New Patent Regime: Implications for Domestic Industry, Research & Development and Consumers

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Where the mind is without fear
and the head is held high;
where the knowledge is free;
Where the world has not been broken up
into fragments by narrow domestic walls;
Where the words come out from the depth of truth;
...es its arms
...ason
...esert sand
...ard
...nd action
...ke.
...nath Tagore

Suggested C...

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PREFACE

The Final Act embodying the results of the Uruguay Round of Multilateral Trade Negotiations provides legal underpinnings for the international order premised on the preservation and perpeturation of the profits and power of the transnational co-operation. The Act foists on unequal treaty on the third world. The intrusion into and the occupation of the sovereign economic spaces of the third world countries have been formally sanctioned by the agreement contained in the Act. Nowhere is this process more blatant than under the international regime visualised in the so-called TRIPs agreement. For us in India, its impact will be devastating. Conformity with the TRIPs agreement will require virtual repeal of the Indian Patents Act, 1970. Various provisions which were carefully built into this law to secure a better balance between the private profit and the public welfare and to promote self-reliant technological development will have to be given up. What is more, the change will have to be brought about rather rapidly contrary to the claims made regarding the "facility" of the transition period.

Mr. B.K. Keayla has lucidly brought out these implications in his essay on the 'Impact of the New Patent Regime'. He has been in the forefront of the struggle carried on by the National Working Group on Patent Laws against the impending changes. Now that the Government of India have formally endoresed the Final Act, it becomes even more urgent to analyse and expose the far reaching, adverse implications of such an endorsement. Mr. Keayla has done precisely that with the wealth of facts and arguments marshalled expertly in his essay.

New Delhi,

S.P. SHUKLA
Former Finance Secretary, Govt. of India,
and Co-Chairman, National Working
Group on Patent Laws.

A PREFATORY NOTE

Mr. B.K. Keayla is a fighting figure in the campaign for the protection of India's industrial potential and the prevention of foreign infiltration which renders Indian self-reliance vulnerable and Indian consumers victimisable by multi-national corporations too powerful to be controlled even by Government once they occupy our economic space in strategic spots. Mr. Keayla, with patriotic intelligence and imaginative appreciation of the purposeful provisions for the Indian Patents Act, has been waging an Information Struggle, as it were, so as to bring home to the Parliamentarians and other leading elements in our public life the perils that India will face if the new Patent Regime, now sought to be forced on the country, is brought into operation. The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) is fraught with deleterious consequences to the health of the Indian economy. That is why, in national interest, informed Indian opinion in and out of Parliament has been challenging the proposed Patent Regime. The wages of surrender is death to the economy and, therefore, this new threat, almost imperialist in its intimidatory impact, must be countered effectively by the entire enlightened intelligentsia as well as the leading elements in the professions. Other countries which have suffered the neo-colonial experiments have provided us with anticipations of what will happen if here in India we give in.

In this backdrop, the critical importance of the understanding, inside out, of the prevalent Patent System of India and the toxic consequences of changes in the Patent System to suit the appetite of foreign invaders must be driven home to every Indian if economic swaraj, in its progressive dynamics, is not to be jettisoned. The implications of the present Import Policies, together with the new Patent procedures, sought to be sold to us under the GATT Scheme, require fuller appreciation by the educated sections of Indians. Who else than Mr. Keayla, with a long record of working in the field of the Information Campaign, can perform so well this militant yet essential task charged with national portents? I have seen Keayla in action; I have participated in his Seminars and Symposia; I have heard him explain lucidly the need for safeguards in the Indian Patent System; I have found him reel off facts and figures supportive of his substantive contentions; I have been convinced of his arguments against the new Patent Regime and its ominous portents for domestic industry, R & D and Consumers. In short, Keayla has a case which he presents to the people on behalf of the Indian Republic in its economic sovereignty and social justice dimensions.

He has prepared a long paper which dispels doubts, marshals facts, carries convictions and exposes the machinations of MNCs with clout on the Moghuls in Delhi. I commend his paper to every reader within and without the country; I plead with every Parliamentarian and every political echelon to rime and resist the new menace of economic subversion. Finally, I adopt and advocate the Keayla thesis and appeal to the Central Cabinet and the Ministries in the States not to be myopic but to be solidly behind the economic stability of the nation and the social necessity of such policies as will benefit the lowliest and the last who, to-day, have to pay the price of hunger and ill-health, high price and resignnation to the destitution. Gandhi and Nehru are not dead.

V.R. KRISHNA IYER

Former Judge, Supreme Court of India.

January 1, 1996

(c) Patent System: Rights and obligations

Over a period, rights and obligations for the patent-holders have been clearly defined in the national patent laws by various countries. Generally, the rights conferred on the patentee are the exclusive rights by himself, his agents or licencees to make, use, exercise, sell or distribute article or substance of the patent invention in the country that grants the exclusive rights. Where a patent is for a method or process of manufacturing an article or substance, exclusive right by himself, his agents or licencees are available to use the method or process in the country of such patent grant. As regards the obligations, the patentee is required to manufacture the patented article or substance to meet the full demand and also that he does not exploit the right given to him by charging unfair monopolistic prices for his products. In certain countries like India, such obligations have been listed in the Patents Act itself as "reasonable requirement of public interest" and they are legally enforceable.

(d) Compulsory Licence

Compulsory licensing is an important element of the patent system. It helps in a way to ensure working of the patent in the country which grants the patent. In the absence of this, particularly the foreign patent holders would resort to imports rather than produce the product in that country. In this way the role of the domestic industry can be ensured through sub-licensing.

A compuslory licensing system is an authorization by the designated authority for the purpose to a person other than the patentee to do, without authorization by the patentee, acts which would otherwise by excluded by the patent. The grounds upon which the compulsory licence may be granted are specified in the patent laws. The designated authority first decides, on the basis of an application made by the person who seeks the compulsory licence, whether the specified grounds have been established. The law also requires that an application for a compuslory licence cannot be made before the expiration of a specified period from the filing date or the date of grant of the patent. The period most commonly adopted for this purpose is four years from the filing date of application or three years from the date of grant of patent, whichever is longer. This period is also specified in the Paris Convention, where the application for a compulsory licence can be made due to non-working or insufficient working of the patented invention. Non-availability of patented product at fair price is also used as ground for sub-licensing. In the Indian patents Act apart from compulsory licensing system, there is provision for "licensing of right", which gives automatic right for exploitation of patents by others.

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 and 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 1641 although the system proper started in 1790. This Act was amended in 1793 and became closer in its terms to the U.K. 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 Authority (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.

The German Patent 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
- Libson Convention, 1958
- Stockholm Convention, 1967

All amending conventions have provided for stiffer provisions granting more protection to patentees. The developing countries are concerned about social obligations for the patentee whereas the Paris Convention does not provide for such obligations. It even provides for maximization of individual rights to create import monopolies (Art.5). Paris Convention does provide for system of compulsory licence which can be applied on the ground of failure to work or insufficient working after three years of patent grant [Art.5(2)]. However, there is also provision that compulsory licence "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 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 harmonious patent system which is known as "Treaty Supplementing Paris Convention". Some critics have observed that the provisions of this Treaty 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 Text.

