Intellectual Property Rights. Accessed on 8-6-2012.
the consequence of emerging out of accepting GATT provisions like price increase, erosion of genetic varieties, dependency on seed companies by the farmers etc. But there seems to be only very little focus on what will happen to the public R & D in agriculture in India and its impact on farmers and farming.

Today, the threat of IPRs on seeds seems remote. Worldwide, about 1.4 billion farmers continue to cultivate their land with seed they or a fellow farmer have saved from previous harvests. In South Asia and sub-Saharan Africa 80 to 90 percent of seeds are produced on-farm. In other words, many farmers, including most of the poorest, do not buy commercially produced seed. Moreover, many countries do not enforce IP laws on seeds or plants. Outside the US, there are only a handful of cases of farmers being taken to court for re-sowing or exchanging IP-protected seed. Thus, the relatively few farmers that are cultivating IP-protected seeds remain largely free to re-use them as they wish.

Nevertheless, each day more farmers become dependent on commercially produced seed, 82 percent of which is protected by an IPR. In parallel, most countries are implementing laws requiring IPRs on seeds and developing mechanisms to enforce these rights. Thus, the likelihood of a farmer sowing an IP-protected seed is growing, as is the likelihood that he will be taken to court or penalized if he re-sows or exchanges that seed.

Patents will reduce access to seeds and genetic resources to farmers and breeders. It could also make seeds more expensive for the small farmers because of royalty payments, restrictive contracts and increased commercialisation. Once the seed is planted companies can insist that farmers purchase new seed every year. This compromises farmers’ rights to save, grow, exchange and sell (protected) seed.76

The ability of farmers to re-use seeds has many advantages. It allows them a measure of independence from the market and a potential source of additional income. Unfettered exchange ensures flows of genetic materials, contributes to locally appropriate seeds and to the diversity of crops, as well as constituting an important element of cultural life and community in many regions.

Patents and PBRs promote industrial-scale agriculture, facilitate increased concentration of seeds and other agricultural inputs in the hands of a few transnational

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corporations, foster inappropriate R&D, threaten sustainability of food production, accelerate the depletion of agricultural biodiversity and permit bio-piracy. All of these have adverse implications for the enjoyment of human rights.

There is no obligation for farmers to buy commercially produced, IP protected seeds. However, many farmers have been seduced by commercial seed advertisements’ promises of greater yields. For example, Monsanto and its local partner Mahyco asserted that farmers who bought their Bt-cotton seeds would have higher yields and reduced production costs because the variety would require less pesticide. Thousands of farmers began cultivating the patented crop, but studies in Andhra Pradesh show that Bt-cotton farmers earned lower net returns than non-Bt farmers, in part because they have had to increase their pesticide use to deal with the previously uncommon diseases that are plaguing the Bt-cotton plant.

Another reason why farmers buy IP-protected seeds is because in some areas there is little else available. Two thirds of IP-protected seeds available today are owned by the ten largest seed companies. This gives them control of the market and the ability to buy up any competition. In India, Monsanto bought up most of the other cotton seed companies in the cotton belt and has been accused of destroying non-Bt seeds – dramatically reducing the availability of non-IP protected seeds in local markets.

Ultimately, millions of farmers could lose their livelihood because they will no longer be able to afford seeds. This is especially true given the vertical integration of seed companies. The same company will provide credit, seeds and pesticides, as well as buying farmers’ produce, thus trapping farmers in a cycle of dependence on one company.

The threat to farmers’ livelihoods is made worse by the increased privatization of research and development (R&D). Until recently, most agricultural R&D was carried out by publicly funded institutions, which encouraged sharing biological resources and related knowledge between people and across countries.

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Today, as almost half of agricultural research is funded by the private sector, research priorities are increasingly oriented towards profitable crops and farming methods, rather than towards public needs.

The world’s poorest inhabitants – small-scale farmers – would benefit most from research into local plant varieties and on-farm technologies, such as irrigation systems, that could dramatically increase agricultural productivity on marginal lands.79

7.3.5 Agricultural production

IPRs affect the sustainability of food production in three critical ways:

Restricting flows of genetic material

As more plant varieties are subject to IP protection, fewer farmers will be able to exchange or re-sow their seeds, ultimately reducing the number of people involved in crop breeding. Fewer farmer-breeders means a much more limited knowledge base of, and less physical access to, the variety of plant genetic resources available worldwide.

