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TRIPS AGREEMENT ON PATENT LAWS; IMPACT ON PHARMACEUTICALS AND HEALTH FOR ALL

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by

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TRIPS AGREEMENT ON PATENT LAWS: IMPACT ON PHARMACEUTICALS AND HEALTH FOR ALL

B.K. Keayla*

Introduction

The public health laws, national drug policy and the patent system are intensely inter- related. This was explained by none other than our great Prime Minister, the Late Mrs. Indira Gandhi while speaking at the historic session of the World Health Assembly in Geneva on May 6, 1981. In her words:

> "Affluent societies are spending vast sums of money understandably on the search for new products and processes to alleviate suffering and to prolong life. In the process, drug manufacturer has become a powerful industry."
>
> Adding further, she commented thus, on the patent system:
>
> "My idea of a better ordered world is one in which medical discoveries would be free of patents and there would be no profiteering from life or death."

In this historic session, the participating countries unanimously adopted a resolution for "Global Strategy on Health for All". Since then, there have been laudable contributions by science and technology to successfully tackle many health problem areas. While there is substantial unfinished agenda on the health front, new formidable challenges have been thrown up by an unequal treaty on all prevasive economic and social aspects by the Final Act embodying the results of the Uruguay Round Negotiations. In particular, the Agreement on Trade Related Aspects of Intellectual Property Rights(TRIPs) is the most contentious part of the Final Act. The aim of this Agreement is to enforce globally tough standards in respect of several forms of intellectual property which include patents, trade marks, protection of undisclosed information, etc., totally forgetting the laudable goals expressed by Mrs. Gandhi in regard to freeing of medical discoveries from the patent system. As opposite to this, the standards of protection provided in the TRIPs Agreement are more or less on the lines of those which are being practiced by the technologically advanced countries like the USA, Germany, Japan, UK, etc. The important issue here is that while the WTO ~ as the successor to GATT ~ was set up to ensure freer trade, the TRIPs Agreement, never earlier a part of international trade regulations framework, makes for the perpetuation of monopolies and crippling of dynamic competition. The developmental objectives and the other critical concerns of the developing countries like population growth, environmental degradation, poverty, sanitation and health related issues were totally ignored in formulating the TRIPs Agreement. The claim that all countries are supposed to benefit from the new framework is patently hollow. In the areas of transfer and dissemination of new technologies, the Agreement has not brought any freedom or respite from monopolies. In fact, it strengthens monopolies. This is objectionable particularly in the area of human health care, thereby increasing the sufferings of the poor due to pushing up of prices of pharmaceutical products in the strong patent regime. As for the domestic enterprises in the developing countries are concerned, they will have to encounter unequal competition with the giant transitional corporations. The general public interest in almost all countries will suffer from the abusive use of strong patent system.

This paper extensively deals with the comparative analysis of the existing and the new patent system and the safeguards which have to be provided in public interest to accomplish the goals of "health for all".

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PART I

PATENT SYSTEM AND BASIC ELEMENTS

(a) Patents : Definition & Subject Matter

Patents rights were introduced in the legal system in the 19th century, with a view to:

- promoting innovation;
- to enable disclosure of inventions for furthering research; and
- for dissemination of fruits of new research for the benefit of the general public.

The broad idea behind the system is to ensure the availability of new knowledge for the prosperity of mankind. These rights are formally granted by Governments under their national laws through an act of Parliament to both nationals and foreigners at par, and are enforceable for a specified period. The rights provide for excluding other enterprises from making, using, offering for sale any of the patented products or products manufactured through the patented processes. In the pharmaceutical fields, thus these laws govern the relations between the patent holder and the public about the health care. The objectives of the patent system and its scope are sought to be enlarged in the TRIPs Agreement.

In order to be patentable, an invention needs to meet the requirement of:

- novelty (previously unknown to the public);
- non-obviousness (containing sufficient innovativeness to merit protection); and
- industrial applicability for usefulness);

Patents may be granted for all kinds of products and processes including those related to the primary sector. Patent protection is only an acquired right under the national laws and as such it is not a natural right and cannot be treated as private right as envisaged in the preamble of the TRIPs Agreement.

(b) Patent System : Types

The patent system provides for two types of patents, viz. product patent and process patent. Product patent provides for absolute protection in respect of patented products, whereas process patent provides for protection only to the technologies and methods of manufacture. Process patent system promotes competitive environment and a strong check on prices, as against monopoly created through product patent system wherein resource power is used for snuffing out competition and fleecing of consumers by charging high prices. In the field of pharmaceuticals, there are certain countries like USA who grant patents even for usage form, dosage form and combinations (formulations) which help the patent holders to enjoy patent rights for much longer period.

(c) Varying Patent Systems

Worldwide, national governments used their prerogative to evolve their own patent system. It is generally related to other stage of development. IPR laws in developing countries,

therefore, are compatible with their developmental objectives. The right to develop in the developing countries prevailed over the intellectual property right in the developed countries. As such, patent systems of countries differed widely from each other. National laws have been gradually upgraded by the developed countries to provide for greater protection to their scientific and technological achievements. They have succeeded only now through TRIPs to ensure global protection to their inventions which have been monopolised by MNCs in these countries for commercial exploitation. For example, Italy, Germany and Japan changed over to product patent from process patent system in pharmaceutical field only in the recent past.

(d) Basic Elements in Patent Systems : Evolved through long practice

Over a long period of operation of the patent system, certain laudable basic elements have found place in almost all national laws, including the laws of the developing countries. The national laws provide for the balancing of rights and obligations for the patent holders. The scope of patentability has been applied in most countries, as stated above, to the stage of development in those countries. Patent monopolies have not been allowed to be established in sectors of vital importance.

The patent system legally ensures the working of the patent in the country which grants the patent rights. Imports beyond a specified period is being regarded as abuse of patent rights (even the Paris Convention also called it abuse of rights) and for this reason the imports are being used as one of the reasons for the grant of sub-licensing to others. A system of compulsory licensing has thus been provided in the national laws. Compulsory licences are granted by the national governments for upholding the public interest.

- due to non-working of the patent or
- inadequate working of the patent or
- due to the charging of monopolistic prices for the patented product or
- due to continued imports beyond 3/4 years from the date of patent grant.

In India, automatic licensing of rights has also been provided for certain products in public interest for ensuring working of patents in a competitive environment. This right is mainly available for chemical based products like pharmaceuticals. As regards the term of the patent, the same varies from country to country. India has been having term of only 5/7 years for process patents for pharmaceuticals and other chemical based products and 14 years for other products whereas USA held a uniform term of 17 years for all patents and now it has changed to 20 years because of TRIPs.

The TRIPs patent system now seeks a uniform patent laws for all member countries of the WTO.

It would be relevant to mention that according to the U.S. Supreme Court "It is undeniably true that the limited and temporary monopoly granted to inventors was never designed for their exclusive profit or advantage, the benefit to the public or community at large was another and doubtless the primary object in granting and securing that monopoly". (Quoted in Vaughan 1956,32). But now this objective is being totally ignored in providing a global strong patent system in TRIPs.

PART II

HISTORY OF THE PATENT SYSTEM

Speaking at the Third World Patent Conference held on 15-16th March, 1990, Mr. K.R. Narayanan (now Hon'ble President of India) said: "The story of the interchange of knowledge, scientific knowledge and technology is a very old one. Today the developed countries of the world have more or less domination in the field of science and technology. But they did not get it from the void; it was a part of continuous process of interchange of knowledge which took place in the world during many centuries. Scientific knowledge was passed on to the industrialised western countries of today from Asia, China and India. In fact, even today in the form of brain drain from the countries like India very significant scientific - technological - knowledge is going from East to West. Some years ago, probably it was in 1953, the then US Ambassador Mr. George Allen said: 'For countless centuries your country (India) was the source of world drugs and spices. It is high time the West began to repay its debt to you by helping you to regain your rightful place in this field.' Those spacious days are no longer there and today the way the West is repaying it is through Special 301 and Super 301. It is neither historically true nor morally valid for the developed countries of the world to take up the position that by transferring technology to the developing countries they are doing a great favour. They had imbibed a lot from India in the past and even currently too". The history of the patent system has to be understood in the background of what Hon'ble Mr. K.R. Narayanan said. The patent system, has a long history. It has its origin in the practice of granting monopolies by the Crown in England. In the reign of Edward-III, some form of patent protection appears to have been given for arts and sciences which were for the public good. In the middle ages in the UK cases are reported of patents being granted to foreign workers to entice them to leave their own country and come to work and teach their skills to native craftsmen. In the beginning UK did not resort to compulsory licensing system. In fact, they even opposed compulsory licensing at the International Conference on Industrial Property at Paris in 1878. However, UK soon changed its mind and made provision for compulsory licensing at the International Conference on Design Act, 1883. Further strengthening of the provision for grant of compulsory license were incorporated in the UK Patents Act in 1919 and 1949. Insofar as the process patent system is concerned, UK had practiced this system between 1918 and 1949. They introduced product patent system only after substantial achievement in technological self reliance.

In France, a Venetian, Thesco Mutio, received a grant of patent in 1551 for a ten year monopoly for the manufacture of a type of Venetian glassware. The earliest law concerning patents for inventions appears to have been that passed in Venice in 1474. In 1594, Gallileo was granted under this law a patent for a device for raising water for irrigating the land. Provision for compulsory working of patented invention was incorporated in the French Law in 1741. Other countries in Europe also provided similar provisions in their laws.

In America, patents were granted as early as in 1641 although the system proper started in 1790. The Patents Act was amended in 1793 and later became closer in its terms to the UK Act. In USA also in the recent past, there has been considerable debate about the choice between competition and innovation in the pharmaceutical field which has continued since investigation of the patent system by Kefauver Committee in 1959. This committee

found that "pharmaceutical patents led to high profits" and proposed that patents be limited to three years only; beyond that time, the patent holder should be required to grant licences to other firms at a maximum royalty rate of 8 per cent. This recommendation, though not implemented, had substantial indirect effect on the stronger authority accorded to the Food and Drug Administration (FDA) whose more comprehensive regulatory approval of new drugs replaced in part the role of weaker patent monopoly. Further, again in USA the hearing led by Rep. Henry Waxman of the House Energy and Commerce Committee during 1988 on the prices of pharmaceutical industry found that "since July 1985 drug prices had risen 4.5 times more than consumer price index" and that "between 1982 and 1986 revenue gains of 24 leading companies were three times higher than the R&D increases". According to Rep. Waxman "an attractive alternative to the problem would be to adopt the Canadian compulsory licensing system which had proved its efficacy in terms of hundreds of millions of savings to the drug consumers". Thus even in USA, the pragmatic approach at highly responsible levels other than pharmaceutical industry had been for the application of the compulsory licensing system in some form or the other to contain the prices of pharmaceuticals and to reduce the cost of health care to its people.

The German Patents Law of 1877 was enacted with only process patents for chemical products (including pharmaceutical products) to encourage development of innovative and cost effective processes for the same. In fact, Germany provided an interesting example about the evolution of process patent system. In 1876 when German industry was in its infancy and the patent law was yet to be evolved, Bismarck appointed a committee to study the likely impact of the patent system on the industry. Among the members of the committee were the founders of Siemens and Hoechst. Their observations made an interesting reading:

> *"Today industry is developing rapidly ..... monopolization of inventions and abuse of patent rights will inevitably expose large segments of industry to serious injury. The Government must protect industry against these dangers. ..... These patents will not be taken out in order to protect industrial plants established or to be established in Germany; they will be taken out to monopolise production abroad. These articles will be imported into this country. Such a danger must be met."*

The history of the patent system would be incomplete without the mention of the Paris Convention administered by the World Intellectual Property Organisation (WIPO). The Paris Convention for the protection of industrial property was established in 1883 and has been revised six times. The amending Conventions are:

~	Brussels Convention,	1900
~	Washington Convention,	1911
~	Hague Convention,	1925
~	London Convention,	1934
~	Lisbon Convention,	1958
~	Stockholm Convention,	1967

All amending conventions have provided for stiffer provisions granting more protection to pantentees. The developing countries are concerned about social obligations for the patentee

whereas the Paris Convention does not provide for any such obligations. It provides for maximization of individual rights (Article 5). Paris Convention does provide for system of compulsory license which can be applied on the ground of failure to work or insufficient working after three years of patent grant [Article 5(2)]. However, there is also provision that compulsory license "shall be refused if patentee justifies inaction by legitimate reasons". The Paris Convention also provides for members to ensure effective protection against "unfair competition". The only reason given for this is "far contrary to honest practices".

There are over 100 countries who are now members of the Paris Convention. Presently, WIPO is engaged in evolving a so called harmonization of patent system which is known as "Treaty Supplementing Paris Convention". Some critics have observed that the provisions of this Treaty under consideration are more onerous than even the patent system provided in the TRIPs Agreement. As it is all the substantive provisions of the Paris Convention (Articles 1 through 12 and Article 19) shall have to be complied with by all members as provided in Article 2 of TRIPs Agreement of WTO. Later the new "Treaty Supplementing Paris Convention" would also become applicable to all Members of WTO because of Article 2 and Article 71 of TRIPs.

Insofar as the developing countries are concerned, the first Patents Act relating to the grant of patent rights was passed in India in 1856. The straits settlements (Singapore, Wellesely Penang and Malacca) were made colonies independent of India in April 1867. In November 1871, it received the patent law which substantially followed the Indian laws. The basic features of laws in the developing countries like India, Malaysia, Thailand, Argentina, Brazil, Mexico, China, Egypt and Canada did follow the principle of encouraging the role of the domestic industry in the field of drugs and pharmaceuticals. In order to achieve this, they had either excluded drugs and pharmaceuticals from the patent system or had provided for only the process patent or the method of manufacturing these substances. They had also provided for compulsory licensing/licensing of right system to ensure that monopolistic regimes are not established by the patent holders under the patent system and the domestic industry is able to play its role in providing pharmaceutical products. Thus the devolution of the patent system, both in industrialised and developing countries, would clearly establish the fact that there has been a close co-relation between the level of economic, industrial and technological development of a country on the one hand and the nature and extent of patent protection granted by it on the other. In the crucial phase of their industrial development, many of the industrialised countries of today had either "on-patent" or weak patent standards in vital sectors in order to strengthen their industrial and technological capabilities. It was only after they attained sufficient technological strength in certain areas that they considered making changes in their patent system. The patent system, in fact, has been an instrument of national economic policy for the industrialisation and technological advancement of a country. In the case of developed countries, it is of foremost importance that the patent system does not block or hinder the building up of their own industrial and technological capabilities. Now these developing countries, under pressure either changed or are changing their patent laws to provide for product and process patents for pharmaceutical products. In any case, all the member countries of WTO have to change the patent system as provided in the TRIPs Agreement. A simmering debate has already been started by the public interest groups in most countries, about the impact of the TRIPs patent regime on the health care system.

PART III

PHARMACEUTICAL MARKET~ GLOBAL SCENARIO

A. Production/Sale of Pharmaceuticals

The global pharmaceutical market has increased dramatically from the past two decades. In 1976 world consumption of drugs amounted to US $43 billion and in 1985 it reached US $94.1 billion; thus registering an overall annual increase of 9.1% in the decade between 1976 and 1985. The world market consumption increased to US $260 billion in 1995 and increased to US $290 billion in 1996. The forecast for the future is that it will grow at a compound annual growth rate of 6.2% in the next 5 years to reach US $378 billion in 2001 according to the recent IMS Report. Both production and sales are heavily concentrated in the developed countries; the US, Europe and Japan account for about 80% of both production and sales. Paradoxically, the population in the developing countries in 1976 was 73% of the world population whereas the pharmaceutical consumption was only 24% of global production During 1989 the developing countries registered population at 75% whereas the pharmaceutical consumption decreased to 21%. The increasing balance was due to the fact that the drug consumption accrued at an average of 9.6% per year in the developed countries and at only 7.2% in the developing countries. In other words, in 1985 1.2 billion people living in the developed countries consumed nearly US $75 billion worth of drugs while the remaining 4 billion living in developing countries consumed only US $20 billion worth.