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 regime 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. Now these countries, under pressure, either changed or are changing their patent laws to provide for product patents in 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

INDIAN PATENTS SYSTEM: SAFEGUARDS NATIONAL INTEREST

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. Following independence, one of the first decisions taken by the national Government was to change the colonial Patents Act. The new Patents Act was eventually enacted in 1970 after in depth study by two high-power Committees, headed by Justice Bakshi Tek Chand and Justice N. Rajagopal Iyengar, and extensive discussions in both Houses of Parliament. In amending its Patents Act, India took a considered decision to stay outside the Paris Convention. The Iyengar Committee advised the Government against India's joining the Convention on the ground that she would lose her 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 and such conditions have been laid down in Section 90 as follows:

> *"90. When reasonable requirement of the public deemed 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 on 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 under him; or
(ii) persons directly or indirectly purchasing from him; or
(iii) other persons against whom the patentee is not taking or 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".

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 deals with :

- Exclusion of certain fields from patentability;
- No product patents in some other important areas;
- Shorter period of patent protection;
- Importation not treated as working of patent;
- Compulsory licensing and licence of right to ensure working;
- Ceiling on royalties on sub-licensing of patents.

PART IV

GROWTH OF PHARMACEUTICAL INDUSTRY IN INDIA

(a) Process Research

Table: 1 indicates the basic drugs manufactured by the domestic sector companies in India based on indigenously developed process technologies. Table 2 indicates the time lag between the introduction of a new drug in the world market and its introduction in India after the domestic enterprises have developed technologies to manufacture the products.

Table : 1

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

1. Acetazolamide
2. Allopurinol
3. Amitryptiline
4. Amidaqine
5. Amoxycillin
6. Ampicillin
7. Analgin
8. Aspirin
9. Atenolol
10. Betamethasone
11. Caffeine
12. Ca. Sennosides
13. Carbamezapine
14. Cephaclor
15. Cephazoline
16. Cephalexin
17. Chloramphenicol
18. Chlordiazepoxide
19. Chlorpropamide
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. Florafur
43. Folic Acid
44. Frusemide
45. Furazolidine
46. Gentamycin
47. Glipimide
48. Glibenclamide
49. Guaphenesin
50. Griseofulvin
51. Heparin
52. Hydrochlorothiazide
53. Hydoxyprogesterone
54. Hydroxyzine
55. Ibuprofen
56. Indomethacin
57. Isopropylantipyrine
58. Kanamycin
59. Ketorolac
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 2:

Time Lag Between Introduction of a New Drug in the World Market and its Introduction in India

Drug	INTRODUCED (Year) In		Time lag:Intrdn in India (Yrs.)
	World Market by the inventor	Indian Market by domestic cos.	
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

(i) Pharmaceutical Industry

After the Patents Act, 1970 was enacted, the production of pharmaceutical products has grown more than sixteen-fold: from Rs. 500 crores in 1974 to over Rs. 8,000 crores in 1994-95. In recent years, there has been a sharp rise in exports also by the industry: between 1985-86 and 1994-95 exports have grown fourteen times from Rs.140 crores to over Rs. 2,000 crores. 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. The Indian industry has emerged as world leader in production of bulk drugs like Ciprofloxacin, Dextrapropoxyphene, Ethambutol, Ibuprofen, Norfloxacin, Sulphamethoxazol, Trimethoprim, etc. Ranbaxy, Cipla, Cadila, Alembic, Lupin, Torrent, Sarabhai, etc. have emerged as major Indian companies meeting requirements of all kinds of drugs in the country.

(ii) Pesticides Industry

The pesticides industry in India has made impressive progress and today more than 60 technical grade pesticides are being successfully manufactured in the country. Some 135 units are currently engaged

in the manufacture of these technical grade pesticides and over 500 units are making pesticide formulations. As a result of the increased production of pesticides in the country import of technical grade pesticides has come down considerably. The estimated production of technical grade pesticides during 1994-95 is over 85,800 MT from an annual installed capacity of 1.25 lakh MT.

In order to use the idle capacity available with pesticide units the country has been able to enter the competitive field of export of pesticides. During 1993-94 the industry had exported pesticides valued at 261.20 crores.

The industry has started producing some new pesticides but are continuing to import the intermediates in the absence of technology for producing them. Efforts are being made to acquire the right technology to manufacture intermediates for pesticides like Butachlor, Endosulfan, etc.

The capacity and production of some of the important technical pesticides during the years 1992-93 and 1993-94 are as under:

Table-3

Production of Pesticides
(Quantity 000 tonnes)

Item	1992-1993 Capacity	1992-1993 Production	1993-1994 Capacity	1993-1994 Production (Estimated)
Malathion	7.6	2.3	7.6	2.4
Methyl Parathion	4.5	2.1	4.5	2.2
Dimethoate	2.3	2.2	2.3	2.4
D.D.V.P.	2.3	1.7	2.3	2.0
Monochrotophos	8.5	6.2	8.5	6.5
Phorate	3.7	3.2	3.7	3.5
Mancozeb	4.0	3.6	4.0	4.0
Isoproturon	3.1	2.1	3.1	2.5
Alumunium Phosphate	1.3	1.0	1.3	1.1

(c) Prices

There is competitive environment in the pharmaceutical field because of the patent system and as such pharmaceutical products are available in India at the lowest price compared to the other countries. As against these, prior to the enactment of the Indian Patents Act, 1970 the prices of drugs in India were "amongst the

highest in the world" as commented by an American Senate Committee headed by Senator Kefauver. The industry in India was then dominated by the drug multi-national companies who could use the colonial product patent regime provided by the Patents and Designs Act of 1911, to reap enormous profits from the Indian markets. The growth of the domestic pharmaceutical industry due to the Patents Act of 1970 reversed the situation on the price front.

PART V

NEW PATENT REGIME UNDER TRIPS AGREEMENT

I. Main Features

(a) Preamble

The preamble of the TRIPS Agreement "recognizes the need for multilateral framework of the principles, rules and discipline in international trade in counterfeit". [According to U.S: interpretation, the goods produced in India even by legally taking process patents, are counterfeit goods.] The preamble also "recognises the intellectual property rights as private rights". Even though many other countries including India are not 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)."

These provisions clearly amplify the designs of the MNCs who are behind the global and monopolistic patents system in the TRIPs Agreement.

(b) Objectives and Principles

Article 7 of the 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."

