CHAPTER III
GLOBALIZATION AND INTELLECTUAL PROPERTY RIGHTS

III. 1. GLOBALISATION AND THE WTO

Globalisation has been established as one of the pre-eminent terms to indicate the idea that a cohesive and sequestered national economy and domestic society no longer exists and that there is a truly global economy and society, in which every day life is dependent on global forces. Economic globalisation has been fundamentally redesigning and centralizing the world’s political and economic arrangements in a way unsurpassed since the Industrial Revolution. Globalisation seeks to integrate economic activity of all countries within a single, homogenized development model. Since the homogenized model is characterized by the advocacy of “free trade” for organizing the global trading system, the World Trade Organization (WTO) has become globalisation’s primary rule-making and governing regime, though it exists in relation with other international institutions such as the International Monetary Fund, the World Bank and the North American Free Trade Agreement.

The main elements of globalisation can be briefly summarized as follows:

a) The ever growing importance of the financial structure and the global creation of credit leading to the dominance of finance over production, at times, finance capital becoming an independent

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force, which some economists prefer to call 'global financial architecture'.

b) The increasing importance of the 'knowledge economy', where knowledge is said to have become a significant factor of production.

c) The rapid growth of knowledge-based industries relying more on technological innovation leading to quick redundancy of given technologies and increasing transnationalisation of technology.

d) The rise to dominance of global oligopolies in the form of MNCs controlling globalised production, knowledge and finance. This development is said to have led to the retreat of nation-state as a regulative power, on the one hand and the globalisation of political power in the form of a plural authority structure associated with the United Nations, on the other. The erosion of the nation state is seen to lead to greater global institutional and regulatory uncertainty and to the weakening and dilution of accountability and regulatory power of national democratic systems.

III.2 THE GENESIS OF GATT AND WTO

The post-Second World War international trading system has undergone a complex array of changes ever since the birth of the General Agreement on Tariffs and Trade (GATT) in 1947 until its latest incarnation as WTO in 1995. A brief discussion on the prelude and genesis of GATT up to its new Avatar WTO is in order, before proceeding to a detailed discussion on intellectual property rights and the Indian pharmaceutical industry.

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5 Susan Strange, 'Wake up Krasner! The World has Changed', Review of International Political Economy, VOL.1 (2), Summer 1994, p.216.

The inter-War period starting from 1911-12 up to 1941-42 experienced severe crises in monetary relations between the countries, marked by a syndrome of 'beggar-thy-neighbour' policies coupled with the onset of Great Depression; this formed the background to GATT. The outbreak of the Second World War gave a decisive push to the efforts of two prime architects of the post-War trade and monetary policies, the UK and the USA, which culminated in the formation of the GATT on 30 October 1947. GATT, in fact, was to be an interim arrangement pending the conclusion of the Havana Charter that embodied the agreement on the International Trade Organization (ITO), which was to be signed about six months after the birth of GATT. However, GATT survived, and the Havana Charter, which was to incorporate GATT, eventually died a couple of years later. Marshall Plan, among other causes, was said to be responsible for the death the Havana Charter.

The GATT system that emerged was governed by eight basic principles:

1. Non-discrimination in the matter of trade regulations among the trading partners who are signatories to the system. If a country chooses to offer certain concessions to a non-member the same must be extended to all the members. This forms Article I of GATT, which became the celebrated ‘most favoured nation’ (MFN) clause.

2. The prohibition of quantitative restrictions and the acceptance of tariffs are provided in Article XI, which implies that price-based measures are the only legitimate tool for regulating external trade.

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iii. The principle of *national treatment* stipulates that internal taxes of regulating must not be used to moderate or counteract tariff rates and concessions.

iv. The Principle of *reciprocity* relates to the process of tariff negotiations modelled on the lines of American reciprocal trade agreements.

v. The ultimate Weapon provided in Article XXIII, is *retaliation*.

vi. The *safeguard mechanism* (Article XIX) can be used in emergency, where excessive imports of a product can cause or threaten to cause serious injury to the domestic producers of similar product; a country can then resort to concessionary measures and suspend obligation.

vii. International, cross-border trade in goods for which GATT is originally intended.

viii. Decision-making procedures and voting rights which are stipulated in Articles XXV and XXX.

On 1 January 1998, GATT entered into force with 23 founding members, 12 developed and 11 developing countries. The Second Round was held at Annecy, France in 1949. From September 1950 to April 1951, the Third Round was held at Torquay, England. In May 1956, the Fourth Round was completed at Geneva. The Fifth Round, named Dillon Round, which started in 1960 was concluded in 1962 in the US. The short term Arrangement covering cotton textiles permitted negotiations of

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quota restrictions affecting cotton-exporting countries and lasted until 1974, which finally culminated in the Multifibre Arrangement, MFA.

A trade negotiation committee meeting at a ministerial level formally opened the Kennedy Round in May 1964. In June 1967, the Round’s Final Act was signed by some 50 participating countries, which together accounted for 75 percent of world trade. Ministers launched in the Japanese capital the Tokyo Round, which was the Seventh Round, in 1973. The major outcome was a reduction in import duties and other trade barriers by industrial countries on tropical products exported by developing countries.

From 1947 until 1974 the major theme of all the negotiations centred around the cutting of tariffs, mostly between the developed countries, involving about $60 billion worth traded commodities from 1947 to 1964 (Kennedy Round) and about $300 billion of traded goods and services in 1973 (Tokyo Round) itself.\(^\text{10}\) In all these negotiations, the value stakes in the world trade of goods and services for the developing country members were almost negligible, and did not constitute even 2 percent of the total.

### III.2.1 THE URUGUAY ROUND

GATT Trade Ministers meeting at Punta del Este, Uruguay launched the Eighth Round of negotiations on 20 September 1986. The negotiations lasted for seven-and-a-half years covering a wider spectrum of issues of than any earlier Round. Ministers signed the Final Act of the Uruguay Round on 15 April 1994 in Marrakech, Morocco. The Uruguay Round results had transformed the provisional multilateral trading system which had existed under the GATT into the permanent World Trade Organization with a significantly strengthened legal structure and mechanism with a provision for punitive retribution. Thus the WTO came into force on 1 January 1995, with Geneva as its headquarters. A

brief GATT/WTO chronology is provided below, which covers up to the IV Ministerial Meeting in Doha, on 14 November 2001.

III.2.1.1 A BRIEF GATT/WTO CHRONOLGY

• **1947** The birth of **GATT**. On 30 October 1947, the General Agreement on Tariffs and Trade was signed by 23 nations-twelve developed and eleven developing economies – at the Palais des Nations in Geneva.

• **1948** On 1 January 1948, **GATT** came into force with 23 founding members.

• **1964** From 1948 until 1964 six Round of negotiations took place between different nations. The **Kennedy Round** in 1964 followed by the **Tokyo Round** in 1973 represented some major agreements in liberalization of trade, reduction of import duties and other trade barriers by industrial countries on tropical products exported by developing countries.

• **1974** On 1 January 1974, the Arrangement Regarding International Trade in Textiles, otherwise known as the **Multifibre Arrangement (MFA)**, came into force.

• **1986** The **Uruguay Round**. GATT Trade Ministers meeting at Punta del Este, Uruguay launched the Eighth Round of trade negotiations on 20 September.

• **1993** Successful Conclusion of the **Uruguay Round** negotiations on 15 December 1993 in Geneva, Switzerland.

• **1994** The Final Act of Uruguay Round signed by Ministers on 15 April 1994 in Marrakesh, Morocco.

• **1995** Emergence of **World Trade Organization** on 1 January 1995 with its Headquarters in Geneva.

• **1997** Successful conclusion of negotiations on financial services on 12 December 1997.

• **2000** Attempts to respond to Developing Country concerns about implementation of Uruguay Round.

• **2001 IV** Ministerial Meeting in Doha, the capital of Qatar in the Middle East on 14 November 2001. More active participation by Developing Countries. Leadership by India, Brazil, Egypt.

The importance of the Uruguay Round negotiations is schematically represented in Figure-1 below.

### III.3 THE WTO ORDER AND THE IPRS

The post-Uruguay Round world trade order was expected to be overseen by a new, more powerful body than the GATT, the WTO, which was to monitor three major areas\(^{11}\); the old GATT plus several understandings on interpretations and associated agreements on trade in goods; the General Agreement on Trade in Services (GATS); and the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS). These agreements were sometimes said to form the 'three pillars' of the WTO system. While the image might suggest more architectural elegance than exists in reality, the important message is that the WTO system had three areas of strength based on the sets of multilaterally agreed roles concerning trade in goods, trade in services and the protection of intellectual property. Each of the agreements covered a separate area of economic activity and a specific government policy. Since the first two do not form part of our inquiry, we shall confine to the last one namely, the TRIPS.

Protection of intellectual property rights was one of the three new issues on the agenda for the Uruguay Round negotiations (1986-94),

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\(^{11}\) WTO, Geneva, 1995 [also available on http://www.wto.org]
FIGURE 1
THE STRUCTURE OF THE URUGUAY ROUND NEGOTIATIONS

This diagram is prepared on the basis of data on GATT/WTO negotiations obtained from http://www.wto.org
along with trade in services and trade-related investment measures (TRIMS). There exists a consensus in the large literature on the history of agenda setting for the Uruguay Round that the inclusion of the three new issues was a fundamental requirement for the US participation in the talks. It is shown also that the US, during 1979-86, worked towards inclusion of these three issues in the GATT agenda as well. This took an extraordinary effort for the US, because initially most members of the GATT, for various reasons, were opposed to expanding the scope of negotiations beyond traditional trade issues.