The regionwise world consumption of pharmaceuticals has been as follows: (Figures in US $ billion, ex-manufacturer price)

Table 1

	1976	1985
North America	8.761	28.141
Western Europe	13.111	22.000
Eastern Europe	6.197	9.600
Japan	4.020	14.038
Oceania	0.480	0.700
Latin America	3.689	5.600
Africa	1.268	2.700
Asia (excluding China and Japan)	2.920	6.600
China	2.600	4.700
Total	43.046	94.079

The above Table indicates substantial increase in consumption of pharmaceuticals in the developing counties, whereas the consumption in developing countries is not growing much even when the actual needs keeping the health care scenario in view are much higher.

Two largest drug markets in the developing countries, viz. China and India had the following sales :

Table 2

Country	1976 Sales (US $ billion)	1976 % of world market	1985 Sales (US $ billion)	1985 % of world market
China	2.600	6.0	4.700	5.0
India	0.508	1.1	1.775	1.9

Source: Global Study of Pharmaceuticals Industry

During the last one decade both these markets have registered substantial increase and are likely to provide largest jump in the market share during the next 5 years according to the latest Global Pharma Forecast 1997-2001.

B. Per Capita Drug Consumption

Another important element to be taken into account while assessing the world drug consumption is per capital drug consumption. As a whole, this indicator does not reflect the consumption of drugs throughout the community, as the average value is likely to be far from the extremes. However, it does help to give an idea of the discrepancies that exist between the developed countries and the developing countries.

Table 3

Value of per capita drug consumption

	1976	1985	Annual growth rate (%)
	US $		
Developed countries	**29.0**	**62.1**	**8.8**
Western Europe	34.0	54.5	5.4
North America	36.3	106.3	12.7
Eastern Europe	17.0	24.5	4.1
Japan	35.6	116.3	14.0
Developing countries	**3.4**	**5.4**	**5.0**
Asia	2.4	4.2	6.3
Africa	3.0	4.9	5.7
Latin America	11.2	13.8	2.3
World	**10.3**	**19.4**	**7.2**

Source: Global study of the pharmaceutical industry, unpublished UNIDO document; IMS Market letter, 11 August 1986; estimates of WHO secretariat.

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

Table 4

	1976	1985	1990
	US $		
India	0.8	2.3	3.0
China	2.7	4.4	7.0
Brazil	10.9	10.3	16.0
UK	18.3	41.4	97.0
USA	36.2	110.5	191.0
Japan	35.6	116.2	412.0

Sources: Global study of the pharmaceutical industry, Unpublished UNIDO document: and Chemical Weekly 1996.

The gap in per capita drug consumption between the developed and developing countries which was already very considerable in 1976 continued to grow in the subsequent 10 years. While in terms of value each inhabitant of a developed country consumed on an average in 1976 8.5 times as many drugs as an inhabitant of a developing country; in 1985 he consumed drugs costing 11.5 times as much. This worsening of the situation is due to both the slower growth of drug consumption in developing countries and the faster growth of population. Whereas the growth rate of the population in developing countries reached 2.1% per year in the period 1976-85, in developed countries it was less than 0.8%. The above consumption figures do not necessarily reflect the true consumption of drugs in these countries as the factors relating to the exchange rate and inflation have not been taken into account. If these factors are accounted for, probably the per capita consumption thus obtained would show that in terms of volume the evolution had been different in different countries. In any case the poverty-health nexus in the developing countries is quite strong. Poor health care conditions retain the poor in these countries in poverty and poverty retains them in poor health. For example, there is 70% population in India which cannot afford modern medicines and this is one of the strong reasons for poor health conditions for its people where there are still 40% population below poverty level.

C. Research and Development in Pharmaceutical Industry

The pharmaceutical industry is characterised by high research and development which has remained the principal mechanism whereby the society is supplied with new drugs to prevent, control and cure diseases. R&D is also extremely important for pharmaceutical firms in maintaining growth and competitive advantage; investment in research and development has to generate products that can be sold in large markets at reasonable profit. Accordingly, economic and social concerns are often in conflict. The leading global companies in the world market spend an average of about 15% of their sales on R&D. These leading companies have their base in France, the Federal Republic of Germany, Japan, Switzerland, the United Kingdom and the United States of America. In 1982, these companies accounted for 75% of the pharmaceutical industry expenditure on the research of new medicines. In 1984, their expenditure on R&D was estimated to be US $6.5 billion. The global R&D expenditure of the

pharmaceutical industry in 1995 was about US $25 billion. The US industry accounted for the largest R&D expenditure. It spent $13.4 billion and 14.5 billion during 1994 and 1995 respectively. The earlier expenditure of US pharmaceutical firms during 1970 was US $0.62 billion; in 1990, it rose to US $8.2 billion. The R&D spending of major pharmaceutical firms during 1995 has been as follows :

Table 5

Firm	R&D Expenditure 1995
	$M
Glaxo Wellcome	1,884
Novartis	1,695
Merck & Co.	1,331
Pfizer	1,295
Hoechst Marion Roussel	1,250
American Home Products	1,220
Pharmacia Upjohn	1,128
Bristol-Myers Squibb	1,007
Eli-Lilly	990
Bayer	903

D. Expenditure on Drug Development

The cost of research and the time required to transfer a drug from the laboratory to the market has increased substantially. In 1963 in the United Kingdom, according to the industry analysis, it took about 3 years and spent 2-3 million pounds to develop and market a new drug. In late 80s, the estimated cost increased to 50 million pounds and the time period also increased to 7-10 years. During the same period, in the Federal Republic of Germany the average duration of R&D on new substances increased from 2-3 for research and 5 years for development in 1964 to 9-13 years in 1981 with a cost in 1981 of about DM 150 and 300 million (US $57 and US $114 million) respectively. In the United States, development time increased from 2 to 7-10 years and cost from US $54 million in 1976 to US $ 75-100 million in 1985. A study conducted by the US Pharmaceutical Manufacturers' Association stated that in 1986 the cost of developing a new chemical entity had risen to US $125 million (US $65 million out of pocket expenditure and US $60 million as opportunity cost). These figures are stated to be averages and cover the failures as well as successes. Some industry analysis consider that much of the cost must relate to R&D products that do not succeed. The actual cost of developing chemical entity must now therefore be far less. According to Burke (1996), the development of drugs has become extremely costly and uncertain. The average cost of developing new drugs was $120 million and $359 million in 1987 and 1992 respectively. According to the latest estimate, the cost has increased to $600 million by 1995. The cost of

drug development has increased for the two main reasons :

- The new generation drugs are very complex and their discovery and development require costly technology; and

- The regulatory control has become very strict. The drug has to pass through more stringent safety and other tests than in the past.

The introduction of new drugs has been on the decline. According to a study, the number of new drugs declined from 564 in 1953 to 166 in 1962. According to Whittakar and Bower (1994), the number of drugs introduced in the US market, for example, declined from early average of 100 in 1960s to less than 40 in 1980s. However, the discovery rate has improved in the recent years. There has been an explosive growth in the biomedical knowledge. Though the discovery rate has increased, the number of drugs has continued to decline in the 90s because of the stricter regulatory requirement. Only 28 new drugs were approved in the USA in 1995 and only 40 new drugs were introduced worldwide during the same year.

PART IV

PHARMACEUTICAL INDUSTRY IN INDIA : A CASE STUDY

India's first Patents Act of 1858 was replaced by a more comprehensive Patents and Designs Act in 1911. This Act was designed to serve foreign interests. The raw materials from India were exported and value added finished goods at monopolistic prices were sold in Indian markets. The industry was dominated by MNCs. They were reaping enormous profits from the Indian markets. An American Senate Committee, headed by Senator Kefauver, stated in 1959 in their report that the prices of drugs in India were "amongst the highest in the world".

Following independence in 1947, one of the first major decisions taken by the Indian National Government was to change the colonial Patents Act of 1911. The new Patents Act was eventually enacted in 1970 after in-depth study by two high-powered Committees, headed by Justice Bakshi Tek Chand and Justice N. Rajagopal Iyenger, and extensive debate in Parliamentary Committees and both the Houses of Parliament. In amending its Patents Act, India took a considered decision to stay outside the Paris Convention. The Iyenger Committee advised the Government against India's joining the Convention on the ground that country would lose freedom to exclude certain areas of development from patentability by foreign and domestic interests and revoke patents when they are not worked in the country. In the recent past, several eminent jurists of the country and former Chief Justices of the Supreme Court of India, viz. Justice M. Hidayatullah, Justice Y.V. Chandrachud and Justice J.C. Shah also advised against India joining the Paris Convention. According to Justice Chandrachud "the creed of the Convention is the protection of private rights, not the securing of public interest". The jurists had doubted the constitutionality of the Paris Convention and its provisions being forced on India.

The Indian Patents Act, 1970 was hailed by many developing countries and UNCTAD as one of the most progressive statute suitable as a model for the developing countries. It safeguards the interest of both the inventor and the consumer in a balanced manner. The interests of the public have been given priority over the private interests of the patent holders. This Act is product of deep consideration and long deliberation to synchronize with the Directive Principles of State Policy contained in the Constitution which provides in Article 39 that:

> *"39. The State shall, in particular, direct its policy towards securing*
>
> *(a) .....*
>
> *(b) that the ownership and control of the material resources of the community are so distributed as best to subserve the common good; and*
>
> *(c) that the operation of the economic system does not result in the concentration of wealth and means of production to the common detriment."*

The Indian Patents Act, 1970 is a landmark in the history of industrial development and forms the basis for transfer of technology. The Act devotes equal attention towards the industry, the scientists, the consumers and the nation as a whole. It has preserved the continuing interest of the inventor in his creation, his social interest in encouraging research, the consumer interest in enjoying the fruits of inventions at reasonable cost and creation of conditions for the acceleration and promotion of economic development of the country.

The important features of the Indian Patents Act, 1970 can be judged from the obligations which have been laid down for the patent holder for working the patent to satisfy the reasonable requirement of the public. One sees competitive environment in the country.

Another important feature of the Indian Patents Act, 1970 relates to the exclusion from patentability of technologies relating to atomic energy and inventions relating to agriculture and horticulture products or methods. As regards the chemical based products, the Act provides that "only methods or processes of manufacture claimed for substances intended for use or capable of being used as food or as medicine by chemical processes including alloys, optical glass, semi-conductor and inter-metallic compounds, would be patentable and that as such no patent shall be granted in respect of claims for the substances themselves". It is because of this provision that it has been possible for the scientists and entrepreneurs in India to develop alternative process technologies which have helped the pharmaceutical industry to produce new drugs in the country in a relatively shorter period. The salient features of the Patents Act, 1970 thus deal with :

- ~ Exclusion of certain fields basic to our economy and well being of Indian people from patentability;
- ~ No product patents in some other important areas like drugs and pharmaceuticals, agro-chemicals, etc.;
- ~ Shorter period of patent protection;
- ~ Importation not treated as working of patent;
- ~ Compulsory licensing and license of right to ensure working and disssemination of technologies;
- ~ Ceiling on royalties on sub-licensing of patents. Thus balancing of rights and obligations and ensuring that patent monopolies are not established.

Because of these features, the Indian industry during the post 1970 period after the new patent system was introduced progressed quite satisfactorily. The pharmaceutical industry especially made excellent progress within the framework of the new patent laws as is evident from the following facts :

(a) Process Research

Table 6 indicates the basic drugs manufactured by the domestic sector companies in India based on indigenously developed process technologies.

Table 6

Basic Drugs Manufactured by Domestic Sector Companies Based on Indigenously Developed Process Technologies Effect of the Process Patent System

1. Acetazotamide
2. Allopurinol
3. Amitryptiline
4. Amidaqine
5. Amoxycillin
6. Ampicillin
7. Analgin
8, Aspirin
9. Atenolol
10. Betarnethasone
11. Caffeine
12. Ca. Sennosides
13. Carbamezapine
14. Cephaclor
15. Cephazoline
16. Cephalexin
17. Chloraphenicol
18. Chiordiazepoxide
19. Chlarpropamide
20. Chloroquine
21. Cimetidine
22. Ciprofloxacin
23. Cisplatin
24. Clonidine
25. Clofibrate
26. Cloxacillin
27. Cyproheptadine
28. Danazol
29. Dapsone
30. Dexamethasone
31. Dextropropoxyphene
32. Diazepam
33. Diloxanide Furoate
34. Diphenylhydantoin
35. Diphenhydramine
36. Doxycycline
37. Emetine
38. Ephedrine
39. Erythromycin
40. Ethambutol
41. Ethinyl Estradiol
42. F!orafur
43. Folic Acid
44. Frusemide
45. Furazolidine
46. Gentamycin
47. Glipimide
48. Glibenclamide
49 Guaphenesin
50. Griseofulvin
51. Heparin
52. Hydrochlorothiazide
53. Hydoxiprogesterone
54. Hydroxyzine
55. Ibuprofen
56. Indomethacin
57. Isopropylantipyrine
58. Kanamycin
59. Keterolac
60. Lorazepam
61. Mebendazole
62, Metoprolol
63. Metoclopramide
64. Metocarbamol
65. Methyldopa
66. Metranidazole
67. Nalidixic Acid
68. Naproxen
69. Niacinamide
70. Nicotinamide
71. Nifedipine
72. Nitrazepam
73. Nitrofurantoin
74. Norethisterone
75. Norfloxacin
76. Ofloxacin
77. Paracetamol
78. Pethidine
79. Pentazocine
80. Phenarimine
81. Piperazine
82. Piracetam
83. Progesterone
84. Propanolol
85. PVT-Iodine
86. Povidine Iodine
87. Pyrental Palmoate
88. Pyrazinamide
89. Quinidine
90. Quinine
91. Ranitidine
92. Roxitidine
93. Salbutamol
94. Silver Sulphadiazine
95. Sulphacetamide
96. Sulphamethoxazole
97. Sulphamoxole
98. Terbutaline
99. Theophylline
100. Thiacetazone
101. Timolol Maleate
102. Tinidazole
103. Trimethoprim
104. Triazolin
105. Vinblastine
106. Vincristine
107. Vitamin B12/ other Vitamins

Table 7 indicates the time lag between the introduction of a new drug in the world market and its introduction in India after the domestic enterprises developed their own technologies to manufacture the products.

Table 7

Time lag between introduction of a new Drug in the World Market and its introduction in India

Drug	Introduced (Year) In		
	World Market by the Inventor	Indian Market by Domestic Cos.	: Time Lag: Introduc- : duction in India (Yrs.)
Salbutamol	1973	1977	4
Mebendazole	1974	1978	4
Rifampicin	1974	1980	6
Naproxen	1978	1982	4
Bromhexin	1976	1982	6
Ranitidine	1981	1985	4
Captopril	1981	1985	4
Norfloxacin	1984	1988	4

In view of indigenously developed process technologies, the pharmaceutical industry has been able to produce basic drugs covering various therapeutic groups and achieve near self-sufficiency in the production of bulk drugs in the country. The industry has also developed capabilities of producing enough surplus of basic drugs and formulations for exports worldwide.

(b) Production

After the Patents Act, 1970 was enacted, the number of pharmaceutical producers (small, medium and large scales) increased from 5,000 to 24,000. The production of pharmaceutical products has also grown more than 38- fold from Rs.250 crores in 1971 to over Rs.9,500 crores in 1995-96. Similarly in recent years, there has been a sharp rise of twenty times in exports by the industry: from Rs.140 crores in 1985-86 to over Rs.2800 crores in 1995-96. The domestic industry has thus greatly helped in providing not only drug security in the country but has also succeeded in getting access to foreign markets both in the developed and developing countries. Of the 465 bulk drugs used in the country, 425 are produced indigenously. The Indian industry has emerged as world leader in the production of bulk drugs like Ciprofloxacin, Dextrapropoxyphene, Ethambutol, Ibuprofen, Norfloxacin, Sulpha-methoxazole, Trimethoprim, etc. Ranbaxy, Cipla, Cadila, Alembic, Lupin, Themis and Torrent enterprises have emerged as major Indian companies meeting requirements of all kinds of drugs in the country and having strong foreign presence by exporting drugs and medicines matching the worldwide quality standards. Ranbaxy alone exported drugs worth Rs.630 crores out of its production of Rs.1153 crores during 1996-97 and during 6 months of 1997-98 they have already exported drugs worth Rs.304 crores.