The above prima facie appear to be laudable objectives. However, the proviso in Article 8 takes away the utility of the principles

stated in Articles 7 & 8 as the domestic laws will have to be changed within the framework of the TRIPs Agreement. Certain experts argue that provisions in these articles could be used to subserve national interest in vital areas by introducing the system of sub-licensing, but some others have expressed serious doubts about the utility of these provisions for transfer of technology or for sub-licensing of patent rights. The latter argument, however, seems more logical when viewed against the designs of powerful interests.

(c) Scope of Patentability

The scope of patentability in TRIPs Agreement has been greatly enhanced and according to Article 27 patents shall be available:

- for any invention whether products or processes in all fields of technologies;
- protection will also be extended to:
  * Micro organisms,
  * 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 and to an extent the biological sector also. No flexibility is available to any country to exclude certain vital areas of economy from patentability in the domestic laws.

(d) Working of Patents : a non-issue

An important aspect of working of the patent in the new patent regime is being 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 as an important element of the system. Even the Paris Convention recognises working of the Patent in the country which grants the Patent. In fact non-working is considered to be an abuse of Patent Rights under the Paris Convention (Art. 5A). The TRIPs Agreement, according to Article 27, 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. Even while granting exclusive rights under Art. 28 for products and processes, exclusive rights have been given for making, using, offering for sale, selling or importing. 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. There will be free flow of imports of patented products. It will not be possible to regulate the prices. As price control system cannot be extended to imported products, patented products would be sold at relatively much higher prices. The dependence upon imports would increase substantially.

(e) Authorization for use of Patent

Art. 31 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", "licences of right" or "revocation of patents" for non-working. For commercial use, it would not be possible to issue any authorization as the scope of authorization under this article is for a limited period and for a limited purpose.

Unless the authorization or sub-licensing is for commercial purposes without any condition or restriction, this article provides absolute monopoly to the patent holder. Even the authorization for other uses which are generally for experimental purposes for research or for educational purposes, the conditions are quite unreasonable. In such cases also, the "right holder shall be paid adequate remuneration in the circumstances of each case taking into account the economic value of the authorization". Compensation at economic value for non-economic purposes virtually removes the possibility of transfer or diffusion of technology at low cost in public interest.

Virtually the scope of authorization under this article is for a limited purpose and limited duration for non-commercial purposes only, which will not serve any purpose of meeting the requirements of general public when the patent holder is exploiting the market in monopolistic manner.

(f) Term of the Patent

Article 33 deals with the term of protection which shall not end before the expiration of a period of twenty years counted from the filing date. Since patentability extends to products or processes, the term would be applied for twenty years for product patent and then twenty years for process patent particularly in chemical field, including drugs and pesticides . In the case of drugs and medicines, patents are available in U.S.A. for usage form, dosage form and combinations. Table-4 (next page) gives an idea of new combinations for which patents are being taken in U.S.A. even when product patent on the basic drug expired long back.

Table 4

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 + Carisoprodol 200 mg + Codeine Phosphate 16 mg b) Aspirin 325 mg + Carisoprodol 200 mg	13/8/2002 13/8/2002
Diazepam (1980)	VALIUM Hoffman La Roche -- -- VALRELEASE	a) 10 mg tab b) 2mg tab c) 5mg tab d) 2 mg/ml inj e) 15 mh Cap	23/2/1999 23/2/1999 23/2/1999 23/2/1999 23/2/1999
Diltiazem Hcl (1988)	CARDIZEM SR Marion Labs	a) 120 mg Caps b) 180 mg Caps c) 60 mg Caps d) 90 mg Caps	26/10/2005 26/10/2005 26/10/2005 26/10/2005
Hydrochlorothiazide (1979)	PRINZIDE - 12 5 Merck Sharpe & Dhome	a) 12.5 mg + Linosporil 20 mg tabs	30/12/2001
Methyldopa (1976)	ALDOMET Merck Sharpe & Dhome	250 mg/ml suspensio	13/09/2000
Norfloxacin (1996)	NOROXIN Merck Sharpe & Dhome	400 mg tabs	27/01/2004
Oxazepam (1984)	SERAX Wyeth Labs	a) 10 mg Caps b) 15 mg Caps c) 30 mg Caps	04/11/2003 04/11/2003 04/11/2003
Ranitidine Hcl (1995)	ZANTAC 150 ZANTAC 300 Glaxo	a) Eq. 150 mg base tab b) Eq. 15 mg base/ml syrup c) Eq. 25 mg base/ml inj. d) Eq. 300 mg base tab. e) Eq 50 mg base/ 100ml inj.	5/12/1995 29/04/2003 29/04/2003 04/06/2002 29/04/2003

Source : FOI Services Inc., USA

The patent protection under the TRIPs patent system thus would be used for extending monopoly by taking process patents and patents for usage form, dosage form and combination form. This monopoly would be extended to the existing products 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 in a country like 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 in the pharmaceutical field. It would become impossible for the domestic industry to subsist without new products and it would also affect their business in the existing products. Their survival would be under a serious question mark.

(g) Reversal of burden of proof

Article 34 provides for reversal of burden of proof during the process patent regime. The onus of proving that the new process is totally different than the patented process would lie with the defendant and he will have to prove that he is not guilty. This provision would also be misused by powerful MNCs to curb competition from others even when their process may be different. Keeping this in view, the legal system to check infringement has to be carefully evolved.

PART VI

TRANSITIONAL ARRANGEMENTS AND PATENTS (AMENDMENT)BILL, 1995

(a) Transitional Arrangements

Part VI of the TRIPs Agreement deals with the tansitional arrangements. Developing countries are entitled to delay the application of the TRIPs Agreement by five years as against one year for the developed countries from the date of entry into force of the agreement establishing the World Trade Organisation (WTO) which was January 1, 1995. Countries who do not extend product patent protection to areas of technology not so protectable on 1.1.95 (like India where technologies relating to atomic energy and chemical based products are exempt from product patent) can delay the application of the provisions of the product patents to such areas of technology for an additional period of five years. This transitional arrangement has been set out in Article 65 of the TRIPs Agreement.

The above consideration has, however, been drastically curtailed in paragraphs 8 & 9 of Article 70 of TRIPs Agreement. In the fields of technologies relating to pharmaceutical and agriculture chemical products, "means (arrangements) for accepting patent applications commensurate with the obligations under Article 27 of TRIPs Agreement will have to be established (by January 1st, 1995) when the World Trade Organization comes into force." Further exclusive market rights will also have to be provided for these

applicants for a period of five years from 1995 onward itself after they have taken the marketing approval from the concerned national drug/pesticide control authorities. Such arrangements will obviously have to be established by changing the existing patent laws by Parliament.

The grant of exclusive marketing right is as good as the product patent for pharmaceuticals and agro chemicals. The exclusive rights shall get established from 1995 itself for new products and not that the new applicants will have to wait for a period of ten years for enforcing the product patent rights.