There also is a general agreement in the literature that the new issues were included in the agenda of the Round either due to internal politics of US, or as a result of the interaction of the US Congress, the Administration and organised group interests. Each of these three principal actors was important. Ryan has shown that the US corporations with strong patent and copy right interests and their alliances had shaped the IPR-related trade diplomacy of the US before and during the Uruguay Round. The pharmaceutical manufacturers led the patent interests, mostly from PhRMA; the copyright interests were canvassed by the publishing, motion picture, recording and software designing industries. These industries had the property in common—that their products could be initiated or copied at a relatively

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15 Cf. Chapter I above for details.
low cost; they therefore had the most to gain from strengthening the protection of intellectual property rights internationally.\textsuperscript{16} In the late 1970s the patent interests had attempted to achieve radical reform of the Paris convention to the effect that it would set minimum standards for patent protection world wide, including patents for pharmaceutical products. But the World Intellectual Property Organisation (WIPO), which administers the Paris Convention, is a UN agency with one-nation, one-vote decision-making, and the developing countries had opposed the reforms, especially for pharmaceuticals. The copyright interests were less concerned about the lack of minimum standards than about the lack of enforcement of existing national standards of copyright protection. A related problem with the WIPO system of intellectual property conventions was the lack of dispute settlement mechanism with sanctions, which members might use to defend the rights of their nationals.\textsuperscript{17}

In the early 1990s, both the US patent interests and the copyright-dependent industries decided to lobby energetically for support from US trade diplomacy. Initially the two groups pursued different strategies. The patent interests concentrated on achieving a multilateral solution proposing new and enforceable GATT rules for the protection of foreign investment and intellectual property.\textsuperscript{18} The copyright-dependent companies had less confidence in a multilateral GATT-based solution; instead they favoured bilateral diplomacy, which frequently was equivalent to unilateral use of US leverage.\textsuperscript{19} The vehicle for this was

\begin{footnotesize}
\begin{enumerate}
\item[16] Klaus Stegemann, "The Integration of Intellectual Property Rights into the WTO System", \textit{World Economy}, 23(9), September 2000, pp.1237-68.
\item[18] Klaus Stegemann, op.cit.
\item[19] ibid, pp.1239-40.
\end{enumerate}
\end{footnotesize}
section 301 of the US trade Act of 1974 or amended by the 1984 Trade and Tariff Act and 1988 Omnibus Trade and Competitiveness Act. The 1988 amendment introduced the so-called Special 301 process mandating the United States Trade Representative (USTR) each year to identify the foreign countries with the most egregious policies denying adequate and effective protection of intellectual property rights, and to announce the USTR's agenda for intervention.\textsuperscript{20} It is not surprising, that the annual Special 301 process agreements of intellectual property protection around the world, the interests of the patent and copyright groups, all converged in the agenda of the Uruguay Round.\textsuperscript{21} Usually the case made for more stringent intellectual property protection is on the grounds that it would enhance efficiency of international production, trade or other spheres of economic activity, and that the absence of such a protection for IPRs would lead to 'market-distortions' or 'trade-distortions'.\textsuperscript{22} In fact, it is argued that the TRIPS Agreement was not needed either to reduce transaction costs for trade or for the registration of intellectual property rights. Rather the Agreement has no function in this regard as all members retain separate national intellectual property regimes for their territories. But surely they have to be TRIPS-compatible in any case. If international cooperation was the objective, enhancing WIPO-based conventions like the Patent Cooperation Treaty of 1970 could have achieved more.\textsuperscript{23}

In his brilliantly developed proposition, Klaus Stegemann,\textsuperscript{24} argues that the traditional principle of GATT, which has been, applied in all rounds of multilateral trade negotiations (MTNs) commencing from 1947,
namely, the principle of reciprocity is nothing but "rule-based mercantilism". According to its preamble, the objectives of the GATT are to be promoted "by entering into reciprocal and mutually advantageous arrangements" and Article XXVIII bis:1 provides that tariff reductions should be negotiated "on a reciprocal and mutually advantageous basis". In fact, it is the same principle of reciprocity, which is stated to be the beneficial principle responsible for contracting tariff reductions amounting to roughly $ 360 billion of trade since the inception of GATT, until the Tokyo Round in 1973.

The process of negotiation requires reciprocity, and the binding force, the validity of the negotiated set of rules and concessions, once agreed, does not require such reciprocity. The important point here is that the TRIPS Agreement became part of the WTO system as a result of the traditional GATT process for negotiating reciprocal and mutually advantageous arrangements.

Reciprocity was supposed to be essential for trade liberalisation because countries generally are unwilling to remove or reduce trade barriers unilaterally. The implication is that national trade policies and multilateral arrangements are still based on mercantilist principles. Tariff reductions or changes in domestic law that facilitate market access for imports are perceived as 'concessions' for which at least equivalent concessions must be received from trading partners to satisfy the national interest. The need for reciprocity has been explained by the observation that policy makers can only overcome the resistance of import-competing domestic interests if exporting interests are assured of improved access to foreign markets. Reciprocity of market access

25 Cf. f.n.23.
26 Please cf. f.n.10 above.
27 Klaus Stegemann, Ibid.
concessions involves an exchange of opportunities to collect additional rents. Foreign market access concessions permit exporters to collect greater rents by making additional sales abroad at prices exceeding the marginal cost of the goods and services supplied and also by obtaining higher net receipts on existing exports when foreign trade barriers decline. A similar exchange of opportunities to collect rent occurs when the reciprocal for domestic market access concessions is something like the TRIPS Agreement. Foreign concessions concerning increased protection of intellectual property permit the owners to collect additional rents from royalties, higher prices and possibly additional sales of their protected products in foreign markets where protection is increased.30

The power and willingness of states to use trade policy for the purpose of helping their nationals or companies to collect rents also from foreigners has been recognised as an essential feature of mercantilist system.31 Prior to the TRIPS Agreement, the US government helped its nationals extract larger rents on claimed intellectual property by subjecting certain target countries, including members of the GATT, to the section 301 process. With the TRIPS Agreement in place, mercantilistic behaviour could continue, but it is subject to the multilaterally agreed limits and the rules and institutions that apply in the integrated WTO system. Owners of intellectual property had obtained new rights to rent appropriation in foreign countries, and their governments have rule-based mandate to see to it that these rights are enforced. For issues covered by the TRIPS Agreement, there no longer is a need to incur the extensive domestic and diplomatic costs of operating a unilateral section 301 machinery, as was the case before. If members

30 Klaus Stegemann, ibid.
31 Ekelund and Tollison state that, one of Smith's principal themes in the Wealth of Nations was that Mercantilism was equivalent to the demand for regulation and rents by merchants and manufacturers, and Smith's emphasis that private interests were deriving the monopoly rights by the mercantilist state. See, R. B. Ekelund and R.D. Tollison, Politicized Economies: Monarchy, Monopoly and Mercantilism, Texas A&M University Press, College station 1997.
do not fulfil their multilaterally agreed obligations, the complainants occupy the moral high ground and can use the less costly WTO dispute settlement mechanism to claim what is owed to them.\textsuperscript{32} However, the whole argument developed above shows that the perceived benefits accruing to the firms in the absence of section 301 machinery seems only as an advantage to the American firms rather than to the firms belonging to the developing countries or for that matter the Indian firms. For example, it is quite unlikely that the principle of reciprocity would benefit the Indian pharmaceutical firms in a similar manner as it would perhaps the American drug firms. Hence, the rule based mercantilism as proposed by Stegemann may not be uniformly benefit all the members of the WTO in the same manner, and rather likely to benefit those firms which possess the largest pool of patent rights with dominant presence in the global market. In the case of the pharmaceutical industry it implies that these firms are mainly the American drug firms.

III.4 THE HISTORY AND ECONOMICS OF IPRS

The history of usage of IPRs in an institutionalised form can be traced back to the fifteenth century when the Venetian state passed the first federal law on patents. The use of some of the earliest patents that can be traced as far back as medieval Europe appears mainly to have been to induce the transfer and disclosure of foreign technologies.\textsuperscript{33} It is somewhat ironic therefore that the present use of patents and other forms of IPRs is to protect technology and prevent its disclosure. Although intellectual property rights were used initially to increase diffusion of technology, e.g., by England in 1300s to try to induce

\textsuperscript{32} Klaus Stegemann, Ibid.

artisans from the continent to move to England and transfer their more advanced technology.\textsuperscript{34}

\textbf{III.4.1 IS KNOWLEDGE A COMMODITY?}

The significance of IPRs is believed to have assumed extraordinary importance in the context of revolutionary changes that have taken place in information technology (IT) and biotechnology (BT) in the last ten years or so. This seems to have ushered in, what is known as the "New Economy", which is knowledge-based and knowledge-driven, through acquisition of new sets of skills, procedures and methods, as opposed to the "Old Economy" which is believed to be based on material physical capital, and the use of material resource inputs. In fact, some economists have termed the new economy as representative of "Intellectual capitalism", distinguishable from the material capitalist production of the twentieth century.\textsuperscript{35}

A simple definition of intellectual property is knowledge or expression of an idea that is "owned" by someone. The emphasis on the term "property" automatically brings in the aspect of "ownership". Intellectual property is intangible and indivisible; usage by any number of consumers will not deplete the magnitude of this intangible property. The owner of intangible information would find it difficult to sell the information to recover any prior or on-going investment, without legal protection for property rights. Intellectual property has been compartmentalized into three historic domains: patents, trademarks, and copyrights. A fourth domain has emerged in the 20\textsuperscript{th} century and that is

\begin{flushleft}
\textsuperscript{35}Paul A. David, "A Tragedy of Public A Knowledge 'Commons'?" University of Chicago Law and Economics, Working Paper No.67, 2000; Also by Paul A. David, "Does the New Economy Need All the Old IPR Institutions?" paper presented to the UN University, WIDER conference on 10-11 May 2002, Helsinki.
\end{flushleft}