There is competitive environment in India in production of almost all essential drugs and it can be judged from the number of total producers in the country and the number of producers of major essential bulk drugs as shown in the following **Table 8**:

Table 8

Drug	Number of Manufacturers
Ampicillin ..	32
Amoxycillin ..	22
Cephalexin ..	25
Chloramphenicol ..	68
Diazepam ..	20
Diclofenac sodium ..	29
Erythromycine ..	22
Ibuprofen ..	52
Mebendazole ..	35
Paracetamol ..	63
Rifampicin ..	27
Tinidazole ..	40
Trimethoprim ..	88

The above competitive environment and self-reliance with the implementation of monopolistic TRIPs Patent System would be totally crippled. The dependence upon imports would make things worst from the consumer angle. They will have to pay high prices in the new situation for their health care needs.

PART V

BASIC FRAMEWORK OF TRIPS AND MAIN FEATURES

Basic Framework

It can be emphatically stated that TRIPs Agreement as such is not based on proper negotiations in the Uruguay Round between the members of the developed and developing countries of the WTO. The basic framework for the TRIPs patent system was conceived and shaped in a Joint Statement (Paper) presented to the GATT Secretariat in June 1988 by :

- the Intellectual Property Committee (IPC) of USA;
- Keidanran of Japan; and
- UNICE of Europe.

IPC is a coalition of thirteen major US Corporations dedicated to the finalisation of TRIPs in GATT in their favour. The member of the IPC then were Bristol Myers, Dupont, General Electric Motors, Hewlett Packered, IBM, Johnson and Johnson, Merck, Monsanto, Pfizer, Rockwell and Warner. Similarly, the other two organisations of Japan and Europe also then represented powerful business and industry interests.

When one compares the framework provided in the Joint Statement and the framework of the TRIPs Agreement, one does not find any basic difference between the two. The three

powerful organisations jointly submitted the Statement only to further the worldwide interests of the TNCs. They have thus been able to ensure their monopolistic rights fully. In the words of James Enyart of Monsanto, "We went to Geneva where we presented (our) document to the staff of the GATT Secretariat. What I have described to you is absolutely unprecedented in GATT. Industry has identified a major problem in international trade. It crafted a solution, reduced it to a concrete proposal and sold it to our own and other governments ..... The industries and traders of world commerce have played simultaneously the role of patient, the diagnostician and the prescribing physician." (Les Nouvelles June 1990 - pp 54-56).

The TRIPs patent system provides for virtually no obligations for the patent holder in the country which gives the patent rights. The system is, in fact, a charter of rights for the patent holders. There is no provision in the proposed patent system for transfer and dissemination of technology, even though the objectives and the principles laid down in Articles 7 & 8 of the TRIPs Agreement provide for the same. The new patent system will thus help the TNCs to achieve their objective of monopolising worldwide markets including the markets of the developing countries.

Patent Regime under TRIPs Agreement ~ Main Features

(a) Preamble

The TRIPs Agreement lays down minimum standards for protection of intellectual property. The Agreement envisages that member countries will not grant protection less than the levels laid down therein and the same has to be implemented through the domestic laws of each country. The preamble of the TRIPs Agreement "recognises the need for multilateral framework of the principles, rules and disciplines dealing with international trade in counterfeit goods". [According to US interpretation, the goods produced in India even by legally taking process patents, are counterfeit goods.] The preamble also explicitly "recognises the underlying public policy objectives of national system for the protection of intellectual property, including developmental and technological objectives". In spite of these provisions, the substantive provisions in "Section 5 : Patents" of TRIPs Agreement do not provide for the objectives and principles laid down in Articles 7 & 8 of the TRIPs Agreement and its preamble.

Even though many countries including India are not yet members of the Paris Convention, according to Article 2 of the TRIPs Agreement "the members shall comply with Articles 1 through 12 and Article 19 of the Paris Convention (1967)." This provision automatically brings all the member countries within the framework of the Paris Convention.
These provisions clearly amplify the designs of the MNCs who conceived and shaped the global and monopolistic patents system in the TRIPs Agreement.

(b) Objectives and Principles

Article 7 of the TRIPs Agreement provides that "the protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations". Similarly, Article 8 of the Agreement provides that "Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development,

provided that such measures are consistent with the provisions of this (TRIPs) Agreement". These are laudable objectives and principles. Notwithstanding the substantive provisions in "Section 5 ~ Patents" in TRIPs Agreement, the developing countries should interpret the provisions of Articles 7 & 8 in such a manner that they are able to safeguard their national interest for 'the promotion of technological innovation and to the transfer and dissemination of technologies' of the patented products in the pharmaceutical field and in other sectors of vital importance to their socio-economic and technological development while changing their national laws to accord with the TRIPs Agreement.

(c) Scope of patentability

When the Uruguay Round started, there were many countries which did not confer protection on pharmaceutical products and as such it was the essential aim of the USA and other technologically advanced industrial countries to extend the scope of patentability to the pharmaceutical products globally. The scope of patentability in TRIPs Agreement has thus been greatly enhanced. According to Article 27,

"patents shall be available :

- for any invention whether products or processes in all fields of technologies ~ provided that they are new, involve an inventive step and are capable of industrial application." [Art.27(1)]

  The above provision is one of the major concessions capitulated by the developing countries for a global scope.

- protection will also be extended to [as per Art.27(3)(b)] :

  - Micro-organism;
  - non-biological and micro-biological processes; and
  - plant varieties either by patents or by an effective *sui generis* system or by any combination thereof.

Thus the scope of patentability has been extended to the entire industrial and agriculture sectors. No flexibility is available to any country to exclude certain vital areas of economy from the scope of patentability in the domestic laws. The WTO will, however, be reviewing the above provision of sub-paragraph 27(3)(b) in four years after 1.1.1995 when WTO Agreement came into force. The *sui generis* provision for plant varieties may be replaced by a global model to be adopted by all countries. It also shows that countries may be called upon to extend patent protection to various categories of bio-technological innovations. There are the areas where European Union and USA could not come to an agreed position and hence they provided for review after four years.

It is reported that the European Council of Ministers on November 27, 1997 approved the EU Commissioner's proposed Directive on the Legal Protection of Biotechnological Invention, otherwise known as the "Life Patent Directive". Despite coming as a major below, people all over the world, as reported by the Genetic Resources Action International (GRAIN), have vowed to continue to fight the legislation which will allow life to become a private commodity, owned by the TNCs in the name of profit.

The concept of non-biological and micro-biological processes and effective *sui generis* system are likely to raise serious problems in legislation and in practice.

(d) Non-patentability

Article 27(2), however, specifically provides for the following exclusions from patentability:

- commercial exploitation of invention prevented by the members within their territory
  - ~ to protect *ordre public* or morality, including to protect human, animal or plant life or health; or
  - ~ to avoid serious prejudice to the environment;

  provided that such exclusion is not made merely because the exploitation is prohibited by the law.

  The existence of a legal provision prohibiting exclusion, if based on other grounds will not be regarded as sufficient ground for non-patentability.

Article 27(3) also excludes the following from patentability:

- diagnostic, therapeutic and surgical methods for the treatment of humans or animals;

  (According to Dr. Carles Correa, an authority on IPR, the exclusion mentioned above would not apply to any apparatus used for diagnostic or therapeutic purposes for its "diagnostic kits" one of the main biotechnology based products on the market at present.)

- plants and animals (other than micro-organisms); and

  (The scope of this exclusion is limited to traditional methods of breeding and improvement ~ thus covering the protection for inventions based on genetic engineering or gene manipulation.)

- essentially biological processes for the production of plants or animals (other than non-biological and microbiological processes).

The conditions for exclusion under Article 27 (2) to protect *ordre public* and serious prejudice to environment are quite complicated ones and in legislating on these aspects special care will have to be taken by the member countries to make them real effective. Further, the special issue No.24 of year 12 of the Revista de Mundo Indusrial, Buenos Aires, mentions about the possible patentability of products which "copy" substances already existing in nature has given rise to animated discussion and different solutions among the industrialised countries.

(e) Working of Patents : A Non-Issue

An important aspect of the working of the patent in the new patent regime has been totally changed. Imports are generally not regarded as working of the patent in the national laws. All along the patent holders had the obligation to work the patent in the country which grants the patent as an important element of the system. Even the Paris Convention recognises working of the patent in the country granting the patent. In fact non-working is considered as an abuse of patent rights under the Paris Convention (Art. 5A). The TRIPs Agreement, according to Article 27, however provides that: "patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced".

The provision for providing patent protection for imported products at par with locally produced products is a major deviation in the patent system as followed hitherto. Even while granting exclusive rights under Article 28 of TRIPs for products and processes, exclusive rights have been extended to making, using, offering for sale or selling and imports subject to the provision of Article 6. The implication of this provision is that the patent holders will have no obligation as such towards the national government conferring the patent rights under the new patent system to produce the patented product in that country. There will be thus free flow of imports of patented products. The right to import the patented products or product produced by patented process will also vest as an exclusive right with the patent holder. This will again be a serious matter particularly when this right is applied with another provision of "reversal of burden of proof" under Article 34. Also it will not be possible to regulate the prices of such products as price control system cannot be extended to imported products. It will be extremely dificult to determine their cost price. Thus patented products would be sold at relatively much higher prices. The dependence upon imports would also increase substantially. The weakening of the obligation to work the patent has thus strengthened the internationalisation of production and marketing by multinational companies as stated by Chesnais (1994). Having chosen to locate production in a place, their (MNCs) strategy is to supply global markets under monopolies conferred by patents, exporting finished or semi-finished products rather than transferring technology or making direct foreign investment (Correct 1989).

The footnote under Article 28 refers to Article 6 which permits member countries to provide for exhaustion of intellectual property rights subject to national and most favoured national treatment. According to Dr. Carlos Correa (Health Economics 1997), exhaustion may only apply to acts occurring within a country ("national exhaustion") in a group of countries or a region ("regional exhaustion") or in the global market as a whole ("international exhaustion). He has further clarified that recent legislative reforms in a number of countries has established the principle of international exhaustion with the aim of introducing a certain degree of competition into the market. He gave an example that if a patented product is sold in country A at a price of $100 and in country B the same (legitimate) product is sold at $80, this principle allows any interested party in country A to import the product from country B without the consent of the patent's owner.

(f) Authorisation for use of Patented Product

Article 31 of TRIPs deals with "other use without authorization of the right holder". The provisions under this article are in no way comparable to the usual provisions of "compulsory licensing" or "licences of right" for non-working. However, this Article does not restrict the rights of the member government to grant compulsory license "where the law of a Member allows for other use". It could be extended to "measures necessary to protect public health and nutrition and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this (TRIPs) Agreement" ~ the criteria which have to be consistent could be interpreted to relate to Articles 27.1 and 31. Further, compulsory license can also be granted when the patent holder has not responded within a reasonable period to efforts by any enterprise to obtain authorisation from the right holder on reasonable commercial terms and conditions.

Further Article 31 provides for licensing 'without authorisation of the right holder'. The scope of this provision, as stated above, is limited and is available only :

- in cases of national emergency;
- in cases of extreme urgency;
- in cases of public non-commercial use;
- in cases to remedy a practice determined after judicial or administrative process to be anti-competitive;
- in cases where second patents are permitted; and
- in cases of Government use.

The scope and duration of such cases are supposed to be limited to the specific purpose for which authorisation may be granted.

Article 31 also deals with the conditions that have to be respected by the member governments for grant of authorisation or compulsory license to third parties. These conditions are as follows:

(i) Compulsory license or 'authorisation of such use' shall be considered on its individual merits. This means that the concerned government has to specifically consider the individual application on merits and not apply any general consideration. [Article 31(a)]

(ii) The individual enterprise desirous of commercial exploitation of patent has to make direct efforts for authorisation with the right holder on reason- able commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. [Article 31(b)]

(iii) The scope and duration of such use shall be limited to the purpose for which it is authorised [Article 31(c)]. Thus for commercial purposes the duration of authorisation for local production will have to be till the patent rights are enjoyed by the patent holder.

(iv) Articles 31(d) & (e) provide for the authorisation/compulsory license, to be non-exclusive and non-assignable. This would imply that there is scope of giving compulsory license to more than one party.

(v) Article 31(f) restricts the compulsory license to predominantly for the supply of the domestic market. This restriction may mean limiting of capacity to an unviable size.

(vi) According to Article 31(h), the patent holder has to be paid adequate royalty taking into account the economic value of authorisation.

The member countries have to ensure while implementing the TRIPs Agreement that their national interests are fully safeguarded keeping the spirit of Articles 7 & 8 in view.

Dr. Colette Kinnon, a health economist and a member of WHO's Task Force on Health Economics, while speaking at Health Action International seminar on GATT/WTO, Pharmaceutical Policies and Essential Drugs, organised in Bielefeld, Germany, in October

1996, on minimising adverse effects said:

> "Government could also consider making use of certain provisions of the agreement for the purpose of avoiding monopolistic practices and encouraging competition among products that are essential for public health, for example, the agreement specifies certain grounds on which a country may employ compulsory licensing, such as protection of public health and nutrition; or for public non-commercial use, for instance when a government is directly interested in using the patented invention. A third one, which is an example of the way the agreement can work in favour of the consumer, is the granting of such licences to deter anti-competitive practices or to penalise abuse of a dominant market position. Furthermore, the agreement does not limit the grounds on which a country may grant compulsory licences. Domestic law can define the grounds for granting them, even if they are not mentioned in the agreement."

Adrian Otten, Director of the Intellectual Property and Investment Division of the WTO Secretariat in Geneva, while speaking at Health Action International seminar on GATT/WTO, Pharmaceutical Policies and Essential Drugs, organised in Bielefeld, Germany, in October 1996, on compulsory licensing said:

> "Under the TRIPs agreement, this option is posssible. The outcome of the debate on compulsory licensing was a set of rules applying to both forms of use without the authorisation of the right owner - that is to say, compulsory licensing and government use and does not limit the grounds on which compulsory licenses can be granted. There are a number of conditions, including:
>
> ~ Compulsory licensing must not discriminate according to the field of technology. A number of countries have special systems operating in the area of pharmaceuticals. These will have to be eliminated.
>
> ~ Patent rights must be enjoyable without discrimination as to whether products are imported or locally produced. Failure to meet the reasonable needs of the market can remain grounds for the grant of a compulsory licence.
>
> ~ The government should authorise the use of the patent after adequate repayment has been agreed upon."

Dr. Carlos M. Correa, Centre of Advanced Studies, University of Buenos Aires, Argentina, in his article on "Patenting Pharmaceuticals: A New Global Order" in Essential Drugs Monitor, a journal published by World Health Organisation, states as follows about "compulsory licences":

> "The Agreement grants members the right to compulsory licences on certain grounds. These include:
>
> **Public health and nutrition or other reasons of public interest**
> Article 8 ('Principles') of the Agreement specifically recognises the right of members to 'adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development...' Many countries, including some developed countries, provide for such compulsory licences in their legislation.

National emergency and extreme urgency
This is specifically mentioned in Article 31(b). It could also be considered to be covered by other general formulations such as 'public interest'. In such cases, prior negotiations with the right holder can be avoided.

Public non commercial use
In this case, a government is directly interested in using the patented invention for non commercial purposes.

Anti competitive practices
Compulsory licences can be granted to prevent abuse of a dominant market position.