IPRs restrict the genetic materials available to commercial breeders and researchers working for public institutions. Optimal development of new varieties of food crops depends on having access to as wide a range of genetic material as possible. Patents and increasingly patent like PBRs restrict access to the genetic material and will limit laboratory based research and innovation.

Encouraging monocultures

IPRs are only granted to genetically uniform seeds and so promote the cultivation of monocultures. By rewarding standardization and homogeneity, the IP system erodes biodiversity.

If the agricultural sector of a given country is increasingly dominated by large monoculture farms, smaller farmers may no longer be able to earn enough to survive because of their inability to compete. This in turn fuels the downward cycle of biodiversity loss as the conservation and development of locally adapted seeds and plants, as well as the knowledge required to maintain them, is not renewed.

79 Supra note 70, p.10.
Planting monocultures is the leading cause of the depletion of local plant varieties and renders production more vulnerable: thousands of acres planted with identical seed can be lost to a single disease or pest.

**Accelerating contamination of the environment**

Most monocultures are dependent on chemical herbicides and pesticides because they lack the genetic variety that protects crops. Planting monocultures often results in massive increases of agro-chemical use. This is especially true of GM monocultures, over 80 percent of which have been modified to withstand specific types of herbicide that kill most other plants in the field. The herbicides are developed by the same companies that produce GM-seed and are sold as a package. Arguably, it is precisely to augment herbicide use, that biotechnology companies promote the use of their herbicide-resistant seeds.

The toxins contained in these chemicals have harmful effects for the farmers that use them and can contaminate the air, rivers and other water sources far beyond the farm. In addition, intensive, pesticide-based agricultural methods tend to deplete the long-term productive capacity of land and thus endanger the right to food of future generations. The realization of the right to food also requires food to be free from adverse substances.\(^{80}\)

Seed exchange practices have long constituted a fundamental aspect of farmers’ cultural life. By limiting such exchange, thus also hindering rituals around planting and harvests, IP protection directly interferes with the enjoyment of the right to take part in cultural life, as well as with minority and indigenous rights.

Another dimension of the right to take part in cultural life is the relationship of many rural and indigenous groups with their land. If farmers leave their land because they are no longer able to derive a livelihood from farming, they will no longer be able to partake in key cultural practices linked to their ancestral land. A number of human rights bodies, including the Inter-American Court of Human Rights, have recognized land as a fundamental basis of culture.

UPOV and TRIPs, as well as the national IP systems that they favour, also fail to acknowledge traditional beliefs about knowledge or nature. Many indigenous groups do

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\(^{80}\) *Id.*, p.14.
not have a concept of ‘ownership’ of knowledge. To the extent that such ‘ownership’ exists, it is often collective and for the benefit of the community.

Permitting IPRs on genetic resources encourages bio-piracy. Indigenous knowledge of the potential uses of a particular plant or genetic resource is invaluable to bio-prospectors seeking to develop, for example, new medicines or drought-resistant crops. However, neither patents nor PBRs oblige the right-holder to recognize or remunerate the source of the knowledge or resources.

If an indigenous group did want to use IPRs to protect its knowledge from biopiracy, it might not succeed. To obtain a patent, the claimant must show that there is an identifiable inventor. This almost immediately dismisses the knowledge systems and innovations of indigenous peoples as well as those of farmers because they innovate communally, over long periods of time. PBRs require that plant varieties be distinct, “clearly distinguishable from any other variety whose existence is a matter of common knowledge.” Again, this disqualifies communally developed varieties.81