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trade secrets. Intellectual property concepts are essentially the product of North American and European legal constructs.36

Since the main component of intellectual property is knowledge—knowledge may be viewed as a commodity. But it is not a commonplace commodity. First, the non-excludable and non-rivalrous nature of information qualifies it as a 'public good'. However, it is differentiated in two respects from the mass of conventional public goods, such as public parks, highways, traffic lights and so on. The first difference is that the attributes of the commodity—i.e., typically the contents of the information itself will not be known beforehand. Indeed, all the interested parties do not automatically know them when the new knowledge becomes available also. This asymmetry in the distribution of information greatly complicates the process of arranging contracts for the production and use of new knowledge. The second differentiating feature is the cumulative and interactive nature of knowledge. It is particularly evident that the stock of scientific and technological knowledge grows by incremental additions, each advance building upon and sometimes altering the significance of previous findings in complicated and often unpredictable ways.37 For those very reasons, there should have been a strong case opposing the IPR protection so that the international knowledge pool could be shared among the peoples of the world. However, there has been a strong policy push in recent years not only to strengthen legal protection for IPRs but also to see the effective enforcement of these IPRs under the stewardship of WTO. However, it must be noted here that, in the realm of knowledge, information and scientific data, an overly literal metaphor—"property"—one that emphasizes the desirability of socially unforced rights to exclude trespassers and to alienate "commodities" by means of exchange, may lead

towards perverse economic policies in the field of scientific and
technological research. In other words, the exclusion of the genuine
users of technology and knowledge based applications through legal fiat
in the short run, may not mean socially desirable and welfare-oriented
policies in the long run.

III.4.2 EVOLUTION OF INTERNATIONAL INTELLECTUAL
PROPERTY LAWS

The first modern national copyright law was the Statute of Anne,
enacted in 1710 in Britain. While the United States Constitution
recognized in 1789 the nature and purpose of copyright, the first US
copyright Act of 1790, like the Statute of Anne, gave writers of books,
maps and charts a fourteen year right, renewable for another fourteen
year term. France’s first modern copyright law was passed in 1793, after
a horrendous experience during the French Revolution when all
restrictions on literary property were lifted, triggering scholastic and at
times, cultural anarchy. However, the term ‘intellectual property’ was
not coined until the late 19th century. It was based on the view that
patents, copyright and trademarks had more in common than the older
forms of tangible property. Intellectual property was divided into two
logical compartments at that time: literary/artistic vs. industrial property
(sometimes seen as art vs. utility or expression vs. product). Thus was
born the dichotomy between patent and copyright, and this dichotomy
existed in ‘The Great Conventions’ of the 19th century that was carried
forward in to the domain of international trade and law, in various
amended forms to this very day: The Paris Convention and The Berne
Convention.

38 P.A. David, (2002), Ibid.
III.4.2.1 PARIS CONVENTION AND PATENTS

A patent is a right granted to an inventor by a national government to exclusively to make, use, and sell, usually through a license or assignment an invention for a certain period of time. Since patents are granted to inventors according to national law, they represent territorial grants of exclusive rights. What exactly constitutes a patent and how it is protected in any country depends on the national law of each country. There are basically two types of patent systems in the world: registration and examination. Countries, such as France, grant a patent upon registration (the payment of a fee together with an application filed at a centralized government office). Since no initial inquiry is made by the government agency at the time of filing about whether the innovation is deserving of patent protection at law, it is difficult to determine the validity of the patent under this system until an alleged infringement is made and court of law makes a determination. Under the second type of system, examination, a patent is granted following a careful investigation by a government agency to determine whether the innovation is worthy of patent protection and whether any prior similar patents have been granted to another person in the nation.40

The oldest of the multilateral international treaties dealing with patents is the International Convention for the Protection of Industrial Property, also known as the Paris Convention. The Paris Convention, originally signed in 1883, revised and amended several times since, has over eighty-five members. Under Paris convention, the treatment of foreigners under patent laws is in the category of ‘national treatment’, which implies that the members of the treaty should not discriminate among each other and should treat ‘foreigners’ without any discrimination.

Copyright is not just one right, but a bundle of rights granted to an author or artist. Copyright can exist in books, movies, artwork, musical works, photography and even some computer software programmes. The main international copyright treaty is the Berne Convention for the Protection of Literary and Artistic Works, 1971, known in short as 'Berne Convention'. At the heart of Berne Convention is again the concept of 'national treatment'. Copyright works are generally protected for at least fifty years after the death of the author. Copyright generally protects the form of an expression of an idea, but not the idea itself.

India is a member of Berne Convention for the protection of Literary and Artistic works, since 1928, the Universal Copyright Convention including the 1971 revision, since 1957 and the Geneva Convention for Producers of Phonograms. It ratified the Washington Treaty on Integrated Circuits in 1989. India preferred to be member of the World Intellectual Property Organisation (WIPO), which came under the purview of the UN. As we have noted before, the Paris Convention seeks to establish the principle of 'national treatment' to foreigners and grant all the foreigners seeking patents the same protection as is given to nationals. The extension of the patent system to the developing countries has consequences that are embedded in the unequal development of the world economy. Indian Patents Act 1970 does not discriminate between foreigners and Indian nationals, quite in conformity with the 'national treatment' clause of the Paris Convention, in spite of the fact that India was not a member of that Convention for a long time. In any case, the alleged reduction of foreign patenting in India due to the Indian Patents Act 1970 does not stand scrutiny. Table III.1 below shows three point estimates of patents filed in India. More than eighty percent of all patent applications filed in India belonged to foreigners and
foreigners controlled more than 85 percent of all patents in force. However, this evidence notwithstanding, the critics continue to point out that patent protection in India has been quite inadequate and stronger and stringent measures have to be incorporated into the Indian Patent Act, 1970.

**TABLE III.1**

<table>
<thead>
<tr>
<th>Year (March)</th>
<th>Indians</th>
<th>Foreigners</th>
</tr>
</thead>
<tbody>
<tr>
<td>1974</td>
<td>3948 (12%)</td>
<td>28270 (88%)</td>
</tr>
<tr>
<td>1979</td>
<td>2469 (15%)</td>
<td>13966 (85%)</td>
</tr>
<tr>
<td>1989</td>
<td>2584 (16%)</td>
<td>13599 (84%)</td>
</tr>
</tbody>
</table>

*Source: Controller General of Patents, Designs and Trade Marks, Govt. of India, National Patents' Office, Calcutta, 1991.*

It is also frequently pointed out that the Indian Patent Act 1970 grants patents for only seven years from the date of application and that only process patents are granted in the case of food, chemical and pharmaceuticals, whereas in other sectors the period of patent protection is for 14 years from the date of application and that the patents are for both products and processes. One of the contentions with regard to pharmaceuticals is that the non-recognition of product patents and the shorter enforcement period have indirectly helped the Indian drug and pharmaceutical firms to manipulate and ‘reverse-engineer’ the drug products amounting to infringement of patents of the “original innovators” causing major losses to the research-based drug-firms mainly from the US. Or so were the allegations mainly lodged by the American drug firms against the Indian firms with the WTO appellate body, and much before its formation with the GATT secretariat.

It is quite well known that India was not the only country, which disallowed patents in drugs, chemicals, food, animal and plant varieties.
As many as 49 countries also did not allow patents in pharmaceuticals, while 59 countries excluded patents in plants and animals (See Table III.2). These included many developed countries like Norway, France, Germany, Australia, Portugal and Spain. As a part of the TRIPS Agreement, India has agreed to increase the term of patent protection to 20 years from the date of application in all categories and grant both product and process patents.

### TABLE III.2

**PATENT EXCLUSIONS**

<table>
<thead>
<tr>
<th>S.No.</th>
<th>Category/ Name of the Product</th>
<th>No. of the countries that exclude</th>
<th>Industrial countries*</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Pharmaceutical product</td>
<td>47</td>
<td>8</td>
</tr>
<tr>
<td>2</td>
<td>Animal Varieties</td>
<td>59</td>
<td>18</td>
</tr>
<tr>
<td>3</td>
<td>Methods of treatment (human and animals)</td>
<td>59</td>
<td>18</td>
</tr>
<tr>
<td>4</td>
<td>Plant varieties</td>
<td>57</td>
<td>18</td>
</tr>
<tr>
<td>5</td>
<td>Biological process for plant and animal varieties</td>
<td>56</td>
<td>18</td>
</tr>
<tr>
<td>6</td>
<td>Food Products</td>
<td>39</td>
<td>8</td>
</tr>
<tr>
<td>7</td>
<td>Computer Programmes</td>
<td>48</td>
<td>20</td>
</tr>
<tr>
<td>8</td>
<td>Chemical Products</td>
<td>21</td>
<td>2</td>
</tr>
<tr>
<td>9</td>
<td>Nuclear inventions</td>
<td>13</td>
<td>2</td>
</tr>
</tbody>
</table>

* These are the Western European countries, and Japan, Canada, Australia, United States, New Zealand and Iceland.

**Source:** WIPO, Geneva, 1988.

#### III.6 TRIPS AND THE INDIAN PHARMACEUTICAL INDUSTRY

The TRIPS agreement, ratified and signed by India in 1994, provides for all countries to make product and process patents available
without discrimination for all inventions, subject to normal tests of novelty, inventiveness and application. This must be implemented by 1 January 2005. Article 27.1 of the TRIPS agreement states, “subject to the provisions of paragraph 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application, subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patents rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced”.41

There were four important issues which had become a bone of contention as regards the Indian Patent Act 1970 and the TRIPS Agreement in respect of pharmaceuticals. Given below is a picture before the required amendment and the changes that were to follow after the amendment.