Even for those developing countries who do not have product patent system for pharmaceuticals and agro chemicals, almost all the provisions relating to the new patent regime under the TRIPS agreement will come into force in a period of five years i.e. by 2000 A.D. As stated earlier, some of the important provision will come into force even from the year 1995. Thus consequences of high monopolistic prices and inability of producing new drugs by the domestic industry in the developing countries, including India will be experienced immediately on extending of the system of exclusive marketing right.

The most contentious provision is contained in para 9 of Article 70 that exclusive marketing rights will have to be given, if the patent applicant has taken patent or marketing approval in any other member country (which may be a small country like Malta, Mauritius etc. not having an adequate system on the subject). This would mean introduction of new drugs in our country without any proper clinical trials. This kind of provision will have to be totally rejected.

(b) Patents (Amendment) Bill, 1995

The Government promulgated an ordinance to amend the Patents Act 1970 on December 31, 1994. Later in the budget session of Parliament, Government introduced the Patents (Amendment) Bill, 1995 to replace the Ordinance. The bill was passed by the Lok Sabha in spite of strong opposition by Members of Parliament belonging to the Opposition parties. The Government, however, could not introduce the bill in Rajya Sabha as they were not sure about the passing of the bill in that House. Government has now succeeded in referring the bill to a Select Committee of Rajya Sabha for detailed examination.

The analysis of the bill indicates that the amendments proposed are neither in the national interest nor are they in consonance with the provisions of the TRIPs Agreement. The objections to the bill are broadly as follows :

(i) The amending bill provides for exclusive rights to "sell or distribute". This may not be tenable under the MRTP Act. The TRIPS Agreement provides for "exclusive marketing right" and the bill also should have provided for the same. (This amendment is not in consonance with the TRIPs Agreement).

(ii) The examination of the patent applications, as provided in the bill, is supposed to be kept pending till 31st day of December, 2004. It would not be desirable to keep the applications unattended. They should be examined immediately in accordance with the provisions in Chapter IV of the Patents Act, 1970. There cannot be any compromise on this requirement. Postponing the examination is fraught with all kinds of complications.(This amendment is not in consonance with the TRIPs Agreement).

(iii) For grant of exclusive marketing right it is important that the inventor should either take the patent rights or exclusive marketing right in his own country to secure these rights in our country. Similarly if the patent application for that subject matter has been rejected any where including the country of invention, the same should be specifically mentioned in the application. (This is to protect our national interest.)

(iv) If the subject matter of the patent application is already in public domain, the grant of product patent or the process patent should not be allowed. The bill is just doing the reverse. There is even no provision in the bill to examine "public domain angle". (It is not understood as to why we are doing this.)

(v) Compulsory licensing has been provided for in the bill for the exclusive right to "sell or distribute". This kind of right has no meaning as under the stated contingencies another source for availability of the product has to be created. As such the compulsory licensing should be for local production to overcome the contigencies. (This is not against Art. 70)

In view of the above objections, the amending bill is not in the national interest and as such should not be passed by Parliament.

PART VII

IMPACT OF THE PROPOSED PATENT REGIME ON PHARMACEUTICAL SECTOR

The specific fall-out of the changes that would be made in the patent laws on the basis of provision in the TRIPs Agreement would be manifold. The TRIPS Agreement is a disaster for consumers all over the world and for small and medium scale industries in the developing world including India. The consumer would be hit

by high prices and erratic availability of pharmaceuticals, pesticides, seeds, etc. and domestic industry would face the question of survival. In the words of Mr.Ralph Nadar, a well known consumers advocate in U.S.A., the consumer in U.S.A. would also be hit. He made the following statement at the National Press Club (U.S.A.) on April 12, 1994:

> *"Nothing is more likely to pull down our present US consumer and environmental projections and derail future advance than the proposed expansion of a global trade agreement called the Uruguay Round of the General Agreement on Tariffs and Trade (GATT)." This statement applies to all Agreements under the Final Act including the TRIPs Agreement.*

(a) Impact on prices

The main impact would be on the prices of medicines which would go up several times making it extremely difficult for the poor people to afford them. Two specific examples of drugs marketed by the same MNCs in four countries are given here to support this point. In India there is process patent at present for medicines whereas in three other countries, viz. Pakistan, UK. and U.S.A., there is product patent regime for medicines.

It is because of the patent system in these countries that the price differential is so high, as indicated in Table 5 below:

Table 5
Price Comparison of Medicines
(Prices converted into Indian Rupees)

Drugs/Brand	Company	India	Pakistan	U.K.	U.S.A.
Ranitidine (Zantac) 300 mg x 10s	**Glaxo**	18.53	260.40	484.42	1050.70
Times Costlier			(14.05)	(26.14)	(56.70)
Diclofenac Sodium (Voveran) 50 mg x 10's	**Ciba Geigy**	4.95	55.80	96.46	334.95
Times Costlier			(11.27)	(19.49)	(67.67)

When our country will switch over to new TRIPS patent system, the prices are bound to go up very high. The price comparison between the four countries for many other medicines is given in the Annexure attached.

(b) Impact on Availability

The 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 recently. Our country 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 Argentinian government 'should look at its neighbours, see what is happening to us, and realise that the promises were false', Muriam Orellana, executive director of the Chilean national industry association, (Asilfa), declared. (The Argentinian 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. Latin-American 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 US, $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.

(c) 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, 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 large scale unemployment, making existing infrastructure redundant and liquidation of competitive environment and closure of many small units.

(d) 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 our country has been mainly concentrated on developing process technologies. This kind of research effort going on 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 MNCs for registering patents worldwide and promoting and marketing thir products in various countries.

It would be relevant to mention here that U.S. Pharmaceutical industry spent $8.2 billion in 1990, $9.1 billion in 1991, $10.96 billion in 1992 and $12.6 billion in 1993 on R&D, and their worldwide sales during 1990 was $57.4 billion. With enormous resources only MNCs can afford to spend large sums on R&D . For MNCs, the entire world is market for them and they spend large sums on R&D to monopolies the markets world over with their innovation products. Table 6 gives an idea of sale turnover and investment in R&D of the top ten MNCs.

It will be observed from Table 6 that Ingelheim spent 19.2%of their total sales on R&D. Compared to this, Ranbaxy, the largest Indian company, invested last year over 6% of its sales on R&D. We are substantially low in profitably and volume of sales for committing our resources for R&D. Sales of our large enterprises have to multiply manifold before they could make any worthwhile investment in R&D. The total pharmaceutical production in India is around $2500 million whereas almost all the 10 MNCs (Table 6) individually are having sales more than what India is producing. Further, our total expenditure on R&D is about $50 million per annum for drugs and pharmaceuticals. There is virtually thus no comparison.