7.4 Impact on Indian economy

India is now a part of the global economic system. Every section of the Indian economy is now linked with the world outside, either through its direct involvement in international trade or through its indirect linkages with the export or import transactions of other sectors in the economy. All trade is now subject to strict and self-abiding multilateral trade obligations, most ostensibly to the overarching principles of most favoured nation and national treatment clauses, international scrutiny and transparency. The WTO obligations, however, do not seem to work equally between the developed and the developing world. Thanks to their limited geo-political prowess, the developing economies have been rather at receiving end, at the time that the Uruguay Round negotiations were getting finalised; the situation has turned to better even in the implementation of whatever asymmetries existed in the WTO agreements, most notoriously under the GATT reformulations and TRIPs provisions. The whole developing world is worried about its economic future. So is India, especially because disturbing

81 Id, p.15.
signals, most distressingly about the basic life sustaining parameters of employment, growth and poverty have started surfacing on a wide scale.\textsuperscript{82}

There has been a lot of controversy on the role of intellectual property protection regime especially the patent system in fostering innovation, technology and industrial development of a country. Intellectual property protection is expected to encourage innovation by rewarding the inventor with the grant of monopoly rights over the commercial exploitation of their inventions for a specified period. On the other hand, strong Intellectual Property regime may inhibit diffusion of knowledge and even technology development in the countries that are technology followers. The history suggests that counties have fine-tuned their Intellectual Property regimes as per their developmental requirements. Typically countries in Asia and other regions have had softer Intellectual Property regimes in the early stages of their development and these regimes have been strengthened as the countries developed and became significant producers of innovations and new technology themselves. In particular, some countries such as India have successfully developed cost effective process to produce life saving drugs with softer patent regimes. This enabled the national health system to provide affordable medicines to masses of poorer people.

Against this backdrop, the ongoing attempt to harmonise and strengthen Intellectual Property regimes worldwide, as a part of the TRIPs agreement, appears to be adversely affecting the technological activity in developing countries by choking the knowledge spillovers from industrialised countries to developing countries. Furthermore the implementation of the provisions of TRIPs agreement threatens the access and affordability of life saving drugs to poor people by pushing up their prices. This has been highlighted by the controversy regarding the availability of AIDS drugs in South Africa.\textsuperscript{83}

There are three ways that the strength of the Intellectual Property regime could affect economic growth indirectly: Intellectual Property regime may affect the innovative activity that in turn is the source of total factor productivity improvements and thus


contributes to growth. The Intellectual Property regime could affect the inflows of FDI and technology transfers and which could impinge upon the growth. Given the international dimension of Intellectual Property regimes, there could be implications for international trade of countries, for instance, on the ability of countries to export certain goods. Finally, the changes in Intellectual Property regime may imply some redistribution of income between the countries and between communities within the country.\textsuperscript{84}

7.4.1 Innovation

One of the key issues to be addressed is whether the new regime is likely to stimulate local innovation. The main argument offered in favour of tighter and more stringent laws to protect intellectual property and patent rights is to provide better conditions for appropriability of innovations. However, the existing empirical literature suggests that the effectiveness of patent protection varies from industry to industry and is most effective only in chemical and pharmaceutical industries. A study by Mansfield showed that around 65 percent of pharmaceutical and 30 percent of chemical inventions would not have taken place but for patent protection. In the case of most other industries patent protection was not important. This finding was confirmed by most of the subsequent studies. For instance a survey conducted by Levin et al showed that product patents were found to be highly effective as means of appropriating returns only in 5 of 130 narrowly defined lines of business. These five included drugs, organic chemical, and pesticides. An analysis of French patent renewal data for the period 1969-72 concludes that while patents may be significant source of return to innovative enterprises, they are not the major ones. The main reason for limited effectiveness of patents is the ability of competitors to legally ‘invent around’ patents.\textsuperscript{85}

In Industrial countries patent protection is a major determinant of the amount of investment in R&D in pharmaceutical drugs. For example, between 1985 and 1989 the total amount of investment in R&D by U.S pharmaceutical industry increased from around U.S $4 billion to U.S $57 billion. This increase of around 75 percent in only four years must be attributed at least in part to the longer protection afforded by the Patent