Refusal of a voluntary licence
The TRIPs Agreement also authorises the granting of a compulsory licence when a patent holder refuses a reasonable commercial offer, which he has been given a reasonable amount of time to consider.

Other grounds
The Agreement does not limit the grounds for granting compulsory licences: domestic law can define the grounds for granting such licences, including those that are not meantioned in the TRIPs Agreement, which is only indicative in this respect."

James Love, an economist working at the Center for Study of Responsive Law in Washington, DC, has commented as follows on compulsory licensing in his article "As They Relate to Rules Regarding Intellectual Property":

"The United States is pushing hard in several forums to ban or severely limit compulsory licensing of pharmaceuticals patents or related property rights. The Trade Related Aspects of Intellectual Property (TRIPS) addresses this in some detail. Compulsory licensing of patents are severely constrained by the TRIPS, but not flatly ruled out. In Article 31, the TRIPS sets out a long check list of procedures a nation must follow. These are sufficiently ambiguous that future jurisprudence before the World Trade Organization (WTO) will be important in defining the limited rights retained by national governments. We have suggested in several forums that nations be permitted to use non-exclusive compulsory licenses based upon a fixed royalty as an alternative to national price controls, possibly where the patent holder could choose between the alternatives. Ultimately, this or other approaches will be resolved through the WTO dispute resolution mechanisms."

Ladas & Parry, Intellectual Property Attorney, having their major operations in New York, Chicago, Los Angeles, London and Munich, have expressed the following views in regard to intellectual property provisions of GATT (particularly compulsory licences):

"Compulsory licenses or other 'official licenses' are only to be permitted after consideration of the individual situation in which such a license is requested and, except in cases of national emergency, the grant of a compulsory license is subject to a number of conditions, including the following:

a) The party requesting the license must have used its best efforts to obtain a voluntary license on reasonable commercial terms;

b) The compulsory license must be terminated if the circumstances leading to its grant have ceased and are unlikely to recur;

c) The holder of the compulsory license must pay adequate compensation for the right to use the invention;

d) The determination of the amount of adequate compensation must be subject to independent review;

e) Where such a license is granted in order to enable use of a subsequent patented invention, a license shall only be granted if the later invention is an 'important technical advance of considerale economic significance' relative to the dominant patent and the owner of the dominant patent is entitled to a cross license under the secured patent."

In their Report of July 1996 on the implications of TRIPs for developing countries, UNCTAD has also commented on the creation and dissemination of IPR as follows:

> "In designing an efficient, rules-based system of intellectual property rights, the following objectives should be pursued:
>
> a. To the extent possible, the system should be based on market-oriented incentives for innovation and creation;
>
> b. The system should attempt to minimize the costs of innovative activity;
>
> c. The system should provide for timely disclosure of innovation or creation and also for reasonable fair use with economic and social goals in mind;
>
> d. The scope and length of protection should be limited in order to strike an appropriate balance between creation and dissemination;
>
> e. There should be coherent interaction with other regulatory or eonomic systems, including antitrust policy to avoid competitive abuses of IPRs, trade and FDI policies affecting the values of IPRs, and general technology development strategies."

The Report also commented about compulsory licensing as follows:

> "Compulsory licenses remain available, but on strict terms and conditions that are more favourable to patentees than under prior law (Article 31)."

The above conclusions are important in taking a view about the importance of compulsory licensing system particularly for the developing countries. The issues are quite complex and framing of provisions relating to compulsory licensing have to be carefully provided so that there is no lacuna from the legal interpretation point of view. The foreign patent holder would use the best legal advice available the world over to contest related issues to protect their monopoly which will become available to them on implementation of the TRIPs Agreement.

(g) Term of the Patent

Article 33 deals with the term, i.e. period of protection which 'shall not end before the expiration of a period of twenty years counted from the filing date'. Under the TRIPs Agreement, this term of 20 years would be globally applicable. There will be no varying the period of patent term as at present in the national laws of developing and developed countries. Since patentability extends to products and processes, the term would be applied for twenty years for product patent and then twenty years for process patent particularly in the chemical field, including drugs and pharmaceuticals. In the case of medicines, patents are available in USA for usage form, dosage form and combinations and

the same would be extended to other countries on implementation of TRIPs provisions. The following **Table** gives an idea of new combinations for which patents have been taken in USA even when the product patent on the basic drug expired long back.

Table 9

Illustrative List of Combinations under Patent in USA

Generic Name and Patent Expiry Year	Brand and Company Names	Dosage/Formulations	Patent Expiry Date
Aspirin (1973)	SOMACOMPOUND.W. CODEINE Wallace Labs	a) Aspirin 325 mg + Carisoprodon 200 mg + Codein Phosphate 16 mg	13/8/2002
		b) Aspirin 325mg + Carisoprodol 200 mg	13/8/2002
Diazepam (1980)	VALIUM Hoffman La Roche	a) 10mg tab	23/2/1999
		b) 2mg tab	23/2/1999
	--	c) 5mg tab	23/2/1999
	--	d) 2 mg/ml inj	23/2/1999
	VALRELEASE	e) 15 mh Cap	23/2/1999
Diltiazem Hcl (1988)	CARDIZEM SR Marion Labs.	a) 120 mg Caps	26/10/2005
		b) 180 mg Caps	26/10/2005
		c) 60 mg Caps	26/10/2005
		d) 90 mg Caps	26/10/2005
Hydro-chlorothiazide (1979)	PRINZIDE - 12.5 Merch Sharpe & Dhome	a) 12.5 mg + Linosporil 20 mg tabs	30/12/2001
Methyldopa (1976)	ALDOMET Merck Sharpe & Dhome	250 mg/ml suspension	13/09/2000
Norfloxacin (1996)	NOROXIN Merck Sharpe & Dhome	400 mg tabs	27/01/2004
Oxazepam (1984)	SERAX Wyeth Labs	a) 10 mg Caps	04/11/2003
		b) 15 mg Caps	
		c) 30 mg Caps	04/11/2003
Ranitidine Hcl (1995)	ZANTAC 150	a) Eq. 150 mg base tab	05/12/1995
		b) Eq. 15 mg base/ml syrup	29/04/2003
	ZANTAC 300 Glaxo	c) Eq. 25 mg base/ml inj	29/04/2003
		d) Eq. 300 mg base tab.	04/06/2002
		e) Eq. 50 mg base/100ml inj.	29/04/2003

Source : FOI Services Inc., USA

The patent protection under the TRIPs patent system would thus be used for extending monopoly by taking process patents and patents for usage form, dosage form and combination form. The monopoly protection would be extended through minor changes to the existing medicines where the product patents have expired long back.

New processes would be patented and new dosage form, etc. would also be patented. This kind of protection would have a far reaching implication for the developing countries including India and in a period of 10-15 years the patent protection in some form or the other would cover almost 70-80 per cent, if not more, of turnover of pharmaceutical products. It would become impossible for the domestic industry to subsist without new products and their business in the existing products would also be affected since protection in one form or the other would be available for such products also. Their survival and role to provide medicines at competitive prices would become a serious question.

(h) Reversal of burden of proof

Article 34 provides for reversal of burden of proof during the process patent regime for civil proceedings in respect of infringement of the rights of the patent owner. The onus of proving on the legal complaint that process used by another enterprise is totally different than the patented process would lie with the defendant and he will have to prove that he is not guilty of infringement. This provision would also be misused by powerful MNCs to curb competition from others, particularly the small companies, even when their process may be different. Serious legal objections might also be raised about the imported products covered by process patent. Keeping this aspect in view, the legal system to check infringement has to be carefully evolved so that the same is not misused.

(i) Protection of test data

Article 39 provides for protection of undisclosed information that test data provided by a company in order to obtain marketing approval from competent authority for pharmaceutical and agricultural chemical products has also to be protected against unfair commercial use; they must also be protected against disclosure, except where necessary to protect the public or unless steps are taken to ensure that the data are protected against unfair commercial use. Protection of such a data would be very difficult task for the authorities concerned. However, there appears to be flexibility available for the national government to frame provisions for implementation of this Article.

(j) Control of anti-competitive practices in contractual licences

Article 40 provides that the TRIPs Agreement recognises that the countries may specify in their domestic legislation the commercial licensing practices that constitute an abuse of intellectual property protection, and take steps to address these through appropriate measures.

(k) Enforcement : General Obligations

Article 41 of the TRIPs Agreement provides that members must provide effective means of action for any right holder, foreign or domestic, to secure the enforcement of rights while at the same time preventing abuse of the procedures. Similarly, Articles 43-50 of the Agreement specifies procedures for civil and judicial action, including means to produce relevant evidence. Civil remedies that must be available should include injunctions, damages and destruction of infringing goods or disposal of these outside the channels of commerce. Provisional measures also have to be available to prevent infringing activity and to preserve relevant evidence.

(l) Dispute Settlement

Article 64 of the Agreement provides that the new WTO dispute settlement procedures will apply to the TRIPs Agreement. However during the first 5 years from 1.1.1995, the dispute settlement procedures under Article XXIII of GATT 1994 shall not apply. During this period, the Council for TRIPs shall examine the scope and modalities for complaints of the type provided for under Article XXIII of GATT 1994. The Council shall submit its recommendations to the Ministerial Conference for approval. The decision of the Ministerial Conference shall be made only by consensus.

(m) Transitional arrangement

(i) Article 65 allows a general grace period of one year from 1.1.1995 to all countries for applying the provisions of TRIPs Agreement. The developing countries have been allowed further four years to implement the Agreement. However, the developing countries who do not extend product patent protection to areas of technology not so protectable in its territory on 1.1.1995 will have further period of five years to give effect to the provisions of product patent. Thus country like India would have a period of ten years to apply product patent for chemical based products including pharmaceuticals.

(ii) According to Article 70(3), the member countries will not be required to give protection to subject matters which have already fallen into the public domain.

(iii) Article 70.8 provides for an obligation to receive applications from 1.1.1995 for product patents for pharmaceuticals and agrochemicals if product patent as such is not available in the domestic laws of a country as on 1.1.1995.

Article 70.9 provides for another obligation for grant of exclusive marketing rights to the applicants of product patents for pharmaceuticals and agrochemicals.

Both the above obligations are subject matter of severe criticism in developing countries including India in particular.

PART VI

TRIPS : AN EXTREME COMPROMISE OF PUBLIC INTEREST

The TRIPs Agreement consolidates new forms of protectionism, which are not exercised through tariffs but through the appropriation of the knowledge applied to produce goods. The new highest expression of protectionism is, in the view of developed countries, a necessary condition to promote innovation and to stimulate technology and the capital flows to developing countries. Their assumption is that people from developed and developing countries will benefit alike from this kind of intellectual property rights.

This assumption is questionable. In the first place, the rationale of conferring monopoly rights over knowledge which can be used by anyone at once and, therefore, many may benefit from its use concurrently. It makes sense for society, as noted by Prof. Hettinger (1992) to grant exclusive rights to tangible objects because by its very nature the use by one person requires excluding others. But this is not the case of a "public good" like knowledge. Secondly, it is not true that a reinforced and expanded protection on intellectual property rights worldwide, shall increase the flow of technology and capital to developing countries. On the contrary, studies undertaken by the United Nations (1993) suggest that "innovatory companies in the North shall growingly opt, in the new post-Uruguay scenario, to directly sell the products or services that incorporate the innovations, rather than transferring the technology through foreign direct investments and licensing agreements". It is in this concept that the usual compulsory licence system in the TRIPs Agreement has been dropped. The likely result: more exports by developed countries, and less opportunities for industrial and technological development for developing countries.

Thirdly, strong patent system establishes monopoly of worst kind. This has been the logic of monopoly to charge as high a price as possible with the purpose of maximizing profits. These prices have no consideration with buying capacity of the consumers. The following **table** of price comparison of medicines between India, Pakistan, Indonesia, UK and USA will bear this out:

Table 10

Price comparison of medicines

(Prices converted into Indian Rupees)

Drugs/Brands	Company	India	Pakistan	Indonesia	UK	USA
Ranitidine (Zantac) 300 mg x 10s	Glaxo	17.39	241.44	658.36	502.70	1080.72
Times costlier			**(13.38)**	**(37.86)**	**(28.91)**	**(62.15)**
Diclofanic Sodium (Voveran) 50 mg x 10s	Ciba Geigy (G. Remedies)	6.49	55.62	177.18	100.10	362.12
Times costlier			**(8.57)**	**(27.30)**	**(15.42)**	**(55.86)**
Piroxicam (Dolonex/Feldene) 20 mg x 10s	Pfizer	28.33	72.50	218.45	117.70	958.32
Times costlier			**(2.56)**	**(7.71)**	**(4.15)**	**(33.83)**

One US $ = Rs.36 Prices compiled in July 1997

The above scenario is directly related to the 'patent system' practised in these countries. It is the same enterprise which is charging highly differential prices in different countries as it is possible to exploit the markets on the consideration of extent of patent monopoly available.

According to Ralph Nader (1995), with the establishing of the global patent system, "they (MNCs) are now moving towards uniform prices in order to avoid the downward ratchet effect of cross-country comparisons. This trend is raising prices for new drugs in the poorest countries". Finally, increased profit neither necessarily means more private R&D, nor a lower contribution by the public to technological development. Prof. Love (1994) has demonstrated that 12 out of 17 significant drugs developed in the United States between 1987 and 1991 were obtained with significant support from government, and that these drugs were much more expensive than those developed without such funding.

Who worries about the societal helplessness? The social implications and cost charges to society due to the intellectual property legislations in the developing countries, was never considered a relevant issue by the governments of developed countries and the powerful industrial lobies of MNCs which managed those changes at the Uruguay Round. Such costs, however, are likely to be substantial as illustrated in the above table and by several other studies in the case of medicines :

- After the introduction of pharmaceutical product patents in Italy in 1979, the prices of medicines increased on average more than 200%, i.e. consumer suffered a net welfare loss (Pablo Challu, 1991).

- In accordance with a World Bank's economist, the minimum welfare loss to a sample of developing countries (Argentina, Brazil, India, Mexico, Korea, and Taiwan) would amount to a minimum of US $3.5 billion and a maximum of US $10.8 billion (Nogues, 1990).

- A "national health disaster" has been anticipated by the Indian Drug Manufacturers' Association as a result of the implementation of the TRIPs Agreement in India where only 30% of the population can afford modern medicines in spite of the fact that drug prices in India are one of the lowest in the world.

- Similarly, the economist A. Subramanian (1992) noted that drug prices in Malaysia, where patent protection existed, were from 20% to 76% higher than India, which reflected a profit-maximizing behaviour based on "what the market can bear".

- A study conducted in Argentina (Pablo Challu, 1991) estimated that the introduction of pharmaceutical product patents in the country would imply an annual additional expenditure of US $194 million with a reduction of 45.5% in the consumption of medicines, as a result of a price increase of around 270%.

- Ralph Nader and James Love (1995) while rejecting TRIPs approach contend that "there would be no generic drugs ~ every drug would have monopoly patent protection for ever. The poorest consumers including large portions of citizens in the poorest countries would suffer from even greater barriers to access to medical care. Middle class consumers in the US also would be forced to pay much higher costs for drugs than they do today". They have also pleaded "to convene a meeting of US and international consumer and health organizations to discuss new framework for trade agreements that address intellectual property rights and health care."

- The Network's Newsletter of Pakistan of September 1996 indicates:

  "Pakistani consumers could have saved over rupees one billion on only nine medicines in 1995 if the companies would have offered the same price as they do in India. Pakistani consumers paid Rs.1,702,883,000 for buying these 9 medicines (14% of the retail market). These drugs are marketed by the same companies in India as well but at much lower prices. If patients in Pakistan were offered by these companies the same prices, their medicine bills would have come down to one-third (a 66% saving) or they would have saved a staggering amount of Rs.1,049,493,000."