Table 6

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	367.0	19.2
9. Rhone-Poulenc	2,784.6	350.9	12.6
10. MMD	2,211.0	329.0	14.9

The profitability of the Indian industry for various reasons is also quite low. In the past, it has been around 4-5% of sale turnover and now it has slightly improved to 6-7% of sale. As against this the MNCs are enjoying substantially high profits. For example, Zantac (Ranitidine) which is a top selling drug in the world, produced and marketed by Glaxo, has been enjoying quite a high profit. Glaxo holds worldwide product patent wherever 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 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 will never be able to match with MNCs 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 equal possibilities of success or failure. Thus pharmaceutical patents by themselves would be industrially 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, the need is to 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 licensing by paying adequate compensation to the patent-holder . Further, to achieve significant performance on the basic R&D front in India, Government will have to come forward in a big way to support public and private efforts on a long term basis. Indian scientists are second to none.The need is for a strong back-up of fiscal concessions to achieve significant results. In regard to tax concessions for R&D the following broad suggestions need to be considered by the Government :

(a) The Income Tax Act provided for deduction under Section 35(2B) which was available to the assessee during 1980-1984. This deduction was to be approved by the prescribed authorities having regard to the socio-economic and industrial climate in the country. The existing provision for allowing the expenditure on scientific research fully as per Section 35(1) (i) is not sufficient. It could be raised to weighted average reduction at 133% of expenditure incurred by the assessee on any scientific research as was available during 1980-1984.

(b) The recurring expenditure on consumption of raw materials also needs fiscal concessions. The imported raw materials and indigenously procured raw materials could be available for research free of customs duties and excise duties respectively.

(c) The State Governments where the research centre may be set up should provide land at a nominal cost. The requirement of each centre for land could be determined by a high level committee under the Department of Scientific and Industrial Research.

(d) The capital expenditure on land and building could be provided as interest free loan by the Central Government to be recovered over a period of 20 years.

(e) Any sum paid for scientific research to universities, colleges or other institutions could also be allowed for deduction under the Income Tax Act in full.

The above are a few suggestions in the direction of providing impetus for basic research.

PART VIII

PATENT SYSTEM FOR SEEDS

Article 27 of the TRIPS Agreement provides that "member countries shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof". In the same Article, it is also provided that "the

provision of this sub-paragraph (relating to protection of plant varieties) shall be reviewed four years after the date of entry into force of the WTO Agreement (i.e. January 1995)". Thus it is expected that review of system of protection of plant varieties would be undertaken during 1999 and global model would be evolved as in the case of other patents for implementation by all member countries. Though for the time being, choice of evolving the system of protection of plant varieties is left to each country, the obligatory provision is that the *sui generis* system (meaning a system of its own) must be effective. The criteria for judging the effectiveness of *sui generis* system has not been specified in the TRIPs Agreement. This again confirms that only temporary respite has been provided to the member countries. Ultimately only the multilateral system will judge the effectiveness of the system and provide for the same.

The transitional arrangements provided in Art.65 of the TRIPs Agreement allow developing countries a period of five years to establish their own system of plant breeders rights (PBRs) which means that there is no obligation to evolve the system as such till 2000 AD. In view of this, there should be no urgency to enact the PBRs system and the developing countries are better advised to wait for the review of this system in 1999. Further, it could also be interpreted from Article 65(4) that "those developing countries who do not extend product patent protection to areas of technology not so protectable in their countries could delay the application of the provision on product patent by an additional five years." Opinions differ as to whether seeds could be treated as "products". Even so, the interpretation of seed as a product should be liberally interpreted by the developing countries to their advantage which will mean that effectively ten years would be available to them for actual application of plant breeder rights. Ten year period is a long period and developing countries can watch the development in the world to take the best advantage of any favourable conditions that might emerge.

Though no specific model has been suggested in the TRIPs Agreement for PBRs, there are models available in UPOV Convention 1978 and UPOV Convention 1991, apart from the model of the draft Treaty Supplementing Paris Convention. The UPOV Convention was initially adopted by the developed countries and its membership was restricted to only five European countries till 1978. At that time, the Convention was revised and membership was opened to all countries. Currently UPOV has twenty member countries including European countries, Japan and the USA. It has no developing country as its member. In view of this, the model which has emerged in the UPOV Convention for plant variety legislation is suitable mainly in the socio-economic context of industrialized countries. The farmers in these countries do not have much role over plant breeding or seed supply as in the case of the developing countries,

where farmers themselves are engaged in the seed production and they were also the main source of supply of seeds to other fellow farmers. Almost about 65 per cent of the seed requirement is met through the exchange system which has been prevalent in countries like India.

In the past, UPOV Convention protected farmers interests by allowing them to save protected varieties of seeds. This protection to farmers was retained in the amendment to the UPOV in 1978. The breeders also enjoyed exemption for free access to protected varieties, for use in further research and for breeding other varieties. However, UPOV Convention 1991 has removed the exemptions which were available under UPOV Convention 1978. Breeders and researchers will have to pay royalty to the plant breeder right holder to use the protected variety for breeding new varieties. UPOV Convention 1991 in Article 15 lays down limitation on farmers' exemption as available under UPOV Convention 1978. It is laid down in this Article that "each contracting party may within reasonable limits and subject to the safeguard of the legitimate interests of the breeder restrict the breeders right in relation to any variety in order to permit farmers to use for propagating purposes on their own holdings the product of the harvest which they have obtained by planting, on their holdings, the protected variety." This would mean that the freedom of farmers would get restricted to protect the interests of the the breeders. Thus, the model of 1991 would clearly restrict the farmers right which they are presently enjoying in the developing countries. Insofar as the draft Treaty Supplementing the Paris Convention is concerned, the system provides for "patents" which will take away all the rights being enjoyed by the farmers at present. As and when this treaty is enforced, India will not escape its inimical impact.

PART IX

STRATEGIES FOR THIRD WORLD INCLUDING INDIA

(a) It has been observed that the TRIPS Agreement is broadly based on the basic framework on intellectual property jointly submitted to GATT in June 1988 by Intellectual Property Committee of U.S.A., Keidanren of Japan and UNICE of Europe. These organisations represent the powerful business interests of MNCs in three continents. The TRIPs Agreement is now nothing short of a charter of rights for the patent holders and in such a regime all the developing countries would face severe implications of degrowth. In view of this, it is important that developing countries must work out a common strategy for non-implementation of the TRIPs Agreement on patents in the present form; thus forcing re-negotiation.

(b) GATT Negotiations revealed some of the major limitations in the negotiating strategy adopted by the developing countries. Till the midterm review they unitedly tried to block the inclusion of intellectual property rights on the agenda of the Uruguay Round. Then suddenly by April 1989 under pressure from U.S.A., the developing countries agreed to the inclusion of intellectual property rights on the GATT agenda and also started agreeing to the changing of their patent system because they were also threatened action by U.S.A. under Special 301. Thereafter, during the negotiations no collective efforts were made by the developing countries to safeguard their interests. One plausible reason was lack of preparedness to face a situation as was presented to them in the negotiations. Even now it is important that the forum is established at governmental level by the developing countries for study of TRIPs in all its perspective so that during the implementation process national interest could be safeguarded.