**I. WTO requirement:** Both process and product patent be granted without discrimination.

**Existing Indian Statutory provision:** Section 5 of the Indian Patent Act, 1970 states, “in the case of inventions- (a) claiming substances prepared or produced by chemical processes (including alloys, optical glass, semi-conductors and inter-metallic compounds), no patent shall be granted in respect of claims for the substances themselves, but claims for the methods or processes of manufacture shall be patentable.” Thus, as mentioned earlier, in case of food products, drugs and chemicals and medicines only process patents are permitted.

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II. **WTO requirement:** Duration of patents must be 20 years

**Existing Indian Law:** The current law in operation makes it clear that when a process patent is granted the duration of the patent is “five years from the date of sealing of the patent, or seven years from the date of patent filing, whichever period is shorter”. For other than the three sectors mentioned above, the duration is 14 years. The TRIPS stipulation requires that the duration of the patent must uniformly be twenty years.

III. **WTO requirement:** Automatic working of a patent without discrimination

By implication this amounts that even imports would also count as working of a patent.

**Existing Indian Legislation:** In the present Indian legal perception of intellectual property the importation of a product into India is not regarded as equivalent to the working of a patent in India.

IV. **WTO requirement:** Conditional grant of compulsory licenses under specified circumstances.

**Existing Indian law:** Under the present law, India sanctions a compulsory license, when “the reasonable requirements of the public with respect to the patented invention are not available to the public at a reasonable time and cost”.

There are a number of serious consequences that follow from the four major issues of the WTO and shall have direct bearing on the Indian drug industry. First, as regards the shift to product patent regime from process patents, a ‘concessional’ transitionary arrangement is provided under Articles 70.8 and 70.9 of the TRIPS Agreement. According to this all the product patent applications from 1 January 1995 will be deposited in a ‘black box’, which will be opened up in 2005 to establish right of priority before granting patents. This is known as “mail box”
arrangement. Meanwhile, for each such application that has been accepted for patent, exclusive marketing rights (EMRs) have to be granted for a period of five years subject to three conditions: (i) there must be valid patent for the product in a WTO member country; (ii) marketing approval must have been obtained in a WTO member country; and (iii) marketing approval must have been obtained in India. In other words EMRs are like patents granted through the back door without checks that the normal scrutiny of a patent application would have required. These are granted in lieu of a patent on sheer benefit of doubt, irrespective of the likelihood of acceptance or rejection of the patent in due course.

There is a good deal of haziness in the content and scope of the EMR clause, and there is a conspicuous silence on the part of TRIPS Agreement in this regard, which is not resolved yet.

For example, it made no reference to the actions, which third parties would be, permitted to take, for instance, with respect to products already marketed or to products manufactured by a process different from the patented process. Third parties may interpret the EMR clause as not including an *ius prohibendi*, i.e. not including the right to exclude others from using the invention, as in the case of pharmaceutical patents.

Apart from the haziness mentioned above, for a developing country like India, we bring the following aspects below, which are clear concerns of the TRIPS Agreement vis-à-vis the pharmaceutical sector. The introduction of product patents may imply significant social costs due to the higher prices charged for drugs and medicines. The access of local firms to protected technology will become more difficult because of the enforcement of the patent holders bargaining position through investments in R & D. There is the possibility that domestic firms will be

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42 WTO, Ibid.
excluded from the most dynamic segments of the pharmaceutical market, where the prospects of growth are the highest. This is likely to be true for drugs based on biotechnology where inventing around, that is developing drugs with similar compositions, is relatively more difficult. In case of process patents, too, under the TRIPS Agreement the "burden of proof" is "reversed" implying that the onus of providing proof in support of non-violation or infringement of patent lies with the 'accused' rather than the complainant i.e. the patent-holder. This will result in a lot of avoidable expenditure and time in the course of litigation, which would result in both 'consumer surplus losses' and 'social welfare losses'.

The fourth WTO requirement mentioned above, as regards the granting of compulsory license a lot of heat was generated at the recent WTO Ministerial Meeting at Doha, particularly the tough stand taken by the Indian delegation that it encroaches the individual nation's autonomy in decision making in the matters of public health and imposes the WTO authority in the "internal matters of importance" concerning the developing nations.

There are certain provisions in the TRIPS Agreement which are supposed to provide some succour to the needy countries. As mentioned in the beginning of this section, Article 21 of the TRIPS prohibits compulsory licensing and Article 30 of the TRIPS Agreement provides exceptions to the provision. In 'WTO requirement IV' discussed earlier in this section some further clarifications are necessary and are provided below:

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43 Both the losses of the variety mentioned here are known in economic theory as "dead-weight" losses. This point is discussed again in Chapter V below.

44 A detailed analysis of Doha Declaration is available in J. Manohar Rao, "Doha, Maran, Manam," Vaartha (Telugu daily from Hyderabad), 20 November 2001 ["Doha, Maran and us" article in Telugu explaining the implications of Doha Ministerial declaration on 14 November 2001 to Indian Industry in general and the pharmaceuticals in particular.]
• Importation of a protected product that has been legitimately put on the market elsewhere;
• Acts carried out privately and on a non-commercial scale or for a non-commercial purpose;
• Use of an invention for research and experimentation and for teaching purposes;
• Preparation of medicines for individual cases according to prescription;
• Compulsory licensing; and
• Use of the invention by a third party who started, or took serious precautionary action, before the application for the patent (or of its publication).

These exceptions, which were made in the TRIPS Agreement and ratified further at the 'Doha Ministerial Meet', are not to be viewed in isolation. In fact, the issue of 'compulsory licensing of patents' has been incorporated and revised several times in the Paris Convention for the Protection of Industrial property of March 20, 1883, itself. It is pertinent here to recapitulate the provisions stipulated in Article 5 (A) of the Paris Convention, which has the sanction of 151 member countries of WIPO, which administers the Paris Convention Treaty:

**Article 5**

A. Patents: Importation of Articles; failure to work or insufficient working; compulsory licenses.

(1) Importation by the patentee into the country where the patent has been granted of articles manufactured in any of the countries of the Union shall not entail forfeiture of the patent.

(2) Each country of the union shall have the right to take legislative measures providing for the grant of
compulsory licenses to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work.

(3) Forfeiture of the patent shall not be provided for except in cases where the grant of compulsory licenses would not have been sufficient to prevent the said abuses. No proceedings for the forfeiture or revocation of a patent may be instituted before the expiration of two years from the grant of the first compulsory license.

(4) A compulsory license may not be applied for on the ground of failure to work or insufficient working before the expiration period of four years from the date of filing of the patent application or three years from the date of the grant of the patent, whichever period expires last; it shall be refused if the patentee justifies his inaction by legitimate reasons. Such a compulsory license shall be non-exclusive and shall not be transferable, even in the form of the grant of a sub-license, except with that part of the enterprise or good will, which exploits such a license.

(5) The foregoing provisions shall be applicable, mutatis mutandis, to utility models.

It must be noted here that Article 2.1 of the TRIPS accord requires compliance with Articles 1 through 12, and Article 19 of the Paris Convention Treaty.

Article 31 of TRIPS deals with compulsory licenses in an entirely different situation which cannot be covered by either Article 5A(2) of Paris Convention, Article 11bis(2) and Article 13(1) of Berne Convention and Article 30 of the TRIPS. This essentially deals with the use of the Patent without authorization by the government or third parties authorized by the government or as directed by the judicial or
administrative processes in anti-competitive proceedings. These are regular features in USA and Europe and shall be examined further below.

Article 31 of TRIPS states:

"Where the law of a Member allows for other use ('Other use' refers to use other than that is allowed under Article 30) of the subject matter of a patent without the authorization of the right holder, including use by the Government or third parties authorized by the government, the following provisions shall be expected:

a) authorization of such use shall be considered on its individual merits;

b) Such use may only be permitted if, prior to such use, the proposed user had made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. A Member in the case of national emergency or in case of public non-commercial use may waive this requirement. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by for the government, the right holder shall be informed promptly";

There are many other conditions mentioned in Article 31 in respect of compulsory licensing but the important ones are:

'...... including the use by the government or third parties authorized by the government', the US law while giving contract for NASA

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or other scientific or technological venture clarifies the situation. It has nothing to do with compulsory, licenses 5(A)2 of Paris Convention, Articles 11bis(2) and 13(1) of Berne Convention and all these compulsory licensing provisions have their own relevant conditions. Article 31 essentially deals with ad-hoc circumstances that may arise like national emergency. 28 U.S.C. Sec. 1498 deals with use of patents or copyrights by the US government. Under this statute, the US government is not required to seek license or negotiate or use of a copyright or a license. A third party at the behest of the government can exercise the government right. By virtue of this statute, the government may be sued for compensation but government may not be prevented from using the patent. The government may be held liable for payment of the 'reasonable and entire compensation' for its unauthorised use of the patent. The first part itself supports the contention that this area covers the ad hoc use of patent as in 28 U.S.C. Sec. 1498.

The ad-hocist nature of exceptions to the rights conferred is evident from Article 31(k) dealing with situation of anti-competitive practices. Article 31(k) of TRIPS states:

'Members are not obliged to apply the conditions set forth in subparagraph (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive ...Competent authorities shall have the authority to refuse termination of authorization if and when the conditions, which led to such authorization, are likely to recur'. Article 31(k) is supposed to deal with situation arising out of judicial or administrative mechanism in anti-competitive decisions, which may arise, for a variety of reasons.