\textsuperscript{84} Id, at p.210.
\textsuperscript{85} Supra note 33.
Restoration Act passed in 1984. More formally in the case of Japan, it was found that the 1976 introduction of patent protection for pharmaceutical drugs resulted in statistically significant increase in R&D.\textsuperscript{86} In a regression equation explaining the investment in pharmaceutical R&D in Japan, the co-efficient of the sales variable by 14-16 percent after 1976.\textsuperscript{87}

Would developing countries experience the same impact as that observed in the United States and Japan? This would appear unlikely. First, for several years now, in several developing countries, physical investment has been declining. In many of the heavily indebted countries, which also provide weak protection, the capital stock has been seriously eroded. In these economies, the discount rate is very high and probably private firms have a priority of investing in machinery which has a faster pay off than investment in R&D which has an uncertain return and will only come. If at all, several years after the investment funds have been allocated.\textsuperscript{88}

More fundamentally, in the case of pharmaceutical drugs, there appears to be a serious financial barrier to undertake R&D. The pharmaceutical manufacturers Association has estimated that on average, it costs around U.S. $150 millions to produce, test and market a successful drug. For the poorest of the developing countries it would appear that R&D in pharmaceutical drugs is simply not possible within the foreseeable future.

In the case of advanced developing countries, the possibility of undertaking successful research would appear to depend on the size of investment relative to the size of the firms and the nature of the regulations. The average cost of developing a successful drug varies with therapeutic categories. For example, the average R&D costs of psychopharmacological and anti-inflammatory drugs are more than three times higher than that of anti infectious drugs.\textsuperscript{89}

\begin{thebibliography}{99}
  \bibitem{88} Ibid.
\end{thebibliography}
Obviously, the smaller the size of the investment that is necessary to undertake successful R&D the higher the probability that this activity can be undertaken in developing countries. Let us assume that it takes an investment of U.S. $100 million to have good chance of producing successful drug in a period of five years, i.e., U.S. $20 million per year. In most of the developing countries this amount of money cannot be borrowed in capital market; it must be self generated. Let us assume furthermore that at least initially, firms would not be willing to devote more than 5 percent of sales to R&D this is the proportion observed in pharmaceutical R&D in Spain. This fact implies that a pharmaceutical company should sell drugs for a value of at least U.S. $400 million per year to have a chance to entering the R&D competition in drugs. This size appears to prevent most of the firms in the developing countries from the possibility of undertaking R&D in pharmaceutical drugs.\textsuperscript{90}

### 7.4.2 Foreign direct investment

There has been a considerable controversy on the role of intellectual property protection in determining inward FDI flows and their effect on technology licensing and trade. The relationship between intellectual property protection and FDI is quite complex. On the one hand, a weak IPR regime increases the probability of imitation, which makes a host country a less attractive location for foreign investors. On the other hand, strong protection may shift the preference of multinational corporations from FDI toward licensing. As surveys of multinationals have shown, the importance of IPR protection varies between industries.\textsuperscript{91}

The various means by which IPRs affect FDI and other channels of information flows are subtle and complex. Moreover it must be emphasised that strong IPRs alone are insufficient for generating strong incentives for firms to invest in a country. If that were the case recent FDI flows to developing economies would have gone largely to sub-Saharan African and Eastern Europe. In contrast, Brazil, China and other high growth

\textsuperscript{90} Supra note 7.

large market developing economies with weak protection would not have attracted nearly as much FDI if investment were heavily dependent solely on IPRs.\textsuperscript{92}

It has been argued that countries with strong protection of intellectual property benefit from the fact that technology owners are more willing to transfer their capital and knowledge to such countries. Despite the emphasis put on this argument the evidence is weak. One could argue for example, that the decision to license and transfer technology depends much more on the legal strength of the licensing agreement and the adaptable capacity of the buyer to absorb the technology. One of the ways of transferring technology to a developing country is through foreign direct investment. The hypothesis has been that investors would send more updated technology if patent protection and more generally intellectual property protection is provided. But again, there is no evidence to support or reject this hypothesis.\textsuperscript{93}

In the case of pharmaceutical drugs the evidence is also weak, and the little that exists suggests that patent protection is not a decisive factor to determine the extent of drug technology available in developing countries.