(c) Developing countries should evolve an alternative patent system. TRIPS Agreement should therefore be taken up in WTO for reconsideration, based on its impact both on industry and consumers, with a definite framework suited to their national needs and priorities.

In the meantime, while the developing countries are amending their national laws, they should keep in view China's Patent Act of 1992. China has also been forced to change its patent law based on the Memorandum of Understanding signed between U.S.A. and China. Even then China has made most progressive provisions in regard to the obligations imposed on the patent holder through compulsory licensing. The relevant chapter of their Patent Laws is reproduced below:

Chapter VI

COMPULSORY LICENCE FOR EXPLOITATION OF THE PATENT.

Art. 51. Where any entity which is qualified to exploit the invention or utility model has made requests for authorization 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 authorize 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 fail 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.

(d) While making provision in the amendments to be carried out for granting exclusive marketing rights, it would be prudent to provide that exclusive marketing rights under Art. 70(9) would be available only if exclusive marketing rights or product patent is available to the applicant in the country of origin of the invention. Further that the product has to be produced in the country that grants the right and also that there would be provision for compulsory licensing on the lines of Chinese Patent Laws of 1992 with reasonable royalty. This action will not be against any of the provisions of the TRIPs Agreement insofar as the grant of exclusive marketing rights are concerned.

(e) There should be price control on the pharmaceutical products enjoying exclusive marketing right during transitional period and product patent protection thereafter.

(f) The exclusive marketing and product patent rights on pharmaceutical and agro-chemical products should be restricted to only the basic material in bulk form and not extended to formulations in dosage form, usage form and combinations as in the latter case no novelty angle as such is justified. For formulations as no novelty angle can be justified exclusive right under the trade marks system should only be granted. In this way, the double advantage of exclusivity of both under the patent and trade marks system could be avoided.

The trade mark system, in fact, prohibits the registration of names of chemical elements or internation non-propreitary names and as such the patent rights could be restricted to only such basic materials. The patent holders, apart from using these basic materials themselves, will have to sell them to the non-associated formulators to comply with the provisions of Art. 40 of the TRIPs Agreement relating to the control of ant-competitive practices. This restriction will help in ensuring competitive environment in the availibility of the formulations and in containing their prices.

(g) Article 7 of the TRIPs Agreement provides that protection and enforcement of IPRs should contribute to the promotion of technological innovation and to the transfer and dissemination of technology. Article 16 of Convention on Bio-diversity also deals with IPR issues, access to transfer of technology and environment and sustainable development. These issues have been raised at WTO Committee on Trade & Environment in June 1995. They should be pursued vigorously by the developing countries and it should be ensured that transfer of technology does take place along with the grant of exclusive marketing or product patent rights. The patent holder could be suitably compensated through payment of royalty.

(h) US must be forced by WTO to withdraw provisions such as Super 3Q1 and Special 301 which are anti-GATT provisions. Such bilateral provisions have no place in the multilteral trading system. This argument should be used emphatically to force renegotiation of TRIPs Agreement on Patents.

INTERNATIONAL PRICES VIS-A-VIS INDIAN PRICES

November 1995

MAJOR DRUGS INTRODUCED IN INDIA DURING THE LAST FIVE YEARS

DRUG & DOSAGE EXPIRY	PACK	BRAND/ COMPANY	INDIA (Rs)	BRAND/ COMPANY	PAKISTAN (Rs)	TIMES COSTLIER	BRAND/ COMPANY	PRICE IN US $	USA (Rs)	TIMES COSTLIER	BRAND/ COMPANY	PRICE IN UK(pnds)	UK (Rs)	TIMES COSTLIER
Anti-bacterials:														
Ofloxacin 200mg 1989	4 s	Tarivid/ Hoechst	92.00	Tarivid/ Hoechst	117.23	1.27	Floxin/ Ortho	11.66	408.10	4.44	Tarivid/ Hoechst	4.10	217.30	2.36
Cefadroxil 500 mg 1987	4's	Cefadur/ Protec	51.75	Duricef/ BMS	82.68	1.60	Duricef/ M Johnson	13.17	460.95	8.91	Baxan/ BMS	1.13	59.89	1.16
Ciprofloxacin 500 mg 1992	4's	Ciprolet/ Stangen	28.40	Ciproxin/ Bayer	234.63	8.26	Cipro/ Miles	12.52	438.20	15.43	Ciproxin/ Bay Pharma	5.50	291.50	10.26
Norfloxacin 400 mg 1998	10's	Tanflox/ TDPL	39.00	Noroxin/ MSD	125.50	3.22	Noroxin/ MSD	25.82	903.70	23.17	Utinor/ MSD	4.80	254.40	6.52
Lomefloxacin 400 mg	5's	Lomaday/ Stangen	99.00	N.A.	-	-	Maxaquin/ Searle	30.53	1068.55	10.79	N.A.	-	-	-
Pefloxacin 400 mg	4's	Proflox/ Protec	15.60	Abaktal/ Lek	59.42	3.81	N.A.	-	-	-	N.A..	-	-	-
Tobramycin 0.3% 1989	5 ml	Tobacin/ Aristo.	20.84 (3 ml)	Tobralex/ Alcon	116.31	5.58	Tobrex/ Alcon	18.13	634.55	30.45	Tobralex/ Alcon	1.39	73.67	3.54
Anti inflammatory:														
Diclofenac-50 tabs 1988	10's	Jonac/ G.Remedies	4.95	Voltaren/ Ciba	55.80	11.27	Voltaren/ Ciba	9.57	334.95	67.67	Voltarol/ Ciba	1.82	96.46	19.49
Piroxicam-20 caps 1988	10's	Movon/ IPCA	14.00	Feldene/ Pfizer	78.12	5.58	Feldene/ Pfizer	25.72	900.20	64.30	Feldene/ Pfizer	2.14	113.42	8.10