Scherer\(^{46}\) has identified more than one hundred instances when compulsory licenses have been provided to remedy the anti-competitive

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practices although such licenses have been granted against a reasonable royalty.

III.6.1 PARALLEL IMPORTING

There has been a lot of hue and cry raised against parallel importing particularly by the so-called research based pharmaceutical firms from the US, which were quite vociferous in their campaign during the Doha Ministerial Meet in November 2001.

Parallel importing consists of purchasing proprietary drugs from a third party in another country, rather than directly from the manufacturer, and taking advantage of the fact that pharmaceutical companies sometimes charge significantly lower prices in one country than in another. For instance, in Britain, where parallel importing is common, the list price for Glaxo Wellcome's Retrovir is $125, but consumers can purchase the same proprietary drug imported from other European countries for as little as $54. Price for the same product can vary widely among countries because of many factors, such as differences in local incomes, degree of competition among producers and differences in intellectual property rules. For example, a 1998 study by the Consumers Project on Technology found prices for SmithKline Beecham's version of Amoxil was $8 in Pakistan, $14 in Canada, $16 in Italy, $22 in New Zealand, $29 in the Philippines, $36 in Malaysia, $40 in Indonesia, and $60 in Germany.

By permitting some form of parallel imports, countries can shop around and get better prices, using market forces to lower national expenditures on a range of goods, including pharmaceuticals. In the European Union, parallel importing of patented products is widely used and is seen as very effective mechanism for keeping down prices.

However, ever since the creation of the WTO the US government has been extremely aggressive in attacking parallel imports by other countries, apparently on the grounds provided by organisations like
PhRMA and International Federation of Pharmaceutical Manufacturers Association (IFPMA). Hence, it is in order that we examine some issues raised by PhRMA.\textsuperscript{47} According to PhRMA, parallel imports violate intellectual property rights as TRIPS includes the right of a patent holder to control importation of a product into third markets. Specifically, TRIPS Article 28 states that "(a) patent shall confer on its owner the following exclusive rights: ...to prevent third parties not having his consent from the acts of-making, using, offering for sale, selling or importing for these purposes that product..."\textsuperscript{48} PhRMA has also stated that the patent holder is given the power not only to enforce but also prevent parallel import, under Article 27.1. PhRMA has also claimed that 'it is generally not possible for a government to permit parallel import of a product under patent protection in that country without recourse to confidential test data or other information protected under TRIPS Article 39(3), or without violating TRIPS enforcement provisions designed to permit a right owner to fast and effective relief for IP infringement'.\textsuperscript{49} The TRIPS does not give patent holder the rights to exclude others from setting, or offering for sale, or importing for these purposes once the patented products have already been sold.

Currently EU permits parallel trade within the EU, but does not permit importation of on-patent drugs from countries outside EU.

In this context, the argument advanced by Danzon\textsuperscript{50} is that efficiency gains by shifting the supply to the most efficient supplier do not work in case of pharmaceuticals because lower prices in the exporting country primarily reflect greater regulatory leverage, not lower

\textsuperscript{47} The arguments relating to parallel imports are available at (http://www.phrma.org/intnatl/intellprop/parallel.html)
\textsuperscript{48} ibid.
\textsuperscript{49} ibid.
real costs of production. Citing Ramsey pricing, Danzon claims that price differentials would lead to more efficient use of the product and more efficient level of R&D than a policy that would result in uniform prices to all consumers. Implicit in these arguments is the idea that greater profits to private firms will lead to greater investments in R&D and newer and larger number of innovations, which in any case is not supported by any empirical evidence or econometric estimates.

III.7 PUBLIC FUNDED R&D IN THE US

Further, there is a blatant and unhindered refusal to recognize the stupendous contribution made by public funded R&D and public sector research institutions and scientists.

A closer examination of public funded research activity in the US itself gives us a clear picture of how important the new drug and pharmaceutical products are and how they are being brought out with the help of government funded research activity and subsidies and so on. For example, there is this distinction between 'industrial research' and 'pre-competitive development activity' in the US Patent Law (United States Code-Title 35-Patents) particularly those of chapter 18 (38). It is explained there that the term 'industrial research' means planned research or critical investigation aimed at discovery of new knowledge, with the objective that such knowledge may be useful in developing new products, processes or services, or in bringing about a significant improvement to existing products, processes or services. The term, 'pre-competitive development activity' means the translation of industrial research

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52 Danzon, ibid.  
findings into a plan, blueprint or design for new, modified or improved products, processes or services whether intended for sale or use, including the creation of a first prototype which wouldn’t be capable of commercial use. It may further “include the conceptual formation and design of alternative products, processes or services and initial demonstration or pilot projects, provided that these same projects can not be converted or used for industrial application or commercial exploitation. It does not include routine or periodic alternations to existing products, production lines, manufacturing, processes, services, and other ongoing operation even though those alterations may represent improvements”.54

This brings us to the research assistance given to a large number of researches leading to patenting of drugs and medicines. The universities in USA have patented practically all the anti-cancer medicines including Taxol manufactured by Squibb-Myers and the development of such patenting are totally financed by government assistance. The assistance is through grant from National Institute of Cancer. Such assistance is not only more than 50% of the costs of ‘pre-competitive development’ or more than 75% of the costs of ‘industrial research’ but 100% of the costs of both industrial research and pre-competitive development activity. If we add the tax concessions given to private R&D, the picture is complete.

Between 1970 and 1999, Federal funding for health related research grew by 400% in real terms to $14.8 billion, which constituted 38% of non-defence Federal research budget.55 US Congress approved a budget of $17.8 billion for the year 2000, an increase of 14.3% over 1999 budget.56 Public sector research spending, according to a study, 57 is

54 Cockburn and Henderson, Ibid.
55 Cockburn and Henderson, ibid.
practically equal to private sector spending and the papers published through public sector spending are far more than those financed by private sector spending in the USA. The important role public sector research has played in private sector research can be gauged from the fact that after 1972 when the structure of the 'renin angiotensive cascade", one of the systems within the body for regulation of blood

TABLE III.3
MAJOR DRUGS OF THERAPEUTIC IMPACT DEVELOPED WITH PUBLIC FUNDED RESEARCH (1965-1992)

<table>
<thead>
<tr>
<th>Generic Name</th>
<th>Trade Name</th>
<th>Indication</th>
<th>Date of Key Enabling Discovery</th>
<th>Public Funded?</th>
<th>Date of Synthesis of Compounds</th>
<th>Public</th>
<th>Date of Market Introduction</th>
</tr>
</thead>
<tbody>
<tr>
<td>AZT</td>
<td>Retrovir</td>
<td>HIV</td>
<td>Contentious</td>
<td>Y</td>
<td>1963</td>
<td>Y</td>
<td>1987</td>
</tr>
<tr>
<td>Captopril</td>
<td>Capoten</td>
<td>Hypertension</td>
<td>1965</td>
<td>Y</td>
<td>1977</td>
<td>N</td>
<td>1981</td>
</tr>
<tr>
<td>Cimetidine</td>
<td>Tagamet</td>
<td>Peptic Ulcer</td>
<td>1948</td>
<td>Y</td>
<td>1986</td>
<td>N</td>
<td>1992</td>
</tr>
<tr>
<td>Finasteride</td>
<td>Proscar</td>
<td>BPH</td>
<td>1974</td>
<td>Y</td>
<td>1986</td>
<td>N</td>
<td>1992</td>
</tr>
<tr>
<td>Fluoxetine</td>
<td>Prozac</td>
<td>Depression</td>
<td>1957</td>
<td>Y</td>
<td>1970</td>
<td>N</td>
<td>1987</td>
</tr>
<tr>
<td>Lovastatin</td>
<td>Mevacor</td>
<td>Hyperlipidemia</td>
<td>1959</td>
<td>Y</td>
<td>1980</td>
<td>N</td>
<td>1989</td>
</tr>
<tr>
<td>Propanolol</td>
<td>Inderol</td>
<td>Hypertension</td>
<td>1948</td>
<td>Y</td>
<td>1964</td>
<td>N</td>
<td>1967</td>
</tr>
<tr>
<td>Sumatriptan</td>
<td>Imitrex</td>
<td>Migraine</td>
<td>1957</td>
<td>Y</td>
<td>1988</td>
<td>N</td>
<td>1992</td>
</tr>
<tr>
<td>Cisplatin</td>
<td>Platinol</td>
<td>Cancer</td>
<td>1965</td>
<td>Y</td>
<td>1967</td>
<td>Y</td>
<td>1978</td>
</tr>
<tr>
<td>Erythropoietin</td>
<td>Epogen</td>
<td>Anemia</td>
<td>1950</td>
<td>Y</td>
<td>1985</td>
<td>N</td>
<td>1989</td>
</tr>
<tr>
<td>Interfermbeta</td>
<td>Beta</td>
<td>Cancer</td>
<td>1950</td>
<td>Y</td>
<td>Various</td>
<td>N</td>
<td>Various</td>
</tr>
</tbody>
</table>

Source: Adapted from Cockburn and Henderson (2000), op.cit.

pressure, had been clarified by the work of Laragh et.al. Several companies drew on this research in designing screens for hypertensive drugs.\textsuperscript{58}

Similarly, the breakthrough discovery by Cohen and Boyer's genetic engineering tools, which revolutionised synthetic generation of proteins, through cell-genetic manipulation are the classic example of drug manufacture through government funded research project.

Cockburn and Henderson,\textsuperscript{59} have compiled a list of 21 drugs introduced between 1965 and 1992 with reference to date of key enabling discovery, date of synthesis of compound, date of market entry and the role public sector has played in those activities.