Substantial consumer welfare losses and the exclusion of a larger proportion of the population (between 75-80%) from the market of modern medicines, are some of the costs to be borne by most developing countries which are under pressure to adopt TRIPs new patent protection for pharmaceuticals. Economic gains by large MNCs will be privileged over the health and life expectancy of millions of suffering people. No mechanism to mitigate these societal implications have been discussed during Uruguay Round negotiations. The issues are quite complex and serious from public interest angle. Any compromise in a haste and without indepth study of IPR issues are fraught with lasting consequences. Thus TRIPs in the present form is a great compromise for the developing countries including India. The availability of patented medicines at high prices will be of no avail as the general public will not be able to afford them and their sufferings will not be mitigated. The MNCs have to understand this moral/human right and about the consequences of strong patent system.

THE ABOVE SCENARIO WILL HAVE DIRECT IMPACT ON HEALTHCARE POLICIES IN DEVELOPING COUNTRIES AND GOAL OF "HEALTH FOR ALL BY 2000 AD".

PART VII

IMPACT ON AVAILABILITY OF PHARMA PRODUCTS

(a) Impact on availability

Apart from the impact on prices of pharmaceutical products, as discussed above, the general availability of new drugs from indigenous sources of the domestic companies would be totally out of question. Dependence upon imports would go up as it has started happening in some Latin American countries, Canada and even Italy, who have changed their patent laws in the recent past. Other countries would also face similar phenomena in the coming future.

The following report from SCRIP of May 24, 1994, substantiates this point :

"ALIFAR DENOUNCES US PATENT MOVES

Plant closures in Chile and increased levels of drug import to Mexico have followed the introduction of 'monopolistic' patent laws in these countries. Although both laws were drawn up in line with US requirements, there is renewed pressure from the US to increase patent protection periods from 15 to 20 years in Chile and from 20 to 23 years in Mexico according to speakers at the 15th meeting of the confederation of Latin American Industry associations (Alifar).

The trade benefits and investments which were promised in exchange for the implementation of a 'US-style' patent laws have never materialized, the Chilean representatives maintained. The Argentinean government 'should look at its neighbours, see what is happening to us, and reality that the promises were false, Muriam Orellana, executive director of the Chilean national industry association, (Asilfa), declared. (The Argentinean draft patent law currently being considered by Senate).

Asilfa president Jose Plubins commented that five multinationals - Pfizer, Parke-Davis, Squib, Bayer and Schering AG had closed manufacturing plants, and started importing to Chile, as allowed by the patent law. The closures have resulted in many job losses, he said. While there have not been any plant closures in Mexico, drug imports by multinationals have been increasing, according to Rafael Gual, executive director of the Mexican association, Anafam.

There was much criticism at the meeting of US government pressure on countries throughout the region to implement new patent laws, and calls for the US to respect the GATT Uruguay Round agreement, which gives developing countries a 10 year. transitional period to do so. LatinAmerican governments should defend national interests by drawing up patent laws which take into account the needs of national companies and consumers, and respect GATT recommendations, ALIFAR says.

There were also speakers from the US at the meeting who denounced the conduct of US pharmaceutical companies. For, example, Professor Stephen Schondelmeyer, director of the pharmacy faculty at the University of Minnesota., criticized us drug price levels noting that the oral contraceptive Ortho Novum costs $20 in the U S, $3 in Argentina, $1.60 in Mexico and $1.20 in France. Peter Arno from the Albert Einstein school New York said that eight million Americans over the age of 55 have to choose between buying food and drugs". Paula Begala an adviser to President Bill Clinton, criticized the 'alarmist campaign' mounted by US companies against the health system reform plans.

The meeting was held in Argentina and attended by national industry associations from Brazil, Colombia, Chile, El Salvador, Guatemala, Mexico, Paraguay, Peru, the Deminical Republic, Uruguay, Venezuela and Argentina."

(b) Impact on Medium and Small Scale Sector

The existing industry, particularly in the medium and small scale sectors, where there are thousands of registered units in the developing countries, will over a period of a decade or so after the introduction of the new patent regime, face serious degrowth as they will have no possibility of taking up new products. Even for the existing products/processes, new patents will be taken creating difficulties for such companies to market their existing products. This will result in liquidation of competitive environment, large scale unemployment, making existing infrastructure redundant and closure of many small units.

(c) Impact on Research and Development

The impact on domestic research and development activity in the developing countries would also be tremendous. Due to paucity of funds, particularly in drugs and pharmaceuticals field, the research in the public and private sectors in developing countries has been mainly concentrated on developing of process technologies. This kind of research effort would be severely affected as there would be no immediate use of process technologies for new drugs in the new patent regime as it would not be possible to commercially exploit them. For basic research neither funds nor capabilities to exploit any such invention worldwide are available with the domestic companies. They do not have infrastructure to match the TNCs for registering patents worldwide and promoting and marketing their products in various countries.

It would be relevant to mention here that US pharmaceutical industry spent $8.2 billion in 1990, $9.1 billion in 1991, $10.96 billion in 1992, $12.6 billion in 1993, $13.4 billion in 1994 and $14.5 billion in 1995 on R&D, and their worldwide sales during 1990 was $57.4 billion and must have doubled if not more than that by now. With enourmous resources available with TNCs only they can afford to invest large outlays on R&D. For TNCs, the entire world is market for them and that is why they spend large sums on R&D to monopolise the markets world over with their innovative products. The TNCs are almost controlling 80% of the global production/sales.

It will be observed from the following **table** that Inngelheim spent 19.2% of their total sales on R&D. Compared to this, Ranbaxy, the largest Indian company, invests only around 4-6% of its sales (Rs.1,000 crores/US $280 million) on R&D. Enterprises in

developing countries are substantially low in profitability and volume of sales for committing their resources for R&D. Sales of their large enterprises have to multiply manifold before they could make any worthwhile investment in R&D. The total pharmaceutical production in India is around $2800 million whereas almost all the 10 TNCs shown in the **table** below individually are having sales more than what India is producing. Further, India's total expenditure on R&D is about $50 million per annum for drugs and pharmaceuticals. There is virtually thus no comparison of sales and R&D expenditure between the developed and developing countries :

Table 11

Leading Companies by Nominal Pharma R&D spending in pharmaceuticals Script Review 1993-94

Company	Sales ($ mill.)	R&D ($ mill.)	R&D as % of sales
1. BMS	4,439.2	657.0	14.8
2. Glaxo	4,679.5	654.2	13.9
3. Hoechst	4,410.6	613.3	13.9
4. SB	3,668.8	552.5	15.1
5. Bayer	4,237.8	487.2	11.5
6. Sandoz	3,464.1	484.1	14.0
7. J&J	2,652.0	419.0	15.8
8. B. Ingelheim	1,914.4	357.0	19.2
9. Rhone-Poulenc	2,184.6	350.9	12.6
10. MMD	2,211.0	329.0	14.9

The profitability of the Indian pharmaceutical industry for various reasons has been also quite low. In the past, it had been around 4-5% of sale turnover and now it has slightly improved to 6-7% of sale. As against this, the TNCs are enjoying substantially high profits. For example, Zantac (Ranitidine) which is a top selling drug in the world, produced and marketed by Glaxo (UK) has been enjoying quite a high profit. Glaxo holds worldwide product patent where-ever such patents are available. Their sale turnover of this drug during 1994 was $4,011 million and they earned profit in 1992 around 35% on their pharma sales.

The above statistics are only indicative of the problems which the domestic companies in the developing countries, including India, have been facing. It would be impossible for them for many more years to embark upon any programme of basic research in a big way. In fact, domestic companies in developing countries will never be able to match with TNCs potential in R&D, sale turnover and worldwide infrastructure for patenting and promotion of their products. Further, there are many other regulatory hurdles of safety and efficacy during a long and difficult development period from discovery to registration which will also have to be cleared before pharmaceutical patents lead to saleable products. Additionally, financial risk is too high as there are more possibilities of failure than success. Thus pharmaceutical patents by themselves would be in fact meaningless if the owner of the patent is not able to organise all these basic requirements before launching his product.

In the background of these hurdles in developing countries, the need is to mainly continue with the existing role in R&D for developing innovative processes for old and new drugs and this can be achieved by having a strong system of compulsory liicensing/licensing of right by paying adequate compensation to the patent holder. THIS MEASURE WILL ALSO HELP IN ACHIEVING THE GOAL OF "HEALTH FOR ALL".

PART VIII

Problems with TRIPs Patent System

There are three major problems with the TRIPs Agreement:

- Transitional arrangement - it is virtually an empty shell;
- Safeguarding of public interest - it is virtually absent; and
- The 'scope of patentability' - it has been widened, with no flexibility available to any country to exclude certain critical technologies from the domestic patent system ~ thus making the accessability of essential products more difficult.

Transitional Arrangement : An Empty Shell

Article 65 of the TRIPs Agreement provides for transitional period of 5/10 years for the developing countries for implementing the TRIPs Agreement. This transitional period has been virtually invalidated in the provision contained in Article 70.8 of the TRIPs Agreement which provides that Member countries which do not provide for product patents for pharmaceuticals and agro-chemicals would provide for means for acceptance of product patent applications for these products from 1.1.1995 on the establishment of WTO. The application of the provisions of the product patent to these areas of technology under Article 65 would be effective from 1.1.2005 . But according to Article 33, the term of the protection, i.e. the patent rights, are to be available to the patent holder from the date of filing of the patent application. The composite interpretation of these three Articles would virtually exclude domestic enterprises from developing process technologies for any new product and market them in the domestic or outside markets from 1.1.1995 onward. They would be able to market only those products which have already fallen in the public domain. Thus, there is a clear distortion in providing the 10-year transitional period for introduction of product patent regime where no such protection is available on the one hand in Article 65, and invalidating the same through Article 70.8 which will establish patent rights from 1995 itself (and 1994 with right of priority where-ever is established).

There is yet a more serious distortion that patent-like protection to such applicants of pharmaceuticals and agro-chemicals will have to be provided on their new products in the form of 'exclusive marketing rights' (EMR) from 1.1.1995. Article 70.9 provides that such a right can be obtained if the following conditions are met :

- a patent application has been filed in a Member country after the entry into force of the Agreement;
- a patent application has been filed in another Member after the entry into force of the Agreement and a patent has been granted;
- Marketing approval has been obtained in the said other Member; and
- marketing approval has been obtained in the concerned Member country mentioned above.

The provision of granting marketing approval for establishing EMR, in view of above, will prove mere a formality.

The combination of the above two provisions implies that any MNC, obtaining a patent and marketing approval for a drug in any small country having no proper system can get exclusive marketing rights for that product in a country, like India, if it amends its laws to provide for EMR. This can happen even when the patent or marketing approval may not have been taken in the country where the research might have actually taken place. Thus a large Indian population may be vulnerable for experimental and clinical testing ~ a really absurd proposition.

The changing of the patent system to accord with the TRIPs Agreement raises fundamental issues having a bearing on the sovereign law-making power without evolving a national consensus on the contentious requirement of legislation on exclusive marketing rights about which the TRIPs Agreement is silent about the content and scope. To what extent the existing laws about licensing of right or compulsory licensing could be applied? Can the third party use the invention for tests, experiments, manufacture, market approval, etc.? An indepth analysis of these issues on the implications of Article 70.9 would be required. The abuse of a dominant position, public health needs etc. would be sufficient ground to contain the exclusivity through strong compulsory licensing/licensing of right like measures. The impact of EMR has thus a disastrous implication. If the existing laws provide for public interest measures, the same could be preserved without any amendment. For example, India does provide for such measures and as such there should be no need to amend them. In this way, it would be possible to contain damage to the public interest in health care areas.

The Patents (Amendment) Bill, 1995 amending the Patents Act, 1970 to provide for India's obligation during the transitional period was passed by the Lok Sabha (Lower House) on March 21, 1995. It could not be introduced in the Rajya Sabha (Upper House) as the ruling party apprehended problems in getting the Bill passed in that House. As a compromise, the Bill was referred to the Rajya Sabha Select Committee. Before the Select Committee could complete their examination of the Bill and finalise their report, the Lok Sabha was dissolved and as such the Bill lapsed as the same had originated from the Lok Sabha. Since then it has not been possible for the government to reintroduce the Bill as the Forum of Parliamentarians on Intellectual Property and WTO Issues has succeeded in pursuading the government to evolve a national consensus on the TRIPs Agreement on the patent system as a whole. Such a consensus has yet to emerge through an expert group. It would be relevant to point out one of the major lacuna in the Bill relating to the examination of applications for grant of exclusive marketing rights. The Bill restricted the examination of EMR applications under section 3 and section 4 of the Patents Act, 1970 as against the comprehensive procedure provided in the Patents Act, 1970 in Chapters IV & V. It is reported that between January 1, 1995 and February 15, 1997 a total of 1,339 applications for pharmaceutical and agro-chemical products have been received by the Patent Office. If the scope of examination had been limited to only section 3 and section 4 of the Patents Act, 1970, all the applications would have qualified for grant of exclusive marketing rights. The patent applications/EMR applications were supposed to be filed keeping the provisions of Article 27 of the TRIPs Agreement in view. Article 27 provides for patents to be available for innovations which are new, involve an innovative step and are capable of industrial use. (The terms "innovative step" and "capable of industrial use" are deemed to be synonymous with the terms "non-obvious" and "useful" respectively. The research in pharmaceuticals has slowed down in the recent past and has come down to an average of around 50 new inventions per annum. Health Horizons (Spring 1997), a journal published

by the Intenational Federation of Pharmaceutical Manufacturers' Associations, also reports about US inventions in 1996 as follows:

> "In its last report, the American research-based pharmaceutical manu- facturers associations PhRMA announced that in 1996 the US Food and Drug Administration (FDA) approved a record 53 new drugs, and increased its approval of new biologics from two products to nine."

Even the President of Organisation of Pharmaceutical Producers of India (MMC's Association) in his evidence before the Department-related Parliamentary Standing Committee 1993-94 (Gujral Committee) stated that "May I point out that not more than 18-20 molecules are introduced each year internationally". In view of this, it is difficult to comprehend as to how such a large number of applications have been filed for grant of patent/EMR when the scenario of new products developed is so low. Surely, there is something fishy in this and it needs to be examined. The Government of India could even consider preliminary examination of these applications to find out whether they relate to such products which have already fallen into public domain for which there is no obligation under Article 70.3 to provide for protection.

Public Interest Element : Absent

The public interest criterion is totally absent in the TRIPs Agreement. As already stated, this Agreement is a "charter of rights" for the patent holders and there are no specific obligations towards the country which gives the patent rights specified for the patentees. The interest of the consumers which is the primary obligation in the patent system has been totally ignored. In the first place, there is a provision allowing the patent rights without discriminating "imports" against domestic production. This is completely antithetical to the provisions of the Patents Act, 1970 [Section 83(b)] which states clearly that Patents "are not granted merely to enable patentees to enjoy a monopoly for the importation of the patented article". The import right has been incorporated in the patent system for the first time. This provision read with the exclusive rights even for imports provided in Article 28 would make the accessability of patented products more difficult for the users. The dependence upon imports would go up substantially. Neither the price nor the quantum of supplies can be regulated, giving a total monopoly to the patentee. Secondly, there is no usual provision for compulsory licensing for 'commercial purposes' in Article 31. Unless there is such a provision in the national patent system, the public interest would not be served at all, and there would be no way to ensure the easy availability of the patented product through commercial channels at competitive prices.