DRUG & DOSAGE EXPIRY	PACK	BRAND/ COMPANY	INDIA (Rs)	BRAND/ COMPANY	PAKISTAN (Rs)	TIMES COSTLIER	BRAND/ COMPANY	PRICE IN US $	USA (Rs)	TIMES COSTLIER	BRAND/ COMPANY	PRICE IN UK(pnds)	UK (Rs)	TIMES COSTLIER
Anti-ulcerants:														
Ranitidine-300 tabs 1995	10's	Ranitin/ Torrent	18.53	Zantac/ Glaxo	260.40	14.05	Zantac/ Glaxo	30.02	1050.70	56.70	Zantac/ Glaxo	9.14	484.42	26.14
Famotidine-40 tabs 2000	10's	Fudone/ Wockhardt	18.61	Pepcidine/ MSD	260.40	13.99	Pepcid/ MSD	28.69	1004.15	53.96	Pepcid/ MSD	9.50	503.50	27.06
Omeprazole 20mg	10's	Lomac/ Cipla	29.00	N.A.	-	-	Prilosec/ Merck	36.30	1270.50	43.81	Losec/ Astra	12.66	670.98	23.14
Cardiovasculars:														
Atenolol-50 tabs 1987	10's	Tenolol/ IPCA	11.00	Tenormin/ ICI	86.63	7.88	Tenormin/ ICI	9.02	315.70	28.70	Tenormin/ ICI	1.91	101.23	9.20
Diltiazem 60 mg 1988	10's	Dilzem/ Torrent	36.90	Herbesser/ Tanabe	74.40	2.02	Cardizem/ MMD	8.83	239.05	6.48	Britiazem/ Thames	1.50	79.50	2.15
Lisinopril 5 mg	10's	Cipril/ Cipla	35.00	N.A.	-	-	Prinivil/ Merck	7.56	264.60	7.56	Zestril/ ICI	3.42	181.26	5.18
Enalapril Maleate 5mg	10's	Vasopril/ Protec	15.91	Renitec/ MSD	37.20	2.34	Vasotec/ MSD	9.11	318.85	20.04	Innovace/ MSD	2.81	148.93	9.36
Prazosin 2mg	10's	Prazopress Sun Pharma	24.04	Minipress Pfizer	13.64	0.57	Minipress Pfizer	6.65	232.75	9.68	Hypovase/ Invicta	0.83	43.99	1.83
Amiodarone 200mg	10's	Cordarone Torrent	77.90	N.A.	-	-	Cordarone Wyeth	29.03	1016.05	13.04	Cordarone Sanofi	2.93	155.29	1.99
Amlodipine Besylate 5mg	10's	Amloz/ Plethico	15.00	N.A.	-	-	Norvasc Pfizer	11.79	412.65	27.51	Istin Pfizer	4.23	224.19	14.95

DRUG & DOSAGE EXPIRY	PACK	BRAND/ COMPANY	INDIA (Rs)	BRAND/ COMPANY	PAKISTAN (Rs)	TIMES COSTLIER	BRAND/ COMPANY	PRICE IN US $	USA (Rs)	TIMES COSTLIER	BRAND/ COMPANY	PRICE IN UK(pnds)	UK (Rs)	TIMES COSTLIER
Anti viral/fungal														
Ketaconazole-200 tabs 1996	10's	Funazole/ Khandelwal	57.90	Nizoral/ Janssen	221.96	3.83	Nizoral/ Janssen	30.94	1082.90	18.70	Nizoral/ Janssen	5.23	277.19	4.79
Zidovudine 100mg caps	10's	Zidovir Cipla	250.00	N.A.	-	-	Retrovir/ B Wellcom	15.48	541.80	2.17	Retrovir B Wellcome	12.50	662.50	2.65
Anti-histamine														
Astemizole 10mg 1997	10's	Alestol/ Indoco	12.00	Mayasen/ Janssen	120.90	10.08	Hismanal/ Janssen	18.50	647.50	53.96	Hismanal/ Janssen	2.69	142.57	11.88
Terfenadine 60mg	10's	Terdane/ Intas	23.00	Teldane/ MMD	60.93	2.65	Seldane/ MMD	12.26	429.10	18.66	Triludan/ MMD	1.64	86.92	3.78
Ceterizine 10mg	10's	Hisnofil/ Croslands	15.00	N.A.	-	-	N.A.	-	-	-	Zirtek UCB	2.91	154.23	10.28
Loratidine 10 mg	10's	Lorfast/ Cadila	69.50	N.A.	-	-	Claritin/ Schering	24.51	857.85	12.34	Clarityn/ Schering	2.52	133.56	1.92
Anti-Anxiolytics														
Alprazolam 0.5 mg 1990	10's	Alprax/ Torrent	12.99	N.A.	-	-	Xanax/ Upjohn	7.05	246.75	19.00	Xanax/ Upjohn	0.88	46.64	3.59
Trazodone HCl 50 mg 1985	10's	Trazalon/ Sun pharma	23.30	Deprel/ Adamjee	17.77	0.76	Desyrel/ M Johnson	12.31	430.85	18.49	Molipaxin/ Roussel	2.06	109.18	4.69
Buspirone 5mg 1999	10's	Buspine/ Intas	9.80	Buspar/ BMS	89.69	9.15	Buspar/ M Johnson	5.78	202.30	20.64	Buspar/ BMS	3.12	165.36	16.87

DRUG & DOSAGE EXPIRY	PACK	BRAND/ COMPANY	INDIA (Rs)	BRAND/ COMPANY	PAKISTAN (Rs)	TIMES COSTLIER	BRAND/ COMPANY	PRICE IN US $	USA (Rs)	TIMES COSTLIER	BRAND/ COMPANY	PRICE IN UK(pnds)	UK (Rs)	TIMES COSTLIER
Anti-cancer														
Mitoxantrone 2mg/ml	10ml	Oncotrone/ TDPL	595.00	N.A.	-	-	Novatrone Lederle	640.82	22428.70	37.70	Novatrone/ Lederle	150.43	7972.79	13.40
Carboplatin 150mg	Vial	Oncocarbin TDPL	995.00	N.A.	-	-	N.A.	-	-	-	Paraplatin BMS	65.83	3488.99	3.51
Vincristine 1mg 1992	Vial	Cytocristn Cipla	60.00	Oncovin/ Lily	323.16	5.39	Oncovin/ Lily	34.62	1211.70	20.20	Oncovin/ Lily	14.18	751.54	12.53
Vinblastine 10 mg	Vial	Cytoblastn Cipla	195.00	Velbe/ Lily	333.85	1.71	Velban/ Lily	38.92	1362.20	6.99	Velbe/ Lily	14.15	749.95	3.85
Etoposide 100mg inj	Vial	Eposed/ Natco	210.00	N.A.	-	-	Vepesid/ B Myers	136.49	4777.15	22.75	Vepesid/ B Myers	14.58	772.74	3.68
Cisplatin 10 mg	Vial	Aquaplat/ Khandelwal	151.35	Platamine/ Carlo Erba	174.70	1.15	N.A.	-	-	-	N.A.	-	-	-
Miscellaneous														
Nimodipine 30mg tabs	10's	Vasotop/ Protec	59.09	N.A.	--	-	Nimotop/ Miles	50.08	1752.80	29.66	Nimotop/ Bayer	3.89	206.17	3.49
Selegiline HCl 5 mg	10's	Selerin/ Protec	24.00	Jumex/ Medimpex	74.00	3.08	Eldepryl/ Somerset	21.37	747.95	31.16	Eldepryl/ Britannia	4.68	248.04	10.34
Ondansetron HCl 4 mg	6's	Oncoden/ Torrent	39.54	N.A.	-	-	Zofran/ Cerenex	64.20	2247.00	56.83	Zofran/ Glaxo	24.30	1287.90	32.57

Note: 1. Price paid by the patient considered.