Out of the 21 drugs, all of them have been developed either by public fund or with the assistance of public fund. Table III.3 provides the history of development of the drugs with highest therapeutic impact introduced between 1965 and 1992.

The table shows clearly that the majority of medicines with highest therapeutic effect have been obtained through screening of compounds against a specifically known or suspected mechanism and through fundamental science, which has been done through public sector funding. We show similar results for the Indian pharmaceutical industry, that the new drug technologies were generated mainly in the public funded research laboratories or the government monitored research institutions during 1970 and 1991 period in Chapter V of Part II below.

Similarly in the case of biotechnology, the bulk of the research is based on very close link up between American biotechnology startups and


\textsuperscript{59} Cockburn and Henderson (2000), op.cit.
the university departments. In fact, the case of AZT is cited as an example of how a public sector's research could be hijacked by Burroughs-Welcome. The National Institute of Health (NIH) discovered AZT when they were looking for cancer drugs. AZT was lying in the library of compounds of BW and BW sent it to NIH for screening against a screen developed by NIH. When it was found to prolong the life of AIDS patients, BW conducted clinical trials and obtained the patent on the use of AZT in treatment of AIDS. "Who discovered what and when" was an integral part of an intense controversy surrounding this case, with the US Supreme Court eventually ruling against claims that NIH scientists should have been listed as inventors on BW's patents on the use of AZT in treatment of AIDS.

Similarly an important drug for regulating blood pressure, captoprill's discovery was constructed on two lines of publicly funded basic research. Captopril is one of the first compounds in the category of drugs known as 'angiotensin-converting-enzyme' inhibitors or "ACE inhibitors" which prevents high blood pressure by inhibiting the enzymatic conversion of angiotensin I to angiotensin II. Although the research on angiotensin-renin system was back in 1934, the actual role of angiotensin I and angiotensin II was identified only in the 1950s. Another line of research was started in Brazil where snake venom was found to lower rate of blood pressure fatally. The venom was found to block the conversion of angiotensin I to angiotensin II. Using the above information Squibb synthesized the first ACE inhibitor in the early 1970s and got the approval for marketing in 1981.

As has been illustrated at length above, essentially all the major drugs have been discovered by public sector research scientists, and the use of public research institutes for clinical trials has been very common in the US itself whose expenditure does not enter into the cost component of the products claimed by the private drug firms.

From the overall discussion above it becomes evident that the reasons advanced by either PhRMA-lobby or the US drug firms that *innovation* as the sole reason for monopolistic use of patents has no relation to history of the mankind, economic theory, or social and legal practices or for that matter current international law. In fact, the whole attempt is to convince the international public that higher prices for pharmaceutical products is very natural in that they are backed by research, and profitability of the innovative firms is beyond any scientific reasoning, as a matter of fact, unquestionable.

The other aspects, which came up for examination, are unsubstantiated allegations levelled against India by PhRMA, which we have mentioned in the beginning of this thesis. While calculating damage estimates in case of India, caused due to weak IPR protection, PhRMA says that it is still working out the methodology for estimating the damages. It is not difficult to evolve any methodology, since all the details pertaining to the list of drugs exported to the US by Indian drug manufacturers are available with the US government or for that matter, with the PhRMA itself. As per PhRMA, “the damages caused to US pharmaceutical manufacturers due to the deficiencies of the Indian patent regime thus goes beyond displaced sales in the Indian market, and reaches to the ability of US companies to compete in other significant markets, especially in the Asia-Pacific and Middle-East-Regions. PhRMA estimates the losses attributable to the deficiencies in the Indian intellectual property system to be approximately US$ 500
million per year”. On this basis PhRMA makes a strong and fervent appeal that “For all the aforementioned reasons, PhRMA believes that India should be listed as Priority Foreign Country under Special 301 in 1999”.

It is important that we take note of the fact PhRMA is yet to develop proper methodology for estimating damages caused by the weak IPR protection in India.

III.8 IS THERE A RELATIONSHIP BETWEEN STRONGER IPRs AND PHARMACEUTICAL INNOVATION?

We have shown above how US and other powerful lobby groups have made all out efforts, sometimes without much scruples, and successfully achieved the inclusion of protection of IPRs in the Uruguay Round as the major agenda. It was also shown that the inclusion of those issues was a fundamental requirement for the US participation in the talks, and on the question of the US pressure there exists a consensus in the large literature on the history of agenda setting for the Uruguay Round, on the creation of WTO and its aftermath.

Now we propose to examine in detail, if there exists any relationship between stronger IPR protection and pharmaceutical innovation, as exists in economic theory and empirical research.

While it has been argued time and again that there are long run benefits and associated economic value, which can be gained by adopting

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strong patent regime, a uniform patent regime was worked out through WTO and its establishment. Even some developing countries do believe honestly that such a strong patent regime is for their economic development.\textsuperscript{66} The celebrated work of Fritz Machlup,\textsuperscript{67} `An Economic Review of the Patent System', and many other similar works had not favoured any strong patent system; on the contrary, they expressed overt hostility for such a system on the grounds that it is against the larger social good. And so did Schumpeter. F.M. Scherer, who had surveyed exhaustively the economic literature on innovations, patents and economic activity of the 1970s and 1980s, had systematically expressed his opinion against stronger protection of patents, and very recently, he has reiterated his position again, to which we shall return later.\textsuperscript{68} Since the 1960s, a series of empirical studies have explored the question of the efficacy of patent protection as a means of reaping the rewards of innovation, and it was found that in most industries patents were not an important part of the incentives that firms have for investing in R&D.\textsuperscript{69} And these industries include many `high-tech' industries like computers and semiconductors. However, pharmaceuticals was the sector, which derived its strength from patents to a major extent. Since the 1980s, the US Patent Policy has been undergoing rapid changes, particularly in favour of stronger patent protection. In 1982 the Court of Appeal for the Federal Circuit (CAFC) was established to deal with patent litigation cases in a unified manner. From 1982 through 1987, the appellate court

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\textsuperscript{66} UNCTAD, \textit{The Outcome of the Uruguay Round: AN Initial Assessment}. UN, New York, 1994.
has upheld 89% of the district court decisions on patent validity, up from 30% prior to the creation of the CAFC. In addition, steps were initiated to strengthen intellectual property of government-funded research. In particular, legislation culminating in the Bayh-Dole Act of 1980 strongly encouraged universities performing government-funded research to apply for patents, while earlier the norm was to place such results in the public domain. Since the 1980s there has also been a trend towards broadening the definition of patentable subject matter, partly in response to the perceived demands from emerging fields of research and technology, like biotechnology and software.

In view of the fact that patents entail social and economic costs, it would seem wise not to push for stronger patent protection, unless the evidence indicated that economic benefits were significant. Such indications are certainly missing from the conventional interpretation of the available empirical studies. On the other hand, as Mazzoleni and Nelson, suggest, much of the current argument points to a broader range of functions served by patents than these studies explored.

The perception that granting patents is not costless to society implies, of course, that one should not grant patents where the benefits do not exceed the costs. The underlying assumption of the theory is that patents are needed to provide firms with the requisite incentive to invent, and that this does justify the costs of the temporary monopoly their granting gives. Motivated partly by this perception, over the last 50 years, there have been a number of empirical studies that have probed the importance of patents to firms that do R&D in an industry. In the 1950s Scherer et. al., studied firms in the US. Taylor and Silberston,

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studied firms in the UK, in the 1970s. Both studies reached the then surprising conclusion that, with the exception of pharmaceuticals, firms in most industries reported that patents were neither particularly effective, nor necessary, for enabling them to appropriate returns from their R&D. In the 1980s, Mansfield, \(^74\) and Levin et al., \(^75\) undertook similar studies. The conclusions were also similar. The very recent studies of Cohen et al., \(^76\) for the US, Goto and Nagata, \(^77\) for Japan, and Arundel and van de Paal, \(^78\) for Europe, suggest that the situation in the 1990s is not very different. A number of industries, which do little R&D, and where technological advance is relatively slow, also reported that patents were not particularly effective for them. In such cases one might conjecture that stronger patents might spur more inventing. But this is not at all clear, and in any case the recent pressures for stronger patent protection have not been coming from ‘low-tech’ industries.

In fact, Mozzoleni and Nelson give a clear warning to the economists, public policy planners and lawmakers around the world to be cautious and ask for restraint in pushing for broader and stronger patents, since in “that direction lies a lot of future trouble”. They assert further “the world economy will not benefit from a general broadening and strengthening of patent rights”. \(^79\)

In quite a revealing argument, Scherer, \(^80\) has suggested that if a patent code specific to a certain country like the US, is applied to other


\(^{74}\) Mansfield, (1986), ibid.

\(^{75}\) Levin et al., 1987, ibid.