The model provision about the reasonable requirements of public interest deemed not satisfied has been quite explicitly stated in the Indian Patents Act, 1970 as follows:

"90. When reasonable requirement of the public decmed not satisfied :

(a) If, by reason of the default of the patentee to manufacture in India to an adequate extent and supply on reasonable terms the patented article or a part of the patented article which is necessary for its efficient working or if, by reason of the refusal of the patentee to grant a licence or licences on reasonable terms -

(i) an existing trade or industry or the development thereof or the establishment of any new trade or industry in India or the trade or industry or any person or classes of persons trading or manufacturing in India is prejudiced; or

(ii) the demand for the patented article is not being met to an adequate extent or an reasonable terms from manufacture in India; or

(iii) a market for the export of the patented article manufactured in India is not being supplied or developed; or

(iv) the establishment or development of commercial activities in India is prejudiced; or

(b) if, by reason of conditions imposed by the patentee upon the grant of licences under the patent or upon the purchase, hire or use of the patented article or process, the manufacture, use or sale of materials not protected by the patent, or the establishment or development of any trade or industry in India, is prejudiced; or

(c) if, the patented invention is not being worked in India on a commercial scale to an adequate extent or is not being so worked to the fullest extent that is reasonably practicable; or

(d) if, the demand for the patented article in India is being met to a substantial extent by importation from abroad by ~

(i) the patentee or persons claiming under him; or
(ii) persons directly or indirectly purchasing from him; or
(iii) other persons against whom the patentee is not taking or has not taken proceedings for infringement; or

(e) if, the working of the patented invention in India on a commercial scale is being prevented or hindered by the importation from abroad of the patented article by the patentee or the other persons referred to in the preceding clause."

Article 31 allows authorisation for "other use" whose parameters are not specified as such, under the TRIPs Agreement. However, the question of categorisation of "other use" is very important, and therefore deserves special emphasis. Member Governments have not been limited to the grounds on which for "other uses" they could grant licences without the authorisation of the patent right holder. The opening sentence of Article 31 does allow freedom to the member countries (governments) to determine the scope of "other use". The wording in the TRIPs Agreement is: "where the law of a Member allows for other use of the subject matter of patent without the authorisation of the right holder". The point to be noted herein is that though the parameters of compulsory licensing without the authorisation of the right holder are totally at variance with the usual compulsory licensing system being practised in the national laws worldwide so far, it should be possible to specifically provide for such parameters consciously for which national legislation has to be very carefully (and incisively) drafted.

The framework of Article 31 is also not in consonance with the spirit of the provisions of Articles 7 & 8 of the TRIPs Agreement. The objectives under Article 7 provide that "the protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations". There is obvious contradiction when we examine the substantive provisions of the TRIPs. The Member countries, while drafting any amendment to their legislation, should focus on the public interest, on social and economic welfare of the people and on the issue of transfer and dissemination of technology. The framework of "other use" for compulsory licensing under Article 31, as discussed above, has therefore to be deliberately specified to provide for the objectives in Article 7 and also to accomplish clearly specified 'public policy' objectives of the national system as recognised in the Preamble of the TRIPs Agreement. Similarly, Article 8 which deals with the 'principles' of the TRIPs Agreement does allow that

'in formulating or amending their national laws and regulations (members may) adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development ....' The implementation of the TRIPs Agreement should, therefore, comply with the 'objectives and principles of Articles 7 & 8 and public policy objectives' as may be provided in the national Constitutions. All this can be accomplished through deliberate action to provide for an active role of domestic industry through a strong compulsory licensing/licensing of right system for patented products, while defining the category of "other use" in the national laws.

The conditions for grant of compulsory licensing for commercial purposes could be that 'the proposed user has made efforts to obtain authorisation from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time' (as provided in Article 31(b) of the TRIPs Agreement). Additionally, it should be provided that this enterprise has to be competent enough to exploit the patent. The Chinese system of compulsory licensing, as provided in their Patent Act of 1992, also provides for similar conditions. The patent holder on such sub-licensing would be entitled to adequate remuneration as provided in Article 31(h) of the TRIPs Agreement. The relevant provisions of the Chinese Patents Act of 1992 on 'Compulsory Licensing' are re- produced below :

COMPULSORY LICENCE FOR EXPLOITATION OF THE PATENT

Art. 51. Where any entity which is qualified to exploit the invention or utility model has made request, for authorisation from the patentee of an invention or utility model to exploit its or his patent on reasonable terms and such efforts have not been successful within a reasonable period of time, the patent office may, upon the application of that entity, grant a compulsory licence to exploit the patent for invention or utility model.

Art.52. Where national emergency or any extraordinary state of affairs occurs or where the public interest so requires, the patent office may grant a compulsory licence to exploit the patent for invention or utility model.

Art.53. Where the invention or utility model for which patent right was granted is technically more advanced than another invention or utility model for which patent right has been granted earlier and the exploitation of the later invention or utility model depends on the exploitation of the earlier -invention or utility model, the patent office may, upon the request of the later patentee, grant a compulsory licence to exploit the earlier invention or utility model.

Where, according to the preceding paragraph, a compulsory licence is granted, the patent office may, upon the request of the earlier patentee, also grant a compulsory licence to exploit the later invention or utility model.

Art.54. The entity or individual requesting, in accordance with the provisions of this Law a compulsory licence for exploitation shall furnish proof that it or he has not been able to conclude with the patentee a licence-contract for exploitation on reasonable terms.

Art. 55. The decision made by the patent office granting a compulsory licence for exploitation shall be registered and announced.

Art.56. Any entity or individual that is granted a compulsory licence for exploitation shall not have an exclusive right to exploit and shall not have the right to authorise exploitation by any others.

Art. 57 - Any entity or individual that is granted a compulsory licence for exploitation shall pay to the patentee a reasonable exploitation fee, the amount of which shall be fixed by both parties in consultations. Where the parties fall to reach an agreement, the patent office shall adjudicate.

Art 58. Where the patentee is not satisfied with the decision of the patent office granting a compulsory licence for exploitation or with the adjudication regarding the exploitation fee payable for exploitation, he or it may, within three months from the receipt of the notification, institute legal proceedings in the people's court."

Even recently enacted amendments to the Patent Laws of Brazil and Argentina state as follows:

Brazil Patent Law of May 1996 provides as follows:

Art. 68. A patent shall be subject to compulsory licensing if the owner exercises his rights therein in an abusive manner or if he uses it to abuse economic power under the terms of an administrative or judicial decision.
(This provision has been further elaborated in the amending Act).

Argentina Patent Law of March 1996 provides as follows:

Art. 42. Where a prospective user has attempted to secure the grant of a license from the owner of a patent on reasonable commercial terms and conditions under Article 43, and the attempts have had no effect after 150 days have elapsed following the date on which the license in question was requested, the National Institute of Industrial Property may allow other uses of the said patent without authorization by the owner thereof.
(This provision has been further elaborated in the amending Act).

There is another strong aspect regarding 'dissemination of technology' as provided in the objectives under Article 7 of TRIPs. This particular objective could be accomplished by adopting the system of 'licensing of right' as is available in Indian Patents Act, 1970. This right could be made applicable after, say, 5 years (instead of 3 years from the date of sealing of patents as in the Indian Patents Act). This longer period should provide sufficient time to the patent holders to ensure dissemination of technology on payment of adequate remuneration. The relevant provisions of "licensing of right" as in the Indian Patents Act, 1972 are reproduced as follows :

"86. (1) At any time after the expiration of three years from the date of the sealing of a patent, the Central Government may make an application to the Controller for an order that the patent may be endorsed with the words "Licences of right" on the ground that the reasonable requirements of the public with respect to the patented invention have not been satisfied or that the patented invention is not available to the public at a reasonable price.

(2) The Controller, if satisfied that the reasonable requirements of the public with respect to the patented invention have not been satisfied or that the patented invention is not available to the public at a reasonable price, may make an order that the patent be endorsed with the words "Licences of right".

(3) Where a patent of addition is in force, any application made under this section for an endorsement either of the original patent or of the patent of addition shall be treated as an application for the endorsement of both patents, and where a patent of addition is granted in respect of a patent which is already endorsed under this section, the patent of addition shall also be so endorsed.

(4) All endorsements of patents made under this section shall be entered in the register and published in the Official Gazette and in such other manner as the Controller thinks desirable for bringing the endorsement to the notice of manufacturers.

87. (1) Notwithstanding anything contained in this Act -

(a) every patent in force at the commencement of this Act in respect of inventions relating to :

(i) substances used or capable of being used as food or as medicine or drug;

(ii) the methods or processes for the manufacture or production of any such substance as is referred to in sub-clause (i);

(iii) the methods or processes for the manufacture or production of chemical substances (including alloys, optical glass, semi-conductors and inter-metallic compounds),

shall be deemed to be endorsed with the words "Licences of right" from the commencement of this Act or from the expiration of three years from the date of sealing of the patent under the Indian Patents and Designs Act, 1911, whichever is later; and

(b) every patent granted after the commencement of this Act in respect of any such invention as is referred to in section 5 shall be deemed to be endorsed with the words "Licences of right" from the date of expiration of three years from the date of sealing of the patent.

(2) In respect of every patent which is deemed to be endorsed with the words "Licences of right" under this section, the provisions of section 88 shall apply."

The above models could be adopted by the member countries to ensure transfer and dissemination of technologies of patented products/processes.

Why public interest is important?

It is extremely important for developing countries to care for public interest angles because their health indicators are still far below than those in the developed countries. There should be no compromise on certain basic and fundamental issues like the competitive environment ensuring the role of domestic industry, dependence upon imports only for a short period, continuance of R&D activity to the extent possible, etc. The following comparative health indicators cannot be ignored to satisfy the vims and fancies of the MNCs:

Table 12

Demographic indicators in India compared with selected countries

	Japan	USA	UK	Malysia	India
Population (millions)	124.5	255.2	57.7	18.8	879.5
Annual births (x1000)	1390	4078	801	545	25900
Life expectancy (Yr)	76	76	76	71	60
Per capita income ($)	26930	22240	16550	2520	330
Infant mortality rate	6	10	7	14	83
Under 5 mortality	4	9	9	19	124

There are many other alarming indicators about diseases pravelant in India which have to be given top priority in deciding about the need to preserve public interest provisions in our patent system. These relate to population of 396 millions in 1993 exposed to flaria, and over 2.27 millions positive cases of malaria in 1993. Pulmonary tuberculosis is India's biggest public health problem. The number of cases of any one time has been estimated to be at least 1.5 per cent of the population, i.e. 12.7 millions suffering from radiologically active tuberculosis with about one fourth of the cases being sputum positive or infectious. Infected and not diseased cases are reported at 36.6 per cent of population, i.e. 308.9 millions in number. The epidemic of HIV/AIDS continue to spread in India. By October 31, 1997 of a total of 3.20 million individuals practising risk behavious and suspected AIDS cases who were screened for HIV infection, 67,311 were found to be seropositive and a cumulative total of 5,002 cases of dreaded AIDS have been reported. Nearly 2.3 million

people scummed to the deadly AID all over the world in 1997 and a total of 5.8 million people were infected with HIV that causes AID in 11 months according to "UNAIDS". Health laws, drug policy and patent system in India have to be intensely inter-related to tackle these problems. There may be compromise upto a point of granting product patents in pharmaceutical field but not beyond that on public interest issues. Even the WTO has also to address itself to this problem.

The Constitution of India provides the right to health as a fundamental right. In Vincent Vs. Union of India (AIR 1987 SC 990), a bench of the Court held:

> "As pointed out by us, maintenance and improvement of public health have to rank high as these are indispensable to the very physical existence of the community and on the betterment of these depends the building of the society which the Constitution makers envisaged. Attending to public health, in our opinion, therefore, is of high priority ~ perhaps the one at the top."

Peoples' Commission on GATT in their Report (1996) also commented on the importance of public interest as follows:

> "Let us remember the sombre realities of Indian life and health. Holistic health strategy pertinent to the Third World traumata, where nutritional deficienncies, medical privations and endemic ~ epidemic diseases are common, forbids patentisation of foreign pharmaceuticals who may monopolize life-giving drugs and essential medicines and keep prices untouchable and unapproachable for the Indian masses. The sequitur is that lethal liberalization of patent law tuned to TRIPs prescriptions is impermissible".

TRIPs Patent System : Scope Enlarged

The scope of patentability in TRIPs Agreement has been greatly enhanced. The parameters of Article 27 about the extent of coverage of patentability and exclusion from patentability has been explained earlier.

Patent rights have been extended to imports at par with the domestic production without any discrimination. The exclusive rights conferred on the patent holder under Article 28 also enlarges the scope of such rights. He will enjoy exclusive rights on imports also for the purpose of making, using, offering for sale and selling of such imported products.

Further, it would be possible to apply the patent rights on product patents for 20 years and therafter another spell of 20 years for products covered by patented processes followed by a further spell of protection for dosage form, usage form and combinations, thereby perpetuating monopolies. All these provisions have serious implications not only for new products, but also for existing products particularly for the health care products. The national governments should consider excluding patentability of formulations.

The scope of exclusion from patentability as provided in Article 27 is quite limited. However, it should be possible to totally exclude bio-technology products to protect *ordre public* or morality. Thus, the patenting of all 'life forms' including seeds, germ plasms, biological cells and cell forms, should be clearly and categorically excluded from the very scope of patenting. Even the UNCTAD Report of July 1996 on the implications of TRIPs

for developing countries has commented on the subject of 'exclusion' as follows:

> "In this connection, it is worth noting that the TRIPs Agreement contains no definitionn of "invention" and, therefore, leaves member countries relatively free to draw the line between nonpatentable "discoveries" and actual "inventions" in the biological field. Thus, domestic legislation may exclude the protection of substances found in nature, including cells and subcellular components (such as genes), and it may develop a policy approach that comprehensively address problems of access to, and appropriation of, genetic resources."

Similarly, the importation right should not be perpetual right. At the most the same could be permitted for a period not more than five/six years when it should be possible to set up economically viable manufacturing capacity.

These considerations could contain the charter of rights in the TRIPs Agreement on the new patent system and help in strengthening the health care laws and programmes from the point of view of easy availability of medicines from domestic sources and at competitive prices.

PART IX

USA ATTITUDE AND THE MULTILATERAL TRADING SYSTEM

Towards the closing years of World War II, a sense of global manifest destiny came to dominate United States policies. It was envisaged that for lasting world peace the purpose of global alliances from the openly military were to be switched to the plainly economic issues. The Bretton Woods Conference (1944) marked the beginning of a new world economic order. This coference envisaged three international institutions, *viz.*,

World Bank
International Monetary Fund
International Trade Organisation

The thrust of the new economic order which was conceived by USA and its allies was to ensure conquest through trade using the blessings of liberalisation, privatisation and globalisation. Calvin Coolidge said that "the business of America is business". USA, however, did not agree to the establishment of International Trade Organisation whose details were worked in the Havana Charter. For the US Congress it was US sovereignty angle due to which they did not ratify the setting up of International Trade Organisation. Later on the basis of selected provisions of the Havana Charter, General Agreement on Trade and Tariffs was established in 1948 as an interim arrangement and this arrangement continued till 1994. GATT had recognised the fact that the world was divided into unequal countries, *viz.* developed, developing and least developed. There is virtually no change in this unequal situation during 4 1/2 decades since 1948 as the per capita income of a major developing country, *viz.* India, is only $330 as compared to per capita income of USA at $22,440 and Japan at $26,930. However, GATT Rules did recognise the inequality of situation and provided for differential and preferential treatment for the developing countries under Article XVIII. Because of this provision, the developing countries for the reasons of balance of payment could create non-tariff barriers, tariff barriers, import policy, import licensing, channelisation of imports and other economic restrictions to safeguard their economic interests. The USA, however, felt that such concessions were hurting their interest in the international trade.