The hypothesis here is that although patents are important for investment decisions in R&D, they are only of second order importance for making decisions on investment in physical assets; these decisions are more likely to be influenced by the investment climate of the country than by incentives to R&D.

7.4.3 Technology transfer

The crucial issue in respect of IP is not whether it promotes trade or foreign investment, but how it helps or hinders developing countries to gain access to technologies that are required for their development. If a supplier of foreign technology licenses production to a domestic firm rather than itself establishing manufacturing locally, less foreign investment would have been attracted. However, the overall result may be more beneficial to the domestic economy because of the indirect contribution to domestic technological capabilities. If high technology imports increase as a result of strengthening IP regimes a transfer of technology may be achieved (for example, as

\textsuperscript{92} Ibid.  
\textsuperscript{93} Supra note 31, p.343.
embodied in capital goods), but there is no guarantee that the domestic economy will be capable of absorbing that technology as a basis for future innovation. Therefore the transfer of technology may not be sustainable. Rather as it is seen, some countries may use weak IP regimes as a means gaining access to foreign technologies and developing them using reverse engineering thereby enhancing indigenous technological capacity. The implementation of TRIPs now restricts the ability of developing countries to follow this path.94

But the determinants of effective technology transfer are many and various. The ability of countries to absorb knowledge from elsewhere and then make use and adapt it for their own purposes is also of crucial importance. This is a characteristic that depends on the development of local capacity through education, through R&D and the development of appropriate institutions without which even technology transfer on the most advantageous terms is unlikely to succeed. The effective transfer of technology also often requires the transfer of “tacit” knowledge, which cannot be easily codified (for example, as in patent disclosures or instruction manuals). This is why even the best-designed programs to foster national capacity for research, which are funded by donors, have not always been successful. Since many technologies of interest to developing countries are produced by organisations from developed countries, the acquisition of technology requires the ability to negotiate effectively based on an understanding of the particular area of technology. This process requires a determined approach on the part of the recipient of technology to acquire the necessary human capital and appropriate institutions.95

This aspect of the process of technology transfer is largely in the hands of developing countries themselves. But this does not mean that developed countries, or international policies more generally, cannot facilitate or hinder the process. The TRIPs agreement recognises in Article 7 that IPRs should contribute to the “transfer and dissemination of technology”, but also in Article 8, that measures may need to be taken to prevent the abuse of IPRs including practices that “adversely affect the international transfer of technology”. Article 40 includes provisions to prevent anticompetitive

94 Supra note 91.
95 Ibid.
practices in contractual license. Article 62.2 obliges developed countries to provide incentives to their enterprises and institutions to promote technology transfer to least developed countries (LDCs) in order to “enable them to create a sound and variable economic base”. These provisions in TRIPs reflect some of the provisions in the draft International Code of Conduct on Technology Transfer, on which negotiations between developed and developing countries failed in 1980s.96

Since then, the global economy has changed. Notable, economic policies around the world have shifted from import substitution and directed industrialisation behind high tariff barriers towards open market policies which emphasize the benefits to be gained through low tariffs, global competition and a less directive role for governments in economic development. The so-called knowledge based industries and trade in high technology products, have gown apace. The importance of R&D has increase and product life cycles have shortened. In this liberalised and competitive environment, firms in developing countries can no longer compete on the basis of importing “mature” technologies from developed countries and producing them behind tariff barriers. Firms are more wary of transferring technology in ways that may increase the competition they face.97

The problem is not so much now about obtaining more or less mature technologies on fair and balanced terms, but of accessing the sophisticated technologies that are required to be competitive in today’s global economy. TRIPs has strengthened the global protection offered to suppliers of technology, but there is no international framework to ensure that the transfer of technology takes place within a competitive framework which minimises the restrictive technology licensing practices with which the code was concerned.

7.5 Conclusion

The protection of intellectual property rights is not an end in itself, but a tool that societies should use to attain higher public interests. The dynamic nature of public interest must recognised and respected. However, from prior to 1970 patent monopolies

96 Ibid.
97 Ibid.
enjoyed by pharmaceutical MNCs prevented the Indian government from protecting public interest. This led to the enactment of Indian Patent Act 1970 which restricted patent protection in respect of pharmaceuticals to processes not the products. This enabled India to produce essential drugs and pharmaceuticals at lower cost and to encourage generic manufacturers and thereby subserve public interest. Generic manufacturers enabled the industry to flourish but attracted the wrath of MNCs resulting in international pressure for higher level of patent protection. This led to the imposition of TRIPs agreement and the product patents.