\(^{80}\) Scherer (2000), ibid.
countries, particularly the developing countries, they will be left with no choice but to resort to infringement under the clause of national interests. In fact the U.S. Patent Code itself includes provisions allowing the federal government to infringe valid patents when infringement serves the national interests and reasonable compensation is paid. The requirements for reasonable compensation have been interpreted historically to imply much lower payments than the foregone monopoly profits standard imposed in private patent infringement damages cases. Scherer quotes a recent case in 1999, in the US. In *Florida Prepaid Post Secondary Education Expense Board Vs. College Savings Bank*, a majority of the Supreme Court ruled (over the strong dissent of a four member minority) that Congress had exceeded its constitutional power in nullifying individual states' sovereign immunity from patent infringement suits in federal courts, provided that the states maintain their own in-state legal procedures (either legislative or judicial) to ensure that patent holder's property is not taken without due process of law. Scherer argues that this may set a precedent for the states which might in the future seek to alleviate their escalating drug cost burdens under Medicaid, by setting up patent-infringing generic drug production operations or importing drugs from no-patent jurisdictions and offering to pay "reasonable compensation" for the use of the infringed patents. Compensation substantially less than the monopoly profits foregone by

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81 Indeed, in the late 1950s, frustrated by the high prices charged for tetracycline by licensees to the patent held by Pfizer, the US, armed forces invoked their statutory right to infringe domestic patents and purchased tetracycline from Italian firms. See also 28 U.S.C. 1498 (1494) quoted in Scherer, Op.cit.
the patent holders might satisfy the due process requirement.\textsuperscript{82} It is apt to quote Scherer’s conclusion regarding stronger IPR protection:

"For the United States to insist that other member nations (of WTO) should not infringe patents issued within their home jurisdictions, paying compensation deemed reasonable under their own judicial or administrative processes, would be hypocritical, given the Supreme Court’s strong states’ rights position in the \textit{Florida Prepaid Postsecondary Education} Case. What seems clear is that controversy over the Uruguay Round TRIPS mandates will continue and indeed intensify".\textsuperscript{83}

\textbf{III.8.1 STRONGER IPRS AND PHARMACEUTICAL INNOVATION: RECENT EMPIRICAL RESEARCH}

First, before undertaking a detailed review of empirical research results, it is in order to make a broad observation: since the world economy comprises heterogeneous systems with different levels and stages of development with variegated levels of techno economic systems, it is not wise to devise a homogenous IPR regime at a global level, which also does not make any economic sense. There are two central objectives of any IPR system. First, to promote investments in knowledge creation and business innovation by creating temporary monopoly rights, in the absence of which, firms would be less prepared to invest in R&D and innovative activity. Second, it is important to promote widespread dissemination of knowledge by enabling the rights holders to place their

\begin{footnotesize}
\textsuperscript{82} Scherer provides an example of the position taken by the courts of Canada in implementing the compulsory licensing of drugs up to 1987. When Hoffmann-La Roche requested a flat fee royalty that would have amounted to 30 percent of the price of Valium before the emergence of generic competition, the Canadian Exchequer Court set an \textit{ad valorem} royalty of four percent on sales after the emergence of generic competition. The court provided that in setting the terms of the license and fixing the amount of royalty or other consideration payable, “the Commissioner shall have regard to the desirability of making the medicine available to the public at the lowest possible price consistent with giving to the patentee due reward for the research leading to the invention”. See Hoffmann-La Roche Ltd. V. Frank W. Horner Ltd., (1970) C.P.R. 107-108. Four percent royalty rates became standard in subsequent drug patent licenses. See F.M. Scherer, \textit{The Economic Effects of Compulsory Patent Licensing}, in Monograph series in Finance and Economics 1977, at G7, New York University Graduate School Business Administration Centre for Study Fin. Inst. Monograph 1977-2, 1977.

\textsuperscript{83} Scherer (2000), ibid.
\end{footnotesize}
ideas and inventions in the public domain; since information is a non-rivalrous public good, developers may not be in a position to exclude, *per se*, others from using it. In economic terms social costs of improving technologies already developed are likely to be zero or very minimal, the net marginal social benefits are likely to be much greater. However, even if we accept this entire manner of reasoning, there is a fundamental trade off between these two objectives. While, an overly protective IPR system could limit social gains by reducing incentives to innovation activity and its distributional gains, a weak system could reduce the activity by not ensuring adequate return on investment. Thus, a policy balance based on the local institutional and market conditions would essentially determine nature and consequences of IPRs and economic growth.

Most recent empirical research available in economic literature does not lend credence to the claim that strong IPRs promote innovation, technical change and economic development.

For example, in a comprehensive study of patent laws covering a set of countries every fifth year from 1960 to 1990, Ginarte and Park,84 have constructed an index of patent rights. They included in the study, five components of the Laws: duration of protection, extent of coverage, membership in international patent agreements, provisions for loss of protection, and enforcement measures. Each of these components was broken down into characteristics determining its effective strength. For example, patent coverage incorporated the eligibility for patents of pharmaceutical and chemical products and the availability of utility models. Enforcement measures included the availability of preliminary injunctions, contributory infringement actions, and reversal of the burden of proof in process patent cases. Each sub-component was assigned a value of one if present and zero if absent, with component

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score being the sum of these values as a percentage of the maximum value. Thus, the minimum possible national score was 0.0 and the maximum was 5.0. To illustrate the index, across all countries in 1985 it averaged 2.44, indicating that roughly half the various sub-components in patent rights existed in the average nation.\textsuperscript{85}

The developed economies had indexes that were both considerably higher and less variable than those of the middle-income and low-income developing economies. The increase in average protection in other words is from poor countries to middle-income countries to rich countries. Overtime, there was a marked increase in the average index across nations. However, there was not much evidence of convergence between developing and developed countries until the 1990s, as was shown by Park and Ginarte. What follows out of this discussion is that the stronger protection of patents is observed more in the developing countries as the greater claim for number of patents increased over a period of time.

Edwin Mansfield\textsuperscript{86} has surveyed 100 leading US corporation in 1991, wherein executives in companies of six industries were asked their views on the importance of whether IPR protection in some 16 countries was perceived by corporations to be too weak for them to engage in FDI, joint ventures; transfer of technology or licensing arrangements. We reproduce his results in Table III.4 below, which shows the type of investment facility.

\textsuperscript{85} Ibid.
TABLE III.4
PERCENTAGE OF FIRMS CLAIMING THAT THE STRENGTH OR WEAKNESS OF INTELLECTUAL PROPERTY RIGHTS HAS A STRONG EFFECT ON WHETHER DIRECT INVESTMENTS WILL BE MADE, BY TYPE OF FACILITY, 1991

<table>
<thead>
<tr>
<th>Sector</th>
<th>Sales Distribution</th>
<th>Basic Production and Assembly</th>
<th>Components and Manufacture</th>
<th>Complete Products Manufacture</th>
<th>R&amp;D Facilities</th>
<th>Average</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemicals</td>
<td>19</td>
<td>87</td>
<td>46</td>
<td>100</td>
<td>71</td>
<td>65</td>
</tr>
<tr>
<td>Transport Equipment</td>
<td>17</td>
<td>33</td>
<td>17</td>
<td>80</td>
<td>33</td>
<td>36</td>
</tr>
<tr>
<td>Electrical Equipment</td>
<td>15</td>
<td>74</td>
<td>40</td>
<td>80</td>
<td>57</td>
<td>53</td>
</tr>
<tr>
<td>Food Products</td>
<td>29</td>
<td>43</td>
<td>29</td>
<td>60</td>
<td>25</td>
<td>37</td>
</tr>
<tr>
<td>Metals</td>
<td>20</td>
<td>50</td>
<td>40</td>
<td>80</td>
<td>50</td>
<td>48</td>
</tr>
<tr>
<td>Machinery</td>
<td>23</td>
<td>65</td>
<td>23</td>
<td>77</td>
<td>50</td>
<td>48</td>
</tr>
<tr>
<td>Average</td>
<td>20</td>
<td>59</td>
<td>32</td>
<td>80</td>
<td>48</td>
<td>48</td>
</tr>
</tbody>
</table>


In no industry was there much concern about IPRs; in the chemical industry, which includes the pharmaceutical products also, 46% firms were concerned about protection for basis production and assembly facilities, 71% for components manufacture, 87% for complete products manufacture, and 100% for R&D facilities.

In a companion paper, Mansfield demonstrated that these findings held also for Japanese and German firms considering foreign investments.\(^87\) Mansfield’s study found no evidence that US direct investment tends to be higher in industries and countries where IPRs are relatively strong. However, the results make clear that IPRs are more relevant for certain sectors of industry, and for certain types of

investment activities, while not for others. In the expanded study where he covered Japan, Germany and US, the results indicate that the country's system of intellectual property protection has a significant effect on investment decisions in high-tech industries.