Between 1980 and 1985 the US trade deficit grew from $36.3 to $148.5 billion ~ a 309% increase. Similarly, the budgetary deficit and foreign loans/debts also mounted to alarming figures. The growing trade deficit led to a totally new approach to trade policy by US Administration. The advocates argued that the US was at a marked disadvantage due to relatively open US market as opposed to relatively closed markets in a number of trade partners. The US President Advisory Committee for Trade Negotiations' Task Force on Intellectual Property Rights advocated in their Report of October 1985 underscoring US interest in getting a multilateral intellectual property agreement. The protection of US intellectual property became a major issue with the US industry to improve their share of trade in the world market. Thus the intellectual property issue became one of the dominant factors for the Uruguay Round of GATT Negotiations which started in 1986. It was during this time that the Omnibus Trade and Competitiveness Act was amended by the USA in 1988 to strengthen the provisions of Section 301 by incorporating new sections of Super 301 and Special 301. Since then, USA started pressurising the developing countries to change their intellectual property laws in a manner which could provide monopolistic exclusive rights to TNCs over the patented products in other countries. The TRIPs Agreement became an offshoot for US to solve its trade problems. Since 1988, USA has been annually reviewing the IPR laws of trading partners. In April 30, 1997 Report, USTR Report on Special 301, named a large number of countries whose trade laws yet have deficiencies compared to the provisions of the TRIPs Agreement. This report summarises the deficiencies as follows :

1. Argentina	Argentina's patent regime denies adequate and effective protection to US right holder, particularly in the pharmaceutical industry. Its patent law contains onerous compulsory licensing provisions and pharmaceutical patent protection will not become available until November 2000. There is also no provision for pipeline protection or protection from parallel imports.
2. Ecuador	Ecuador patent laws are not in accord with the TRIPs Agreement in regard to local working requirements, compulsory licences, exclusion of certain products from patentability.
3. Egypt	There is lack of patent protection in Egypt. USA urges Egypt to enact promptly a modern patent law that provides immediate patent protection for all types of products, including pharmaceuticals, agricultural chemicals and foodstuffs.
4. India	India has not implemented its obligations under Articles 70.8 and 70.9 of the TRIPs Agreement. These articles require developing countries not yet providing patent protection for pharmaceutical and agricultural chemical products to provide a "mailbox" in which to file patent applications and the possibility of up to five years of exclusive marketing rights for these products until patent protection becomes available.
5. Brazil	USA remains concerned that Brazil has not enacted modern intellectual property laws to protect computer software, copyright and integrated circuits.
6. Chile	Chile's patent term is stated to be TRIPs-inconsistent and pipeline protection remains unavailable.
7. Colombia	Colombia has not yet fully implemented the WTO TRIPs Agreement. Deficiencies in its patent and trademark regime include insufficiently restrictive compulsory licensing provisions, working requirements, inadequate protection of pharmaceutical patents and lack of protection against parallel imports.

8. Costa Rica	Costa Rica's patent law is deficient in several key areas. The term of patent coverage is a non-extendable 12 year term from the date of grant. In the case of products deemed to be in the 'public interest', such as pharmaceuticals, chemicals and agro-chemicals, fertilizers and beverage/ food products, the term of protection is only one year from the date of grant. The US looks to the Government of Costa Rica, as it implements its WTO obligations, to adopt a term of patent protection of 20 years from filding as required by TRIPs.
9. Denmark	Denmark has not yet provided TRIPs-level protection for exclusive test data submitted in the marketing approval process.
10. Dominican Republic	There is lack of adequate and effective intellectual property protection.
11. Guatemala	Guatemala does not adequately protect pharmaceuticals and its copyright law is deficient.
12. Honduras	Honduras needs to improve patent and trademark laws and intellectual property enforcement.
13. Jordan	The inadequacies of the patent law have led to a growing problem of patent infringement for pharmaceuticals which are manufactured for both domestic and export markets.
14. Kuwait	Pharmaceutical patents fail to meet international standards in numerous other regards.
15 Peru	USA's concern is for imposition of a domestic working requirment in its patent regime.
16. Thailand	Thailand is still in the process of amending its patent law to comply with the TRIPs Agreement.
17. U.A.E.	UAE's patent law exempts medicines and pharmaceutical compounds from protection and contains onerous compulsory licensing provisions. Concerns remain about reports of the unauthorised production of pharmaceutical products.
18. Venezuela	There are deficiencies in the patent and trademark regime which include overly restrictive compulsory licensing provisions, working requirements, inadequate protection of pharmaceutical patents and lack of protection against parallel imports.
19. Cyprus	The current patent regime in Cyprus is inadequate as well as inconsistent with TRIPs.

The above would indicate that worldwide there are still many countries who have to change their patent laws to accord with the TRIPs Agreement. In fact, there are many developed countries who are still maintaining their earlier compulsory licensing system to protect their public interest. This conclusion has been drawn from the monthly reports of 1995, 1996 & 1997 of the World Intellectual Property (WIPO) which reports on amendments on patent laws by different countries.

The above indicates as to how under a multilateral free trade system, after the establishment of WTO, USA is pressurising various countries under threat of naming countries under Special 301 to achieve its own agenda of monopolising the world market. Not only this, the US Act cited as the 'Uruguay Round Agreement Act' which was adopted on 8.12.94 to approve and implement the trade agreements concluded in the Uruguay Round contains

certain specific provisions which are WTO miltilateral trade system inconsistent. The relevant sections are reproduced as follows:

Section 102 (a)

"(a) RELATIONSHIP OF AGREEMENTS TO UNITED STATES LAW. -
(1) UNITED STATES LAW TO PREVAIL IN CONFLICT. - No provision of any of the Uruguay Round Agreements, nor the application of any such provision to any person or circumstance, that is inconsistent with any law of the United States shall have effect.

(2) CONSTRUCTION. - Nothing in this Act shall be construed -
(A) to amend or modify any law of the United States, including any law relating to -
(i) the protection of human, animal, or plant life or health,
(ii) the protection of the environment, or
(iii) worker safety, or

(B) to limit any authority conferred under any law of the United States, including section 301 of the Trade Act of 1974,

unless specifically provided for in this Act."

Section 102 (b)(2)(A):

"(2) LEGAL CHANGE.-

(A) IN GENERAL.- No State law, or the application of such a State law, may be declared invalid as to any person or circumstance on the ground that the provision or application is inconsistent with any of the Uruguay Round Agreements, except in an action brought by the United States for the prupose of declaring such law or application invalid."

By Section 313, the following provision is added in connection with enquiry and report by USTR.

Section 182 (4)

"(4) A foreign country may be determined to deny adequate and effective protection of intellectual property rights, notwithstanding the fact that the foreign country may be in compliance with the specific obligations of the Agreement of Trade-Related Aspects of Intellectual Property Rights referred to in section 101(d)(15) of the Uruguay Round Agreements Act."

The above would show that USA is behaving like a superior authority above the sovereign rights of all countries and the WTO Agreement. If USA laws have to prevail even when they are inconsistent with Uruguay Round Agreements, why not then the laws of other countries should also prevail. Their sovereign rights are in no way inferior to the sovereign rights of USA.

The Final Act of Uruguay Round of GATT Negotiations is a package of unequal treaty comprising about 28 Agreements. This treaty is a self-fulfilling treaty which means that the member countries have to implement the Agreements without any change. There is no flexibility available to the members. There was no such a situation in the past seven rounds. The members could choose any protocol for implementation as agreed upon during the seven rounds. The Final Act now envisages adoption of global standards for all economic issues by all developed, developing and least developed countries. The only concession which is available to them is in the shape of transitional period ranging from 5 to 10 years due to large disparities between the member countries' economic status. There are serious problems in implementing various agreements as have been finally provided in the Final Act.

PART X

CONCLUSIONS

What should be the approach for Developing Countries?

In order to ensure public interest for achieving the laudable objectives of health for all and to provide for pragmatic approach for health care programmes, it is necessary that the domestic pharmaceutical industry in the developing countries, particularly in India, must be facilitated to play a major role in the health care sector. For achieving this objective which is totally in consonance with Articles 7&8 of TRIPs, joint efforts of developing countries will have to be made for ensuring unrestricted role in the patented products. In the meantime while amending the Patent Laws the developing countries could keep in mind the following three principles:

(a) Countries could express their readiness to amend their patent laws by 2000 AD and set about redrafting their own amendments keeping the long term challenges particularly relating to health care and the international scenario in mind;

(b) Developing countries should in the meanwhile reject the idea of any transitional arrangements of providing EMR as a first choice. As a second choice, Member countries could at the most consider bare minimum changes to their national Patents Act without compromising in any way the framework of national public policy parameters :

(i) legal provisions for accepting product patent applications for making available patent protection and redefining of the scope of patentability excluding certain inventions as discussed above; and

(ii) allowing grant of EMR/patent protection after the applicant has obtained marketing approval in the concerned country and also in the country in which the research originated. This protection could be made available from the date of application of the TRIPs Agreement as provided by Article 65(2) of TRIPs. There should be no other change to the existing patent laws at this stage. All other public interest provisions *mutatis mutandis* should be applicable on the grant of exclusive marketing right on the product patent so that the role of domestic industry is also fully ensured under the relevant provisions; and

(c) They should also clearly provide, in the amendments ~ with all necessary prologues under the 'objectives' of the amending legislation :

(i) exclusion of all life forms/germplasms, biological cells and cell forms and dosage form, usage form and combination formulations (in order to protect the existing formulations from small changes for taking patent protection in some form);

(ii) provision of strong compulsory licensing and licensing of right on the lines indicated earlier to ensure transfer and dissemination of technology as stated in the "Article 7 ~ Objectives" and "Article 8 ~ Principles" of TRIPs; and

(iii) broad negation of the concept of 'import' as equivalent to the working of a patent and allowing imports only for a limited period ~ not more than 5/6 years.

The developing countries should also collectively evolve their future "Agenda" for restoring the balance of rights and obligations in TRIPs patent system so that there is smooth implementation of TRIPs (Patents) Agreement.

Finally, the Governments in developing countries must strengthen the basic R&D activity in their countries through direct funding or through strengthening the tax concessions so that the industry is able to gear itself to meet the global challenges of uniform patent system of TRIPs Agreement. Even the developing countries should also consider collaborative research for such diseases as are prevalent in their countries.

INTERNATIONAL PRICES VIS-A-VIS INDIAN PRICES

SOME SELECT PRODUCTS

Drug & Dosage	Pack	Brand/ Company	India (Rs.)	Brand/ Company	Pakistan (Rs.)	Times Costlier	Brand/ Company	Price US $	Price (Rs.)	Times Costlier	Brand/ Company	Price in UK (pnds)	Price (Rs.)	Times Costlier
Anti-bacterials														
Ofloxacin 200 mg	4's	Tarivid/ Hoechst	100.00	Tarivid/ Hoechst	116.85	1.17	Floxin/ Ortho	12.71	457.56	4.58	Tarivid/ Hoechst	4.10	225.50	2.26
Cefadroxil 500 mg	4's	Cefadur/ Protec	42.29	Duricef/ BMS	81.27	1.92	Duricef/ BMS	13.76	495.36	11.71	Baxan/ BMS	1.13	62.15	1.47
Ciprofloxacin 500 mg	10's	QUINTOR/ TORRENT	59.75	Ciproxin/ Bayer	496.65	8.31	Cipro/ Miles	33.4	1202.40	23.33	Ciproxin/ Bayer	13.75	756.25	12.66
Norfloxacin 400 mg	10's	Norspan/ Bluecross	20.55	Noroxin/ MSD	114.25	5.56	Noroxin/ Merck	25.82	929.52	45.23	Utinor/ MSD	4.80	264.00	12.85
Lomefloxacin 400 mg	4's	Lomitas/ Intas	34.00	N.A.	---	---	Maxaquin/ Searle	25.4	914.40	26.89	N.A.	---	---	---
Pefloxacin 400 mg	4's	Proflox/ Protec	15.60	Abaktal/ Lek	84.00	5.38	N.A.	---	---	---	N.A.	---	---	---
Tobramycin 0.3%	5ml	Tobacin/ Aristo	17.20 (3 ml)	Tobralex/ Alcon	129.05	7.50	Tobrex/ Alcon	19.69	708.84	41.21	Tobralex/ Alcon	1.39	76.45	4.44
Anti Inflammatory														
Diclofenac 50 mg	10's	Voveran/ Ciba	6.49	Voltaren/ Ciba	55.62	8.57	Voltaren/ Ciba	10.07	362.52	55.86	Voltarol/ Ciba	1.82	100.10	15.42
Piroxicam 20 mg	10's	Dolonex/ Pfizer	28.33	Feldene/ Pfizer	72.50	2.56	Feldene/ Pfizer	26.62	958.32	33.83	Feldene/ Pfizer	2.14	117.70	4.15

Drug & Dosage	Pack	Brand/ Company	India (Rs.)	Brand/ Company	Pakistan (Rs.)	Times Costlier	Brand/ Company	Price US $	Price (Rs.)	Times Costlier	Brand/ Company	Price in UK (pnds)	Price (Rs.)	Times Costlier
Anti-Ulcerants														
Ranitidine 300 mg	10's	Zinetac/ Glaxo	17.39	Zantac/ Glaxo	241.44	13.88	Zantac/ Glaxo	30.02	1080.72	62.15	Zantac/ Glaxo	9.14	502.70	28.91
Famotidine 40 mg	14's	Topcid/ Torrent	15.26	Pepcidine/ MSD	363.37	23.81	Pepcid/ Merck	41.69	1500.84	98.35	Pepcid/ Morson	13.30	731.50	47.94
Omeprazole 20 mg	10's	Cozep/ S G Pharm	28.00	N.A.	---	---	Prilosec/ Astra	36.30	1306.80	46.67	Losec/ Astra	12.66	696.30	24.87
Lansoprazole 30 mg	7's	LAN-1D/30 INTAS	44.00	Zoton/ Lederle	350.00	7.95	N.A.	---	---	---	Zoton/ Lederle	9.09	499.95	11.36
Cardiovasculars														
Atenolol 50 mg	14's	Tenormin/ ICI	29.24	Tenormin/ ICI	118.25	4.04	Tenormin/ Zeneca	13.13	472.68	16.17	Tenormin/ Stuart	2.67	146.85	5.02
Diltiazem 60 mg	10's	Dilzem/ Torrent	36.90	Herbeser/ Tanabe	74.18	2.01	Cardizem/ MMD	6.96	250.56	6.79	Britiazem/ Thames	1.50	82.50	2.24
Lisinopril 5 mg	10's	Cipril/ Cipla	37.50	N.A.	---	---	Prinivil/ Merck	7.86	282.96	7.55	Zestril/ Zeneca	3.42	188.10	5.02
Enalapril Maleate 5mg	10's	Envas/ Cadila	16.20	Renitec/ MSD	39.67	2.45	Vasotec/ Merck	9.12	328.32	20.27	Innovace/ MSD	2.81	154.55	9.54
Prazosin 2 mg	10's	Prazopress Sun Pharm	37.50	Minipress/ Pfizer	12.65	0.34	Minipres/ Pfizer	6.89	248.04	6.61	Hypovase/ Invicts	0.83	45.65	1.22
Amiodarone 200 mg	10's	Cordarone -X /Torrent	87.50	N.A.	---	---	Cordarone/ Wyeth	30.46	1096.56	12.53	Cordarone -X /Sanofi	2.93	161.15	1.84
Amlodipine Besylate 5mg	10's	KLOPID/ KOPRAN	7.00	N.A.	---	---	Norvasc/ Pfizer	11.79	424.44	60.63	Instin/ Pfizer	4.23	232.65	33.24