The consequence of TRIPs was the series of amendments to the Indian Patent Act 1970 culminating in the introduction of product patents and the heightened protection of the right of the patent holders. Thus the TRIPs compliant patent law is argued to be against public interest on following grounds.

First patent holders can exclude direct competition and charge higher prices for patented medicines than those would have prevailed in a competitive market. Further this would make life saving drugs unaffordable, particularly those suffering from diseases like HIV/AIDS, malaria etc. in developing countries.

Second, the developing countries may not be able to compete with large MNCs who have already monopolised the market as they lack necessary scientific infrastructure and capital, required for research and development.

Third, the MNCs claim that they have to invest heavily on R&D often fails as the study indicated that their investment on R&D is much less compared to their investment on marketing. Thus the patent is used only to make high profits.

Fourth, it has been pointed out that these MNCs are not investing to discover new drugs for diseases afflicting the poor such as malaria, tuberculosis, diarrhea. So that their claim namely patent protection promotes public health is hollow.

Fifth, it has been asserted that TRIPs compliant patent law would stimulate technology transfer, FDI in pharmaceutical sector, but the experience of some of the developing countries has been the opposite. The entry of such pharmaceutical MNCs was to neutralise the local firms and many such firms went in to liquidation.
Sixth, there is some truth in the assertion that the heightened patent protection has in fact reduced access to medicine, increased the prices of essential drugs and made it difficult for the developing countries to promote public health.

Lastly, the reduced access to medicines has resulted in large scale violation of human rights in general and the right to health in particular. This is so in spite of the fact that international law imposes the positive obligation on every state to promote public health.

Despite the fact that patent protection may not be conductive to promote public health, there are positive aspects also. Developing countries by using TRIPs flexibilities in their favour can attract foreign investment and technology transfer. But their ability to use appears to be limited.

*Sui generis* protection to the IP in agriculture has helped the nations to incorporate plant breeder’s rights and well as provide for farmer’s rights. India has used the *sui generis* protection tool to balance the plant breeder’s rights and the farmer’s rights with wide scope. The introduction of diverse forms of intellectual property rights in the agricultural field is on the whole completely novel in India and mainly linked to the necessity to comply with India’s existing international obligations and to the general trend towards the privatisation of knowledge in recent decades.

International Union for the Protection of Plant Varieties (UPOV) style new plant variety protection may provide a limited scope of protection recognizing only value-addition in new varieties, and is oriented towards advanced breeders. Therefore India has adopted a mid-way by recognizing the rights of the breeders as well as the farmers. Thus, India has tried through its enactment not to upset the global legal order while preserving the nation’s interest.

The Act is the first of its kind which included provisions for protecting the rights of the farmers. However, it can’t said to be very effective because there is no obligation on the part of breeders, to take prior consent of farmers whose genetic material or knowledge they may be using for commercializing their varieties. There is also no compulsory benefit-sharing requirement between breeders and such farmers. Both these
omissions are a violation of India’s commitment under Article 8j and 10c of the Convention on Biological Diversity.

Regarding Traditional Knowledge, although provisions like benefit sharing have been included in the Act, yet there is a further need to have a separate legislation for affording protection to this segment of the society. Considering the fact that there is already substantial use of traditional knowledge by industries, provisions must be included to safeguard the business interest of the persons already in use of traditional knowledge. Remedies, both in Civil and Criminal law must be employed to prevent unauthorized use of traditional knowledge for commercial exploitation.

India could have actually gone in for a truly independent legislation. One that actually promotes comprehensive farmers’ rights, including full protection of their knowledge and agro-diversity and sensitive to the ethical issues involved in commercializing life forms. The law should encourage public and private sector crop breeding within an overall framework of social justice and ecological sustainability.