**TABLE III.5**

PERCENTAGE OF FIRMS CLAIMING THAT INTELLECTUAL PROPERTY PROTECTION IS TOO WEAK TO PERMIT TYPES OF INVESTMENT, 1991

<table>
<thead>
<tr>
<th>Country</th>
<th>Chemicals</th>
<th>Transport Equipment</th>
<th>Electrical Equipment</th>
<th>Food</th>
<th>Metals</th>
<th>Mechninary</th>
<th>Average</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<td></td>
</tr>
<tr>
<td><strong>Panel A: Joint Ventures with Local Partners</strong></td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Argentina</td>
<td>40</td>
<td>0</td>
<td>0</td>
<td>29</td>
<td>27</td>
<td>12</td>
<td>18</td>
</tr>
<tr>
<td>Brazil</td>
<td>47</td>
<td>40</td>
<td>0</td>
<td>31</td>
<td>65</td>
<td>12</td>
<td>32</td>
</tr>
<tr>
<td>India</td>
<td>80</td>
<td>40</td>
<td>20</td>
<td>39</td>
<td>48</td>
<td>38</td>
<td>44</td>
</tr>
<tr>
<td>Indonesia</td>
<td>50</td>
<td>40</td>
<td>0</td>
<td>29</td>
<td>25</td>
<td>25</td>
<td>28</td>
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<tr>
<td>Mexico</td>
<td>47</td>
<td>20</td>
<td>0</td>
<td>30</td>
<td>17</td>
<td>25</td>
<td>22</td>
</tr>
<tr>
<td>Korea</td>
<td>33</td>
<td>20</td>
<td>25</td>
<td>21</td>
<td>26</td>
<td>12</td>
<td>23</td>
</tr>
<tr>
<td>Thailand</td>
<td>43</td>
<td>80</td>
<td>0</td>
<td>32</td>
<td>20</td>
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<td>31</td>
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<tr>
<td>Average (A)</td>
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<td>34</td>
<td>6</td>
<td>30</td>
<td>33</td>
<td>19</td>
<td>-</td>
</tr>
<tr>
<td><strong>Panel B: Transfer of Newest or Most Effective Technology to Wholly Owned Subsidiaries</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Argentina</td>
<td>44</td>
<td>20</td>
<td>0</td>
<td>21</td>
<td>14</td>
<td>12</td>
<td>18</td>
</tr>
<tr>
<td>Brazil</td>
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<td>40</td>
<td>0</td>
<td>24</td>
<td>39</td>
<td>12</td>
<td>28</td>
</tr>
<tr>
<td>India</td>
<td>81</td>
<td>40</td>
<td>20</td>
<td>38</td>
<td>41</td>
<td>38</td>
<td>43</td>
</tr>
<tr>
<td>Indonesia</td>
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<td>0</td>
<td>31</td>
<td>23</td>
<td>25</td>
<td>23</td>
</tr>
<tr>
<td>Mexico</td>
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<td>0</td>
<td>21</td>
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</tr>
<tr>
<td>Korea</td>
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<td>40</td>
<td>28</td>
<td>22</td>
<td>12</td>
<td>26</td>
</tr>
<tr>
<td>Thailand</td>
<td>60</td>
<td>80</td>
<td>0</td>
<td>31</td>
<td>18</td>
<td>12</td>
<td>20</td>
</tr>
<tr>
<td>Average (B)</td>
<td>48</td>
<td>34</td>
<td>9</td>
<td>28</td>
<td>26</td>
<td>19</td>
<td>-</td>
</tr>
<tr>
<td><strong>Panel C: Licensing of Newest or Most Effective Technology to Unrelated Firms</strong></td>
<td></td>
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<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Argentina</td>
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<td>0</td>
<td>0</td>
<td>26</td>
<td>29</td>
<td>12</td>
<td>22</td>
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<tr>
<td>Brazil</td>
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<td>40</td>
<td>0</td>
<td>29</td>
<td>73</td>
<td>25</td>
<td>39</td>
</tr>
<tr>
<td>India</td>
<td>81</td>
<td>40</td>
<td>20</td>
<td>38</td>
<td>50</td>
<td>38</td>
<td>44</td>
</tr>
<tr>
<td>Indonesia</td>
<td>73</td>
<td>20</td>
<td>0</td>
<td>33</td>
<td>37</td>
<td>25</td>
<td>31</td>
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<tr>
<td>Mexico</td>
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<td>0</td>
<td>28</td>
<td>36</td>
<td>25</td>
<td>28</td>
</tr>
<tr>
<td>Korea</td>
<td>38</td>
<td>20</td>
<td>40</td>
<td>34</td>
<td>29</td>
<td>12</td>
<td>29</td>
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<tr>
<td>Thailand</td>
<td>73</td>
<td>80</td>
<td>0</td>
<td>36</td>
<td>25</td>
<td>12</td>
<td>38</td>
</tr>
<tr>
<td>Average (C)</td>
<td>65</td>
<td>31</td>
<td>9</td>
<td>32</td>
<td>42</td>
<td>21</td>
<td>-</td>
</tr>
</tbody>
</table>


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Table III.5 above presents additional results for selected countries with weak IPRs at the time of Mansfield’s survey. India was a cause of great concern about IPRs, as 80% of the chemical firms surveyed indicated they could not engage in joint ventures or transfer new technology to subsidiaries or unrelated firms in that nation. Interestingly, in chemicals there was little difference between joint ventures and subsidiaries in this regard. Both investments evidently provided foreign firms with approximately the same level of security about their technologies. However, across all countries licensing to unrelated firms was seen as riskier in the face of weak IPRs.

A somewhat similar study was conducted by Carlos A. Primo Braga.88 Using larger pool of nations, 57 in place of Mansfield’s 16, Braga’s results indicate the impact of IPRs on the level of US investment to be minimal. The UN also conducted a study to ascertain the relationship between FDI and IPRs.89

The US International Trade Commission (ITC) examined the effect of foreign protection of intellectual property rights on US industry and trade. A ranking of nations, by impact on US marketplace losses, was determined for individual industry factors. The ITC study found that the degree of worldwide losses of revenue resulting from intellectual property inadequacies varies significantly depending upon the nature of industry.90 Another study, by M.J. Ferrantion, considered the role of IPRs in influencing various types of US trade. The results of this study indicate at best a weak association between IPRs and arm’s length US exports and there is no significant influence of IPRs on the establishment

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of trade; but significant effects were observed with respect to intra-firm trade.\textsuperscript{91} Such results tend to suggest that certain activities are conducted domestically to avoid weaker intellectual property laws, regardless of country. A study by the practising Belgian attorney, Marco Bronckers, found 'no evidence that patent protection by itself brings investment, especially in poor countries'.\textsuperscript{92} In fact he asserts that, without an attractive overall financial and economic climate, and LDC such as Egypt is unlikely to attract much foreign investment even with better IP protection.

In summary, even though each study dealt with the relationship between levels of foreign investment and intellectual property protection, the results they reached differed significantly, for example, both the Mansfield study and the ITC study ranked nations according to losses imposed on the US industry. Yet, when comparing these rankings, the rank order correlation was a mere 0.33.\textsuperscript{93} Interestingly, while Japan and South Korea have less impact on the US industry and India and Nigeria had a greater impact according to the Mansfield study; the results reached by the ITC study were to the contrary. All these studies reviewed so far, fail to establish the clear relationship between IPR protection, innovation and FDI. Hence, it can be concluded in summary that what is best to a country should be decided by the individual national governments in the best interests of the country's interests, level of economic development and indigenous techno-economic capabilities.

\textbf{III.9 SUMMARY}

Globalisation seeks to integrate economic activity of all countries within a single, homogenized developmental model. Since the homogenized model is characterized by the advocacy of "free trade" the WTO has become globalisation's primary rule making and governing

\textsuperscript{91} In Primo Braga, op.cit., p.399.
\textsuperscript{93} Mansfield, op.cit. p.123.
regime along with the IMF and the NAFTA. We have described the origin, genesis and final appearance of the WTO starting from its erstwhile existence in the form of the GATT in 1947 and its various metamorphoses through the MFA, the Uruguay Round and finally the WTO in 1995.

There exists a consensus in the large literature on the history of agenda setting for the Uruguay Round that the inclusion of the three new issues, namely the TRIMS, the GATS and more important the TRIPS, was a fundamental requirement for the US participation in the talks. It is shown also that the US, during 1979-86 worked towards inclusion of these three issues in the GATT agenda as well. This took an extraordinary effort for the US, because initially most members of the GATT were opposed to expanding the scope of negotiation beyond traditional trade issues. We have also shown above that the patent interests led by the American pharmaceutical companies, copyright interests canvassed by the publishing, motion picture, recording and software designing industries of the US and the US trade diplomacy had all got converged in the agenda of the Uruguay Round. In other words, the TRIPS Agreement was to be used as a vehicle to execute increased protection of IPRs which permit the owners to collect additional rents from royalties, higher prices and possibly additional sales of their protected products in foreign markets where protection would be increased.

It was brought out in this Chapter that the allegations regarding weak IPR protection in India was not exclusive to India alone. In fact there were 49 other countries which did not allow patents in pharmaceuticals. Further, it is not possible to verify various levels of patent legislations followed in different countries and would require enormous amount of resources, apart from the problem of logistics. In fact there were four major issues which became contentious with regard to the IPA 1970 in the context of the TRIPS Agreement: 1. Both process
and product patent be granted without discrimination; 2. Duration of patents must be 20 years; 3. Automatic working of a patent without discrimination; and 4. Conditional grant of compulsory licenses under special circumstances. Now that India has become a member of the WTO, these four clauses would have far reaching implications, which was shown at length by presenting contradictions that existed in the TRIPS clauses themselves, which were untenable. It was also shown that compulsory licensing and parallel importing had offered only limited amelioration and that too with inadequate safeguards. However, it was observed the world pharmaceutical MNCs did not endorse even these concessional mechanisms. The argument advanced by the drug companies, especially from the US, is that parallel imposts violate the rights of patent holder who is entitled to control imports as well.

There was this claim by Danzon that greater profits to private firms would lead greater investments in R&D and newer and larger number of innovations. Any empirical evidence did not support this claim. On the contrary we have shown that even in the US public funded R&D played a crucial role in the pharmaceutical innovations. Between 1970 and 1999, Federal investments for health related research grew by 400 percent in real terms to $14.8 billion, which constituted 38 percent of non defence Federal research budget. Also it was shown that major drugs of therapeutic impact developed were mainly with the public funded research during 1965-1992. We shall show similar results for the Indian drug industry during 1970 and 1991 in Chapter V of Part II below.

A large amount of evidence has been marshalled to show that there is no close relationship between strong IPR protection and pharmaceutical innovation. In view of the fact that patents entail social and economic costs, it would seem not to push for stronger patent protection. Most recent empirical research available in economic literature does not lend credence to the claim that strong IPRs promote innovation, technical change and economic development. Even the
relationship between foreign investment and IPR protection was too weak. All the studies reviewed in the foregoing analysis in this Chapter have failed to establish any clear relationship between stronger IPR protection, innovation and FDI.

In the following Chapters IV and V of Part II we shall provide detailed empirical evidence in the growth and self-reliance of the Indian pharmaceutical industry and the implications of the WTO.
PART II