2. Conversion rate of exchange considered : 1 USD = Rs.35.00, 1 GBP = Rs.53.00 & 1 PAK RS = Rs.1.07

3. Source for prices : USA prices - Red Book 1995
UK prices - UK MIMS September 1995
Pakistan - QIMP Annueal 1991-92
MIMS India - October 1995

24/11/1995

IMPACT OF STRONG PATENT SYSTEM

QUOTATIONS

Without adequate explanation, one can only conclude that what is going on in this industry is greed on a massive scale. This is an industry that insists on increasing its profits at the expense of the sick, the poor and the elderly.

U.S. Congressman Henry Waxman

The pharmaceutical industry is unique in that it can make exploitation appear a noble purpose.

Dr. Dale Console, former Medical Director of Squibb

In this industry the mere existence of patent protection is not a guarantee of invention, nor is its absence much of a barrier.

Kefauver Report

Most new drugs introduced into the U.S. market in this decade have been assessed by the Food and Drug Administration (FDA) as essentially duplicating already available products.

U.S. Congress. Senate, Special Committee on Aging, 1990

Our elderly, in particular, must frequently choose between going hungry at the end of the month or refilling an essential but costly prescription.

U.S. Congress. Senate, Special Committee on Aging, 1989

With many of these products, it is clear while they are on the drawing board that they promise no utility. They promise sales. It is not a question of pursuing them because something may come of it .....it is pursued simply because there is profit in it.

Dr Dale A Console before US Congress, Senate, Committee on the Judiciary, 1960

The Indian drug price index, calculated on the basis of prices in eight age-old static drugs, rose by 41.9 percent between 1961 to 1970. Further more, the brand name drugs manufactured by foreign controlled companies in India were priced 150-300 percent above the formulation prices of Indian public sector companies.

UNCTAD, "Case Studies in the transfer of technology in the pharmaceutical industry in India, 1977

The Patents Act, 1970, was passed on the basis of the findings of the judicial enquiry conducted by Mr Justice Rajagopala Iyengar, former Justice of the Supreme Court of India. Justice Iyengar concluded that 90 percent of patents were taken out by foreigners who evinced no interest in working them in India. The enquiry revealed that foreign owned patents are never worked in India but are held either to block the industry in the country and protect export markets.

Report of the Ayyangar Committee, 1959

Overpricing of drugs imported into India has ranged from 24 percent in the case of Metronidazole to 1100 percent in the case of Indomethacin.

Dr Satwinder Singh in his book, Multinational Corporations and Indian Drug Industry

Companies with an innovative drug often enjoy years without price competition, during which "they can price anyway they want".

Stephen Schondilmeyer, University of Minnesota

US drug price are the highest in the world because patents prevent competition. The US stands naturally alone in allowing drug manufacturers to charge high prices.

The literature of Northam Medication Service, Nassan, Bahamas

We have given the pharmaceutical industry a licence to price gouge the American public and it is time to revoke that licence.

Senator Pryor

Many of these (prescription) drugs were not even invented in this country, but are licensed on a monopolistic basis to American companies which tested the drugs for FDA approval and marketed them.

U.S. Congress, House, Subcommittee on Health and the Environment, Testimony of William Hutton, National Council of Senior Citizens, July 15,1985

The amount of basic research done by the U.S. drug firms is so small as to be negligible. Practically all drug industry research can be considered product development. Basic research in this country is conducted or financed largely by the United Stated Government and universities."

U.S. Congress, Senate, Committee on the Judiciary, April 30, 1981
Statement of Public Citizen Health Research Group

.....the R & D budget is the hiding place for promotion disguised as research and clinical studies that are designed to produce noise instead of new products. Inflated R & D budgets are then used to justify inflated prices. If it is preapproval publicity, publicity for a product prior to the time it gets on the market, or a claim prior to the time it is approved, then medical education will almost be budgeted somewhere in phase 3 research .... So all the communications associated with that product can easily be cross-charged into the R and D budget, so those figures in the kinds of reports that PMA issues to be expenditures for actual research when they are not - they are promotional - related expenditures using medical education.

David Jones, former executive director, Ciba Geigy
Before the U.S. Congress, Senate, Committee on Labour and Human Resources, December 11, 1990

They stress that there are many failures for each successful drug. This is true since it is the very essence of research. The problem arises out of the fact that they market so many of their failures."

Dr. Dale Console, former Medical Director, Squibb

The Kefauver hearings in the US has concluded that patenting, branding and advertising of the products had resulted in an absence of effective competition and had been against the public interest."

Scrip No.1707

Years ago, the big profits in the U.S. were made in oil. These days they come from pharmaceuticals.

Art Buchwald, Washington Post

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.

Mrs Gandhi, WHO Conference, Geneva, May 1981

An unprecedented corporate power grab is underway within the Uruguay Round Negotiations of a new version of the GATT, the treaty which governs most of the world's trade. By clever manipulation of free trade symbols and dependency between nations, multinational corporations hope to harmonise downwards : consumer protection, environmental and worker safety standards and wage levels. Special burdens are in store for Third Word countries whose sovereignity the multinational companies are hoping to further erode.

Ralph Nader, USA's foremost Consumer Rights Activist

Nothing can be more absurd or outrageous than that a foreign patentee can come here and get a patent and use it, not for the purpose of encouraging industries of this country but to prevent our people doing otherwise what they would do. To allow our laws to be used to give preference to foreign enterprise is to my mind ridiculous."

Sir Robert Reid, Eminent Jurist and Member, House of Lords, U.K.

This is only the first step in the attempt by foreign owned multinational drug firm to end drug price competition. Their mandate is to get the best return for their shareholders and they will be able to do that even more with their longer monopolies.

President Jack Kay, Canadian Drug Manufacturers Association

Brazil has never promised the United States that it would base its trade mark and patent legislation on parameters that the US government considers appropriate.

Celso Amorin, Secretary General, Foreign Relations Ministry, Brazil

American companies regularly infringe British patents knowing that the only redress for Britons is a lengthy and expensive haul through courts in the United States.

British Technology Group

AIMS AND OBJECTIVES OF THE NATIONAL WORKING ON PATENT LAWS

- To discuss issues relevant and related to the Patent Laws and Paris Convention;
- To Discusss issues of national interest arising out ot the Uruguay Round of GATT Negotiations;
- To discuss other economic issues raised at various multi-lateral fora having a bearing on the national economy;
- To arrange for research and publication of papers relating to these issues;
- To help create a better understanding of these issues by organising meetings, seminars and debates;
- To press for open discussion/debate in Parliament and other fora so that there is transparency on major economic issues being taken up in multi-lateral negotiations;
- To represent to the Government and those concerned with the formulation of policy on agreed views of the Group;
- Publicise and organise publicity in respect of India's and international patent and other economic laws and policies;
- To forge a National Alliance of various Organisations/Forum/ Associations, etc. to work towards and campaign for patent and other economic laws and policies best suited for India's interests.