Drug & Dosage	Pack	Brand/ Company	India (Rs.)	Brand/ Company	Pakistan (Rs.)	Times Costlier	Brand/ Company	Price US $	Price (Rs.)	Times Costlier	Brand/ Company	Price in UK (pnds)	Price (Rs.)	Times Costlier
Anti-viral/ fungal														
Ketoconazole 200 mg	10's	Funazole/ Khandelwal	57.90	Nizoral/ Janssen	221.23	3.82	Nizoral/ Janssen	28.15	1013.40	17.50	Nizoral/ Janssen	5.23	287.65	4.97
Zidovudine 100 mg	10's	Zidovir/ Cipla	250.00	N.A.	---	---	Retrovir/ Wellcome	15.48	557.28	2.23	Retrovir/ Wellcome	12.50	687.50	2.75
Anti-histamine														
Astemizole 10 mg	10's	Alestol/ Indoco	12.00	Mayasen/ Janssen	110.00	9.17	Hismanal/ Janssen	19.22	691.92	57.66	Hismanal /Janssen	1.80	99.00	8.25
Terfenadine 60 mg	10's	Terdane/ Intas	23.00	N.A.	---	---	Seldane/ MMD	12.50	450.00	19.57	Triludan/ MMD	1.70	0.90	0.04
Ceterizine 10 mg	10's	C2-3 LUPIN	7.00	N.A.	---	---	N.A.	---	---	---	Zirtek/ UCB	2.91	160.05	22.86
Loratadine 10 mg	10's	Lorfast/ Cadila	39.50	N.A.	---	---	Claritin/ Schering	25.74	926.64	23.46	Clarityn/ Schering	2.53	139.15	3.52
Anti-Anxiolytics														
Alprazolam 0.5 mg	10's	Alprax/ Torrent	12.26	N.A.	---	---	Xanax/ Upjohn	7.73	278.28	22.70	Xanax/ Upjohn	0.88	48.40	3.95
Trazodone HCl 50 mg	10's	Trazalon/ Sun Pharm	30.00	Deprel/ Adamjee	40.00	1.33	Desyrel/ Apothecon	13.00	468.00	15.60	Molipaxin /MMD	2.06	113.30	3.78
Buspirone 5 mg	10's	Buspin/ Intas	9.50	Buspar/ BMS	88.17	9.28	Buspar/ BMS	5.96	214.56	22.59	Buspar/ BMS	3.12	171.60	18.06

Drug & Dosage	Pack	Brand/ Company	India (Rs.)	Brand/ Company	Pakistan (Rs.)	Times Costlier	Brand/ Company	Price US $	Price (Rs.)	Times Costlier	Brand/ Company	Price in UK (pnds)	Price (Rs.)	Times Costlier
Anti-Cancer														
Mitoxantrone 2mg/ml	10ml	Oncotron/ TDPL	395.00	N.A.	---	---	Novantrone /Immunax	679.28	24454.08	61.91	Novantrone /Lederle	150.43	8273.65	20.95
Carboplatin 150 mg	Vial	Oncocarbin /TDPL	850.00	N.A.	---	---	N.A.	---	---	---	Paraplatin/ BMS	65.83	3620.65	4.26
Vincristine 1 mg	Vial	Oncocristin -AQ /TDPL	46.79	Oncovin/ Lilly	358.54	7.66	Oncovin/ Lilly	34.62	1246.32	26.64	Oncovin/ Lilly	14.18	779.90	16.67
Vinblastine 10 mg	Vial	Cytoblastin /Cipla	195.00	Velbe/ Lilly	370.41	1.90	Velban/ Lilly	38.92	1401.16	7.19	Velbe/ Lilly	14.15	778.25	3.99
Etoposide 100 mg	Vial	Etosid/ Cipla	250.00	N.A.	---	---	Vepesid/ BMS	136.49	4913.64	19.65	Vepesid/ BMS	9.96	547.80	2.19
Anti-Depressant														
Fluoxetine 20 mg	10's	Dawnex/ Micro	11.95	Prozac/ Lilly	397.86	33.29	Prozac/ Dista	22.46	808.56	67.66	Prozac/ Dista	6.92	380.60	31.85
Miscellaneous														
Nimodipine 30 mg	10's	Vasotop/ Protec	59.09	N.A.	---	---	Nimotop/ Miles	55.04	1981.44	33.53	Nimotop/ Bayer	3.89	213.95	3.62
Selegiline HCl 5 mg	10's	Selerin/ Protec	32.00	Jumex/ Medimpex	105.20	3.29	Eldepryl/ Somerset	21.37	769.32	24.04	Eldepryl/ Britannia	4.68	257.40	8.04

Drug & Dosage	Pack	Brand/ Company	India (Rs.)	Brand/ Company	Pakistan (Rs.)	Times Costlier	Brand/ Company	Price US $	Price (Rs.)	Times Costlier	Brand/ Company	Price in UK (pnds)	Price (Rs.)	Times Costlier
Miscellaneous (Contd.)														
Ondansetron HCl 4 mg	10's	Zofer/ Natco	96.50	N.A.	---	---	Zofran/ Cerenex	112.23	4040.28	41.87	Zofran/ Glaxo	40.50	2227.50	23.08
Lovastatin 20 mg	10's	Recol/ Themis	130.00	N.A.	---	---	Mevacor/ Merck	21.66	779.76	6.00	N.A.	---	---	---

NOTE : 1. RETAIL PRICES IN INDIA & WHOLESALE PRICES IN OTHER COUNTRIES CONSIDERED.

2. CONVERSION RATE OF EXCHANGE CONSIDERED : 1 USD = Rs.36.00, 1 GBP = Rs.55.00 AND 1 PAK. RS = Rs.1.00

3. SOURCE FOR PRICES : USA PRICES - RED BOOK 1996
UK PRICES - UK MIMS MAY 1997
PAKISTAN - QIMP ANNUAL 1995 - 96
INDIA - IDR MAY - JUNE 97

JULY 97

INTERNATIONAL PRICES VIS-A-VIS INDIAN PRICES

Drug & Dosage	Pack	Brand/ Company	India (Rs.)	Brand/ Company	Pakistan (Rs.)	Times Costlier	Brand/ Company	Thailand-Baht 1 Baht=Rs.1.38		Price (Rs.)	Times Costlier	Brand/ Company	Indonesia (Rp) 1 Rp=Rs.0.0151		Price (Rs.)	Times Costlier
								Pack	Price				Pack	Price		
Anti-bacterials																
Ofloxacin 200 mg	4's	Tarivid/ Hoechst	100.00	Tarivid/ Hoechst	116.85	1.17	Tarivid/ Daiichi	10s	---	---	---	Tarivid/ Daiichi	4s	14000	211.40	2.11
Cefadroxil 500 mg	4's	Cefadur/ Protec	42.29	Duricef/ BMS	81.27	1.92	Duricef/ BMS	100s	---	---	---	Duricef/ BMS	4s	12760	192.68	4.56
Ciprofloxacin 500 mg	10's	QUINTOR TORRENT	59.75	Ciproxin/ Bayer	496.65	8.31	Ciprobay/ Bayer	10s	900	1242.00	20.79	Ciproxin/ Bayer	10s	69300	1046.43	17.51
Norfloxacin 400 mg	10's	Norspan/ Bluecross	20.55	Noroxin/ MSD	114.25	5.56	Norflocin/ Polio Pha.	10s	200	276.00	13.43	Norbactin/ Sunti Sep.	10s	20873	315.18	15.34
Lomefloxacin 400 mg	4's	LOMITAS INTAS	34.00	N.A.	---	---	Maxaquin/ Searle	4s	232	320.16	9.42	N.A.	---	---	---	---
Pefloxacin 400 mg	4's	PROFLOX PROTEC	15.60	Abaktal/ Lek	84.00	5.38	Abaktal/ Lek	100s	---	---	---	Abaktal/ Lek	4's	22000	332.20	21.29
Tobramycin 0.3%	5ml	Tobacin/ Aristo	17.20 (3 ml)	Tobrex/ Alcon	129.05	7.50	Tobrex/ Alcon	5ml	---	---	---	Optosin/ Kenrose	5ml	---	---	---
Anti Inflammatory																
Diclofenac 50 mg	10's	Voveran/ Ciba	6.49	Voltaren/ Ciba	111.24	17.14	Diclosian/ Asian Pha	10s	15	20.70	3.19	Voltaren/ Ciba	10s	11734	177.18	27.30
Piroxicam 20 mg	10's	Dolonex/ Pfizer	28.33	Feldene/ Pfizer	72.50	2.56	Feldene/ Pfizer	10s	164.3	226.73	8.00	Feldene/ Pfizer	10s	14467	218.45	7.71

Drug & Dosage	Pack	Brand/ Company	India (Rs.)	Brand/ Company	Pakistan (Rs.)	Times Costlier	Brand/ Company	Thailand-Baht Pack	Thailand-Baht Price	Price (Rs.)	Times Costlier	Brand/ Company	Indonesia (Rp) Pack	Indonesia (Rp) Price	Price (Rs.)	Times Costlier
Anti-Ulcerants																
Ranitidine 300 mg	10's	Zinetac/ Glaxo	17.39	Zantac/ Glaxo	241.44	13.88	Zantac/ Glaxo	30s	---	---	---	Zantac/ Glaxo	10s	43600	658.36	37.86
Famotidine 40 mg	14's	TOPCID TORRENT	15.26	Pepcidine/ MSD	363.37	23.81	Pepcidine/ MSD	30s	---	---	---	Facid/ Kalbe	14s	28700	433.37	28.40
Omeprazole 20 mg	10's	GOZEP S G PHAR	28.00	N.A.	---	---	Losec/ Astra	7s	---	---	---	Losec/ Astra	10s	58150	878.07	31.36
Lansoprazole 30 mg	10's	LAN-15/30 INTAS	44.00	Zoton/ Lederle	500.00	11.36	Prevacid/ Takeda	10s	450.00	621.00	14.11	N.A.	---	---	---	---
Cardiovasculars																
Atenolol 50 mg	14's	Tenormin/ ICI	29.24	Tenormin/ ICI	118.25	4.04	Tenolol/ Siam Phar	10s	---	---	---	Tenormin/ Zeneca	14s	22580	340.96	11.66
Diltiazem 60 mg	10's	DILZEM TORRENT	36.90	Herbeser/ Tanabe	74.18	2.01	Herbeser/ Tenabe	10s	90.00	124.20	3.37	Herbeser/ Tenabe	10s	6677	100.82	2.73
Lisinopril 5 mg	10's	CIPRIL CIPLA	37.50	N.A.	---	---	Lispril/ Siam Phar	10s	---	---	---	Zestril/ Zeneca	10s	14291	215.79	5.75
Enalapril Maleate 5mg	10's	ENVAS CADILA	16.20	Renitec/ MSD	79.34	4.90	Renitec/ MSD	10s	59.50	82.11	5.07	Inoprilat/ Pharos	10s	7800	117.78	7.27
Prazosin 2 mg	10's	Prazopres Sun Phar	37.50	Minipress/ Pfizer	12.65	0.34	Minipres/ Pfizer	10s	44.00	60.72	1.62	Minipres/ Pfizer	10s	5300	80.03	2.13
Amiodarone 200 mg	10's	Cordarone TORRENT	87.50	N.A.	---	---	Cordarone Sanofi	10s	136.67	188.60	2.16	Cordarone Sanofi	10s	10000	151.00	1.73
Amlodipine Besylate 5mg	10's	KLOPID KOPRAN	7.00	N.A.	---	---	Norvasc/ Pfizer	10s	187.33	258.52	36.93	Norvasc/ Pfizer	10s	14553	219.76	31.39

Drug & Dosage	Pack	Brand/ Company	India (Rs.)	Brand/ Company	Pakistan (Rs.)	Times Costlier	Brand/ Company	Thailand-Baht Pack	Thailand-Baht Price	Price (Rs.)	Times Costlier	Brand/ Company	Indonesia (Rp) Pack	Indonesia (Rp) Price	Price (Rs.)	Times Costlier
Anti-viral/ fungal																
Ketoconazole 200 mg	10's	Funazole/ Khandelwal	57.90	Nizoral/ Janssen	221.23	3.82	Funginox/ Charoen	10s	60.00	82.80	1.43	Nizoral/ Jannsen	10s	17783	268.53	4.64
Zidovudine 100 mg	10's	Zidovir/ Cipla	250.00	N.A.	---	---	Retrovir/ Wellcome	100s	---	---	---	Retrovir/ Wellcome	10s	36110	545.26	2.18
Anti-histamine																
Astemizole 10 mg	10's	ALESTOL INDOCO	12.00	Mayasen/ Janssen	110.00	9.17	Hisno/ Milano	500s	20.00	27.60	2.30	Hismanal/ Jannsen	10s	10250	154.78	12.90
Terfenadine 60 mg	10's	TERDANE INTAS	23.00	N.A.	---	---	Teldane/ MMD	100s	---	---	---	Hiblorex/ Otto	10s	3850	58.14	2.53
Ceterizine 10 mg	10's	C2-3 Lupin	7.00	N.A.	---	---	Zyrtec/ UCB	20s	---	---	---	Ryzen/ UCB	10s	11500	173.65	24.81
Loratadine 10 mg	10's	LORFAST CADILA	39.50	N.A.	---	---	Clarityne/ Schering	10s	93.00	128.34	3.25	Clarityne/ Schering	10s	12000	181.20	4.59
Anti-Anxiolytics																
Alprazolam 0.5 mg	10's	ALPRAX TORRENT	12.26	N.A.	---	---	Xanax/ Upjohn	100s	---	---	---	Xanax/ Upjohn	10s	5165	77.98	6.36
Trazodone HCl 50 mg	10's	Trazalon Sun Pharma	30.00	Deprel/ Adamjee	40.00	1.33	Desirel/ Codal Syn	500s	---	---	---	Trazone/ Kolbe	10s	8700	131.37	4.38
Buspirone 5 mg	10's	Buspin INTAS	9.50	Buspar/ BMS	88.17	9.28	Barpril/ Biolab	100s	---	---	---	Buspar 10mg/BMS	10s	14355	216.76	22.82

Drug & Dosage	Pack	Brand/ Company	India (Rs.)	Brand/ Company	Pakistan (Rs.)	Times Costlier	Brand/ Company	Thailand-Baht Pack	Thailand-Baht Price	Price (Rs.)	Times Costlier	Brand/ Company	Indonesia (Rp) Pack	Indonesia (Rp) Price	Price (Rs.)	Times Costlier
Anti-Cancer																
Mitoxantrone 2mg/ml	10ml	Oncotron/ TDPL	395.00	N.A.	---	---	Novantron/ Lederle	10ml	6740	9301.20	23.55	Novantron/ Lederle	10ml	49500	747.45	1.89
Carboplatin 150 mg	Vial	Oncocarbin /TDPL	850.00	N.A.	---	---	Paraplatin/ Bristol	vial	---	---	---	Paraplatin/ Bristol	vial	333300	5032.83	5.92
Vincristine 1 mg	Vial	Oncocristin TDPL	46.79	Oncovin/ Lilly	358.54	7.66	Oncovin/ Lilly	vial	---	---	---	Krebin/ CarloErba	vial	29000	437.90	9.36
Vinblastine 10 mg	Vial	Cytoblastin /Cipla	195.00	Velbe/ Lilly	370.41	1.90	Blastovin/ Teva	NA	---	---	---	Erbablas/ CarloErba	vial	75000	1132.50	5.81
Etoposide 100 mg	Vial	ETOSID CIPLA	250.00	N.A.	---	---	Lastet/ Nipon Kay	vial	---	---	---	Vepesid/ BMS	vial	84700	1278.97	5.12
Anti-Depressant																
Fluoxetine 20 mg	10's	Dawnex/ Micro	11.95	Prozac/ Lilly	397.86	33.29	Prozac/ Eli Lilly	28s	---	---	---	Prozac/ Eli Lilly	10s	28679	433.05	36.24
Miscellaneous																
Nimodipine 30 mg	10's	Vasotop/ Protec	59.09	N.A.	---	---	Nimotop/ Bayer	30s	173.33	239.20	4.05	Nimotop/ Bayer	10s	16269	245.66	4.16
Selegiline HCl 5 mg	10's	Selerin/ Protec	32.00	Jumex/ Medimpex	105.20	3.29	Jumex/ Chinom	50s	---	---	---	N.A.	---	---	---	---

NOTE : 1. RETAIL PRICES IN INDIA & WHOLESALE PRICES IN OTHER COUNTRIES CONSIDERED.

2. CONVERSION RATE OF EXCHANGE CONSIDERED : 1 Pak. Rs. = Rs.1.00, 1 Thailand Baht=Rs.1.38, 1 Indonesian Rp=Rs.0.0151

3. SOURCE FOR PRICES : THAILAND PRICES = TIMS APRIL - JULY 1997
INDONESIAN PRI NOV. - FEB 1997
PAKISTAN = QIMP ANNUAL 1995 - 96
INDIA = I D R MAY - JUNE 1997

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